EXTERNAL SCIENTIFIC REPORT

Statistical analysis of the *Listeria Monocytogenes* EU-wide baseline survey in certain ready-to-eat foods Part B*:* analysis of factors related to the prevalence of *Listeria Monocytogenes*, predictive models for the microbial growth and for compliance with food safety criteria[1]

Rakhmawati, T.W., Nysen, R., Aerts, M.

CenStat, Interuniversity Institute for Biostatistics and statistical Bioinformatics (I-BIOSTAT)
Hasselt University, Martelarenlaan 42, 3500 Hasselt, Belgium

ABSTRACT

A European Union-wide survey on *Listeria monocytogenes* in selected categories of ready-to-eat food at retail was carried out in 2010-2011. A total of 13 088 products were sampled: 3 053 packagesd (not frozen) hot or cold smoked or gravad fish at time of sampling and at the end of shelf-life; 3 530 packaged heat treated meat products at the end of shelf-life and 3 452 soft/semi-soft cheese products at the end of shelf-life. In Part A, the prevalence of *Listeria monocytogenes* was estimated according to two prevalence measures: using a scheme combining detection and enumeration testing (detection positive or enumeration result of at least 10 cfu/g); and based on enumeration testing only (> 100 cfu/g). In this Part B, all potential factors are investigated separately and jointly, in their effect on both prevalence measures (Part B-I). Part B-II looks into models for microbial growth of *Listeria monocytogenes*, using the enumeration data from the surveys in packaged (not frozen) hot or cold smoked or gravad fish at the date of testing on the arrival at the laboratory and at the end of shelf-life; and the effect of temperature, pH and water activity is addressed. Finally, in part B-III, predictive models are developed for the compliance with the *Listeria monocytogenes* criteria laid down in Regulation 2073/2005 on microbiological criteria for food.

© Rakhmawati, T.W., Nysen, R., Aerts, M., 2014

KEY WORD

Listeria monocytogenes, ready-to-eat foods, fish, cheese, meat, enumeration, prevalence, potential risk factors, predictive models, growth, compliance, survey, EU

DISCLAIMER

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European Food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

[1] Question No EFSA-Q-2012-00851 (and part of EFSA-Q-2012-00224).
Any enquiries related to this output should be addressed to zoonoses@efsa.europa.eu

Suggested citation: Rakhmawati T.W., Nysen R., Aerts M., 2014. Statistical analysis of the *Listeria monocytogenes* EU-wide baseline survey in certain ready-to-eat foods Part B: analysis of factors, predictive models for growth, predictive models for compliance. EFSA supporting publication 2014:EN-606. [368 pp.].

Available online: www.efsa.europa.eu/en/publications.htm

© European Food Safety Authority, 2014

SUMMARY

In order to estimate at the European Union-level the prevalence and level of *Listeria monocytogenes* (*L. monocytogenes*) in packaged hot or cold smoked or gravad fish, packaged heat-treated meat products and soft and semi-soft cheeses (excluding fresh cheeses), and in order to determine the factors effect for the occurrence of *Listeria monocytogenes* in the packaged (not frozen) hot or cold smoked fish and packaged heat-treated meat products, a European Union-wide *Listeria monocytogenes* baseline survey was conducted at retail. This was the eighth baseline survey to be conducted in the European Union and the first baseline survey to investigate ready-to-eat foods at retail and also the first to be designed to yield estimates at the EU-level only and not at the MS-level.

Sampling took place between January 2010 and January 2012. A total of 3 053 batches of packaged hot or cold smoked or gravad fish, 3 530 packaged heat-treated meat products and 3 452 soft or semi-soft cheeses were sampled from 3 632 retail outlets in 26 European Union Member States, plus Norway. For packaged (not frozen) hot or cold smoked or gravad fish, two samples were collected from each sampled batch: one analysed on arrival at the laboratory and the other one at the end of shelf-life. For the packaged heat-treated meat products and soft or semi-soft cheese samples one sample was taken from the selected batch and was analysed at the end of shelf-life. All 13 088 food samples were examined for the presence of *Listeria monocytogenes*, in addition to the determination of the *Listeria monocytogenes* counts. The prevalence of *Listeria monocytogenes* was estimated using a scheme combining detection and enumeration testing (detection positive or enumeration result of at least 10 cfu/g). Besides the prevalence, interest also goes to the proportion of samples with *Listeria monocytogenes* enumeration result counts exceeding the level of 100 cfu/g, as this proportion reflects an exposure to *Listeria monocytogenes* in ready-to-eat foods with relatively long shelf-life that implies increased risk for human health.

The External Scientific EFSA Report "Statistical analysis of the *Listeria monocytogenes* EU-wide baseline survey in certain ready-to-eat foods Part A: *Listeria monocytogenes* prevalence estimates showed that the EU prevalence of *Listeria monocytogenes* contaminated fish samples at time of sampling was 10.4% while at the end of shelf-life it was 10.3%. The EU-level proportion of samples with counts exceeding the level of 100 cfu/g at the time of sampling was 1.0% while for packaged (not frozen) hot or cold smoked or gravad fish at end of shelf-life it was 1.7%. For meat the EU prevalence of *Listeria monocytogenes* contaminated samples at the end of shelf-life was 2.07% while the EU-level proportion of samples with counts exceeding the level of 100 cfu/g was 0.43%.

In Part I of the present report all potential factors are investigated separately and jointly, in their effect on the prevalence and on the proportion of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g. The results of the statistical analyses of all potential factors for the prevalence of *Listeria monocytogenes* for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling for all participating countries showed statistically significant effects (at 5% level) for the factors Subtype of the fish product, Fish species, Number of preservatives and acidity regulators, Possible slicing, remaining shelf-life and the interaction between the ''EC 2073/2005 NSG'' indicator and Fish species. The biologically relevant interaction between Storage temperature at retail and Packaging type[2] appeared to be not significant. For the proportion of samples with counts exceeding the level of 100 cfu/g for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling for all participating countries, it is shown that there is only a statistically significant effect (at 5% level) for the Sampling season with an increase in the odds (for a sample with counts exceeding the level of 100 cfu/g) with a factor 4.5 when comparing summer to winter.

[2] Binary variable: "Modified atmosphere" versus "All other packaging types" (more details in Section 4.3.3)

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The results of the statistical analyses of all potential factors for the prevalence of *Listeria monocytogenes* for packaged (not frozen) hot or cold smoked or gravad fish at end of shelf-life for all participating countries showed that the factors Sampling season, Subtype of the fish product, Fish species, Number of preservatives and acidity regulators, ‘‘EC 2073/2005 NSG’’ indicator; the interactions between ‘‘EC 2073/2005 NSG’’ indicator and Fish species and the interaction between Storage temperature at laboratory and ‘‘EC 2073/2005 NSG’’ indicator have significant effects (at 5% level) on the prevalence. For the proportion of samples with counts exceeding the level of 100 cfu/g for packaged (not frozen) hot or cold smoked or gravad fish at end of shelf-life for all participating countries, statistically significant effects (at 5% level) are identified for the factors Type of retail outlet[3], Sampling season and Possible slicing. For this model the ‘‘EC 2073/2005 NSG’’ indicator was not included due to sparseness issues.

The results of the statistical analyses of all potential factors for the prevalence of *Listeria monocytogenes* for packaged heat-treated meat products at end of shelf-life for all participating countries showed statistically significant effects (at 5% level) for the factor Type of the meat product. The final model also included the non-significant factors Possible slicing, temperature during the laboratory storage, Packaging type[2] and an interaction between temperature during the laboratory storage and Packaging type[2]. For the proportion of samples with counts exceeding the level of 100 cfu/g for packaged heat-treated meat products at end of shelf-life for all participating countries, it is shown that there are statistically significant effects (at 5% level) for the factors Animal species[4] of the origin of the meat product and remaining shelf-life.

Part II of the present report focuses on the development and application of models for microbial growth of *L. monocytogenes*. The first type of models are statistical growth models; basic linear as well as non-linear mixed models. The mean level of the enumeration counts (on log10 scale, at both dates of testing) is modelled as a function of time in terms of fixed effects, and with a random effect for batch (representing the correlation between the levels for samples of the same batch) and with random error terms to represent the remaining heterogeneity. Applying and fitting this type of model is complicated by the lack of a known common time scale at which growth was initiated for each batch, or each sample from each batch. All models showed a statistically increasing growth effect over time and provided a quantification of microbial growth. The Gompertz model was fitting best. The extension of the statistical models with factors affecting growth did only identify water activity as a statistically significant factor in the Gompertz model, and taking into account the different sources of variability and uncertainty in the data.

Deterministic growth models, as known from literature, and with parameter values as available from scientific literature, were applied to estimate the concentration at the date of testing at the end of shelf-life, based on the model and on the concentration at the date of testing on the arrival at the laboratory. Then the different deterministic models were evaluated by comparing the observed with the predicted growth rates. There was no single model outperforming the others throughout. Depending on the subset of samples under consideration, depending on how negative samples were treated, and depending on scenarios of sensitivity on the concentrations at the date of testing on the arrival at the laboratory, different models appeared to be the best.

A final statistical approach based on a model for the change rate in the $\log_{10}$ count of *L. monocytogenes*, including samples with decreasing growth, did not identify any factor affecting

[3] Binary variable: “Supermarket or small shop” versus “All other types of retail outlet” (more details in Section 4.3.3)
[4] Binary variable: “Avian species” versus “Other species” (more details in Section 4.3.3)

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

growth to be significant (except for the concentration at the date of testing at the arrival at the laboratory).

Commission Regulation 2073/2005 mentions two microbiological criteria applicable for food at different stages. The criterion with which compliance might usefully be considered at the retail stage, is the requirement for food to harbour *Listeria monocytogenes* counts not exceeding 100 cfu/g at the end of shelf-life. Part III of the present report is devoted to the development of predictive models for the compliance with the specific criterion, as described above. Based on the well-known beta-binomial distribution for clustered binary data, a probability for a sample to be compliant according to the criteria laid down in Regulation (EC) No 2073/2005 is defined. This probability can be interpreted as the proportion of ready-to-eat food samples of a particular category that are compliant at the EU level. The methodology allows to evaluate the effect of different sampling designs and corresponding correlation structure in the units comprising the sample on the probability to be compliant.

The compliance probability can be estimated and confidence intervals can be constructed using estimates for the proportion of samples with counts exceeding the level of 100 cfu/g for several ready-to-eat foods as estimated in the external Scientific EFSA Report "Statistical analysis of the *Listeria monocytogenes* EU-wide baseline survey in certain ready-to-eat foods Part A: *Listeria monocytogenes* prevalence estimates". The results show that the proportion compliant to the European Union food safety criteria as laid down in the Regulation (EC) No 2073/2005, at the end of shelf-life, is highest for cheese (with 95% above 0.988), followed by meat (95% CI (0.964, 0.997)) and by fish (95% CI (0.890, 0.987)). In any situation, compliance increases with the level of correlation.

Throughout, the estimates, confidence intervals and hypothesis tests are based on appropriate statistical methodology, taking into account the survey design and the hierarchical structure of the data, as well as the low number of cases and consequently the small values for the prevalence and the proportion of samples with counts exceeding the level of 100 cfu/g. Nevertheless, one needs to be cautious not to overinterpret the results.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

TABLE OF CONTENTS

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

ANALYSIS

1. Background as provided by EFSA

EFSA was asked by the European Commission to prepare a proposal for technical specifications for a harmonized monitoring[5] scheme for *Listeria monocytogenes* (*L. monocytogenes*) in ready-to-eat (RTE) foods able to support the growth of this microorganism, other than those intended for infants and for special medical purposes, within the framework of Directive 2003/99/EC (EC, 2003) and the implementation of Regulation (EC) No 2073/2005. In particular, the harmonized monitoring scheme were to allow a comparison of the contamination of *Listeria monocytogenes* in RTE foods in the European Union and the verification of the European Union food safety criteria laid down in Regulation (EC) No 2073/2005.

Prior to the legislative work regarding the mentioned *Listeria monocytogenes* EU-wide baseline survey in certain RTE foods, EFSA issued a Report on Proposed technical specifications for a survey on *Listeria monocytogenes* in selected categories of RTE food at retail in the EU.[6]

Having considered this scientific proposal the European Commission in collaboration with the Member States decided upon the technical specifications of the baseline surveys on the prevalence of *Listeria monocytogenes* in certain RTE foods which are laid down in the Commission Decision 2010/678/EU.[7]

2. Terms of reference as provided by EFSA

After the execution of the EU-wide survey in 2010-2011 in the Member States, the Commission requested EFSA to analyze and report the results of this baseline survey. Two reports will be issued:

- Report A will focus on *Listeria monocytogenes* prevalence estimates in the surveyed RTE foods as well as the analysis of the qualitative and quantitative survey test results,
- Report B will focus on the analysis of factors related to the prevalence of contaminated foods. It will also report on the development of predictive models for microbial growth of *L. monocytogenes* under the various storage conditions, on the development of predictive models for compliance with *L. monocytogenes* food safety criteria in foods as well as on other interesting information.

This contract/grant was awarded by EFSA to:

Contractor/Beneficiary: CenStat, Interuniversity Institute for Biostatistics and statistical Bioinformatics (I-BIOSTAT) Hasselt University, Martelarenlaan 42, 3500 Hasselt, Belgium

Contract/grant title: Assistance in statistical analysis of the EU coordinated monitoring programme on the prevalence of *Listeria monocytogenes* in certain RTE foods -Lot 1 and Lot 2

Contract/grant number: SC/EFSA/BIOMO/2012/01

5 From the epidemiological viewpoint, this is a 12-month survey aimed at estimation of a period prevalence.
6 This report can be found at http://www.efsa.europe.eu/en/efsajournal/pub/300r.htm .
7 Commission Decision 2010/678/EU concerning a financial contribution from the Union towards a coordinated monitoring programme on the prevalence of *Listeria monocytogenes* in certain ready-to-eat foods to be carried out in the Member States.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

3. Introduction

Aims of the Commission Decision 2010/678/EU

- To establish a coordinated monitoring programme on the prevalence of *Listeria monocytogenes* in certain ready-to-eat (RTE) food categories at retail level.
- Sampling will concern the following three RTE food categories: packaged (not frozen) hot or cold smoked or gravad fish, soft or semi-soft cheeses, excluding fresh cheeses, and packaged heat-treated meat products.
- The sampling activities of the coordinated monitoring programme provided shall be carried out starting in 2010 and covering at least 12 months.
- Detection and enumeration of *Listeria monocytogenes* will be made at the end of shelf-life for all three types of RTE foods and, additionally, at the time of sampling for the packaged (not frozen) hot or cold smoked or gravad fish samples (see Figure 1). For those latter samples, pH and water activity measurements will also be made.
- A proportionate stratified sampling scheme will be used for the coordinated monitoring programme whereby the samples will be allocated to every Member State proportionally to the size of the human population in that Member State.

After the execution of the EU-wide survey, the data of this baseline survey are analysed and the results are reported as follows:

- Estimation of EU prevalence of *Listeria monocytogenes* in the surveyed RTE foods.
- Analysis of the qualitative and quantitative survey test results.
- Analysis of factors related to the prevalence of contaminated foods.
- Development of predictive models for the microbial growth of *Listeria monocytogenes* under various storage conditions.
- Development of predictive models for compliance with *Listeria monocytogenes* food safety criteria in foods.

3.1. Objectives

The overall objective for both lots is to analyze and report the results of the EU-wide baseline survey on the prevalence of *Listeria monocytogenes* in certain RTE foods.

The objective of Lot 1 is the statistical analysis of the qualitative and quantitative results of the EU-wide baseline survey on the prevalence of *Listeria monocytogenes* in certain RTE foods as well as on the analyses of factors associated with the prevalence. Lot 2 covers the development of predictive models for growth of *Listeria monocytogenes* and for compliance with *Listeria monocytogenes* food safety criteria in foods covered by the baseline survey.

The specific objectives for Lot 1 are:

1. Statistical analyses related to the estimation of the prevalence and mean counts of *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling and at the end of shelf-life, as well as in soft or semi-soft cheeses and packaged heat-

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

treated meat products at the end of shelf-life.

2. Statistical analysis as well as tabular and graphical presentations of the qualitative and the quantitative survey test results.

3. Statistical analysis of the factors potentially associated with the prevalence of *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish, soft or semi-soft cheeses, packaged heat-treated meat products, including a preliminary descriptive analysis of all recorded potential factors, univariable models describing the relationship between each of those potential factors and the examined outcomes and appropriate multiple regression analysis of associations between factors and the examined outcomes.

The specific objectives for Lot 2 are:

1. Development of predictive models for microbial growth of *L. monocytogenes* under the various storage conditions. These models will use enumeration data from the surveys in packaged (not frozen) hot or cold smoked or gravad fish at two different time points (at time of sampling and at end of shelf-life). The effect of temperature, pH and water activity should be addressed. Detailed results and summary tables and graphs of the data should be provided, when necessary.

2. Development of predictive models for the compliance with the *L. monocytogenes* criteria laid down in Regulation 2073/2005 on microbiological criteria for food. The purpose of the model-based approach will be to assess whether the observed prevalence estimates of *L. monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish, in soft or semi-soft cheeses and in packaged heat-treated meat products at the end of the shelf-life are compatible with the *L. monocytogenes* criteria described in the above Regulation. Detailed results and summary tables and graphs of the data should be provided, when necessary.

This scientific report summarizes the main findings of the statistical analyses regarding the third specific objectives of Lot 1 and both objectives of Lot 2.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

PART I: ANALYSIS OF FACTORS RELATED TO THE PREVALENCE OF LISTERIA MONOCYTOGENES

4. Material and Methods

4.1. Survey design

Sampling concerns the following three RTE food categories: packaged (not frozen) hot or cold smoked or gravad fish, soft or semi-soft cheeses, excluding fresh cheeses, and packaged heat-treated meat products, and the sampling activities of the coordinated monitoring programme provided were carried out starting in 2010 and covering at least 12 months. Detection and enumeration of *Listeria monocytogenes* was made at the end of shelf-life for all three types of RTE foods and, additionally, at time of sampling for the packaged (not frozen) hot or cold smoked or gravad fish samples (see Figure 1). For those latter samples, pH and water activity measurements were also made.

A proportionate stratified sampling scheme was used for the coordinated monitoring programme whereby the samples have been allocated to every Member State proportionally to the size of the human population in that Member State.

For more details, we refer to the Report of Task Force on Zoonoses Data Collection on proposed technical specifications for a survey on *Listeria monocytogenes* in selected categories of ready-to-eat food at retail in the EU, *The EFSA Journal*, (2009), 300, 1- 66.

4.2. Data validation and cleaning

A set of data exclusion criteria was used by the EC to identify and exclude non-valid and non-plausible information in the dataset submitted by the MSs. MSs corrected the excluded data.

The final cleaned, validated dataset of the survey was provided by EFSA, and this validated dataset formed the basis for all subsequent analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

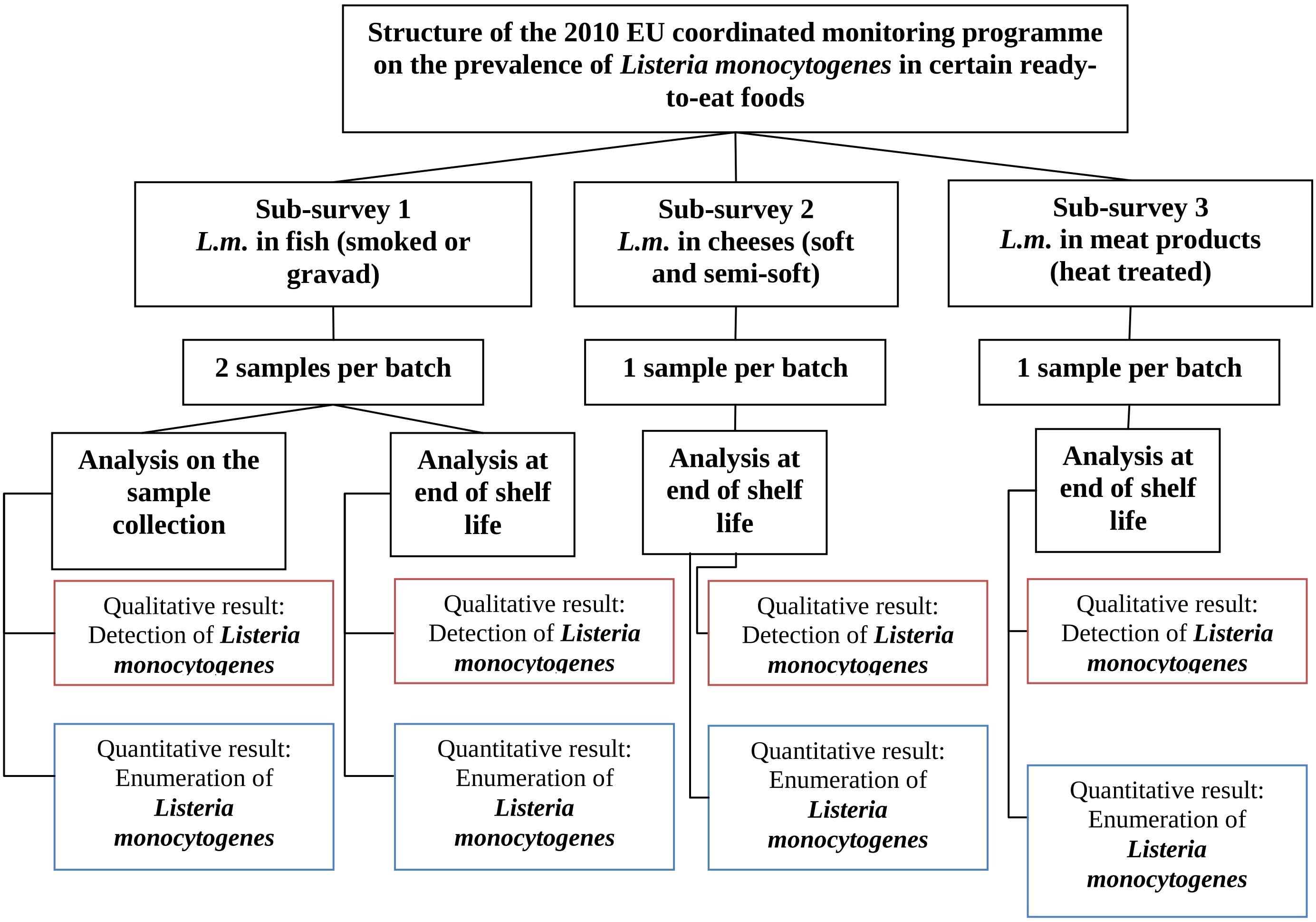


Figure 1: Structure of the 2010 EU coordinated monitoring programme on the prevalence of *Listeria monocytogenes* in certain ready-to-eat foods

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

4.3. Statistical analysis

This section provides an overview of statistical methods and models to study analysis of factors, for descriptive/explorative analysis and for inference purposes. The analyses use all country-specific datasets (MS and Norway).

The analysis of factors are performed for two different definitions of outcome parameters (see also Rakhmawati T W, Nysen R, Aerts M, 2013):

- **Prevalence:** for a contaminated sample using a scheme that combines detection and enumeration testing; a sample is contaminated if at least one of detection or enumeration testing is positive (a positive enumeration test being a test result of at least 10 cfu/g).

- **Proportion (%) of samples with enumeration above level 100 cfu/g:** based only on enumeration result according to a cut-off value of 100 cfu/g. In this case estimates of the proportion of samples with an enumeration test > 100 cfu/g are produced.

All models in this scientific report are extensions of the logistic regression model. The following extensions were considered:

- **Exact logistic regression** (Hirji *et al.* 1987): exact inference as an alternative to asymptotic inference in case the latter might not be valid (e.g. when probabilities to be estimated are very small).

- **Method of Firth** (1993), applied to logistic regression: bias correction in case the maximum likelihood (ML) estimates might be biased (e.g. when probabilities to be estimated are very small).

- **Generalized Estimating Equations** (Liang and Zeger, 1986): inference valid for hierarchical and clustered data. In our application there are three levels of hierarchy: retail outlets nested in cities/towns, and cities/towns nested in countries. The independence correlation structure is applied.

  Another option to analyse hierarchically structured data is the application of (generalized) linear mixed models (GLMM or LMM). Both approaches have their strengths and weaknesses. GEE methodology is a so-called marginal approach, as its interpretation is population averaged; whereas GLMM (for categorical outcomes) and LMM (for continuous outcomes) are conditional models, with an interpretation conditional on the hierarchical units, being in this case the retail outlets nested in cities/towns. However, as the LMM model is a linear model, the fixed effects also allow a marginal interpretation. For GLMM this is also possible, but at the cost of an additional and computer intensive step of integration over the random effect(s). In this particular setting the marginal, population averaged, interpretation is the relevant one and therefore GEE is the preferred methodology.

  Another major difference between the GEE and (G)LMM approaches is that GEE is a so-called semi-parametric model, as it does not require the full specification of the distribution of the outcome. GEE only requires a correct specification of the first moment and a working specification (allowed to be incorrect) for the second moment. The cost for this robustness however is a (minor) loss in efficiency (accuracy). For more details we refer to Liang and Zeger (1986), Aerts *et al*. (2002) and Molenberghs and Verbeke (2005).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- **Weighted Estimation.** Another relevant issue that has to be taken in consideration, in combination with the hierarchical data structure and the use of GEE, is the need to use weights for modelling the outcome parameters at EU-level. These weights correct for over- or underrepresentation of certain Member States. Main question however is which weights should be used for RTE foods.

  One option is to use weights based on the size of the human population of the respective MSs. The assumption underpinning this choice is that the human population sizes are fairly proportional to the volume sizes of the selected food categories on the market. As the sizes of the samples allocated to every MS were planned to be taken proportional to the sizes of the human populations in the MSs (Rakhmawati T W, Nysen R, Aerts M, 2013: Section 4.1), there was initially no need to apply any weights. The analysis shows however that the achieved samples sizes deviate substantially from the planned sample sizes for some MS's (Rakhmawati T W, Nysen R, Aerts M, 2013: Appendix A), and therefore weights will be used to correct for this unproportiateness of the sample sizes.

  In Commision Decision (2010/678/EU), no sample was planned for Norway. However, data were collected from Norway and these data will be used in the analysis. For the weighted analysis, with weights based on planned sample sizes, we decided to include the data from Norway but with a very small weight. More precisely, for the calculation of the weights, this means that we assign an *imaginary planned sample size* of 0.5 to Norway.
  However, a closer investigation of the planned sample sizes also reveals that for some countries these planned sample sizes are quite disproportional to the human population sizes. For practical purposes the planned sample sizes were rounded and taken equal to 30, 60 or 400 per food category. So a second weighted analysis was carried out with weights to relate the achieved sample sizes directly to the population sizes. Since populations size is only a rough proxy for the true volume sizes, both weighted analyses should not be over-interpreted, but should be considered rather as sensitivity analyses, to investigate the sensitivity of the analyses for this issue.

4.3.1. Descriptive analyses

A thorough description was made for the association between potentially associated factors and the outcome variables. Categorical variables were analysed through frequency tables, meanwhile the quantitative variables were described through measures of central tendency and dispersion such as mean and standard deviation as well as median and first and third quartiles. Boxplots and histogram were used for graphical visualisation.

4.3.2. Sparseness

Sparseness is a well-known phenomenon complicating the analysis of categorical data. It already appears in the basic chi-square test for dependency between two (categorical or categorized) variables. In case the expected frequencies are less than 5 in one of the inner cells, the asymptotic chi-squared null distribution of the Pearson or deviance test statistic for testing the null hypothesis of independence becomes questionable. As the expected frequency of a cell equals the total sample size times the probability for that particular cell, sparseness manifests itself when the sample size is too small in relation to the probability for that cells. In other words, the sample size needs to be large enough in combination with a cell probability that needs to be not too small. This same issue appears in models for

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

categorical outcomes, such as logistic regression and extensions thereof, and it might affect inference through biased estimates as well as through invalid asymptotic distributions for these estimates and (null) distribution for test statistics such as the Wald test, the likelihood ratio test or the score test.

The more categorical covariates appear in a logistic type of regression model, the more likely it gets to be faced with this issue. Indeed more categorical covariates and interaction effects thereof is equivalent to the analysis of more dimensional tables, spreading the (fixed) number of observations of more and more cells in such tables. More "thinner" cells defined by combination of values of more and more covariates will be populated by less and less observations and thus will lead to erroneous or misleading estimates and conclusions from hypothesis tests.

It is needless to mention that sparseness also interferes with the model building process. Indeed, backward selection, gradually reducing a full or most complex model, might not be an option (as the full model has the highest number of covariates one reasonably decides to consider), where a forward procedure might meet the same problem at an intermediate stage.

Pragmatic remedial actions and alternative methods of inference might resolve matters. We consider the following approaches:

- Firth's bias reduction method (reducing the bias of the estimates).
- Exact logistic regression (based on conditional likelihood and exact (discrete) null distribution).
- And more dramatically and if necessary (e.g. in case the above approaches are not fully resolving the problems): a reduction of the number of cells, implying an increase in the number of observations in the cells; by collapsing/merging categories. But then the question arises how one should collapse such categories. In case of ordinal variables, it seems natural to collapse neighboring cells with low frequencies. In any case it is recommended to collapse categories in a way that interpretation is still possible and of relevance for the application at hand and for the research questions.

A concrete example in Appendix A illustrates sparseness, its consequences as well as some alternative methods of inference and more pragmatic remedial actions.

4.3.3. Additional and modified variables

To facilitate the implementation, interpretation and feasibility of statistical models, some additional variables were defined, and some existing categorical variables were redefined by collapsing some of the categories.

"EC 2073/2005 NSG" variable

We define a variable ''EC 2073/2005 NSG'' as the category of not supporting the growth, based on Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs". This ''EC 2073/2005 NSG'' indicator is defined by the following thresholds:

if

- pH less than or equal to 4.4, or,
- water activity less than or equal to 0.92, or,
- pH less than or equal to 5 AND water activity less than or equal to 0.94,

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

this variable takes the value 0 (samples not included in 'EC 2073/2005 NSG') and the value 1 otherwise (samples included in "EC 2073/2005 NSG").

Next to this "EC 2073/2005 NSG" indicator, also a continuous variable estimating the probability of *Listeria monocytogenes* growth was considered. Tienungoon *et al*. (2000) modeled the probability of "supporting growth" as the following function of pH measurement, water activity and temperature:

$$\ln[P/(1-P)] = b_0 + b_1\ln(T - T_{\min}) + b_2\ln^2(T - T_{\min}) + b_3\ln\{1 - \exp[0.536\,(T - 48)]\}$$
$$+ b_4\ln(a_w - a_{w_{\min}}) + b_5\ln(1 - 10^{pH_{\min} - pH}) + b_6\ln^2(1 - 10^{pH_{\min} - pH})$$
$$+ b_7\ln(1 - \{[LAC]/[U_{MIC}(1 + 10^{pH - pK_a})]\}) + e$$

with $T_{\min}=0.4164$, $a_{w\ min} = 0.9142$, $pH_{\min}=3.35$ and values for the parameters b0 – b7 based on estimated ranges for Scott A strain of *Listeria monocytogenes* (Tienungoon *et al*. 2000).

This definition was used to create a *continuous variable expressing the no-growth probability* by expressing the not-supporting growth probability (*1-P)* in terms of the right hand side of the above formula. In case the temperature, wateractivity and the pH value was below their respective minimal values $T_{\min}=0.4164$, $a_{w\ min} = 0.9142$, $pH_{\min}=3.35$, the continuous variable expressing the no-growth probability was taken equal to 1.

For more insights in the relation between the "EC 2073/2005 NSG" indicator and the continuous variable expressing the no-growth probability, we refer to Appendix B.2.

Packaging type

The variable Packaging type (with four categories) caused sparseness problems in some of the final models and therefore a binary variable (Modified atmosphere versus All other packaging types) was defined. The binary variable will be denoted by Packaging type$^{(c)}$. To have a consistent presentation of the final models, it was decided to replace the variable Packaging type in all final models by the binary variable Packaging type$^{(c)}$.

Type of retail outlet

The variable Type of retail outlet (with four categories) caused sparseness problems in some of the final models and therefore a binary variable ("Supermarket or small shop" versus "All other types of retail outlet") was defined. The binary variable will be denoted by Type$^{(c)}$ of retail outlet. To have a consistent presentation of the final models, it was decided to replace the variable Type of retail outlet in all final models by the binary variable Type$^{(c)}$ of retail outlet.

Animal species of the origin of the meat product

The variable Animal species of the origin of the meat product (with eight categories) caused sparseness problems in some of the final models and therefore a binary variable ("Avian species" versus "Other species") was defined. The binary variable will be denoted by Animal species$^{(c)}$ of the origin of the meat product. To have a consistent presentation of the final models, it was decided to replace the variable Animal species of the origin of the meat product in all final models by the binary variable Animal species$^{(c)}$ of the origin of the meat product.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sampling season

The variable "date of sampling" was transformed into "Sampling season", where "winter" represents the months December, January and February, and so on for the other seasons.

Remaining Shelf-life

The remaining shelf-life was defined as the difference between the final date for using the product (as labelled "use by date") and the date of collection of the sample ("date of sampling").

Optional data and variables

Some additional (optional) data and variables were collected on a voluntary basis by MS. However, the effects of these optional factors could not be evaluated due to the scarcity and/or imbalance or responses of the data reported.

4.3.4. Single-factor model

In order to take into account the hierarchical structure in the dataset (country, city and store), GEE (with Independence correlation structure) was used to study the association between the outcome variable and a potentially associated factor. Weighted and unweighted models were fitted. A sensitivity analysis was performed through a logistic regression using the method of Firth.

For packaged (not frozen) hot or cold smoked or gravad fish, the **"EC 2073/2005 NSG" indicator**, as well as its interaction with the potentially associated factor, is included in the single-factor model. So in this situation, the "single-factor model" sections refer to models with **one factor in addition to the "EC 2073/2005 NSG" indicator** (and their interaction). As the results of the fits of these single-factor models are considered as preliminary explorative analyses, no model reduction techniques were applied.

4.3.5. Multiple-factors model

The joint association between the outcome variable and all potentially associated factors was examined by fitting multiple factor regression models. Main effects and interaction effects between all factors were included in the full model, which was reduced to a final model using model selection techniques. The main effect of the "EC 2073/2005 NSG" indicator was always included in the final model, even if it appeared to be not significant. As a sensitivity analysis, the final model was refit with the continuous variable expressing the no-growth probability.

4.3.5.1. Analysis of multicollinearity among potentially associated factors

Highly intercorrelated factors may cause multicollinearity problems when included all together in regression models. Such models may get computationally unstable and inference may become spurious. The Variance Inflation Factor (VIF) was used as a formal method to detect correlation among factors (multicollinearity). This VIF factor measures how much the variances of the estimated regression coefficients are inflated compared to when the factors are perfectly unrelated. Essentially, each potential risk factor X_k is regressed against all other factors. The corresponding coefficient of multiple determination R_k^2 is then used to calculate the VIF:

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

$VIF = (1 - R_k^2)^{-1}$.

A VIF value that equals 1 indicates that there is totally no correlation among factors, whereas VIF values greater than 1 indicate some correlation. Small to moderate values of VIF do not cause any problem, but VIF values exceeding 10 are interpreted as an indication of strong multicollinearity and consequently of potential problems.

For the categorical covariates, the VIF can be calculated in a similar way using:

$R^2 = 1 - \exp(2[\ln L(M) - \ln L(0)]/n)$,

With ln *L(M)* and ln *L(0)* representing the maximised log-likelihoods for the fitted model and the null model, containing only the intercept, and n referring to the sample size (Neter *et al*., 1996; Agresti, 2013).

4.3.5.2. Model building

Building a multi-factor model while accounting for all complexities (low prevalence, hierarchical data, multiple factors) is a challenging exercise. In order to take the hierarchical structure into account, GEE models were fitted. The complexity of the model increases as the number of explanatory variables increases, especially in case of nominal categorical variables with many categories. This condition of many categorical variables may also cause sparseness and may lead to computational/convergence problems. Hence, the number of factors in the final model needs to be reduced. In any case it is easier to interpret a univariabler model, and it is an unwritten law in statistics to find the right balance between accuracy and complexity: find the univariablest model that reaches sufficient accuracy.

As there are so many explanatory variables in the dataset, a semi-automatic procedure of variable selection and reduction was considered. One effective way to do the variable reduction in case of a binary outcome is by using automatic selection procedures for logistic regression (as automatic procedures are not available in SAS (or R) for GEE). A selected submodel resulting from an automated logistic regression procedure needs to be examined further in order to get a fine-tuned final model. Indeed, as logistic regression typically leads to consistent estimates but too small estimated standard errors in case of hierarchically clustered data, the selected logistic regression model, now refit as a GEE model, can be further reduced by deleting those factors which are no longer significant in the corresponding GEE model (see e.g. Aerts *et al.* 2002).

Therefore an appropriate procedure contains the following steps:

1. automated model selection using logistic regression (possibly indicating too many significant effects as clustering/correlation has been ignored),
2. refitting the selected model by GEE and reduce that model to get a final model,
3. further sensitivity analyses using Firth's approach, exact logistic regression and weighted GEE analyses.

In more detail, the following procedure was applied:

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Step 1: Subset selection approach using logistic regression.

The "all subsets" selection approach of ordinary logistic regression was used to identify a small group of models that are "good" according to a specific criterion.
The subset selection approach finds a specified number of models with the highest likelihood score (chi-square) statistic for all possible model sizes, from 1, 2, 3 multiple-factors models, and so on, up to the single model containing all of the factors (and their interactions). The best reduced model is then determined using the AIC value, where the lower AIC corresponds to a better model.

An automatic procedure was used to run the "all subsets" selection approach. In this procedure a categorical variable with more than two categories is represented by a set of dummy variables (*c-1* dummy variables in case of *c* categories). A dummy variable is an indicator variable that takes the value *one* or *zero* to indicate the presence or absence of a certain category of a categorical risk factor. For each categorical variable with *c* categories, we need *c-1* dummy variables. We illustrate this with the variable Fish species. It has 5 categories: salmon, herring, mackerel, mixed fish and other fish. We choose one reference or baseline category: e.g. salmon. The outcome of this reference category will be compared to the outcome of the other categories. However the choice of the reference category does not influence the model building and model inference. Four dummy variables are created:

Categorical variable: Fish Species	**Dummy D_1: herring**	**Dummy D_2: mackerel**	**Dummy D_3: mixed fish**	**Dummy D_4: other fish**
Salmon	0	0	0	0
Herring	1	0	0	0
Mackerel	0	1	0	0
Mixed fish	0	0	1	0
Other fish	0	0	0	1

Consider the following logistic regression model for the prevalence π = Pr(*P=1*) of *Listeria monocytogenes* (*P=1* for a positive outcome, and *0* otherwise) and with Fish species as a risk factor

$$\ln\left\{\frac{\pi}{1-\pi}\right\} = \beta_0 + \beta_1 D_1 + \beta_2 D_2 + \beta_3 D_3 + \beta_4 D_4.$$

For the salmon Fish species (the reference category), the model simplifies to the intercept only (as all dummies equal 0)

$$\ln\left\{\frac{\pi(\text{salmon})}{1-\pi(\text{salmon})}\right\} = \beta_0 ,$$

whereas for mackerel the model reduces to (as only the second dummy variable equals 1)

$$\ln\left\{\frac{\pi(\text{mackerel})}{1-\pi(\text{mackerel})}\right\} = \beta_0 + \beta_2.$$

Consequently the parameter β_2 expresses the change in the log odds $\ln\left\{\frac{\pi}{1-\pi}\right\}$ and hence in the prevalence when looking at mackerel as compared to the baseline or reference category *salmon*. After some basic manipulations, $\exp(\beta_2)$ appears to be nothing else than the odds ratio for a positive outcome when comparing *mackerel* to *salmon* (as a two by two table with positive/negative classification in one direction and mackerel/salmon in the other direction)

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

$$\exp(\beta_2) = \frac{\pi(\text{mackerel}) \times (1 - \pi(\text{salmon}))}{(1 - \pi(\text{mackerel})) \times \pi(\text{salmon})}.$$

This can be done in the same way for the “herring”, “mixed fish” and “other fish” species, always in comparison with the baseline “salmon”.

Regarding the choice of the baseline category, one has the following considerations:

- It does not matter which category is chosen as baseline, as one can derive any comparison from the model with a specific baseline category. For instance in the above model formulated with *salmon* as a reference category, one can easily see that the odds ratio for a positive outcome when comparing *mackerel* to *herring* (instead of *salmon*) is given by

$$\exp(\beta_2 - \beta_1) = \frac{\pi(\text{mackerel}) \times \left(1 - \pi(\text{herring})\right)}{\left(1 - \pi(\text{mackerel})\right) \times \pi(\text{herring})}.$$

- An optimal choice from computational perspective is to select the category with the highest occurance as the baseline or reference category.

- But another criterion is to take that category that allows the most natural interpretation (which actually often corresponds the most frequently observed categeory)..

Since the automatic procedure is unaware of the connection between the dummy variables, it is possible that the selected model does not contain all dummy variables corresponding to this single categorical variable. Therefore an updated selected model needs to be fitted manually which contains the complete set of dummy variables. The update of the selected model is done in Step 2, together with the sensitivity analysis.

Step 2: GEE Model and Sensitivity Analysis.

After updating the model to contain the complete set of dummy variables related to a particular categorical variable, the model selected by the subset selection approach of step 1, is refit under a GEE approach. Thus, we fit the GEE model using the subset of the selected (categorical) variables in order to take into account the hierarchical structure of the data. It is expected that the significance of some factors might disappear, and consequently the model can be further simplified accordingly. Weighted (based on sample planned and population) and unweighted GEE (Ind) were fitted for the final model.

Sensitivity analysis using the method of Firth was used for the final model for the unweighted and weighted model.

Moreover, the interaction between packaging type and temperature has been added to the final model as they are considered to be biologically meaningful. The variable Possible slicing was also kept in the model because of its biological relevance. For packaged (not frozen) hot or cold smoked or gravad fish, the “EC 2073/2005 NSG” indicator as well as its interaction with the potentially associated factor is considered as an additional factor. As a sensitivity analysis, the “EC 2073/2005 NSG” indicator was replaced by the continuous variable expressing the no-growth probability in the final model.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

4.3.5.3. Goodness of fit

To check the goodness of fit of the final model, the test of Hosmer and Lemeshow was applied. Agresti (2013) shows that the test is based on partitioning the observations and fitted values according to their success predicted probabilities. The Hosmer–Lemeshow test statistic is given by:

$$\sum_{i=1}^{G} \frac{\left(\sum_j y_{ij} - \sum_j \hat{\pi}_{ij}\right)^2}{\left(\sum_j \hat{\pi}_{ij}\right)\left[1 - \left(\sum_j \hat{\pi}_{ij}\right)/n_i\right]}$$

Where y_{ij} denote the binary outcome for observation j in group i of the partition , $i = 1,2, \dots, g$, $j = 1,2, \dots, n_i$. And $\hat{\pi}_{ij}$ denote the corresponding fitted probability for the model fitted to the ungrouped data.

However, the test is developed for logistic regression only and not for GEE or Firth's method. Consequently it is not known what effect the clustered nature in combination with the sparseness of the data has on the validity of the test. All possible models will be investigated through the subset selection approach. If the test of Hosmer and Lemeshow would suggest lack of fit of the chosen model, it is therefore not obvious how to extend or improve the model. Nonlinear models were not feasible to fit. We also used the Deviance and the Pearson Chisquare goodness of fit, which both compare the current model with the saturated model (the most complicated model available for the data at hand). If necessary conditions for valid tests are met, both test results are expected to be close. In section 5.2.1.4 however the Deviance test does not reject whereas the Pearson test does. This extreme difference between both tests is an indication that asymptotics are problematic in these goodness of fit tests. So, it seems that the conclusions of these goodness of fit tests needs to be interpreted with cautiousness in such settings. For technical details on the approach, see e.g. Agresti (2013).

4.3.5.4. Interpretation as odds ratios

The interpretation of the regression parameters in the final multiple-factors model needs to be handled with care. The interpretation is based on odds ratios. An odds ratio (OR) is a measure of association between an exposure to a risk factor and a binary outcome. It is the ratio of the odds of a positive outcome under two different conditions for the risk factor. The odds is the ratio $\pi/(1-\pi)$ of the probability that an event will occur to the probability that it will not occur. It is different from the risk π, which is simply the probability that the event will occur. In the same way an odds ratio is the ratio of two odds, whereas the relative risk is the ratio of two risks. In case of a (very) rare phenomenon (low prevalence, so π small), both are approximately the same, as the denominator in an odds $1 - \pi$ is close to 1 in that case.

The regression coefficients (*β*s) are related to the ORs as follows: the exponentiated value of a regression coefficient *exp(β)* equals the odds ratio associated with a one-unit increase in the exposure. This applies to factors that do not have any interaction terms.

When interaction is present, the odds ratio between a particular risk factor and the outcome varies according to and depends upon the value of the other risk factor involved in the interaction term. Interaction between two variables can be positive (their joint role increases the effect) or negative (their joint role decreases the effect).

Single-factor model:
Suppose we are studying the role of two binary factors: Possible slicing (*S=1* in case of slicing and *0* otherwise) and "EC 2073/2005 NSG" indicator (*NG=1* in case of samples included in ''EC 2073/2005

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

NSG'' and *0* otherwise), for estimating e.g. the prevalence π = Pr(*P=1*) of *Listeria monocytogenes* (*P=1* for a positive outcome, and *0* otherwise). The logit of the probability π is modeled as a function of S and NG (including main effects and an interaction effect) as follows:

$$\ln\{\pi/(1-\pi)\} = \beta_0 + \beta_1 S + \beta_2 NG + \beta_3 (S \times NG)$$

or equivalently

$$\text{odds} = \pi/(1-\pi) = \exp(\beta_0 + \beta_1 S + \beta_2 NG + \beta_3 S \times NG)$$

or

$$\pi = \frac{\exp(\beta_0 + \beta_1 S + \beta_2 NG + \beta_3 (S \times NG))}{1+\exp(\beta_0 + \beta_1 S + \beta_2 NG + \beta_3 (S \times NG))}.$$

This leads to the following four combinations:

Possible slicing (S)	**EC 2073/2005 NSG (NG)**	**Odds for a positive outcome**	**OR as compared to the reference category**
0	0	$\exp(\beta_0)$	1 as it is the reference
1	0	$\exp(\beta_0 + \beta_1)$	$\exp(\beta_1)$
0	1	$\exp(\beta_0 + \beta_2)$	$\exp(\beta_2)$
1	1	$\exp(\beta_0 + \beta_1 + \beta_2 + \beta_3)$	$\exp(\beta_1)\exp(\beta_2)\exp(\beta_3)$

The prevalence for the baseline category (*no slicing* and *sample not included in "EC 2073/2005 NSG"*) equals

$$\pi = \frac{\exp(\beta_0)}{1+\exp(\beta_0)}.$$

From the above table, it follows that the model reduces in case of supporting growth (*NG=0*) to:

$$\ln\{\pi/(1-\pi)\} = \beta_0 + \beta_1 S$$

where $\exp(\beta_1) = OR(P,S|NG=0)$ represents the ratio of the odds on a positive outcome for sliced fish to that odds for non-sliced fish, in the subset of supporting growth samples (*NG=0*). Note that no effect ($\beta_1 = 0$) corresponds to an OR=1. An OR larger than 1 quantifies a positive effect of Possible slicing (higher chances for contamination), whereas an OR smaller than 1 quantifies a negative effect of Possible slicing.

Meanwhile, for samples included "EC 2073/2005 NSG" (*NG=1*), the model can be rewritten as

$$\ln\{\pi/(1-\pi)\} = (\beta_0 + \beta_2) + (\beta_1 + \beta_3)S$$

where $\exp(\beta_1 + \beta_3) = OR(P,S|NG=1)$ represents the ratio of the odds on a positive outcome for sliced fish to that odds for non-sliced fish, in the sample included in "EC 2073/2005 NSG" (*NG=1*).

Since $\exp(\beta_1 + \beta_3) = \exp(\beta_1)\exp(\beta_3)$, we have that :

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

$$OR(P,S|NG=1) = OR(P,S|NG=0) \times \exp(\beta_3)$$

which illustrates how $\exp(\beta_3)$ quantifies the way in which the effect of possible slicing (S) on the prevalence changes for the "EC 2073/2005 NSG" samples as compared to the supporting growth subset. So the effect of Possible slicing depends on the value of the "EC 2073/2005 NSG" indicator *NG*. That is the interpretation of an interaction term.

Not that in case of no interaction ($\beta_3 = 0$)

$$OR(P,S|NG=1) = OR(P,S|NG=0) = \exp(\beta_1)$$

regardless the value of the "EC 2073/2005 NSG" indicator.

In case one or both factors is continuous, the interpretation is similar. For example, replacing the Possible slicing indicator *S* with temperature *T*, the odds ratio $OR(P,T|NG=1)$ represents the ratio of the odds on a positive outcome for temperature *T=t+1* to that odds for temperature *T=t* (i.e. the change in the odds for a unit increase of temperature), in the sample that included in "EC 2073/2005 NSG" (*NG=1*).

If the interaction between factors is significant, the main effects are no longer summarizing the effect of the factors. Indeed, the effect of one risk factor varies with the value of the other risk factor, and one needs to look at the main effects together with the interaction effect. It is common practice to keep the main effects in the model even if they are not significant.

For more details on the interpretation of ORs in logistic regression models and extensions thereof, see Agresti (2013).

4.3.6. Testing hypotheses and level of significance

Throughout this scientific report the level of significance for hypotheses testing was set to 0.05. All confidence intervals are constructed with 95% coverage probability.

Different test statistics are available in general, but the most commonly used statistic is the Wald statistic, which is very similar to the well-known t-test statistic but squared. In case one wants to test whether a particular regression coefficient β is zero or not, so one is interested in testing the null hypothesis

$$H_0: \beta = 0$$

versus the alternative hypothesis H_1: $\beta \neq 0$, the Wald statistic *W* equals a t-statistic squared

$$W = \left(\frac{\hat{\beta}}{\mathrm{se}(\hat{\beta})}\right)^2$$

which has an apporoximate chi-squared distribution with 1 degree of freedom under the null hypothesis (its approximation is valid if the sample size is large enough). This type of quadratic form can be generalized to test the null hypothesis that 2 or more parameters are all equal to 0. The degrees of freedom of the chi-squared null distribution is then equal to the number of parameters set all together to 0 in the null hypothesis. Such null hypotheses are of interest when testing whether the coefficients of all dummies representing one and the same categorical variable are equal to 0 or not. It is also the case

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

when we test the significance of a factor that interacts with another factor, as the total effect is represented by the main effect as well as the interaction effect.

4.3.7. Cautiousness for the interpretation of factors and the conclusions from statistical models

More advanced statistical models and methods aimed at accounting for all complexities in the data, as far as possible. The results from the final models however have to be interpreted with care, for several reasons:

- First of all, the significant effects point at relevant statistical associations, but cannot be interpreted as causal relationships.

- It can be expected that many factors and explanatory variables may cause heterogeneity in the prevalence. But due to the high dimensionality and the sparseness of data in particular combinations, it is not possible to take all sources of heterogeneity into account. As known and discussed extensively in literature (see e.g. Agresti, 2013) this implies that one has to be very careful with interpretation of estimated effects. To get some further insights in the impact of the sparseness, the final models were refitted with exact logistic regression and with Firth's method, as part of the sensitivity analyses. However, we could only include the results of the exact logistic regression for one final model, because convergence issues occured for all other final models.

- As discussed above the sampling size did not perfectly follow the survey design, and the survey design did as well not perfectly reflect population sizes. For that reason, unweighted analyses were complemented with weighted analyses with two types of weights (based on planned sample size or based on population size). However, all weights are approximate weights for unknown optimal weights. Therefore the weighted analyses were considered as part of the sensitivity analyses, but again the estimated effects should not be overinterpreted.

Nevertheless, despite the above considerations, we believe that the data and the results from the fitted models can provide new insights, by confirming the role of certain factors as known from literature, or by pointing at some unexpected effects which then can be examined in more detail. Such investigations might shed some light on the complex interplay of all factors on the prevalence of *Listeria monocytogenes.*

4.3.8. Software

SAS and R software are used. SAS is mainly used for the estimation of the models, whereas R will be mainly used for graphical presentations and visualizations.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5. Results

In this section all results are presented, according to the methodology as explained in Section 4.3. For each of the food categories, we first present the descriptive statistics of potentially associated factors, followed by the results of the analysis of each separate factor. Next all factors are analysed in a multi-factor model. For packaged (not frozen) hot or cold smoked or gravad fish, the "EC 2073/2005 NSG" indicator is included as an additional factor. Unweighted as well as weighted estimation was considered for all final models, in order to examine the sensitivity of the estimates (ORs) and corresponding standard errors to corrections for the non-optimally achieved sampling schemes. All countries (MS and Norway) are included in the analysis.

5.1. Results for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling for all participating countries

5.1.1. Prevalence for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling

In this section, samples were considered contaminated by *Listeria monocytogenes* if they were positive with the detection test or had a count of at least 10 cfu/g with the enumeration test, for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling.

5.1.1.1. Description of the samples

The following tables and figures provide further insights for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling. It is important to realize that the observed differences might be due to other factors, which is the reason for considering the multivariable analysis in the next section.

The percentage of contaminated samples (prevalence) for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling shows that only 10.25% are contaminated with *Listeria monocytogenes* (Table 1:).

Table 1: Descriptive statistics for the prevalence of packaged (not frozen) hot or cold smoked or gravad fish samples contaminated by *Listeria monocytogenes*, at time of sampling for all participating countries*

Samples	Frequency	Percentage
Not contaminated	2 740	89.75
Contaminated	313	10.25
Total	3 053	

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 2: shows the number of contaminated samples by country and Table 3: the number of samples, towns, and outlets by country.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 2: Number of samples contaminated and not contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples by country

Country	Number of samples not contaminated	Number of samples contaminated
Austria	123	5
Belgium	22	5
Bulgaria	31	14
Cyprus	24	3
CzechRepublic	9	3
Denmark	51	9
Estonia	25	5
Finland	53	10
France	370	21
Germany	445	29
Greece	59	0
Hungary	50	11
Ireland	30	1
Italy	316	73
Latvia	26	3
Lithuania	25	5
Luxembourg	17	5
Malta	36	0
Netherlands	59	7
Norway	56	3
Poland	150	50
Romania	57	3
Slovakia	56	4
Slovenia	22	7
Spain	191	11
Sweden	55	12
United Kingdom	382	14
Total	2 740	313

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 3: Number of samples, towns and outlets by country

Country	Number of Samples	Number of Towns	Number of Outlets
Austria	128	7	123
Belgium	27	19	22
Bulgaria	45	4	3
Cyprus	27	4	9
CzechRepublic	12	8	12
Denmark	60	4	35
Estonia	30	5	20
Finland	63	8	61
France	391	8	3
Germany	474	271	404
Greece	59	2	7
Hungary	61	10	13
Ireland	31	2	15
Italy	389	14	386
Latvia	29	6	21
Lithuania	30	3	27
Luxembourg	22	9	10
Malta	36	16	17
Netherlands	66	12	58
Norway	59	6	50
Poland	200	8	87
Romania	60	8	37
Slovakia	60	8	48
Slovenia	29	10	27
Spain	202	8	96
Sweden	67	8	64
United Kingdom	396	10	121
Total	3 053	478	1 776

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The prevalence of contaminated samples in all participating countries (Table 4:) is 10.25 % for “Supermarket or small shop”. For “Street market or farmers’ market”, “Speciality delis” and “Other (free text field)” the corresponding prevalences are 50%, 33.33% and 6.82%.

Table 4: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling by Type of retail outlet for all participating countries*

Type of retail outlet	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Supermarket or small shop	2 696	308	3 004	10.25
Speciality delis	2	1	3	33.33
Street market or farmers’ market	1	1	2	50.00
Other (free text field)	41	3	44	6.82
Total	**2 740**	**313**	**3 053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Because of sparseness issues, the four original categories of Type of retail outlet were merged to two categories (“Supermarket or small shop” and “All other types of retail outlet”). Both categories give almost the same percentage (about 10%) of contaminated samples (Table 5:).

Table 5: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling by Type[(c)] of retail outlet for all participating countries*

Type[(c)] of retail outlet	Sample		Total	Prevalence of contaminated samples
	Not Contaminated	Contaminated		
Supermarket or small shop	2 696	308	3 004	10.25
All other types of retail outlet	41	5	49	10.20
Total	**2 740**	**313**	**3 053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The variable “date of sampling” was transformed into “Sampling season”, where “winter” represents the months December, January and February, and so on for the other seasons. Table 6: shows that the prevalence is 11.30% for autumn, 7.41% for spring, 11.05% for summer and 10.74% for winter.

Table 6: Prevalence of samples contaminated by *L. monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling by Sampling season for all participating countries*

Sampling Season	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Autumn	832	106	938	11.30
Spring	625	50	675	7.41
Summer	676	84	760	11.05
Winter	607	73	680	10.74
Total	**2 740**	**313**	**3 053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

For the Subtype of the fish product in all participating countries, Table 7: shows that there are 8.8% contaminated samples in the category “Unknown smoked fish”, 16.72% in the category “Cold smoked fish”, and for “Hot smoked fish” and “Gravad fish” there are 6.17% and 11.86% of contaminated samples respectively.

Table 7: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling by Subtype of the fish product for all participating countries*

Subtype of the fish product	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Unknown smoked fish	1 482	143	1625	8.80
Cold smoked fish	533	107	640	16.72
Hot smoked fish	502	33	535	6.17
Gravad fish	223	30	253	11.86
Total	**2 740**	**313**	**3 053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The Fish species in all participating countries (Table 8:): 12.26% are contaminated in the category "Salmon" and 5.85% in the category "Mackerel". For the category "Other Fish", "Mixed Fish" and "Hering" the corresponding prevalences are 8.36% , 6.44% and 9.29% .

Table 8: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling by Fish Species for all participating countries*

Fish Species	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Salmon	1 631	228	1 859	12.26
Mackerel	386	24	410	5.85
Mixed Fish	305	21	326	6.44
Herring	166	17	183	9.29
Other Fish	252	23	275	8.36
Total	**2 740**	**313**	**3 053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The preservative and acidity regulators for all participating countries: Table 9: , showing that there are 9.74%, 4% and 45.45% of contaminated samples in the category "no AP and AR", "AP or AR" and "AP and AR" respectively.

Table 9: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling by preservative and acidity regulators for all participating countries*

Preservatives and acidity regulators	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
0: Products with no AP and AR (no AP and AR)	2 631	284	2 915	9.74
1: Products with 1 AP+AR (AP or AR)	79	4	83	4.82
2: Products with 2 or more AP+AR (AP and AR)	30	25	55	45.45
Total	**2 740**	**313**	**3 053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The distribution of pH test results for packaged (not frozen) hot or cold smoked or gravad fish samples at sample collection is shown in Table 10: , Figure 2: and Figure 3: .

Table 10: Summary statistics of pH test result (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*, for samples being contaminated and not contaminated by *Listeria monocytogenes* at time of sampling

pH test result	Number of samples		Total
	Not contaminated	Contaminated	
n	2 740	313	3 053
mean	6.03	6.02	6.03
sd	0.34	0.28	0.34
min	3.22	4.2	3.22
lower whisker	5.59	5.68	5.61
Q1	5.95	5.95	5.59
median	6.05	6.04	6.05
Q3	6.19	6.14	6.19
Upper whisker	6.55	6.4	6.52
max	7.6	6.7	7.6
range (max-min)	4.38	2.5	4.38

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

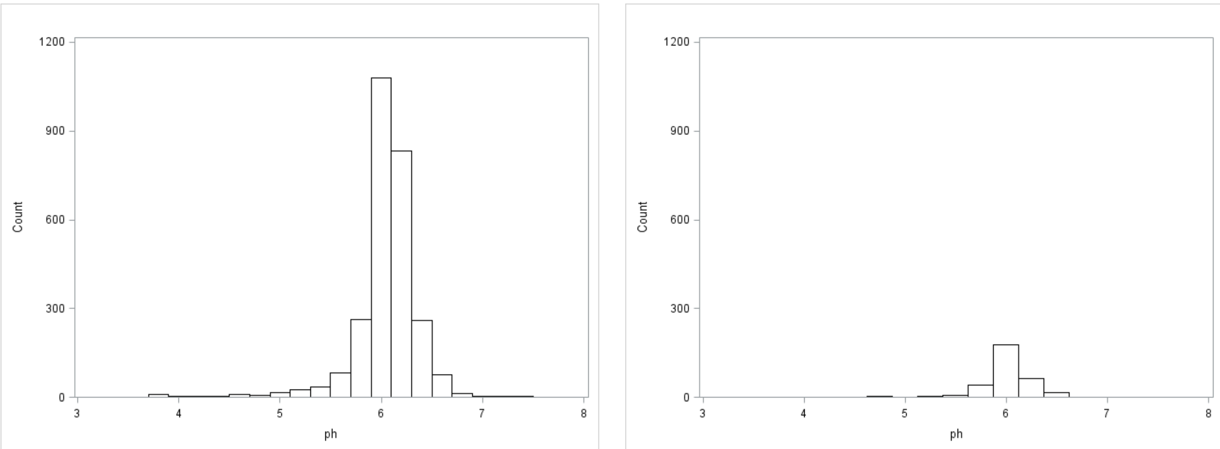


Figure 2: Histogram of pH test result (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* at time of sampling.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

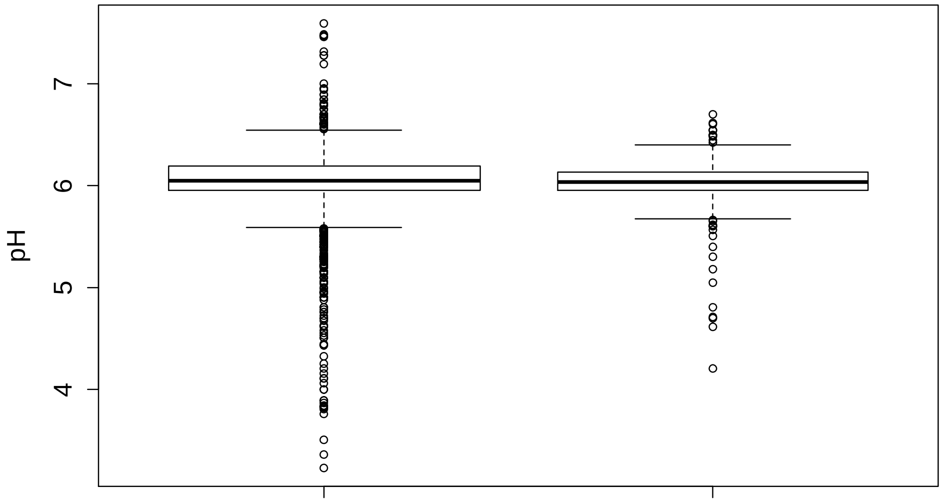


Figure 3: Boxplot[8] of pH test result (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* at time of sampling

The distribution of water measurement results for packaged (not frozen) hot or cold smoked or gravad fish samples at time of sampling is shown in Table 11: , Figure 4: and Figure 5: .

Table 11: Summary statistics of water activity result (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*, for samples being contaminated and not contaminated by *Listeria monocytogenes* at time of sampling

Water activity result	Sample: Not contaminated	Sample: Contaminated	Total
N	2 740	313	3 053
Mean	0.96	0.96	0.96
Sd	0.02	0.02	0.02
min	0.88	0.88	0.88
lower whisker	0.92	0.92	0.92
Q1	0.95	0.95	0.95
median	0.96	0.96	0.96
Q3	0.97	0.97	0.97
Upper whisker	1	0.99	1
max	1	0.99	1
range (max-min)	0.12	0.11	0.12

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

[8] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

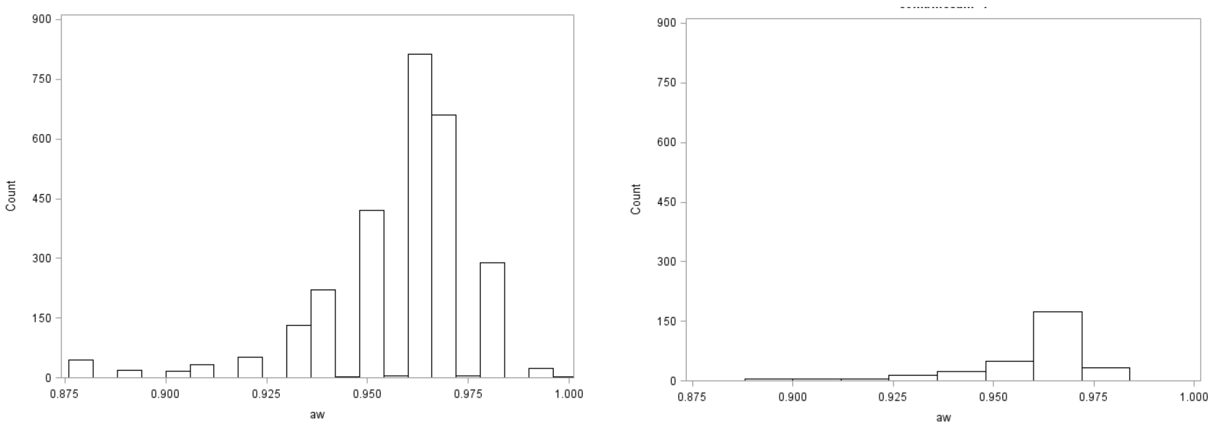


Figure 4: Histogram of water activity result (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples not contaminated (left) and contamianted (right) by *Listeria monocytogenes* at time of sampling

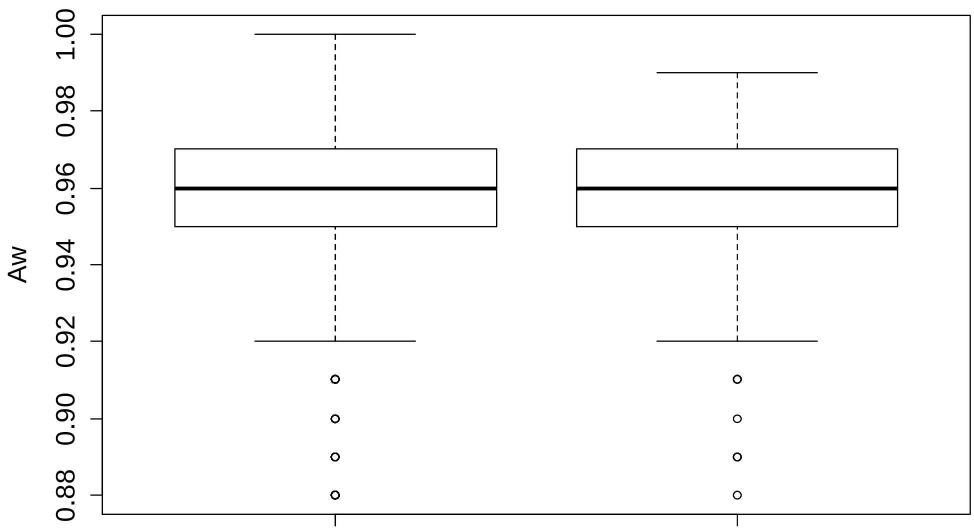


Figure 5: Boxplot[9] of water activity result (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples not contaminated (left) and contamianted (right) by *Listeria monocytogenes* at time of sampling

[9] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 12: shows that the prevalence of *Listeria monocytogenes* at time of sampling for sliced fish is 11.82%, while it is only 5.66% for non-sliced fish.

Table 12: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling by Possible slicing for all participating countries*

Possible slicing	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Sliced	2 006	269	2 275	11.82
Non-Sliced	734	44	778	5.66
Total	**2 740**	**313**	**3 053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

For "Packaging type" Table 13: shows that the prevalence of contaminated samples in the category "Vacuum", "Modified atmosphere", "Normal atmosphere" and "Other (free text)" is 12.77%, 7.94%, 4.18% and 11.11% respectively.

Table 13: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling by packaging type for all participating countries*

Packaging Type	Sample		Total	Prevalence of contaminated samples
	Not contaminated	contaminated		
Vacuum	1592	233	1825	12.77
Modified atmosphere	533	46	579	7.94
Normal atmosphere	527	23	550	4.18
Other (free text)	88	11	99	11.11
Total	**2 740**	**313**	**3 053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Because of sparseness issues, the binary variable Packaging type[(c)] was used, with 10.79 % contaminated samples in the category All other packaging types and 7.94% for samples in the category Modified atmosphere (Table 14:).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 14: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling by Packaging type[(c)] for all participating countries*

Packaging Type[(c)]	**Sample**		**Total**	**Prevalene of contaminated samples**
	Not contaminated	**Contaminated**		
Modified atmosphere	533	46	579	7.94
All other packaging types	2207	267	2474	10.79
Total	**2 740**	**313**	**3 053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The number of samples contaminated and not contaminated by *Listeria monocytogenes* by Country of production for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling is shown in Table 15: .

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 15: Number of samples contaminated and not contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples by Country of production

Country of production	Number of samples not contaminated	Number of samples contaminated
Austria	27	1
Belarus	1	0
Belgium	5	4
Bulgaria	28	11
Canada	2	0
Croatia	3	0
Cyprus	11	3
Czech Republic	22	0
Denmark	155	21
Estonia	26	6
Faroe Islands	0	1
Finland	40	4
France	434	21
Germany	164	4
Greece	61	0
Greenland	3	2
Hungary	8	3
Ireland	27	2
Italy	59	16
Latvia	40	9
Lithuania	95	21
Luxembourg	1	0
Netherlands	51	4
Norway	216	30
Poland	438	109
Romania	56	4
Slovakia	9	0
Slovenia	3	3
Spain	189	11
Sweden	52	7
Switzerland	1	0
Turkey	48	1
Ukraine	1	0
United Kingdom	456	15
United States	3	0
Vietnam	5	0
Total	2740	313

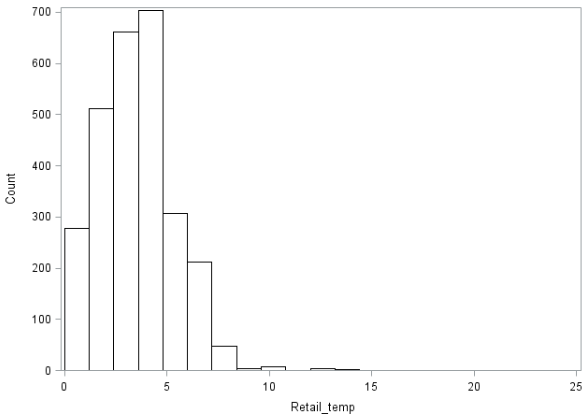
The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The distribution of storage temperature at retail (sample surface) for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling is summarized in Table 16: , Figure 6: and Figure 7: .

Table 16: Summary statistics of Storage Temperature at Retail by outcome (contaminated/not contaminated/total) in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling for all participating countries

Storage temperature at retail	Sample		Total
	Not contaminated	Contaminated	
n	2 740	313	3 053
mean	3.47	3.31	3.45
sd	1.83	1.43	1.79
min	0	0	0
lower whisker	0	0	0
Q1	2	2	2
median	3	3	3
Q3	4	4	4
Upper whisker	7	7	7
max	25	10	25
range (max-min)	25	10	25

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.



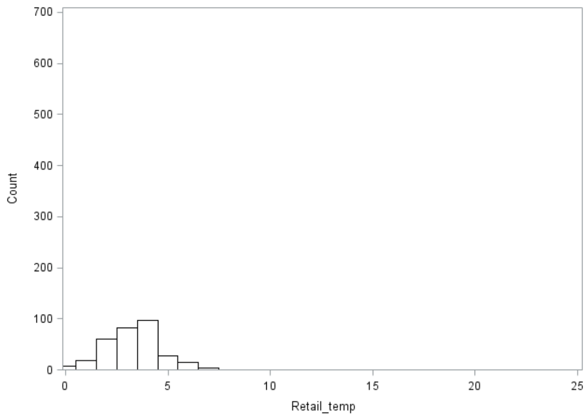


Figure 6: Histogram of storage temperature at retail (sample surface) of packaged hot or cold smoked or gravad fish samples for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* at time of sampling in all participating countries

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

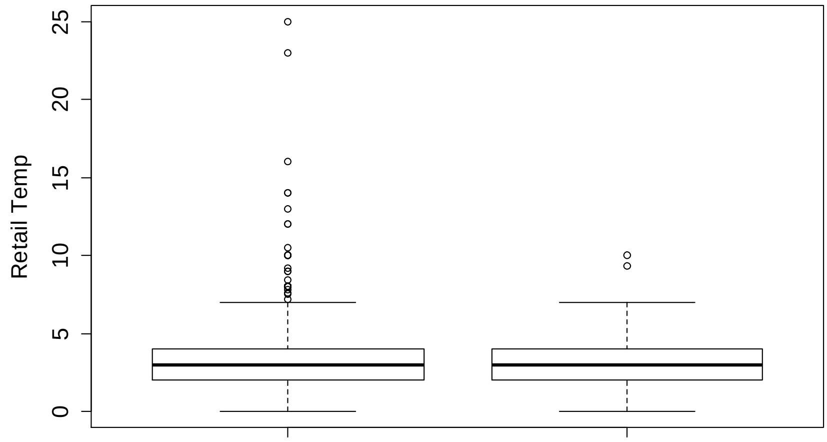


Figure 7: Boxplot[10] of storage temperature at retail for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* on the arrival at the laboratory for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries

Table 17: shows the prevalence of samples contaminated by *Listeria monocytogenes* for samples that are guaranteed to be transported in line with technical specifications. The transport protocol states that during the transport the sample was kept between 2 and 8 °C, if original storage temperature at retail was below 8 °C and remained free of external contamination and that the sample reached the laboratory in less than 48 hours. Table 17: shows that only one sample was not guaranteed to be transported in line with the technical specifications.

Table 17: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling by transport protocol for all participating countries*

Transport Protocol	Sample		Total	Prevalence of contaminated Samples
	Not contaminated	Contaminated		
Yes a)	2739	313	3052	10.26
No b)	1	0	1	0.00
Total	**2 740**	**313**	**3 053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) in line with technical specifications
b) not in line with technical specifications

[10] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The boxplot and histogram for the distribution of the remaining shelf-life in days are shown in Table 18: , Figure 8: and Figure 9: .

Table 18: Summary statistics of remaining shelf-life by outcome (contaminated / not contaminated / total) in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling for all participating countries*

Remaining shelf-life	Sample		Total
	Not contaminated	Contaminated	
N	2 740	313	3 053
Mean	22.97	20.22	22.68
Sd	38.47	13.96	36.73
Min	1	1	1
lower whisker	1	1	1
Q1	9	10	9
Median	14	16	15
Q3	23	28	23
Upper whisker	44	55	44
Max	519	92	519
range (max-min)	518	91	518

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

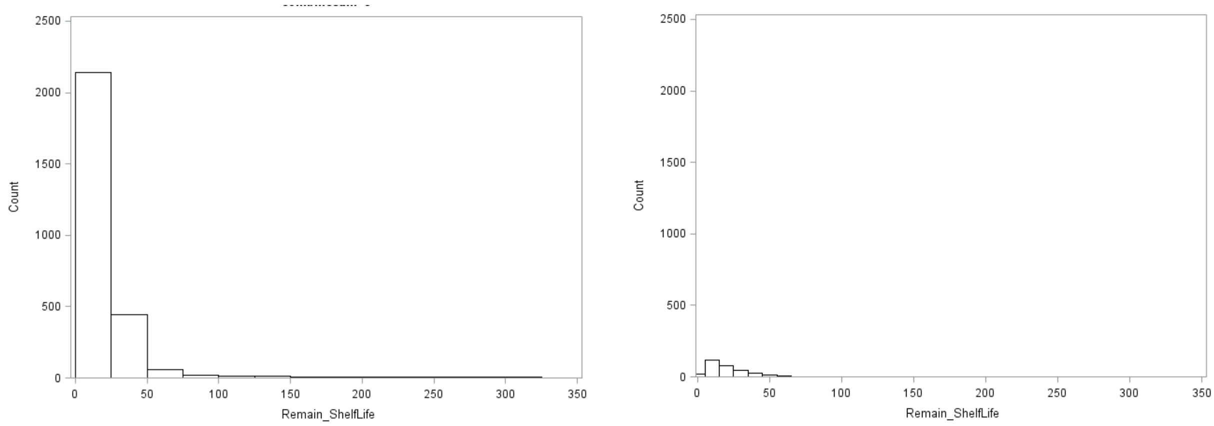


Figure 8: Histogram of remaining shelf-life for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* in all participating countries

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

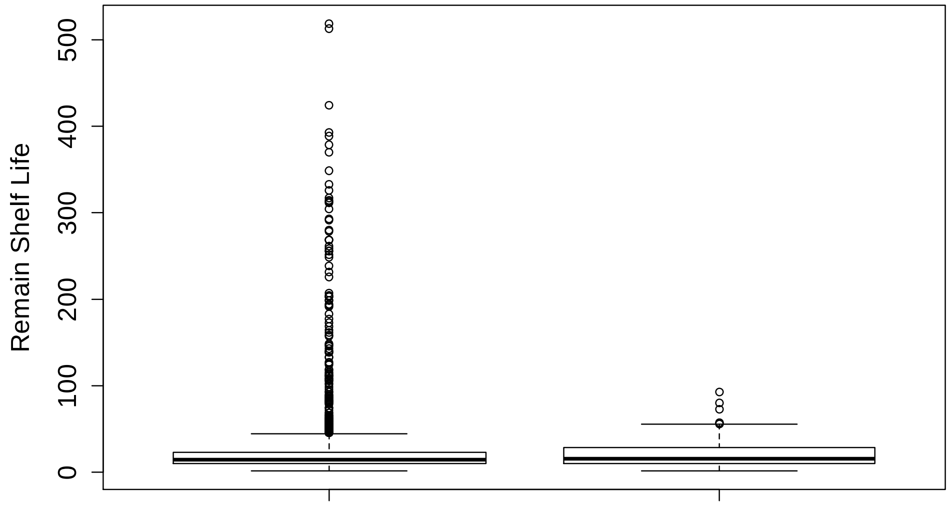


Figure 9: Boxplot[11] of remaining shelf-life for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* on the arrival at the laboratory for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries

The "EC 2073/2005 NSG" indicator is summarized in Table 19: , with 10.34% contaminated samples in the category 'not included in EC 2073/2005 NSG' and 9.05% contaminated samples in the category 'included in EC 2073/2005 NSG'.

Table 19: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling by "EC 2073/2005 NSG" indicator for all participating countries*

"EC 2073/2005 NSG"	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
For samples 'not included in EC 2073/2005 NSG'	2 549	294	2 843	10.34
For samples included in 'EC 2073/2005 NSG '	191	19	210	9.05
Total	**2 740**	**313**	**3 053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

[11] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.1.1.2. Single-factor model

GEE (Ind) has been applied to the analysis of single-factor model along with unweighted and weighted (based on planned sample and population sizes) approaches. In the end a sensitivity analysis has been considered using logistic regression with Firth approach.

All variables in the dataset have been fitted in the single-factor model, including the interaction with the "EC 2073/2005 NSG" indicator. Since the inclusion in "EC 2073/2005 NSG" indicator is based on pH and water activity, it was considered not to put pH and water activity in the model. Due to sparseness and separation (low or zero counts for one or more cells), most of the single factor analyses for variables with many categories did not converge, i.e. for country, the town retail outlet, date of testing, use by date, production date, packaging date and country of production. The single-factor model using transport protocol variable did also not converge.

The results of the single-factor model ("single") may not be over-interpreted since this step of analysis is mainly a preliminary analysis, preceeding the full multiple factor analyses.

The results of the single-factor model are presented in Appendix D.1.

5.1.1.3. Multiple-factors model

ANALYSIS WITH 'EC 2073/2005 NSG' INDICATOR

As described in the Material and Methods section, an "all subsets" model selection approach of multiple logistic regression was used for selecting variables. All variables together with interactions and the "EC 2073/2005 NSG" indicator including interactions were included in the model selection. The AIC criterion (the lower the better) was used to select the model (Appendix C.1). The selected model includes Subtype of the fish product, Fish species, Number of preservatives and acidity regulators, Possible slicing, Packaging type, remaining shelf-life, "EC 2073/2005 NSG" indicator and the interaction between Type[(c)] of retail outlet and the "EC 2073/2005 NSG" indicator as well as the interaction between Fish species and "EC 2073/2005 NSG" indicator. The main effect of Type[(c)] of retail outlet was added in the model since it appears in an interaction term[12]. The interaction between Packaging type and Storage temperature at retail as well as their main effects were included in the final model because of their biological relevance, even if not significant.

For further analysis, GEE (Ind) was used to analyse the selected model while accounting for the hierarchal nature of the data. After removing the non-significant effects from the GEE model, the final model is shown in Table 20: (overall result) and Table 21: (odds ratio estimate) .Weighted and unweighted analyses were applied for the final model as sensitivity analyses.

[12] It is a general guideline to include a main effect in the model if such an effect interacts with another effect in a significant manner, even if the main effect itself is statistically not significant.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 20: Wald Statistics For Type 3 GEE Analysis for model of prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Subtype of the fish product	3	14.02	0.00	3	18.79	0.00	3	15.19	0.00
Fish species	4	10.48	0.03	4	9.99	0.04	4	10.59	0.03
Preservatives and acidity regulators	2	43.11	<.0001	2	17.56	0.00	2	15.62	0.00
Possible slicing	1	4.35	0.04	1	2.74	0.10	1	1.96	0.16
Packaging type(c)	1	0.03	0.87	1	0.06	0.81	1	0.02	0.90
Remaining Shelf-life	1	3.77	0.05	1	3.07	0.08	1	0.57	0.45
Type(c) **of retail outlet**	1	0.13	0.72	1	0.07	0.78	1	0.21	0.65
Temperature at retail	1	0.56	0.46	1	0.45	0.50	1	0.56	0.45
"EC 2073/2005 NSG"	1	1.76	0.18	1	2.34	0.13	1	0.56	0.45
"EC 2073/2005 NSG" * Type(c) **of retail outlet**	1	6.39	0.01	1	5.31	0.02	1	6.51	0.01
"EC 2073/2005 NSG" * Fish species	4	21.68	0.00	4	22.91	0.00	4	18.79	0.00
Temperature at retail * Packaging type(c)	1	0.58	0.44	1	0.73	0.39	1	0.37	0.54

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 21: Odds ratios of GEE (Ind) for model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.16	0.09	0.31	<.0001	0.22	0.11	0.43	<.0001	0.20	0.10	0.40	<.0001
Subtype of the fish product [a)]	Gravad fish	0.73	0.46	1.16	0.19	0.69	0.42	1.11	0.13	0.61	0.37	1.01	0.05
Subtype of the fish product	Hot smoked fish	0.50	0.30	0.83	0.01	0.43	0.25	0.74	0.00	0.45	0.26	0.78	0.00
Subtype of the fish product	Unknown smoked fish	0.53	0.38	0.75	0.00	0.44	0.30	0.64	<.0001	0.48	0.33	0.71	0.00
Fish species [b)]	Herring	1.08	0.55	2.14	0.81	0.99	0.50	2.00	0.99	0.99	0.47	2.10	0.99
Fish species	Mackerel	0.52	0.29	0.93	0.03	0.50	0.27	0.92	0.03	0.49	0.26	0.92	0.03
Fish species	Mixed Fish	0.48	0.28	0.84	0.01	0.47	0.26	0.85	0.01	0.42	0.22	0.80	0.01
Fish species	Other Fish	0.82	0.49	1.37	0.45	0.78	0.46	1.32	0.35	0.72	0.41	1.25	0.24
Preservatives and acidity regulators [c)]	1: Products with 1 AP+AR	0.60	0.22	1.62	0.31	0.56	0.21	1.50	0.25	0.65	0.23	1.88	0.43
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	7.39	4.03	13.55	<.0001	5.32	2.32	12.21	<.0001	6.67	2.52	17.65	0.00
Possible slicing [d)]		1.61	1.03	2.53	0.04	1.48	0.93	2.37	0.10	1.43	0.87	2.37	0.16
Packaging type[(c) e)]	Modified atmosphere	0.94	0.42	2.07	0.87	0.91	0.40	2.04	0.81	0.95	0.42	2.17	0.90
Remaining Shelf-life		1.00	0.99	1.00	0.05	1.00	0.99	1.00	0.08	1.00	0.99	1.00	0.45
Type[(c)] of retail outlet [f)]	All other types of retail outlet	0.83	0.29	2.38	0.72	0.85	0.27	2.72	0.78	0.78	0.26	2.30	0.65
Temperature at retail		0.97	0.91	1.04	0.46	0.97	0.90	1.05	0.50	0.97	0.89	1.05	0.45
"EC 2073/2005 NSG" [g)]		0.53	0.21	1.35	0.18	0.48	0.19	1.23	0.13	0.67	0.23	1.92	0.45
"EC 2073/2005 NSG" * Type[(c)] of retail outlet	All other types of retail outlet	49.81	2.40	1032.15	0.01	40.82	1.74	956.42	0.02	47.23	2.45	911.69	0.01

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

"EC 2073/2005 NSG" * Fish species	Herring	0.63	0.11	3.68	0.61	0.74	0.12	4.68	0.75	0.65	0.10	4.24	0.66
"EC 2073/2005 NSG" * Fish species	Mackerel	6.95	1.91	25.28	0.00	7.74	2.20	27.26	0.00	5.29	1.33	21.00	0.02
"EC 2073/2005 NSG" * Fish species	Mixed Fish	1.00	0.17	5.90	1.00	1.30	0.22	7.73	0.77	0.81	0.10	6.48	0.85
"EC 2073/2005 NSG" * Fish species	Other Fish	0.80	0.13	4.82	0.81	0.97	0.17	5.46	0.97	0.60	0.10	3.51	0.57
Temperature at retail * Packaging type	Modified atmosphere	0.92	0.75	1.14	0.44	0.91	0.74	1.13	0.39	0.94	0.76	1.16	0.54

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Subtype of the fish product is "Cold smoked fish"
b) : The reference category for Fish Species "Salmon"
c) : The reference category for Preservatives and acidity regulators is "0: ProductsProducts with no AP and AR"
d) : The reference category for Possible slicing is "Non-Sliced"
e) : The reference category for Packaging Type[(c)] is "All other packaging types"
f) : The reference category for Type[(c)] of retail outlet is "Supermarket or small shop"
g) : The reference category for 'EC 2073/2005 NSG' is "not included in EC 2073/2005 NSG"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

However, the interaction effect of "EC 2073/2005 NSG" indicator and Type$^{(c)}$ of retail outlet (Table 21:) resulted in a huge OR and an extremely wide confidence interval, caused by the very low count in the category "All other types of retail outlet" for both values of the "EC 2073/2005 NSG" indicator (Table 22:). Therefore it was considered to drop this interaction from the model. As also the main effect of Type$^{(c)}$ of retail outlet was not significant, this variable no longer appears in the final model.

Table 22: Three-way cross classification table of Type$^{(c)}$ of retail outlet, "EC 2073/2005 NSG" indicator and outcome (*Listeria monocytogenes* contaminated/not contaminated) for samples in packaged (not frozen) hot or cold smoked or gravad fish at time of sampling.

Type$^{(c)}$ of retail outlet	**Not included in "EC 2073/2005 NSG"**			**Included in "EC 2073/2005 NSG"**		
	Sample			**Sample**		
	Not contaminated	**Contaminated**	**Total**	**Not contaminated**	**Contaminated**	**Total**
Supermarket or small shop	2 506	290	2 796	190	18	208
All other types of retail outlet	43	4	47	1	1	2
Total	2 549	294	2 843	191	19	210

The following tables show the result of GEE (Table 23: and Table 24:) along with the sensitivity analysis using Firth approach (Table 25: and Table 26:) after removing the interaction between the "EC 2073/2005 NSG" indicator and the Type$^{(c)}$ of retail outlet. As the main effect of Type$^{(c)}$ of retail outlet turned out to be not significant, it was also dropped from the model. The weighted and unweighted analyses were applied for this final model.

The unweighted GEE(Ind) result shows that the main effects of Subtype of the fish product, Fish species, Number of preservatives and acidity regulator, Possible slicing, remaining shelf-life and the interaction between the "EC 2073/2005 NSG" indicator and Fish species has statistically significant effects on the prevalence. Apparently the biologically relevant interaction between Storage temperature at retail and Packaging type$^{(c)}$ is not significant (p-value=0.45).

Table 24: shows the effect of each risk factor in the final model, in terms of odd ratios. The odds ratio of being contaminated (compared to not being contaminated) for hot smoked fish compared to cold smoked fish is equal to 0.50 (significantly different from 1). Consequently, the odds of being infected with *Listeria monocytogenes* is smaller for hot smoked fish than for cold smoked fish. The odds ratio for being *Listeria monocytogenes* contaminated for unknown smoked fish compared to cold smoked fish is equal to 0.54 (significantly different from 1). The odds of being infected with *Listeria monocytogenes* is larger for cold smoked fish than for unknown smoked fish. The odds for being infected with *Listeria monocytogenes* for cold smoked fish vs. gravad fish are not significantly different.

The odds ratio of being contaminated by *Listeria monocytogenes* for "Products with 2 or more AP+AR" compared to "0: Products with no AP and AR" is 7.15 with CI (3.92,13.02).

The odds of being contaminated by *Listeria monocytogenes* in sliced fish is 1.58 times the odds of non-sliced fish. Therefore the risk of being contaminated by *Listeria monocytogenes* is significantly larger for sliced fish.

The odds ratio of being contaminated by *Listeria monocytogenes* for one additional day remaining shelf-life is 0.997 (CI: 0.994 , 1). This seems to indicate a decreasing effect of remaining shelf-life on the prevalence, but one has to be cautious with interpretation. Statistical relationships are not necessarily reflecting causal relationships and non-explained heterogeneity might obscure observed effects.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Packaging type[(c)] appears in interaction with Storage temperature at retail, but the interaction effect is not significant.

The interaction between the non-supporting growth indicator and Fish species gave a significant effect for mackerel as compared to salmon. For samples not included in "EC 2073/2005 NSG", the odds for a sample with coutns exceeding the level of 100 cfu/g is significantly smaller for mackerel than for salmon (OR=0.51), whereas for the samples included in "EC 2073/2005 NSG" the situation is significantly different: the OR=0.51×6.94=3.54, indicating an opposite relationship.

Mixed fish has a significantly lower odds to have a *Listeria monocytogenes* count exceeding the level of 100 cfu/g as compared to salmon (OR=0.48). Interaction with the "EC 2073/2005 NSG" indicator is however not significant.

GEE Analysis for final model

Table 23: Wald Statistics For Type 3 GEE Analysis for final model (after dropping Type[(c)] of retail outlet) of prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi Square	P-Value	DF	Chi Square	P-Value	DF	Chi Square	P-Value
Subtype of the fish product	3	13.81	0.00	3	18.69	0.00	3	15.04	0.00
Fish species	4	10.68	0.03	4	10.20	0.04	4	10.83	0.03
Preservatives and acidity regulators	2	42.96	<.0001	2	17.66	0.00	2	15.75	0.00
Possible slicing	1	4.04	0.04	1	2.52	0.11	1	1.75	0.19
Packaging type[(c)]	1	0.04	0.85	1	0.07	0.79	1	0.02	0.88
Remaining Shelf-life	1	3.95	0.05	1	3.20	0.07	1	0.67	0.41
Temperature at retail	1	0.71	0.40	1	0.56	0.46	1	0.71	0.40
"EC 2073/2005 NSG"	1	1.72	0.19	1	2.30	0.13	1	0.54	0.46
"EC 2073/2005 NSG" * Fish species	4	15.15	0.00	4	18.29	0.00	4	11.87	0.02
Temperature at retail * Packaging type[(c)]	1	0.57	0.45	1	0.72	0.40	1	0.37	0.54

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 24: Odds ratios of GEE (Ind) for final model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.17	0.09	0.32	<.0001	0.22	0.11	0.44	<.0001	0.20	0.10	0.41	<.0001
Subtype of the fish product [a)]	Gravad fish	0.72	0.45	1.15	0.17	0.68	0.42	1.10	0.12	0.60	0.36	1.00	0.05
Subtype of the fish product	Hot smoked fish	0.50	0.30	0.84	0.01	0.44	0.26	0.75	0.00	0.46	0.27	0.79	0.00
Subtype of the fish product	Unknown smoked fish	0.54	0.38	0.75	0.00	0.44	0.31	0.65	<.0001	0.49	0.33	0.71	0.00
Fish species [b)]	Herring	1.08	0.55	2.13	0.83	0.99	0.49	1.98	0.98	0.99	0.47	2.09	0.98
Fish species	Mackerel	0.51	0.28	0.92	0.02	0.50	0.27	0.91	0.02	0.48	0.26	0.90	0.02
Fish species	Mixed Fish	0.48	0.28	0.84	0.01	0.47	0.26	0.85	0.01	0.42	0.22	0.80	0.01
Fish species	Other Fish	0.82	0.49	1.37	0.45	0.77	0.46	1.32	0.34	0.71	0.41	1.25	0.24
Preservatives and acidity regulators [c)]	1: Products with 1 AP+AR	0.58	0.22	1.58	0.29	0.55	0.21	1.48	0.24	0.64	0.22	1.84	0.40
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	7.15	3.92	13.02	<.0001	5.22	2.29	11.90	<.0001	6.51	2.49	17.03	0.00
Possible slicing [d)]		1.58	1.01	2.46	0.04	1.46	0.92	2.31	0.11	1.40	0.85	2.30	0.19
Packaging type[(c) e)]	Modified atmosphere	0.93	0.42	2.05	0.85	0.90	0.40	2.02	0.79	0.94	0.41	2.15	0.88
Remaining Shelf-life		0.997	0.994	1.000	0.047	0.997	0.995	1.000	0.074	0.998	0.994	1.002	0.411
Temperature at retail		0.97	0.90	1.04	0.40	0.97	0.90	1.05	0.46	0.97	0.89	1.05	0.40
"EC 2073/2005 NSG" [f)]		0.54	0.21	1.36	0.19	0.48	0.19	1.24	0.13	0.67	0.24	1.93	0.46
"EC 2073/2005 NSG"*Fish species	Herring	0.87	0.14	5.61	0.89	0.93	0.15	5.89	0.94	0.93	0.13	6.66	0.95
"EC 2073/2005 NSG"*Fish species	Mackerel	6.94	1.91	25.25	0.00	7.73	2.20	27.20	0.00	5.32	1.34	21.06	0.02

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

"EC 2073/2005 NSG"*Fish species	Mixed Fish	1.28	0.24	6.72	0.77	1.60	0.30	8.63	0.58	1.27	0.21	7.72	0.80
"EC 2073/2005 NSG"*Fish species	Other Fish	0.82	0.14	4.93	0.83	0.98	0.17	5.55	0.98	0.62	0.11	3.61	0.60
Temperature at retail * Packaging type(c)	Modified atmosphere	0.92	0.75	1.14	0.45	0.91	0.74	1.13	0.40	0.94	0.76	1.16	0.54

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Subtype of the fish product is "Cold smoked fish"
b) : The reference category for Fish Species "Salmon"
c) : The reference category for Preservatives and acidity regulators is "0: Products with no AP and AR"
d) : The reference category for Possible slicing is "Non-Sliced"
e) : The reference category for Packaging Type(c) is "All other packaging types"
f) : The reference category for 'EC 2073/2005 NSG' is "not included in EC 2073/2005 NSG"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

SENSITIVITY ANALYSES FOR FINAL MODEL

To get further insights in the stability of the final model, we investigate its sensitivity to some modifications:

- The weighted analyses as compared to the unweighted analyses.
- The use of Firth's method and exact logistic regression, as methods that can cope with sparseness to some larger extent. Exact logistic regression was computationally not feasible. It is extremely computer intensive and lead to memory problems.
- The deletion of the interaction of Storage temperature at retail and Packaging type[c].
- The deletion of the not significant factors (eg. Remaining shelf-life)
- The use of the continuous variable expressing the no-growth probability instead of the "EC 2073/2005 NSG" indicator.

Weighted analyses versus unweighted analyses

Table 23: and Table 24: indicate that most of the factors of the final model are quite insensitive to the weighing. But there are some remarkable differences however:

- Possible slicing is no longer significant in the weighted analyses.
- Remaining shelf-life is no longer significant in the weighted analyses.

As both weights are merely proxy weights for unknown true weight (that would correct for over- or underrepresentation), it is not straightforward how to interpret these differences. Major conclusion is that one should be careful with formulating strong statements about those factors that are unstable across such unweighted and weighted analyses.

Logistic regression with Firth's correction method for sparseness

Table 25: and Table Table 26: that the results of the GEE model are very close to that with the Firth method. This indicates and confirms that there are no major sparseness issues in our final GEE model.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 25: Wald Statistics For Logistic Regression (Firth Approach) Analysis of multiple-factors model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Subtype of the fish product	3	20.02	0.00	3	33.96	<.0001	3	26.32	<.0001
Fish species	4	11.54	0.02	4	12.01	0.02	4	13.40	0.01
Preservatives and acidity regulators	2	37.59	<.0001	2	36.08	<.0001	2	39.88	<.0001
Possible slicing	1	4.76	0.03	1	3.28	0.07	1	2.36	0.12
Packaging type[(c)]	1	0.03	0.87	1	0.05	0.82	1	0.02	0.90
Remaining Shelf-life	1	1.28	0.26	1	1.12	0.29	1	0.20	0.65
Temperature at retail	1	0.53	0.47	1	0.50	0.48	1	0.67	0.41
"EC 2073/2005 NSG"	1	1.33	0.25	1	1.84	0.18	1	0.39	0.53
"EC 2073/2005 NSG" * Fish species	4	10.37	0.03	4	12.04	0.02	4	7.38	0.12
Temperature at retail * Packaging type[(c)]	1	0.55	0.46	1	0.63	0.43	1	0.36	0.55

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 26: Odds ratios of Logistic Regression (Firth Approach) of final model for multiple-factors model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.17	0.10	0.29	<.0001	0.22	0.13	0.38	<.0001	0.20	0.12	0.35	<.0001
Subtype of the fish product [a)]	Gravad fish	0.73	0.46	1.16	0.18	0.69	0.43	1.09	0.11	0.61	0.37	0.99	0.05
Subtype of the fish product	Hot smoked fish	0.51	0.33	0.79	0.00	0.44	0.29	0.68	0.00	0.47	0.30	0.73	0.00
Subtype of the fish product	Unknown smoked fish	0.54	0.40	0.72	<.0001	0.44	0.34	0.59	<.0001	0.49	0.36	0.65	<.0001
Fish species [b)]	Herring	1.10	0.61	2.00	0.74	1.01	0.56	1.81	0.97	1.02	0.56	1.84	0.96
Fish species	Mackerel	0.52	0.30	0.90	0.02	0.51	0.30	0.86	0.01	0.49	0.28	0.85	0.01
Fish species	Mixed Fish	0.50	0.29	0.85	0.01	0.49	0.28	0.85	0.01	0.44	0.24	0.79	0.01
Fish species	Other Fish	0.84	0.50	1.39	0.49	0.79	0.49	1.28	0.34	0.73	0.44	1.20	0.21
Preservatives and acidity regulators [c)]	1: Products with 1 AP+AR	0.65	0.24	1.73	0.39	0.61	0.23	1.60	0.31	0.70	0.28	1.76	0.44
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	6.88	3.66	12.95	<.0001	5.09	2.95	8.80	<.0001	6.32	3.53	11.32	<.0001
Possible slicing [d)]		1.56	1.05	2.32	0.03	1.44	0.97	2.14	0.07	1.38	0.91	2.09	0.12
Packaging type[(c) e)]	Modified atmosphere	0.94	0.44	2.02	0.87	0.91	0.41	2.02	0.82	0.95	0.44	2.06	0.90
Remaining Shelf-life		1.00	0.99	1.00	0.26	1.00	0.99	1.00	0.29	1.00	0.99	1.00	0.65
Temperature at retail		0.97	0.90	1.05	0.47	0.97	0.90	1.05	0.48	0.97	0.90	1.05	0.41
"EC 2073/2005 NSG" [f)]		0.59	0.24	1.45	0.25	0.53	0.21	1.33	0.18	0.74	0.28	1.91	0.53
"EC 2073/2005 NSG" * Fish species	Herring	0.94	0.17	5.12	0.95	0.99	0.19	5.15	0.99	0.99	0.18	5.50	0.99
"EC 2073/2005 NSG" * Fish species	Mackerel	6.40	1.73	23.75	0.01	7.04	1.98	25.10	0.00	4.94	1.23	19.91	0.02
"EC 2073/2005 NSG" * Fish species	Mixed Fish	1.30	0.24	6.96	0.76	1.62	0.30	8.77	0.57	1.40	0.18	10.78	0.75
"EC 2073/2005 NSG" * Fish	Other Fish	0.89	0.16	5.04	0.89	1.03	0.20	5.42	0.97	0.71	0.11	4.51	0.71

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

species													
Temperature at retail * Packaging type(c)	Modified atmosphere	0.92	0.75	1.14	0.46	0.92	0.73	1.14	0.43	0.94	0.76	1.16	0.55

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Subtype of the fish product is “Cold smoked fish”
b) : The reference category for Fish Species “Salmon”
c) : The reference category for Preservatives and acidity regulators is “0: Products with no AP and AR”
d) : The reference category for Possible slicing is “Non-Sliced”
e) : The reference category for Packaging Type(c) is “All other packaging types”
f) : The reference category for ’EC 2073/2005 NSG’ is “not included in EC 2073/2005 NSG”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Note

The interaction between Storage temperature at retail and Packaging type(c) in the above analysis appears to be not significant. Due to its meaningful biological interpretation, it was considered not to remove this interaction term from the final model. Although it is expected that the OR estimates of the other effects will hardly change when dropping an insignificant variable, it was considered to present the analysis without the interaction between Storage temperature at retail and Packaging type(c).

Moreover, after removing the interaction between Storage temperature at retail and Packaging type(c), it was also considered to drop the main effect of Storage temperature at retail and Packaging type(c) (as these were not significant at the level of 5%). The result are in the following tables.

GEE Analysis without the interaction of Storage temperature at retail and Packaging type(c)

A quick comparison of Table 23: and Table 24: with Table 27: and Table 28: respectively shows that results are very similar. The only effect on inference is that the significance of remaining shelf-life decreased, because the borderline p-value 0.05 increased to 0.08 (or even higher for the weighted analyses).

Table 27: Wald Statistics For Type 3 GEE Analysis for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi Square	P-Value	DF	Chi Square	P-Value	DF	Chi Square	P-Value
Subtype of the fish product	3	11.79	0.01	3	16.76	0.00	3	14.07	0.00
Fish species	4	11.77	0.02	4	11.36	0.02	4	12.02	0.02
Preservatives and acidity regulators	2	46.84	<.0001	2	19.83	<.0001	2	17.25	0.00
Possible slicing	1	4.35	0.04	1	2.81	0.09	1	1.90	0.17
Remaining Shelf-life	1	3.00	0.08	1	2.36	0.12	1	0.40	0.53
“EC 2073/2005 NSG”	1	1.67	0.20	1	2.26	0.13	1	0.52	0.47
“EC 2073/2005 NSG” * Fish species	4	15.98	0.00	4	19.65	0.00	4	12.37	0.01

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 28: Odds ratios of GEE (Ind) for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.13	0.08	0.23	<.0001	0.18	0.10	0.31	<.0001	0.16	0.09	0.29	<.0001
Subtype of the fish product a)	Gravad fish	0.72	0.45	1.15	0.17	0.68	0.42	1.10	0.11	0.60	0.36	0.99	0.05
Subtype of the fish product	Hot smoked fish	0.53	0.32	0.88	0.01	0.46	0.27	0.78	0.00	0.48	0.28	0.82	0.01
Subtype of the fish product	Unknown smoked fish	0.58	0.42	0.80	0.00	0.48	0.34	0.69	<.0001	0.52	0.36	0.74	0.00
Fish species b)	Herring	1.11	0.57	2.17	0.76	1.03	0.52	2.03	0.94	1.01	0.48	2.13	0.97
Fish species	Mackerel	0.52	0.29	0.93	0.03	0.50	0.28	0.92	0.03	0.48	0.26	0.90	0.02
Fish species	Mixed Fish	0.46	0.27	0.79	0.00	0.44	0.24	0.78	0.01	0.40	0.21	0.74	0.00
Fish species	Other Fish	0.81	0.48	1.35	0.42	0.76	0.45	1.30	0.32	0.70	0.40	1.23	0.22
Preservatives and acidity regulators c)	1: Products with 1 AP+AR	0.58	0.22	1.57	0.28	0.55	0.21	1.46	0.23	0.64	0.22	1.85	0.41
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	7.83	4.30	14.27	<.0001	5.80	2.55	13.21	<.0001	7.14	2.73	18.70	<.0001
Possible slicing d)		1.61	1.03	2.51	0.04	1.49	0.94	2.36	0.09	1.42	0.86	2.32	0.17
Remaining Shelf-life		1.00	0.99	1.00	0.08	1.00	1.00	1.00	0.12	1.00	0.99	1.00	0.53
"EC 2073/2005 NSG" e)		0.54	0.22	1.37	0.20	0.49	0.19	1.24	0.13	0.68	0.24	1.92	0.47
"EC 2073/2005 NSG" * Fish species	Herring	0.85	0.13	5.45	0.86	0.91	0.14	5.74	0.92	0.90	0.13	6.41	0.92
"EC 2073/2005 NSG" * Fish species	Mackerel	7.29	2.00	26.59	0.00	8.18	2.32	28.88	0.00	5.49	1.38	21.86	0.02
"EC 2073/2005 NSG" * Fish species	Mixed Fish	1.34	0.26	6.93	0.72	1.72	0.32	9.11	0.52	1.33	0.22	7.90	0.76
"EC 2073/2005 NSG" * Fish species	Other Fish	0.82	0.14	4.82	0.83	0.99	0.18	5.46	0.99	0.61	0.11	3.54	0.59

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Subtype of the fish product is "Cold smoked fish"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

b) : The reference category for Fish Species “Salmon”
c) : The reference category for Preservatives and acidity regulators is “0: Products with no AP and AR”
d) : The reference category for Possible slicing is “Non-Sliced”
e) : The reference category for ’EC 2073/2005 NSG’ is “not included in EC 2073/2005 NSG”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Firth's method without the interaction of Storage temperature at retail and Packaging type(c)

Further comparison with Table 29: and Table 30: confirms that remaining shelf-life is apparently not so important, as its p-value increases further up to 0.32, or even higher for the weighted analyses.

Table 29: Wald Statistics For Logistic Regression (Firth Approach) Analysis of multiple-factors model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Subtype of the fish product	3	16.65	0.00	3	29.25	<.0001	3	23.26	<.0001
Fish species	4	12.60	0.01	4	13.23	0.01	4	14.58	0.01
Preservatives and acidity regulators	2	41.62	<.0001	2	41.48	<.0001	2	44.80	<.0001
Possible slicing	1	5.18	0.02	1	3.68	0.05	1	2.56	0.11
Remaining Shelf-life	1	0.97	0.32	1	0.80	0.37	1	0.10	0.75
"EC 2073/2005 NSG"	1	1.26	0.26	1	1.76	0.18	1	0.36	0.55
"EC 2073/2005 NSG" * Fish species	4	10.96	0.03	4	12.83	0.01	4	7.76	0.10

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 30: Odds ratios of Logistic Regression (Firth Approach) of final model for multiple-factors model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.14	0.09	0.21	<.0001	0.18	0.11	0.28	<.0001	0.16	0.10	0.26	<.0001
Subtype of the fish product [a)]	Gravad fish	0.73	0.46	1.15	0.18	0.68	0.43	1.09	0.11	0.61	0.37	0.99	0.04
Subtype of the fish product	Hot smoked fish	0.54	0.35	0.83	0.00	0.47	0.30	0.72	0.00	0.49	0.31	0.76	0.00
Subtype of the fish product	Unknown smoked fish	0.58	0.44	0.76	0.00	0.48	0.36	0.63	<.0001	0.52	0.39	0.68	<.0001
Fish species [b)]	Herring	1.14	0.63	2.06	0.67	1.05	0.59	1.88	0.87	1.04	0.57	1.88	0.90
Fish species	Mackerel	0.53	0.31	0.91	0.02	0.52	0.30	0.87	0.01	0.49	0.29	0.85	0.01
Fish species	Mixed Fish	0.47	0.28	0.80	0.01	0.45	0.26	0.78	0.00	0.41	0.23	0.74	0.00
Fish species	Other Fish	0.82	0.50	1.37	0.45	0.78	0.48	1.27	0.31	0.72	0.44	1.18	0.19
Preservatives and acidity regulators [c)]	1: Products with 1 AP+AR	0.65	0.24	1.73	0.38	0.61	0.23	1.59	0.31	0.70	0.28	1.75	0.44
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	7.55	4.02	14.16	<.0001	5.66	3.29	9.73	<.0001	6.93	3.90	12.32	<.0001
Possible slicing [d)]		1.59	1.07	2.37	0.02	1.47	0.99	2.18	0.05	1.40	0.93	2.12	0.11
Remaining Shelf-life		1.00	0.99	1.00	0.32	1.00	0.99	1.00	0.37	1.00	0.99	1.00	0.75
"EC 2073/2005 NSG" [e)]		0.59	0.24	1.47	0.26	0.54	0.21	1.34	0.18	0.75	0.29	1.93	0.55
"EC 2073/2005 NSG" * Fish species	Herring	0.92	0.17	4.99	0.92	0.96	0.18	5.04	0.97	0.96	0.17	5.33	0.96
"EC 2073/2005 NSG" * Fish species	Mackerel	6.73	1.82	24.95	0.00	7.47	2.10	26.57	0.00	5.11	1.27	20.59	0.02
"EC 2073/2005 NSG" * Fish species	Mixed Fish	1.37	0.26	7.32	0.71	1.74	0.32	9.40	0.52	1.46	0.19	11.32	0.72
"EC 2073/2005 NSG" * Fish species	Other Fish	0.89	0.16	5.06	0.90	1.04	0.20	5.47	0.96	0.70	0.11	4.50	0.71

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

a) : The reference category for Subtype of the fish product is "Cold smoked fish"
b) : The reference category for Fish Species "Salmon"
c) : The reference category for Preservatives and acidity regulators is "0: Products with no AP and AR"
d) : The reference category for Possible slicing is "Non-Sliced"
e) : The reference category for 'EC 2073/2005 NSG' is "not included in EC 2073/2005 NSG"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Note

The remaining shelf-life in the above analysis appears to be not significant. It was considered to include an additional analysis, without remaining shelf-life. This simplification did not affect the conclusions regarding the other remaining factors. The results are summarized in the following tables.

<u>GEE Analysis without the remaining shelf-life</u>

Table 31: Wald Statistics For Type 3 GEE Analysis for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi Square	P-Value	DF	Chi Square	P-Value	DF	Chi Square	P-Value
Subtype of the fish product	3	11.99	0.0074	3	17.12	0.0007	3	14.51	0.0023
Fish species	4	11.57	0.0208	4	11.27	0.0237	4	12	0.0173
Preservatives and acidity regulators	2	47.36	<.0001	2	20.32	<.0001	2	17.32	0.0002
Possible slicing	1	4.22	0.04	1	2.7	0.1005	1	1.85	0.1736
"EC 2073/2005 NSG"	1	1.86	0.1731	1	2.45	0.1178	1	0.55	0.4578
"EC 2073/2005 NSG"*Fish species	4	15.98	0.003	4	19.68	0.0006	4	12.17	0.0161

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 32: Odds ratios of GEE (Ind) for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.129	0.075	0.222	<.0001	0.171	0.095	0.307	<.0001	0.160	0.088	0.292	<.0001
Subtype of the fish product [a)]	Gravad fish	0.724	0.453	1.158	0.178	0.676	0.417	1.096	0.112	0.595	0.358	0.987	0.044
Subtype of the fish product	Hot smoked fish	0.538	0.326	0.887	0.015	0.467	0.275	0.792	0.005	0.482	0.284	0.819	0.007
Subtype of the fish product	Unknown smoked fish	0.574	0.415	0.794	0.001	0.476	0.333	0.680	<.0001	0.513	0.359	0.734	0.000
Fish species [b)]	Herring	1.087	0.557	2.121	0.807	1.006	0.509	1.987	0.987	1.000	0.477	2.094	1.000
Fish species	Mackerel	0.519	0.290	0.929	0.027	0.506	0.277	0.923	0.026	0.480	0.257	0.899	0.022
Fish species	Mixed Fish	0.461	0.268	0.793	0.005	0.439	0.245	0.786	0.006	0.397	0.212	0.745	0.004
Fish species	Other Fish	0.804	0.479	1.348	0.407	0.761	0.448	1.293	0.313	0.702	0.401	1.228	0.215
Preservatives and acidity regulators [c)]	1: Products with 1 AP+AR	0.552	0.204	1.489	0.240	0.525	0.197	1.399	0.198	0.622	0.214	1.806	0.383
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	7.890	4.327	14.390	<.0001	5.845	2.573	13.275	<.0001	7.131	2.726	18.649	<.0001
Possible slicing [d)]		1.591	1.022	2.478	0.040	1.469	0.928	2.326	0.101	1.405	0.861	2.294	0.174
"EC 2073/2005 NSG" [e)]		0.526	0.209	1.325	0.173	0.476	0.188	1.207	0.118	0.675	0.239	1.905	0.458
"EC 2073/2005 NSG" * Fish species	Herring	0.777	0.119	5.075	0.792	0.846	0.131	5.446	0.860	0.874	0.122	6.259	0.893
"EC 2073/2005 NSG" * Fish species	Mackerel	6.759	1.857	24.609	0.004	7.653	2.181	26.856	0.002	5.165	1.290	20.689	0.020
"EC 2073/2005 NSG" * Fish species	Mixed Fish	1.408	0.273	7.262	0.683	1.794	0.339	9.507	0.492	1.354	0.228	8.033	0.739
"EC 2073/2005 NSG" * Fish species	Other Fish	0.699	0.118	4.150	0.694	0.861	0.152	4.881	0.866	0.558	0.092	3.367	0.524

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Subtype of the fish product is “Cold smoked fish”
b) : The reference category for Fish Species “Salmon”
c) : The reference category for Preservatives and acidity regulators is “0: Products with no AP and AR”
d) : The reference category for Possible slicing is “Non-Sliced”
e) : The reference category for ’EC 2073/2005 NSG’ is “not included in EC 2073/2005 NSG”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Firth's method without remaining shelf-life

Table 33: Wald Statistics For Logistic Regression (Firth Approach) Analysis of multiple-factors model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Subtype of the fish product	3	16.767	0.0008	3	29.567	<.0001	3	24.016	<.0001
Fish species	4	12.311	0.0152	4	13.021	0.0112	4	14.558	0.0057
Preservatives and acidity regulators	2	42.343	<.0001	2	42.239	<.0001	2	44.831	<.0001
Possible slicing	1	5.023	0.025	1	3.527	0.0604	1	2.484	0.115
"EC 2073/2005 NSG"	1	1.433	0.2313	1	1.945	0.1632	1	0.390	0.5322
"EC 2073/2005 NSG" * Fish species	4	10.817	0.0287	4	12.693	0.0129	4	7.613	0.1068

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 34: Odds ratios of Logistic Regression (Firth Approach) of final model for multiple-factors model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.131	0.084	0.206	<.0001	0.173	0.111	0.271	<.0001	0.162	0.102	0.258	<.0001
Subtype of the fish product [a)]	Gravad fish	0.731	0.462	1.156	0.180	0.682	0.428	1.087	0.107	0.601	0.369	0.981	0.042
Subtype of the fish product	Hot smoked fish	0.543	0.353	0.835	0.005	0.472	0.308	0.724	0.001	0.488	0.313	0.760	0.002
Subtype of the fish product	Unknown smoked fish	0.574	0.433	0.759	0.000	0.476	0.361	0.628	<.0001	0.513	0.388	0.678	<.0001
Fish species [b)]	Herring	1.115	0.617	2.017	0.718	1.031	0.576	1.846	0.918	1.027	0.568	1.855	0.931
Fish species	Mackerel	0.532	0.309	0.916	0.023	0.517	0.305	0.877	0.014	0.492	0.284	0.851	0.011
Fish species	Mixed Fish	0.475	0.280	0.806	0.006	0.453	0.260	0.788	0.005	0.412	0.230	0.739	0.003
Fish species	Other Fish	0.821	0.495	1.362	0.445	0.776	0.477	1.261	0.306	0.717	0.435	1.181	0.191
Preservatives and acidity regulators [c)]	1: Products with 1 AP+AR	0.617	0.231	1.646	0.335	0.585	0.224	1.529	0.274	0.686	0.273	1.727	0.424
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	7.615	4.064	14.269	<.0001	5.706	3.320	9.804	<.0001	6.926	3.894	12.321	<.0001
Possible slicing [d)]		1.576	1.059	2.347	0.025	1.458	0.984	2.161	0.060	1.393	0.922	2.103	0.115
“EC 2073/2005 NSG” [e)]		0.574	0.231	1.424	0.231	0.520	0.207	1.304	0.163	0.738	0.285	1.913	0.532
“EC 2073/2005 NSG” * Fish species	Herring	0.853	0.156	4.652	0.854	0.910	0.174	4.765	0.911	0.941	0.169	5.239	0.944
“EC 2073/2005 NSG” * Fish species	Mackerel	6.327	1.717	23.327	0.006	7.079	2.001	25.051	0.002	4.873	1.234	19.248	0.024
“EC 2073/2005 NSG” * Fish species	Mixed Fish	1.433	0.268	7.658	0.674	1.812	0.335	9.806	0.490	1.491	0.193	11.513	0.702
“EC 2073/2005 NSG” * Fish species	Other Fish	0.775	0.139	4.318	0.772	0.922	0.178	4.774	0.923	0.644	0.103	4.014	0.637

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

a) : The reference category for Subtype of the fish product is “Cold smoked fish”
b) : The reference category for Fish Species “Salmon”
c) : The reference category for Preservatives and acidity regulators is “0: Products with no AP and AR”
d) : The reference category for Possible slicing is “Non-Sliced”
e) : The reference category for ’EC 2073/2005 NSG’ is “not included in EC 2073/2005 NSG”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

GEE Analysis for final model with continuous variable expressing the no-growth probability

The results as shown in Table 35: up to Table 38: show that most factors and interactions behave quite robust with respect to the use of the binary ("EC 2073/2005 NSG" indicator) or continuous version (continuous variable expressing the no-growth probability), whereas one factor seems to be more sensitive:

- Stable: Subtype of the fish product, Number of preservatives and acidity regulator, Possible slicing, Packaging type(c), remaining shelf-life, Storage temperature at retailerature.
- Sensitive: Fish species (no longer significant, main effect nor interaction effect).

Table 35: Wald Statistics For Type 3 GEE Analysis for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries* for continuous variable expressing the no-growth probability.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi Square	P-Value	DF	Chi Square	P-Value	DF	Chi Square	P-Value
Subtype of the fish product	3	14.71	0.00	3	19.81	0.00	3	15.66	0.00
Fish species	4	2.35	0.67	4	3.44	0.49	4	5.00	0.29
Preservatives and acidity regulators	2	43.03	<.0001	2	18.44	<.0001	2	16.35	0.00
Possible slicing	1	4.10	0.04	1	2.70	0.10	1	1.85	0.17
Packaging type(c)	1	0.02	0.90	1	0.05	0.83	1	0.00	0.97
Remaining Shelf-life	1	4.84	0.03	1	3.78	0.05	1	0.78	0.38
Temperature at retail	1	0.10	0.75	1	0.02	0.88	1	0.01	0.90
Continuous no-growth probability	1	0.13	0.71	1	0.14	0.71	1	0.07	0.79
Continuous no-growth probability * Fish species	4	2.66	0.62	4	3.25	0.52	4	4.43	0.35
Temperature at retail * Packaging type(c)	1	0.74	0.39	1	0.90	0.34	1	0.61	0.44

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 36: Odds ratios of GEE (Ind) for final model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries* for continuous variable expressing the no-growth probability

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.15	0.06	0.40	0.00	0.19	0.07	0.53	0.00	0.17	0.06	0.50	0.00
Subtype of the fish product [a)]	Gravad fish	0.66	0.42	1.05	0.08	0.61	0.38	0.98	0.04	0.55	0.33	0.91	0.02
Subtype of the fish product	Hot smoked fish	0.49	0.29	0.81	0.01	0.42	0.25	0.73	0.00	0.46	0.26	0.79	0.00
Subtype of the fish product	Unknown smoked fish	0.53	0.37	0.74	0.00	0.43	0.30	0.63	<.0001	0.48	0.32	0.70	0.00
Fish species [b)]	Herring	1.26	0.20	8.15	0.81	1.21	0.20	7.28	0.84	0.30	0.03	3.51	0.34
Fish species	Mackerel	0.34	0.08	1.45	0.15	0.28	0.06	1.24	0.09	0.27	0.05	1.37	0.11
Fish species	Mixed Fish	0.95	0.30	3.03	0.94	0.92	0.28	2.98	0.89	0.86	0.24	3.04	0.82
Fish species	Other Fish	0.73	0.20	2.72	0.64	0.55	0.14	2.09	0.38	0.37	0.10	1.33	0.13
Preservatives and acidity regulators[c)]	1: Products with 1 AP+AR	0.55	0.21	1.48	0.24	0.51	0.19	1.35	0.17	0.60	0.21	1.72	0.34
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	6.80	3.77	12.28	<.0001	5.01	2.24	11.20	<.0001	6.24	2.45	15.93	0.00
Possible slicing [d)]		1.57	1.01	2.44	0.04	1.46	0.93	2.29	0.10	1.40	0.86	2.28	0.17
Packaging type[(c) e)]	Modified atmosphere	0.95	0.43	2.12	0.90	0.91	0.41	2.06	0.83	0.98	0.43	2.26	0.97
Remaining Shelf-life		1.00	0.99	1.00	0.03	1.00	0.99	1.00	0.05	1.00	0.99	1.00	0.38
Temperature at retail		0.98	0.89	1.09	0.75	0.99	0.89	1.10	0.88	0.99	0.88	1.12	0.90
Continuous no-growth probability		1.13	0.60	2.12	0.71	1.13	0.59	2.18	0.71	1.10	0.54	2.21	0.79
Continuous no-growth probability * Fish species	Herring	0.75	0.09	6.22	0.79	0.70	0.09	5.41	0.74	3.61	0.24	55.36	0.36
Continuous no-growth probability * Fish species	Mackerel	2.24	0.40	12.56	0.36	2.84	0.47	17.08	0.26	2.57	0.39	16.94	0.33
Continuous no-growth probability *	Mixed Fish	0.41	0.11	1.61	0.20	0.42	0.10	1.72	0.23	0.38	0.08	1.76	0.22

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Fish species													
Continuous no-growth probability * Fish species	Other Fish	1.06	0.24	4.68	0.93	1.44	0.31	6.65	0.64	2.09	0.47	9.38	0.34
Temperature at retail * Packaging type(c)	Modified atmosphere	0.91	0.74	1.13	0.39	0.90	0.73	1.12	0.34	0.92	0.74	1.14	0.44

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Subtype of the fish product is “Cold smoked fish”
b) : The reference category for Fish Species “Salmon”
c) : The reference category for Preservatives and acidity regulators is “0: Products with no AP and AR”
d) : The reference category for Possible slicing is “Non-Sliced”
e) : The reference category for Packaging Type(c) is “All other packaging types”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Firth's method for final model with continuous variable expressing the no-growth probability

Table 37: Wald Statistics For Logistic Regression (Firth Approach) Analysis of multiple-factors model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling for all participating countries* with continuous variable expressing the no-growth probability.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Subtype of the fish product	3	21.98	<.0001	3	37.19	<.0001	3	28.34	<.0001
Fish species	4	2.35	0.67	4	3.47	0.48	4	4.06	0.40
Preservatives and acidity regulators	2	38.19	<.0001	2	36.33	<.0001	2	40.15	<.0001
Possible slicing	1	4.87	0.03	1	3.46	0.06	1	2.50	0.11
Packaging type(c)	1	0.01	0.93	1	0.03	0.85	1	0.00	0.99
Remaining Shelf-life	1	1.77	0.18	1	1.62	0.20	1	0.33	0.56
Temperature at retail	1	0.06	0.80	1	0.02	0.90	1	0.01	0.93
Continuous no-growth probability	1	0.13	0.72	1	0.14	0.71	1	0.07	0.79
Continuous no-growth probability * Fish species	4	3.19	0.53	4	3.93	0.42	4	4.44	0.35
Temperature at retail * Packaging type(c)	1	0.73	0.39	1	0.80	0.37	1	0.63	0.43

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 38: Odds ratios of Logistic Regression (Firth Approach) of final model for multiple-factors model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling for all participating countries* with continuous variable expressing the no-growth probability.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.15	0.06	0.37	<.0001	0.19	0.08	0.47	0.00	0.18	0.07	0.44	0.00
Subtype of the fish product a)	Gravad fish	0.67	0.42	1.05	0.08	0.62	0.39	0.97	0.04	0.56	0.34	0.90	0.02
Subtype of the fish product	Hot smoked fish	0.49	0.32	0.76	0.00	0.43	0.28	0.66	0.00	0.46	0.30	0.72	0.00
Subtype of the fish product	Unknown smoked fish	0.53	0.40	0.70	<.0001	0.43	0.33	0.57	<.0001	0.48	0.36	0.63	<.0001
Fish species b)	Herring	1.53	0.28	8.36	0.63	1.45	0.27	7.80	0.66	0.48	0.05	4.61	0.52
Fish species	Mackerel	0.39	0.10	1.50	0.17	0.32	0.08	1.27	0.11	0.32	0.08	1.27	0.10
Fish species	Mixed Fish	1.02	0.35	2.99	0.97	0.99	0.33	2.97	0.98	0.93	0.31	2.78	0.89
Fish species	Other Fish	0.81	0.24	2.76	0.73	0.61	0.18	2.07	0.43	0.42	0.11	1.65	0.22
Preservatives and acidity regulators c)	1: Products with 1 AP+AR	0.61	0.23	1.64	0.33	0.56	0.21	1.48	0.24	0.66	0.26	1.66	0.37
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	6.64	3.58	12.31	<.0001	4.94	2.88	8.46	<.0001	6.12	3.45	10.86	<.0001
Possible slicing d)		1.56	1.05	2.30	0.03	1.44	0.98	2.12	0.06	1.39	0.92	2.08	0.11
Packaging type (c) e)	Modified atmosphere	0.96	0.45	2.08	0.93	0.93	0.42	2.07	0.85	1.00	0.46	2.17	0.99
Remaining Shelf-life		1.00	0.99	1.00	0.18	1.00	0.99	1.00	0.20	1.00	0.99	1.00	0.56
Temperature at retail		0.99	0.89	1.10	0.80	0.99	0.89	1.10	0.90	0.99	0.89	1.11	0.93
Continuous no-growth probability		1.12	0.60	2.08	0.72	1.12	0.61	2.09	0.71	1.09	0.58	2.06	0.79
Continuous no-growth probability * Fish species	Herring	0.63	0.09	4.16	0.63	0.60	0.09	3.85	0.59	2.26	0.20	25.42	0.51
Continuous no-growth probability * Fish species	Mackerel	1.97	0.44	8.81	0.37	2.47	0.54	11.26	0.24	2.23	0.49	10.22	0.30
Continuous no-growth probability * Fish species	Mixed Fish	0.40	0.11	1.46	0.17	0.41	0.11	1.54	0.18	0.37	0.09	1.47	0.16
Continuous no-growth probability *	Other Fish	0.98	0.24	4.03	0.98	1.32	0.32	5.40	0.70	1.83	0.39	8.53	0.44

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Fish species												
Temperature at retail * Packaging Modified atmosphere type(c)	0.91	0.74	1.13	0.39	0.90	0.72	1.13	0.37	0.92	0.74	1.13	0.43

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Subtype of the fish product is “Cold smoked fish”
b) : The reference category for Fish Species “Salmon”
c) : The reference category for Preservatives and acidity regulators is “0: Products with no AP and AR”
d) : The reference category for Possible slicing is “Non-Sliced”
e) : The reference category for Packaging Type(c) is “All other packaging types”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.1.1.4. Diagnostic Test

In this last section some last checks are performed, including an examination of the goodness of fit of the final model, a multicollinearity analysis of the factors appearing in the final model.

Goodness of fit test

Goodness of fit test was performed using the Hosmer and Lemeshow Chi-Square test. The result show that there is no lack of fit in the model since p-value is larger than 5% alpha. The null hypothesis that the final model is an appropriate model cannot be rejected, or there is no evidence of any lack of fit.

Table 39: Hosmer and Lemeshow test

Chi-Square	DF	P-value
13.661	8	0.091

Multicolinearity analysis

The VIF values for the potentially intercorrelated factors from the final model are presented in the following table. This analysis showed that multicollinearity was not important for the full model since all the VIF values were very small.

Table 40: Variance Inflation Factor values for factors

Variable	VIF
Subtype of the fish product	1.91
Fish species	3.65
Number of preservatives and acidity regulators	6.25
Possible slicing	1.65
Packaging type(c)	1.70
"EC 2073/2005 NSG"	2.64
Remaining Shelf-life	1.14
Temperature at retail	1.01

Additional analysis about Number of preservatives and acidity regulator

The VIF of Number of preservatives and acidity regulator is larger than others, though the value is still considerably less than 10 and consequently there is no major concern here. However in order to get some information about which covariates are correlated with Number of preservatives and acidity regulator, the result of an ordinal logistic regression is presented in the following table. It shows that most of the covariates have a significant effect Number of preservatives and acidity regulator, except for remaining shelf-life and the "EC 2073/2005 NSG" variable. Despite the fact that there are quite strong intercorrelations, the VIF remains quite moderate and below 10, so that no remedial action has to be taken.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 41: Wald Statistics For Type 3 ordinal logistic regression analysis with response variable "Number of preservatives and acidity regulator"

Variable	DF	Wald Chi-Square	P-value
Possible slicing	2	86.27	<.0001
Subtype of the fish product	6	182.01	<.0001
Fish species	8	44.82	<.0001
Packaging type(c)	2	23.75	<.0001
Remaining Shelf-life	2	4.48	0.11
Temperature at retail	2	68.49	<.0001
"EC 2073/2005 NSG"	2	3.57	0.17

5.1.1.5. Other analyses

Table 42: below goes a bit more into the opposite effect of mackerel as compared to salmon depending on the value of the "EC 2073/2005 NSG" indicator. The odds for a contaminated sample for mackerel compared to salmon for samples not included in "EC 2073/2005 NSG" is = (17*1570)/(352*223)= 0.34. It shows that the odds for a contaminated sample is lower for mackerel than for salmon. Meanwhile, for samples included in "EC 2073/2005 NSG", this same OR now equals (7*61)/(34*5)= 2.51, which is the opposite. This descriptive data analysis is in line with the GEE result.

We also performed some additional explorative analysis to see whether the contaminated mackerel samples are clustered in a specific country, city, etc. Table 43: shows that the 24 contaminated mackerel samples come from 7 countries, 16 cities and 16 outlets.

Table 42: Cross classification table between Fish species, prevalence and "EC 2073/2005 NSG" indicator

Fish Species	Not included in "EC 2073/2005 NSG"				Included in "EC 2073/2005 NSG"			
	Sample				Sample			
	Not contaminated	Contaminated	Total	Prevalence of contaminated samples	Not contaminated	Contaminated	Total	Prevalence of contaminated samples
Herring	128	15	143	10.49	38	2	40	5.00
Mackerel	352	17	369	4.61	34	7	41	17.07
Mixed Fish	286	18	304	5.92	19	3	22	13.64
Salmon	1570	223	1793	12.44	61	5	66	7.58
Other Fish	213	21	234	8.97	39	2	41	4.88
Total	2549	294	2843	10.34	191	19	210	9.05

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 43: Cross Classification Table of the mackerel samples being contaminated by *Listeria monocytogenes* at time of sampling, with the number of cities and outlets by country

Country	Number of City	Number of Outlet	"EC 2073/2005 NSG"		Total Sample per country
			Not Included	Included	
Bulgaria	4	2	5	5	10
Estonia	2	2	1	1	2
Germany	1	1	1	0	1
Hungary	1	1	1	0	1
Latvia	1	2	1	1	2
Poland	6	7	7	0	7
United Kingdom	1	1	1	0	1
Total	**16**	**16**	**17**	**7**	**24**

Table 44: provides some further insights in the OR related to Number of preservatives and acidity regulator. The odds for a sample being contaminated for "2: Products with 2 or more AP+AR" as compared to "0: Products with no AP and AR" is = (25*2631)/(284*30)= 7.72. Meanwhile the odds for a sample being contaminated for "1: Products with 1 AP+AR" as compared to "0: Products with no AP and AR" is = (4*2631)/(284*79)= 0.47. These descriptive findings are again in line with the GEE result.

Table 44: Cross classification table between Number of preservatives and acidity regulator and Prevalence of contaminated samples

Preservatives and acidity regulators	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
0: Products with no AP and AR	2631	284	2915	9.74
1: Products with 1 AP+AR	79	4	83	4.82
2: Products with 2 or more AP+AR	30	25	55	45.45
Total	2 740	313	3 053	10.25

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 45: Cross classification table between Number of preservatives and acidity regulator and Prevalence of contaminated samples according to the “EC 2073/2005 NSG” indicator

Preservatives and acidity regulators	Not included in “EC 2073/2005 NSG”				Included in “EC 2073/2005 NSG”			
	Not contaminated sample	Contaminated sample	Total	Prevalence of contaminated samples	Not contaminated sample	Contaminated sample	Total	Prevalence of contaminated samples
0: Products with no AP and AR	2478	271	2749	9.86	153	13	166	7.83
1: Products with 1 AP+AR	51	3	54	5.56	28	1	29	3.45
2: Products with 2 or more AP+AR	20	20	40	50.00	10	5	15	33.33
Total	2549	294	2843	10.34	191	19	210	9.05

Figure 10: shows a scatter plot of the pH test results as a function of water activity. It does not reveal any clear pattern between both factors.

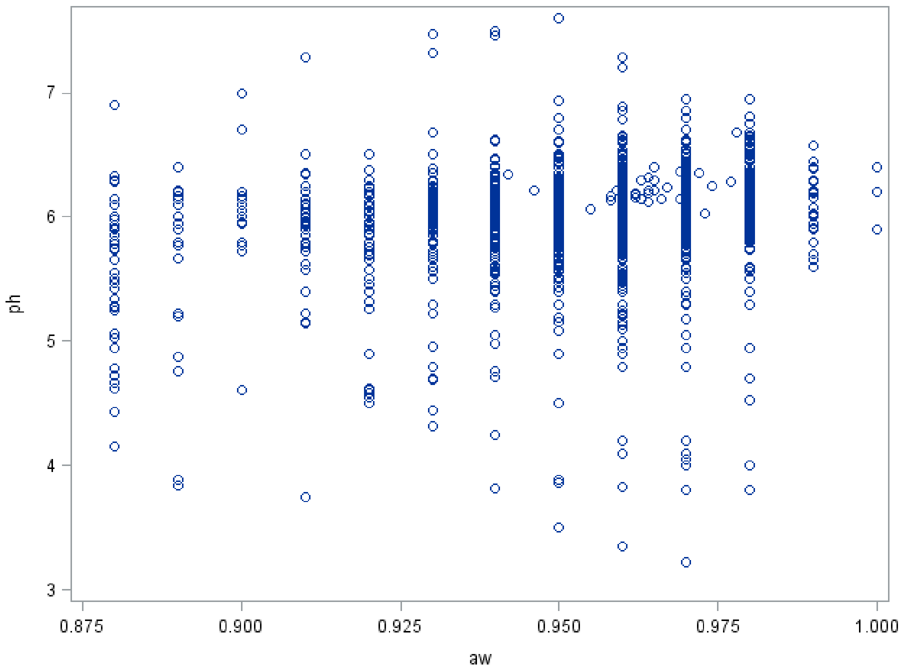


Figure 10: Scatter plot between pH test result and water activity result (on the arrival at the laboratory)

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 46: , Table 47: and Figure 11: provide some further information about the effect of water activity and pH on the prevalence of samples being contaminated by *Listeria monocytogenes* at time of sampling, and the distribution of water activity result for both categories of Packaging type(c).

Table 46: Summary statistics for water activity result and pH test result (on the arrival at the laboratory) by "EC 2073/2005 NSG"

	Not included in "EC 2073/2005 NSG"			Included in "EC 2073/2005 NSG"		
	water activity result	pH test result	Temperature at retail	water activity result	pH test result	Temperature at retail
N	2843	2843	2843	210	210	210
Mean	0.96	6.06	3.44	0.91	5.55	3.67
Std Dev	0.01	0.25	1.79	0.02	0.76	1.74
Minimum	0.93	4.5	0.00	0.88	3.22	0.00
Maximum	1	7.6	25	0.98	7.28	10

Table 47: Summary statistics for water activity result (on the arrival at the laboratory) by Packaging type(c)

	Modified atmosphere	All other packaging types
N	579	2474
Mean	0.96	0.96
Std Dev	0.02	0.02
Minimum	0.88	0.88
Maximum	1.00	1.00

Table 48: Summary statistics for water activity result (on the arrival at the laboratory) by Packaging type

	Modified atmosphere	Normal atmosphere	Vacuum	Other (free text)
N	579	550	1825	99
Mean	0.96	0.95	0.96	0.96
Std Dev	0.02	0.02	0.02	0.02
Minimum	0.88	0.88	0.88	0.89
Maximum	1	0.99	0.99	

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

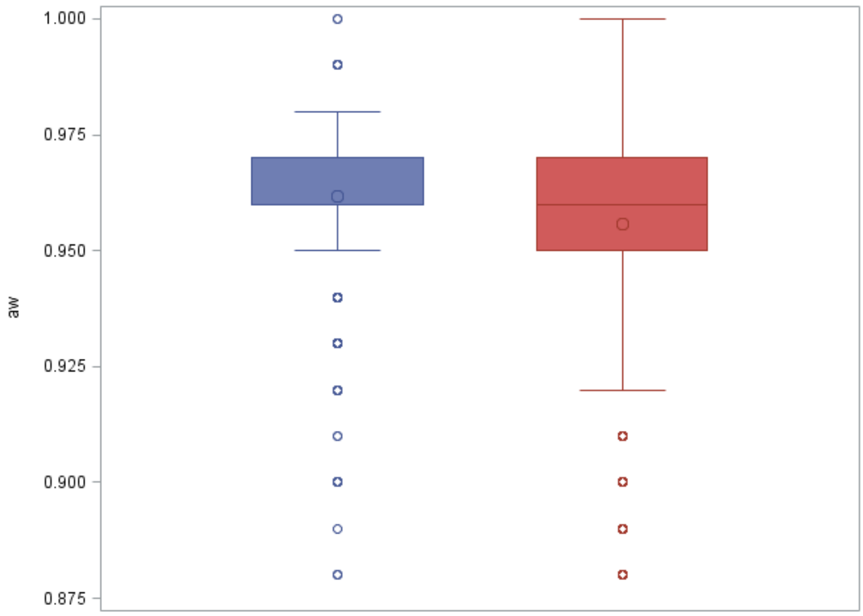


Figure 11: Boxplot[13] of water activity result (on the arrival at the laboratory) for Modified atmosphere (left) and All other packaging types (right).

[13] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.1.2. Proportion of samples with counts exceeding the level of 100 cfu/g for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling

5.1.2.1. Descriptions of the samples

The following tables and figures provide further insights for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling. It is important to realize that the observed differences might be due to other factors, which is the reason for considering the multivariable analysis in the next section.

The percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling is only 0.95% (Table 49:). This will undoubtedly complicate the fitting of logistic regression models.

Table 49: Descriptive statistics of percentage of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100cfu/g for all participating countries*

	Frequency	Percentage of samples with counts exceeding 100 cfu/g
Samples with counts not exceeding the level of 100 cfu/g	3 024	99.05
Samples with counts exceeding the level of 100 cfu/g	29	0.95
Total	3 053	

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 50: shows the number of samples with counts exceeding and not exceeding the level of 100 cfu/g at time of sampling in packaged (not frozen) hot or cold smoked or gravad fish samples by country.

Table 50: Number of samples with counts exceeding and not exceeding the level of 100 cfu/g at time of sampling in packaged (not frozen) hot or cold smoked or gravad fish samples by country

Country	Number of samples with counts not exceeding the level of 100 cuf/g	Number of samples with counts exceeding the level of 100 cuf/g
Austria	128	0
Belgium	27	0
Bulgaria	42	3
Cyprus	26	1
Czech Republic	12	0
Denmark	57	3
Estonia	30	0
Finland	62	1
France	391	0
Germany	472	2
Greece	59	0
Hungary	61	0
Ireland	31	0
Italy	379	10
Latvia	28	1
Lithuania	29	1
Luxembourg	21	1
Malta	36	0
Netherlands	66	0
Norway	59	0
Poland	197	3
Romania	60	0
Slovakia	59	1
Slovenia	27	2
Spain	202	0
Sweden	67	0
United Kingdom	396	0
Total	3 024	29

Table 51: shows that the percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is equal to 0.93 % and 33.33% for the “Supermarket or small shop” and “Speciality delis” category respectively. Meanwhile for “Street market or farmers’ market”, and “Other (free text field)” the percentages are exactly 0%. Merging the categories of Type of retail outlet shows that the category “All other types of retail outlet” now reaches 2.04% (Table 52:).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 51: Percentage of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100 cfu/g by Type of retail outlet for all participating countries*

Type of retail outlet	Samples with count exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Supermarket or small shop	2 976	28	3 004	0.93
Speciality delis	2	1	3	33.33
Street market or farmers' market	2	0	2	0.00
Other (free text field)	44	0	44	0.00
Total	**3 024**	**29**	**3 053**	**0.95**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 52: Percentage of smoked or gravad fish samples at time of sampling, with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g by Type[(c)] of retail outlet for all participating countries*

Type[(c)] of retail outlet	Samples with count exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Supermarket or small shop	2 976	28	3 004	0.93
All other types of retail outlet	48	1	49	2.04
Total	**3 024**	**29**	**3 053**	**0.95**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

For the different seasons "Autumn", "Spring", "Summer" and "Winter" the percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g are 0.64%, 0.74%, 1.97% and 0.44% respectively (Table 53: Table 54:).

Table 53: Percentage of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100 cfu/g by Sampling season for all participating countries*

Sampling Season	Samples with count exceeding 100 cfu/g		Total	Percentage of samples with count exceeding 100 cfu/g
	No	Yes		
Autumn	932	6	938	0.64
Spring	670	5	675	0.74
Summer	745	15	760	1.97
Winter	677	3	680	0.44
Total	**3 024**	**29**	**3 053**	**0.95**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 54: shows that the the percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is 0.62% in the category "Unknown smoked fish" and 1.56% in the category "Cold smoked fish". Meanwhile the percentages for the categories "Hot smoked fish" and "Gravad Fish" are 1.31% and 0.79% respectively.

Table 54: Percentage of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100 cfu/g by Subtype of the fish product for all participating countries*

Subtype of the fish product	Samples with count exceeding 100 cfu/g		Total	Percentage of samples with count exceeding 100 cfu/g
	No	Yes		
Unknown smoked fish	1 615	10	1625	0.62
Cold smoked fish	630	10	640	1.56
Hot smoked fish	528	7	535	1.31
Gravad fish	251	2	253	0.79
Total	**3 024**	**29**	**3 053**	**0.95**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 55: (Fish species in all participating countries) shows that the percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is 1.02% in the category "Salmon" and 0.73% in the category "Mackerel". For the categories "Other Fish" , "Mixed Fish" and "Hering" the percentages are 1.82% , 0.61% and 0% respectively.

Table 55: Percentage of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100 cfu/g by Fish Species for all participating countries*

Fish Species	Samples with count exceeding 100 cfu/g		Total	Percentage of samples with count exceeding 100 cfu/g
	No	Yes		
Salmon	1 840	19	1 859	1.02
Mackerel	407	3	410	0.73
Mixed Fish	324	2	326	0.61
Herring	183	0	183	0.00
Other Fish	270	5	275	1.82
Total	**3 024**	**29**	**3 053**	**0.95**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

For the preservative and acidity regulators for all participating countries, Table 56: shows that the percentages of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g are 0.96%, 0% and 1.82% in the category "no AP and AR", "AP or AR" and "AP and AR" respectively.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 56: Percentage of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100 cfu/g by preservative and acidity regulators for all participating countries*

Preservatives and acidity regulators	Samples with count exceeding 100 cfu/g		Total	Percentage of samples with count exceeding 100 cfu/g
	No	Yes		
0: Products with no AP and AR	2 887	28	2 915	0.96
1: Products with 1 AP+AR	83	0	83	0.00
2: Products with 2 or more AP+AR	54	1	55	1.82
Total	**3 024**	**29**	**3 053**	**0.95**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The distribution of the pH test results for packaged (not frozen) hot or cold smoked or gravad fish samples at time of sampling is summarized in Table 57: Figure 12: and Figure 13: .

Table 57: Summary Statistics of pH test result (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at time of sampling

pH test result	Samples with count exceeding 100 cfu/g		Total
	No	Yes	
N	3 024	29	3 053
Mean	6.03	6.07	6.03
Sd	0.34	0.33	0.34
Min	3.22	5.18	3.22
lower whisker	5.61	5.5	5.61
Q1	5.59	5.9	5.59
median	6.05	6.07	6.05
Q3	6.18	6.25	6.18
Upper whisker	6.52	6.7	6.52
max	7.6	6.7	7.6
range (max-min)	4.38	1.18	4.38

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

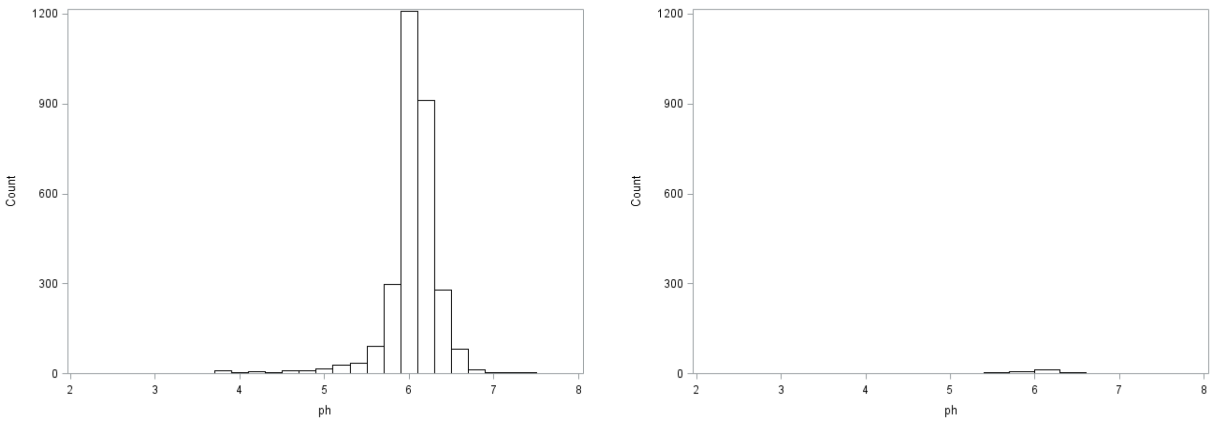


Figure 12: Histogram of pH test result (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at time of sampling

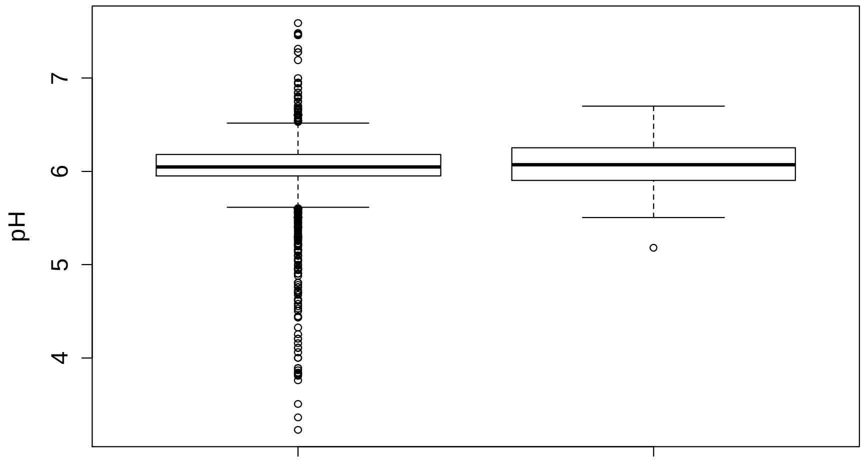


Figure 13: Boxplot[14] of pH test result (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at time of sampling

The distribution of the water activity results for packaged (not frozen) hot or cold smoked or gravad fish samples at time of sampling is summarized in Table 58: , Figure 14: and Figure 15: .

[14] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 58: Summary statistics of water activity result (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at time of sampling

Water activity result	Samples with count exceeding 100 cfu/g		Total
	No	**Yes**	
n	3 024	29	3 053
mean	0.96	0.96	0.96
sd	0.02	0.02	0.02
min	0.88	0.88	0.88
lower whisker	0.92	0.93	0.92
Q1	0.95	0.95	0.95
median	0.96	0.96	0.96
Q3	0.97	0.97	0.97
Upper whisker	1	0.98	1
max	1	0.98	1
range (max-min)	0.12	0.07	0.12

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

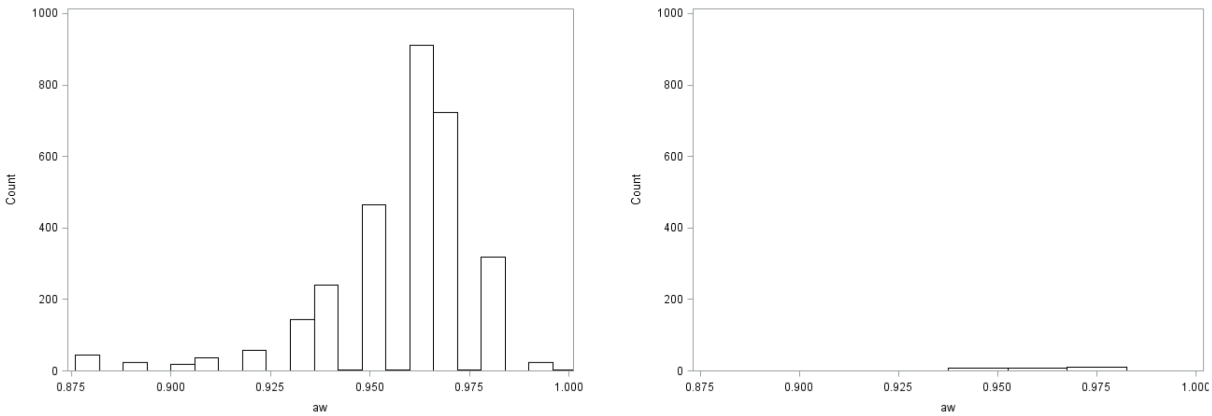


Figure 14: Histogram of water activity result (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at time of sampling

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

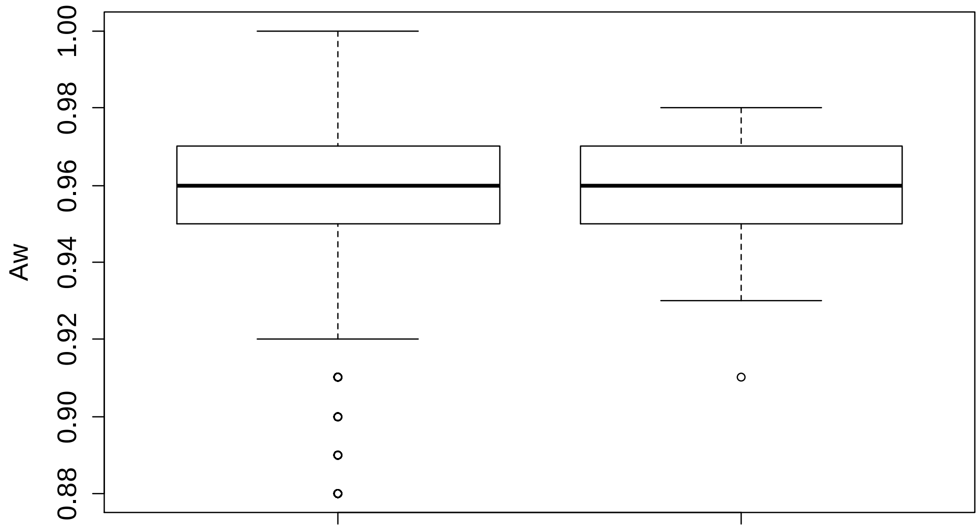


Figure 15: Boxplot[15] of water activity result (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at time of sampling

Table 59: shows that the percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g equals 1.14% for sliced fish, while for the non-sliced fish it is only 0.39%.

Table 59: Percentage of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100 cfu/g by Possible slicing for all participating countries*

Possible slicing	Samples with count exceeding 100 cfu/g		Total	Percentage of samples with count exceeding 100 cfu/g
	No	Yes		
Sliced	2 249	26	2 275	1.14
Non-Sliced	775	3	778	0.39
Total	**3 024**	**29**	**3 053**	**0.95**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

For the packaging type, Table 60: shows that the percentages of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g in the categories “Vacuum”, “Modified atmosphere”, “Normal atmosphere” and “Other (free text)” are 1.32%, 0.69%, 0.18% and 0% respectively. When merging the packaging type categories, Table 61: indicates that about 1.01% of the samples has a count exceeding the level of 100 cfu/g in the category “All other packaging types”.

[15] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 60: Percentage of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100 cfu/g by Packaging type for all participating countries*

Packaging Type	Samples with count exceeding 100 cfu/g		Total	Percentage of samples with count exceeding 100 cfu/g
	No	Yes		
Vacuum	1 801	24	1 825	1.32
Modified atmosphere	575	4	579	0.69
Normal atmosphere	549	1	550	0.18
Other (free text)	99	0	99	0.00
Total	**3 024**	**29**	**3 053**	**0.95**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 61: Percentage of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100 cfu/g by Packaging type[(c)] for all participating countries*

Packaging Type[(c)]	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with count exceeding 100 cfu/g
	No	Yes		
Modified atmosphere	575	4	579	0.69
All other packaging types	2 449	25	2 474	1.01
Total	**3 024**	**29**	**3 053**	**0.95**

The number of samples with counts exceeding the level of 100 cfu/g by Country of production are shown in Table 62: .

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 62: Number of samples with counts exceeding and not exceeding the level of 100 cfu/g for every country of production for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling

Country of production	Number of samples with counts not exceeding the level of 100 cuf/g	Number of samples with counts exceeding the level of 100 cuf/g
Austria	28	0
Belarus	1	0
Belgium	9	0
Bulgaria	37	2
Canada	2	0
Croatia	3	0
Cyprus	13	1
Czech Republic	22	0
Denmark	175	1
Estonia	32	0
Faroe Islands	1	0
Finland	43	1
France	455	0
Germany	167	1
Greece	61	0
Greenland	3	2
Hungary	11	0
Ireland	29	0
Italy	72	3
Latvia	48	1
Lithuania	113	3
Luxembourg	1	0
Netherlands	55	0
Norway	239	7
Poland	541	6
Romania	60	0
Slovakia	9	0
Slovenia	6	0
Spain	200	0
Sweden	59	0
Switzerland	1	0
Turkey	49	0
Ukraine	1	0
United Kingdom	470	470
United States	3	0
Vietnam	5	0
Total	3024	498

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The distribution of temperature of retail (sample surface) for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling is summarized in Table 63: , Figure 16: and Figure 17: .

Table 63: Summary Statistics of Storage Temperature at Retail by proportion of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100cfu/g in all participating countries*

Temperature at retail	Samples with counts exceeding 100 cfu/g		Total
	No	Yes	
n	3 024	29	3 053
mean	3.46	3.06	3.45
sd	1.8	1.26	1.79
min	0	0	0
lower whisker	0	0	0
Q1	2	2	2
median	3	3	3
Q3	4	4	4
Upper whisker	7	5	7
max	25	5	25
range (max-min)	25	5	25

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

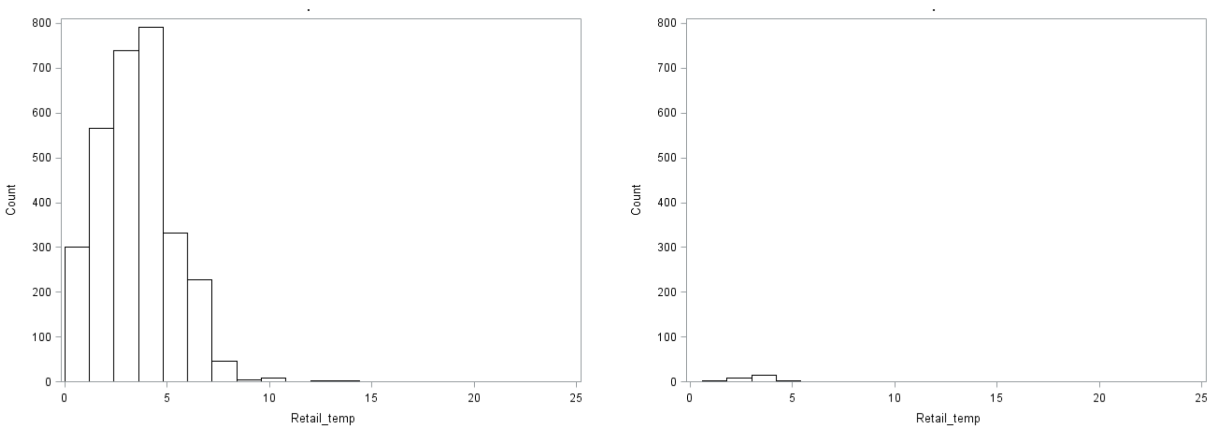


Figure 16: Histogram of storage temperature at retail (sample surface) for samples with *Listeria monocytogenes* counts not exceeding (left) and exceeding (right) the level of 100 cfu/g of packaged hot or cold smoked or gravad fish samples at time of sampling in all participating countries

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

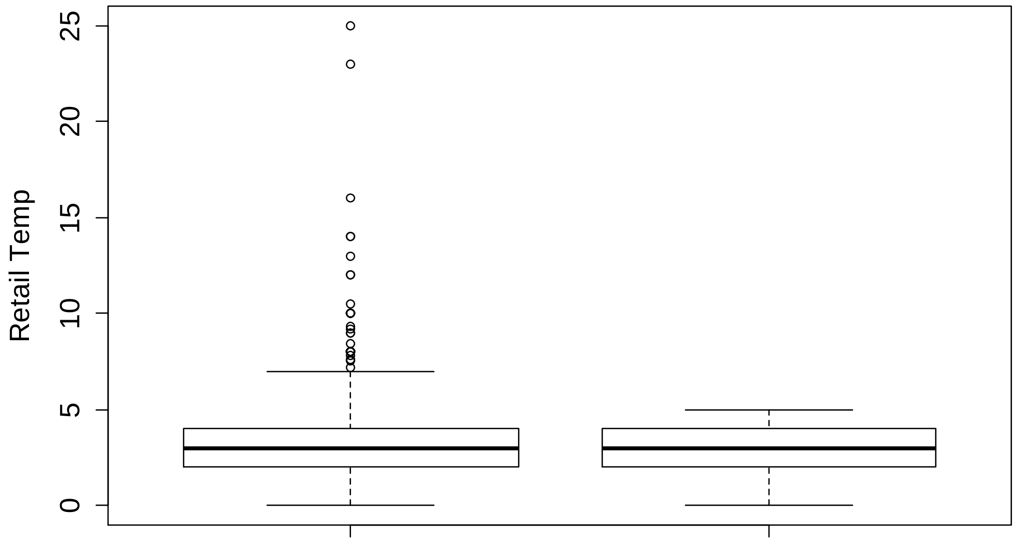


Figure 17: Boxplot[16] of Storage Temperature at Retail for samples with counts not exceeding (left) and exceeding (right) the level of 100 cfu/g of gravad fish samples at time of sampling on the arrival at the laboratory for all participating countries

As shown in Table 64: only one sample was not transported in line with technical specifications.

Table 64: Proportion of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100 cfu/g by transport protocol for all participating countries*

Transport Protocol	Samples with counts exceeding 100 cfu/g		Total	Proportion of samples with counts exceeding 100 cfu/g
	No	Yes		
Yes[a)]	3 023	29	3052	0.95
No[b)]	1	0	1	0.00
Total	**3 024**	**29**	**3 053**	**0.95**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) in line with technical specifications
b) not in line with technical specifications

The boxplot and histogram for the distribution of the remaining shelf-life in days are shown in Table 65: , Figure 18: and Figure 19: .

[16] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 65: Summary Statistics of Remaining shelf-life by proportion of enumeration of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100cfu/g for all participating countries*

Remaining shelf-life	Samples with counts exceeding 100 cfu/g		Total
	No	Yes	
n	3 024	29	3 053
mean	22.72	19.45	22.68
sd	36.88	11.84	36.73
min	1	3	1
lower whisker	1	3	1
Q1	9	9	9
median	14	18	15
Q3	23	28	23
Upper whisker	44	47	44
max	519	47	519
range (max-min)	518	44	518

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

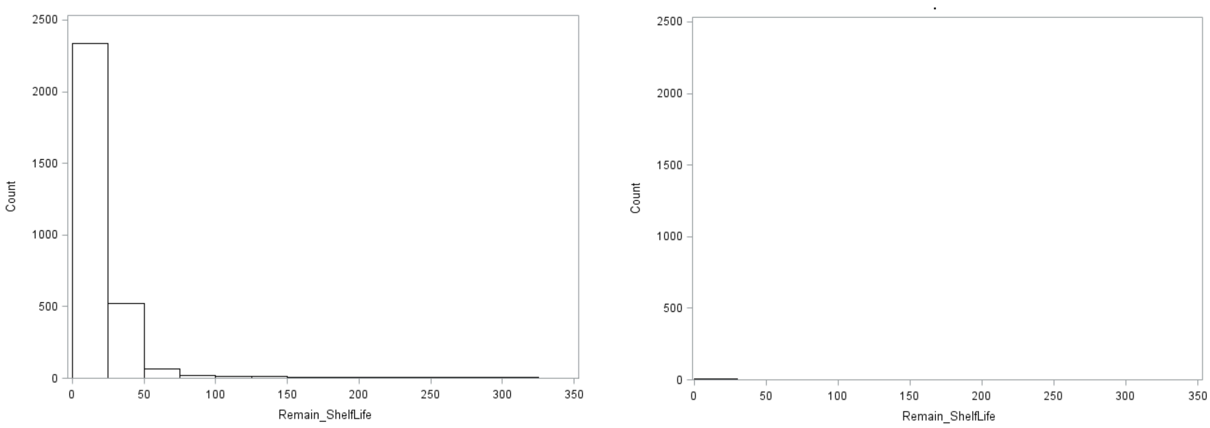


Figure 18: Histogram of remaining shelf-life for samples with counts not exceeding (left) and exceeding (right) the level of 100 cfu/g of packaged (not frozen) hot or cold smoked or gravad fish at time of sampling in all participating countries

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

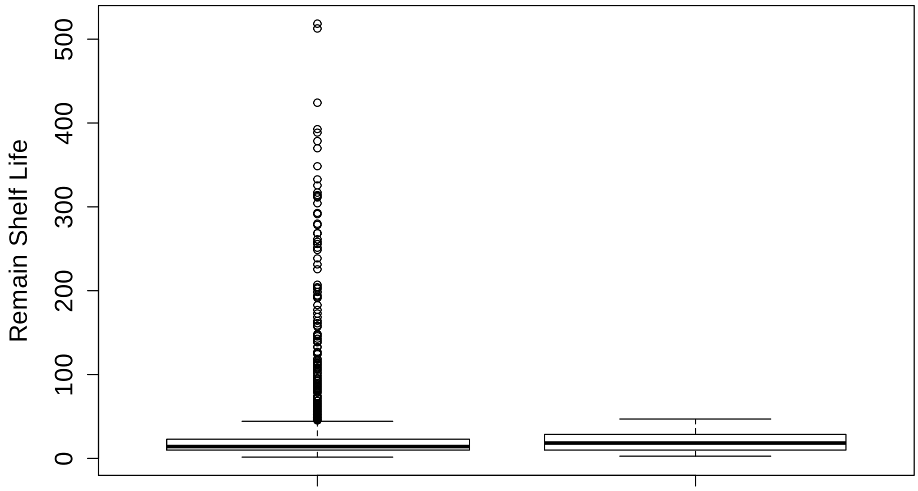


Figure 19: Boxplot[17] of Remaining shelf-life for samples with counts not exceeding (left) and exceeding (right) the level of 100 cfu/g of packaged (not frozen) hot or coldsmoked or gravad fish at time of sampling for all participating countries

For the "EC 2073/2005 NSG" indicator (Table 66:), the percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g in the category supporting growth is 0.98%, whereas it only reaches 0.48% in the category "EC 2073/2005 NSG".

Table 66: Percentage of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100 cfu/g by 'EC 2073/2005 NSG' for all participating countries*

"EC 2073/2005 NSG"	**Samples with counts exceeding 100 cfu/g**		**Total**	**Percentage of samples with counts exceeding 100 cfu/g**
	No	**Yes**		
For samples not included in 'EC 2073/2005 NSG'	2 815	28	2 843	0.98
For samples included in 'EC 2073/2005 NSG '	209	1	210	0.48
Total	**3 024**	**29**	**3 053**	**0.95**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

[17] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.1.2.2. Single-factor model

GEE (Ind) has been applied to the analysis of single-factor model along with unweighted and weighted (based on planned sample and population sizes) approaches. In the end a sensitivity analysis has been considered using logistic regression with the Firth approach.

All variables in the dataset have been fitted in the single-factor model, including the interaction with the "EC 2073/2005 NSG" indicator. Due to sparseness and separation, most of the single factor analyses for variables with many categories did not converge, i.e. for country, the town retail outlet, date of testing, use by date, production date, packaging date and country of production. Since"EC 2073/2005 NSG" depends on pH and water activity, it was considered not to put pH and water activity in the model. Meanwhile, the single-factor models for Sampling season, Type$^{(c)}$ of retail outlet, Subtype of the fish product, Fish species, Number of preservatives and acidity regulator, Possible slicing, Packaging type and Transport protocol did not converge.

The result of the single-factor model ("single") may not be over-interpreted since this step of analysis is mainly serving as a preliminary analysis, proceeding the full analysis ("multiple analysis").

The result of single-factor model presents in the Appendix D.2.

5.1.2.3. Multiple-factors model

ANALYSIS WITH VARIABLE 'EC 2073/2005 NSG' INDICATOR

The same procedure was followed as in Section 5.1.1.3. In the first step, the selected model included Sampling season, Subtype of the fish product, Fish species, Possible slicing, Packaging type, "EC 2073/2005 NSG", the interactions Subtype of the fish product*"EC 2073/2005 NSG" and Fish species*"EC 2073/2005 NSG". The interaction between Packaging type and Storage temperature at retail as well as their main effects were included in the final model because of their biological importance.

For further analysis, GEE (Ind) was used to analyse and investigate the selected model. However, this model was undefined due to the hessian matrix not being positive definite. This problem was caused by the zero and low counts in the packaging type factor (see Table 60:) Therefore, it was considered to use the binary variable Packaging type$^{(c)}$.

After removing the non-significant effects from the model, the final model is presented in the Table 67: and Table 68: .

The only significant effect came from Sampling season. Possible slicing, Packaging type$^{(c)}$, Storage temperature at retail,"EC 2073/2005 NSG" and the interaction between Storage temperature at retail and Packaging type$^{(c)}$ were no longer significant at 5% level. However, due to the biological relevance, those effects were remained in the final model.

The result of the unweighted GEE(Ind) shows that the odds for a proportion of enumeration above 100cfu/g for the summer season is 4.47 times the odds for the winter season (Table 68:).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

GEE Analysis for final model

Table 67: Wald Statistics For Type 3 GEE Analysis for model of proportion of samples with counts exceeding the level of 100cfu/g of *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi Square	P-Value	DF	Chi Square	P-Value	DF	Chi Square	P-Value
Sampling season	3	10.26	0.02	3	11.55	0.01	3	12.37	0.01
Possible slicing	1	2.86	0.09	1	2.28	0.13	1	2.49	0.11
Packaging type(c)	1	0.25	0.61	1	0.21	0.64	1	0.14	0.71
Temperature at retail	1	2.28	0.13	1	1.98	0.16	1	2.53	0.11
"EC 2073/2005 NSG"	1	0.29	0.59	1	0.37	0.55	1	0.69	0.40
Temperature at retail * Packaging type(c)	1	0.08	0.78	1	0.06	0.81	1	0.07	0.79

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 68: Odds ratios of GEE (Ind) for final model proportion of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100cfu/g with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.00	0.00	0.02	<.0001	0.00	0.00	0.02	<.0001	0.00	0.00	0.02	<.0001
Sampling season a)	autumn	1.44	0.36	5.76	0.60	1.43	0.36	5.71	0.61	1.34	0.31	5.72	0.69
Sampling season	spring	1.73	0.40	7.53	0.46	1.98	0.45	8.73	0.36	1.06	0.22	5.19	0.94
Sampling season	summer	4.47	1.27	15.77	0.02	4.91	1.38	17.42	0.01	4.17	1.12	15.55	0.03
Possible slicing b)		2.68	0.86	8.41	0.09	2.40	0.77	7.46	0.13	2.63	0.79	8.73	0.11
Packaging type(c) c)	Modified atmosphere	0.58	0.07	4.76	0.61	0.60	0.07	5.22	0.64	0.66	0.08	5.81	0.71
Temperature at retail		0.86	0.71	1.05	0.13	0.87	0.72	1.06	0.16	0.82	0.65	1.05	0.11
“EC 2073/2005 NSG” d)		0.58	0.08	4.12	0.59	0.55	0.08	3.87	0.55	0.43	0.06	3.14	0.40
Temperature at retail * Packaging type(c)	Modified atmosphere	1.08	0.63	1.84	0.78	1.07	0.62	1.86	0.81	1.07	0.63	1.84	0.79

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is “winter”
b) : The reference category for Possible slicing is “Non-Sliced”
c) : The reference category for Packaging Type(c) is “All other packaging types”
d) : The reference category for ’EC 2073/2005 NSG’ is “not included in EC 2073/2005 NSG”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

SENSITIVITY ANALYSES FOR FINAL MODEL

To get further insights in the stability of the final model, we investigate its sensitivity to some modifications:

- The weighted analyses as compared to the unweighted analyses.
- The use of Firth's method and exact logistic regression, as methods that can cope with sparseness to some larger extent. Exact logistic regression was computationally not feasible. It is extremely computer intensive and lead to memory problems.
- The deletion of the interaction of Storage temperature at retail and Packaging type(c).
- The use of the continuous variable expressing the no-growth probability instead of the "EC 2073/2005 NSG" indicator.

Weighted analyses versus unweighted analyses

Table 67: and Table 68: indicate that the factors in the final model are all insensitive to the weighing. So, all conclusions remain the same, regardless the weighting scheme.

Logistic regression with Firth's correction method for sparseness

Table 69: and Table 70: confirm the results of the GEE analysis. All estimates are in line with the earlier results.

Table 69: Wald Statistics For Type 3 Firth Analysis for model of proportion of samples with counts exceeding the level of 100cfu/g of *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	10.13	0.02	3	11.81	0.01	3	9.81	0.02
Possible slicing	1	2.52	0.11	1	2.18	0.14	1	1.72	0.19
Packaging type(c)	1	0.19	0.66	1	0.16	0.69	1	0.09	0.76
Temperature at retail	1	1.43	0.23	1	1.34	0.25	1	1.91	0.17
"EC 2073/2005 NSG"	1	0.04	0.85	1	0.09	0.77	1	0.03	0.87
Temperature at retail * Packaging type(c)	1	0.14	0.71	1	0.12	0.73	1	0.13	0.71

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 70: Odds ratios of Logistic Regression (Firth Approach) of final model with interaction of for proportion of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100cfu/g for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.00	0.00	0.02	<.0001	0.00	0.00	0.02	<.0001	0.00	0.00	0.03	<.0001
Sampling season [a)]	autumn	1.33	0.38	4.70	0.66	1.32	0.37	4.67	0.67	1.25	0.34	4.58	0.74
Sampling season	spring	1.63	0.45	5.96	0.46	1.85	0.52	6.64	0.35	1.06	0.25	4.57	0.93
Sampling season	summer	3.96	1.29	12.19	0.02	4.34	1.41	13.29	0.01	3.69	1.17	11.66	0.03
Possible slicing [b)]		2.35	0.82	6.74	0.11	2.14	0.78	5.85	0.14	2.20	0.68	7.15	0.19
Packaging type[(c) c)]	Modified atmosphere	0.63	0.08	5.13	0.66	0.65	0.08	5.44	0.69	0.71	0.08	6.54	0.76
Temperature at retail		0.87	0.69	1.10	0.23	0.88	0.70	1.10	0.25	0.83	0.63	1.08	0.17
“EC 2073/2005 NSG” [d)]		0.86	0.18	4.12	0.85	0.79	0.17	3.74	0.77	0.86	0.13	5.77	0.87
Temperature at retail * Packaging type[(c)]	Modified atmosphere	1.11	0.63	1.97	0.71	1.11	0.62	1.97	0.73	1.12	0.61	2.08	0.71

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is “winter”
b) : The reference category for Possible slicing is “Non-Sliced”
c) : The reference category for Packaging Type[(c)] is “All other packaging types”
d) : The reference category for ’EC 2073/2005 NSG’ is “not included in EC 2073/2005 NSG”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

GEE Analysis without the interaction of Storage temperature at retail and packaging type [c]

Again, the effect of deleting the interaction of Storage temperature at retail and Packaging type[c] as well as their main effects (as these are no longer significant) on the final model is investigated. As expected and as shown in Table 71: and Table 72: the results of the remaining variables are essentially unchanged.

Table 71: Wald Statistics For Type 3 GEE Analysis for proportion of samples with counts exceeding the level of 100cfu/g of *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi Square	P-Value	DF	Chi Square	P-Value	DF	Chi Square	P-Value
Sampling season	3	10.25	0.02	3	11.50	0.01	3	12.45	0.01
Possible slicing	1	3.19	0.07	1	2.59	0.11	1	2.80	0.09
"EC 2073/2005 NSG"	1	0.36	0.55	1	0.44	0.51	1	0.83	0.36

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 72: Odds ratios of GEE (Ind) for final model proportion of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100cfu/g with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.00	0.00	0.01	<.0001	0.00	0.00	0.01	<.0001	0.00	0.00	0.01	<.0001
Sampling season [a)]	autumn	1.35	0.34	5.44	0.67	1.35	0.33	5.47	0.67	1.25	0.29	5.35	0.76
Sampling season	spring	1.65	0.39	6.92	0.49	1.90	0.45	8.06	0.38	1.01	0.21	4.77	0.99
Sampling season	summer	4.29	1.22	15.03	0.02	4.75	1.34	16.80	0.02	4.01	1.07	14.98	0.04
Possible slicing [b)]		2.79	0.90	8.58	0.07	2.49	0.82	7.59	0.11	2.72	0.84	8.74	0.09
"EC 2073/2005 NSG" [c)]		0.55	0.08	3.94	0.55	0.51	0.07	3.70	0.51	0.39	0.05	2.92	0.36

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is "winter"
b) : The reference category for Possible slicing is "Non-Sliced"
c) : The reference category for 'EC 2073/2005 NSG' is "not included in EC 2073/2005 NSG"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Firth's method without the interaction of Storage temperature at retail and packaging type (c)

As expected the results in Table 73: and Table 74: confirms the stability of the model as observed in Table 71: and Table 72: .

Table 73: Wald Statistics For Type 3 Firth Analysis for proportion of samples with counts exceeding the level of 100cfu/g of *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	9.65	0.02	3	11.32	0.01	3	9.28	0.03
Possible slicing	1	2.60	0.11	1	2.29	0.13	1	1.75	0.19
"EC 2073/2005 NSG"	1	0.07	0.79	1	0.13	0.71	1	0.06	0.81

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 74: Odds ratios of Firth for final model proportion of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100cfu/g with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.00	0.00	0.01	<.0001	0.00	0.00	0.01	<.0001	0.00	0.00	0.01	<.0001
Sampling season [a)]	autumn	1.26	0.35	4.54	0.73	1.26	0.35	4.55	0.73	1.17	0.31	4.44	0.82
Sampling season	spring	1.55	0.41	5.83	0.51	1.77	0.48	6.52	0.39	1.01	0.23	4.51	0.99
Sampling season	summer	3.80	1.21	11.95	0.02	4.20	1.34	13.13	0.01	3.55	1.09	11.50	0.03
Possible slicing [b)]		2.44	0.83	7.18	0.11	2.21	0.79	6.20	0.13	2.27	0.67	7.63	0.19
"EC 2073/2005 NSG" [c)]		0.80	0.16	3.99	0.79	0.74	0.15	3.62	0.71	0.78	0.11	5.55	0.81

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is "winter"
b) : The reference category for Possible slicing is "Non-Sliced"
c) : The reference category for 'EC 2073/2005 NSG' is "not included in EC 2073/2005 NSG"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

GEE Analysis for final model with continuous variable expressing the no-growth probability

The results in Table 75: and Table 76: show that the final model is also quite insensitive to the choice of the "EC 2073/2005 NSG" indicator or the continuous variable expressing the no-growth probability.

Table 75: Wald Statistics For Type 3 GEE Analysis for model of proportion of samples with counts exceeding the level of 100cfu/g of *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi Square	P-Value	DF	Chi Square	P-Value	DF	Chi Square	P-Value
Sampling season	3	10.30	0.02	3	11.54	0.01	3	12.28	0.01
Possible slicing	1	2.57	0.11	1	2.09	0.15	1	2.31	0.13
Packaging type(c)	1	0.32	0.57	1	0.27	0.60	1	0.20	0.65
Temperature at retail	1	0.12	0.73	1	0.06	0.80	1	0.15	0.69
Continuous no-growth probability	1	0.89	0.35	1	1.01	0.32	1	1.64	0.20
Temperature at retail * Packaging type(c)	1	0.16	0.69	1	0.13	0.72	1	0.18	0.67

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 76: Odds ratios of GEE (Ind) for final model proportion of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100cfu/g with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.00	0.00	0.01	<.0001	0.00	0.00	0.02	<.0001	0.00	0.00	0.01	<.0001
Sampling season [a)]	autumn	1.43	0.36	5.72	0.61	1.42	0.35	5.68	0.62	1.33	0.31	5.63	0.70
Sampling season	spring	1.71	0.39	7.45	0.47	1.97	0.45	8.71	0.37	1.06	0.21	5.23	0.95
Sampling season	summer	4.46	1.26	15.72	0.02	4.90	1.38	17.42	0.01	4.12	1.10	15.37	0.04
Possible slicing [b)]		2.64	0.81	8.65	0.11	2.38	0.73	7.70	0.15	2.57	0.76	8.73	0.13
Packaging type[(c) c)]	Modified atmosphere	0.53	0.06	4.74	0.57	0.55	0.06	5.23	0.60	0.59	0.06	5.92	0.65
Temperature at retail		0.95	0.71	1.28	0.73	0.96	0.72	1.29	0.80	0.93	0.65	1.33	0.69
Continuous no-growth probability		2.52	0.37	17.28	0.35	2.63	0.40	17.48	0.32	3.50	0.51	23.81	0.20
Temperature at retail * Packaging type[(c)]	Modified atmosphere	1.12	0.64	1.95	0.69	1.11	0.63	1.98	0.72	1.13	0.63	2.03	0.67

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is “winter”
b) : The reference category for Possible slicing is “Non-Sliced”
c) : The reference category for Packaging Type[(c)] is “All other packaging types”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Firth's method for final model with continuous variable expressing the no-growth probability

The results in Table 77: and Table 78: confirm the results from Table 75: and Table 76: ; they confirm that the final model is quite insensitive to the choice of the "EC 2073/2005 NSG" indicator or the continuous variable expressing the no-growth probability.

Table 77: Wald Statistics For Type 3 Firth Analysis for model of proportion of samples with counts exceeding the level of 100cfu/g of *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at time of sampling with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	10.21	0.02	3	11.88	0.01	3	9.75	0.02
Possible slicing	1	2.39	0.12	1	2.11	0.15	1	1.61	0.21
Packaging type[(c)]	1	0.26	0.61	1	0.23	0.63	1	0.17	0.68
Temperature at retail	1	0.08	0.78	1	0.04	0.84	1	0.15	0.69
Continuous no-growth probability	1	0.79	0.37	1	0.94	0.33	1	0.91	0.34
Temperature at retail * Packaging type[(c)]	1	0.24	0.62	1	0.23	0.63	1	0.28	0.59

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 78: Odds ratios of Logistic Regression (Firth Approach) of final model with interaction of for proportion of smoked or gravad fish samples at time of sampling, with counts exceeding the level of 100cfu/g for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.00	0.00	0.02	<.0001	0.00	0.00	0.02	<.0001	0.00	0.00	0.03	<.0001
Sampling season [a)]	autumn	1.32	0.37	4.68	0.67	1.31	0.37	4.66	0.68	1.23	0.33	4.55	0.75
Sampling season	spring	1.62	0.44	5.94	0.47	1.84	0.51	6.63	0.35	1.06	0.25	4.57	0.94
Sampling season	summer	3.95	1.28	12.23	0.02	4.34	1.41	13.35	0.01	3.66	1.16	11.62	0.03
Possible slicing [b)]		2.31	0.80	6.66	0.12	2.12	0.77	5.81	0.15	2.15	0.66	7.06	0.21
Packaging type[(c) c)]	Modified atmosphere	0.57	0.07	4.92	0.61	0.58	0.07	5.18	0.63	0.62	0.06	6.15	0.68
Temperature at retail		0.96	0.71	1.30	0.78	0.97	0.72	1.30	0.84	0.93	0.66	1.32	0.69
Continuous no-growth probability		2.20	0.39	12.44	0.37	2.31	0.43	12.47	0.33	2.70	0.35	20.68	0.34
Temperature at retail * Packaging type[(c)]	Modified atmosphere	1.16	0.65	2.08	0.62	1.16	0.64	2.08	0.63	1.19	0.63	2.25	0.59

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is “winter”
b) : The reference category for Possible slicing is “Non-Sliced”
c) : The reference category for Packaging Type[(c)] is “All other packaging types”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.1.2.4. Diagnostic test

Goodness of fit test

A goodness of fit test was performed using the Hosmer and Lemeshow Chi-Square test. The result shows that there is no evidence for lack of fit in the model since the p-value is larger than 5%.

Table 79: Hosmer and Lemeshow test

Chi-Square	DF	P-value
6.10	8	0.64

Multicolinearity analysis

The VIF values were very small.

Table 80: Variance Inflation Factor values for factors potentially related to Fish Product

Variable	VIF
Sampling season	1.03
Possible slicing	1.27
Packaging type[(c)]	1.49
"EC 2073/2005 NSG"	2.38
Temperature at retail	1.01

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.2. Results for packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life for all participating countries

5.2.1. Prevalence for packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life

Samples were considered contaminated if they were positive with the detection test or they had a count of *Listeria monocytogenes* of at least 10 cfu/g.

5.2.1.1. Descriptions of the samples

The following tables and figures provide further insights for packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life. It is important to realize that the observed differences might be due to other factors, which is the reason for considering the multivariable analysis in the next section.

Table 81: shows that 10.22% of packaged (not frozen) hot or cold smoked or gravad fish are contaminated at the end of shelf-life

Table 81: Descriptive statistics of prevalence of contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at end of shelf-life for all participating countries*

Sample	Frequency	Percentage
Not contaminated	2 741	89.78
Contaminated	312	10.22
Total	3 053	

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The number of contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life are shown by country in Table 82: .

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 82: The number of samples contaminated and not contaminated by *Listeria monocyotogenes* by country for packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life, for all participating countries*

Country	Number of samples not contaminated	Number of samples contaminated
Austria	125	3
Belgium	23	4
Bulgaria	36	9
Cyprus	24	3
CzechRepublic	12	0
Denmark	51	9
Estonia	24	6
Finland	53	10
France	375	16
Germany	434	40
Greece	58	1
Hungary	50	11
Ireland	30	1
Italy	299	90
Latvia	26	3
Lithuania	26	4
Luxembourg	20	2
Malta	36	0
Netherlands	59	7
Norway	56	3
Poland	157	43
Romania	57	3
Slovakia	55	5
Slovenia	22	7
Spain	188	14
Sweden	54	13
United Kingdom	391	5
Total	2 741	312

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The prevalence of contaminated samples for each type of retail outlet in all participating countries (Table 83:) show that 10.15 % is contaminated by *Listeria monocytogenes* for “Supermarket or small shop” category, while for “Street market or farmers’ market”, “Speciality delis” and “Other (free text field)” we have 50%, 33.33% and 11.36% respectively. For the category “All other types of retail outlet” we get 14.29% of contaminated samples (Table 84:).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 83: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life by Type of retail outlet for all participating countries*

Type of retail outlet	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Supermarket or small shop	2 699	305	3 004	10.15
Street market or farmers' market	1	1	2	50.00
Speciality delis	2	1	3	33.33
Other (free text field)	39	5	44	11.36
Total	**2 741**	**312**	**3 053**	**10.22**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 84: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life by Type[(c)] of retail outlet for all participating countries*

Type[(c)] of retail outlet	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Supermarket or small shop	2 699	305	3 004	10.15
All other types of retail outlet	42	7	49	14.29
Total	**2 741**	**312**	**3 053**	**10.22**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

For the Sampling season (Table 85:), the estimated prevalences in the category "Autumn", "Spring", "Summer" and "Winter" are 13.22%, 7.7%, 10.66% and 8.09% respectively.

Table 85: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish ate the end of shelf-life by Sampling season for all participating countries*.

Sampling Season	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Autumn	814	124	938	13.22
Spring	623	52	675	7.70
Summer	679	81	760	10.66
Winter	625	55	680	8.09
Total	**2 741**	**312**	**3 053**	**10.22**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

For the Subtype of the fish product in all participating countries (Table 86:), we observe 9.11% contaminated samples in the category "Unknown smoked fish" and 15.47% in the category "Cold smoked fish", while in the category "Hot smoked fish" and "Gravad Fish" the prevalence estimates are 6.54% and 11.86% respectively.

Table 86: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life by Subtype of the fish product for all participating countries*

Subtype of the fish product	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Unknown smoked fish	1477	148	1625	9.11
Cold smoked fish	541	99	640	15.47
Hot smoked fish	500	35	535	6.54
Gravad fish	223	30	253	11.86
Total	**2 741**	**312**	**3 053**	**10.22**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

For the Fish species in all participating countries, Table 87: shows that that there are 12.43% of contaminated samples in the category "Salmon" and 4.39% in the category "Mackerel". For the category "Other Fish" , "Mixed Fish" and "Hering" the percentages are 8% , 7.76% and 8.74% respectively.

Table 87: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life by Fish Species for all participating countries*

Fish Species	Sample		Total	Prevalence of contamintaed samples
	Not contaminated	Contaminated		
Salmon	1628	231	1859	12.43
Mixed Fish	301	25	326	7.67
Mackerel	392	18	410	4.39
Herring	167	16	183	8.74
Other Fish	253	22	275	8.00
Total	**2 741**	**312**	**3 053**	**10.22**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

For the preservative and acidity regulators for all participating countries, Table 88: shows that there are 9.81%, 4.82% and 40% of contaminated samples in the category "no AP and AR", "AP or AR" and "AP and AR" respectively.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 88: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life by preservative and acidity regulators for all participating countries*

Preservatives and acidity regulators	Sample: Not contaminated	Sample: Contaminated	Total	Prevalence of contaminated samples
0: Products with no AP and AR	2 629	286	2 915	9.81
1: Products with 1 AP+AR	79	4	83	4.82
2: Products with 2 or more AP+AR	33	22	55	40.00
Total	**2 741**	**312**	**3 053**	**10.22**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 89: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life by preservative and acidity regulators for all participating countries* with the decomposed further according to the "EC 2073/2005 NSG" indicator

Preservative and acidity regulators	Not included in "EC 2073/2005 NSG"				Included in "EC 2073/2005 NSG"			
	Not contaminated sample	Contaminated sample	Total	Prevalence of contaminated samples	Not contaminated Sample	Contaminated Sample	Total	Prevalence of contaminated Ssmples
0: Products with no AP and AR	2 478	271	2 749	9.86	151	15	166	9.04
1: Products with 1 AP+AR	50	4	54	7.41	29		29	0.00
2: Products with 2 or more AP+AR	20	20	40	50.00	13	2	15	13.33
Total	2 548	295	2 843	10.38	193	17	210	8.10

The table below shows that the contaminated samples for the different categories of the preservative and acidity regulators originate from a varying number of countries, cities and outlets.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 90: Cross Classification Table of the preservative and acidity regulators in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life across countries, with number of cities and outlets by country.

Preservatives and acidity regulators	Country	Number of City	Number of Outlet	"EC 2073/2005 NSG" Not Included	"EC 2073/2005 NSG" Included	Total Sample per country
0: Products with no AP and AR	Austria	7	123	127	1	128
	Belgium	19	22	27	0	27
	Bulgaria	4	3	16	12	28
	Cyprus	4	9	15	10	25
	CzechRepublic	7	8	8	0	8
	Denmark	4	32	55	2	57
	Estonia	5	19	22	3	25
	Finland	8	36	17	20	37
	France	8	3	381	10	391
	Germany	271	401	460	10	470
	Greece	2	7	26	23	49
	Hungary	9	13	43	9	52
	Ireland	2	14	30	0	30
	Italy	14	385	386	2	388
	Latvia	6	21	14	14	28
	Lithuania	3	27	24	6	30
	Luxembourg	9	10	20	1	21
	Malta	16	17	21	12	33
	Netherlands	12	58	65	1	66
	Norway	6	50	56	3	59
	Poland	8	86	184	2	186
	Romania	8	24	37	1	38
	Slovakia	8	44	51	0	51
	Slovenia	10	25	22	5	27
	Spain	8	93	196	3	199
	Sweden	8	64	65	1	66
	United Kingdom	10	121	381	15	396
0: Products with no AP and AR Total		476	1715	2749	166	2915
1: Products with 1 AP+AR	Bulgaria	4	2	1	11	12
	Cyprus	1	1	1	0	1
	Denmark	1	1	1	0	1
	Estonia	3	5	3	2	5
	Finland	3	5	3	2	5
	Germany	3	3	4	0	4
	Greece	1	5	2	7	9

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

	Hungary	6	5	7	2	9
	Ireland	1	1	0	1	1
	Italy	1	1	1	0	1
	Latvia	1	1	1	0	1
	Luxembourg	1	1	1	0	1
	Malta	2	2	2	1	3
	Poland	1	2	2	0	2
	Romania	6	16	19	2	21
	Slovakia	1	1	0	1	1
	Slovenia	2	2	2	0	2
	Spain	2	3	3	0	3
	Sweden	1	1	1	0	1
1: Products with 1 AP+AR Total		41	58	54	29	83
2: Products with 2 or more AP+AR	Bulgaria	2	1	1	4	5
	Cyprus	1	1	1	0	1
	CzechRepublic	4	4	4	0	4
	Denmark	2	2	2	0	2
	Finland	6	20	12	9	21
	Greece	1	1	0	1	1
	Poland	4	9	12	0	12
	Romania	1	1	1	0	1
	Slovakia	4	6	7	1	8
2: Products with 2 or more AP+AR Total		25	45	40	15	55

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The distribution of pH test results (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish samples at the end of shelf-life is summarized in Table 91: Figure 20: and Figure 21: . Note that the pH measurement was done at the arrival at the laboratory, and the comparison in the plot is based on the prevalence of *Listeria monocytogenes* contaminated samples at the end of shelf-life.

Table 91: Summary Statistics of pH test result (on the arrival at the laboratory) in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*, for samples contaminated and not contaminated by *Listeria monocytogenes* at the end of shelf-life

pH test result	Sample: Not contaminated	Sample: Contaminated	Total
n	2 741	312	3 053
mean	6.03	6.01	6.03
sd	0.35	0.25	0.34
min	3.22	4.2	3.22
lower whisker	5.59	5.65	5.61
Q1	5.95	5.92	5.59
median	6.05	6.005	6.05
Q3	6.19	6.12	6.19
Upper whisker	6.55	6.42	6.52
max	7.6	6.85	7.6
range (max-min)	4.38	2.65	4.38

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

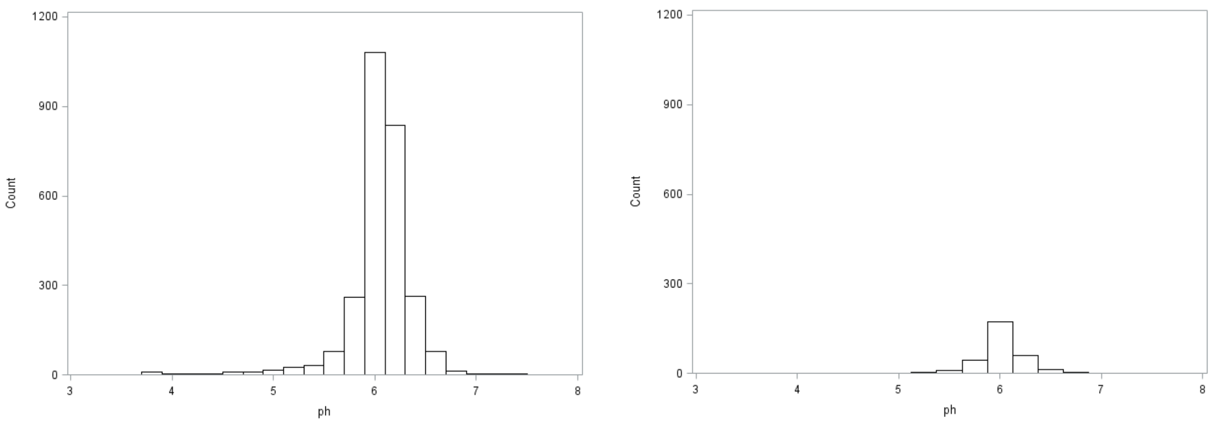


Figure 20: Histogram of pH test result (on the arrival at the laboratory) in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* at the end of shelf-life

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

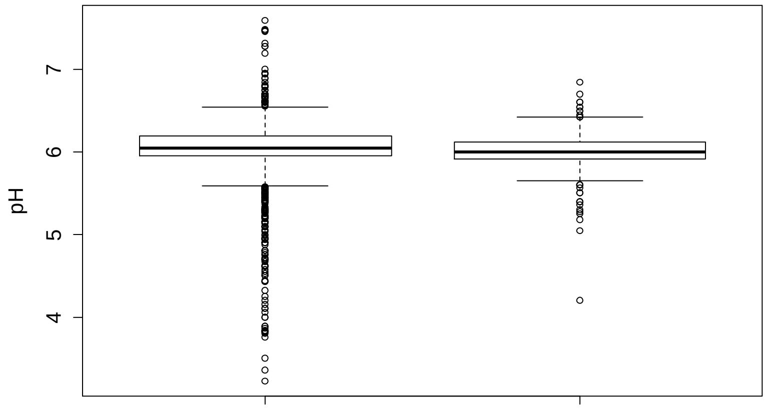


Figure 21: Boxplot[18] of pH test result (on the arrival at the laboratory) in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* at the end of shelf-life

The distribution of water activity results (on the arrival at the laboratory) for packaged (not frozen) hot or cold smoked or gravad fish samples at the end of shelf-life is summarized in Table 92: , Figure 22: and Figure 23: . Note that the water activity result was obtained at the arrival at the laboratory, and the comparison in the plot is based on the prevalence at the end of shelf-life.

Table 92: Summary statistics of water activity result (on the arrival at the laboratory) in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*, for samples contaminated and not contaminated by *Listeria monocytogenes* at the end of shelf-life

Water activity result	Sample		Total
	Not contaminated	Contaminated	
n	2 741	312	3 053
mean	0.96	0.96	0.96
sd	0.02	0.02	0.02
min	0.88	0.88	0.88
lower whisker	0.92	0.92	0.92
Q1	0.95	0.95	0.95
median	0.96	0.96	0.96
Q3	0.97	0.97	0.97
Upper whisker	1	0.99	1
max	1	0.99	1
range (max-min)	0.12	0.11	0.12

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

[18] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

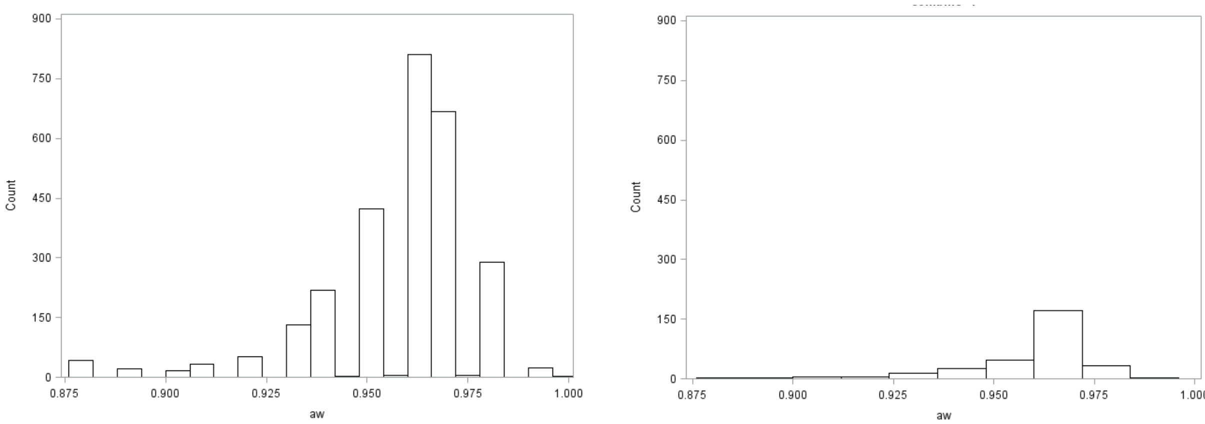


Figure 22: Histogram of water activity result (on the arrival at the laboratory) in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* at the end of shelf-life

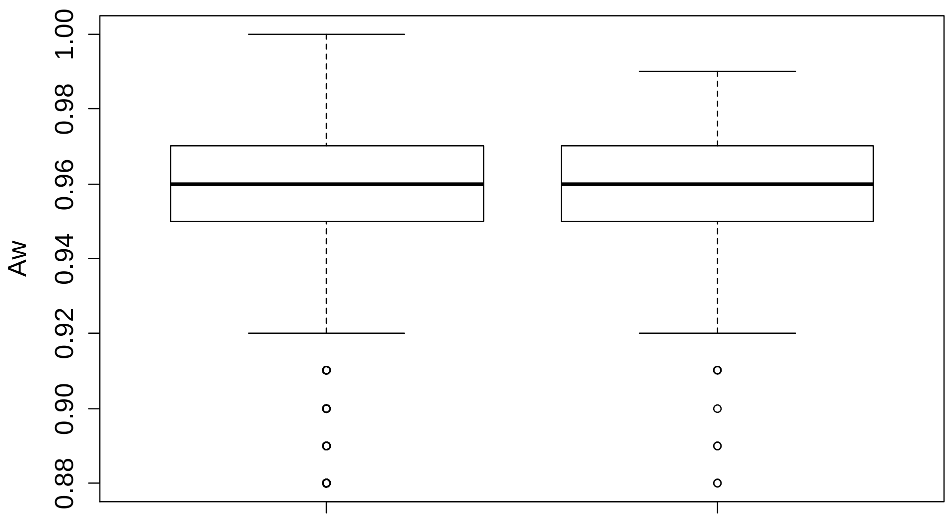


Figure 23: Boxplot[19] of water activity result (on the arrival at the laboratory) in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* at the end of shelf-life

Table 93: shows that the prevalence of *Listeria monocytogenes* at the end of shelf-life for sliced fish is 11.78%, while for the non-sliced fish it is only 5.66%.

[19] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 93: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at end of shelf-life by Possible slicing for all participating countries*

Possible slicing	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Sliced	2 007	268	2 275	11.78
Non-Sliced	734	44	778	5.66
Total	**2 741**	**312**	**3 053**	**10.22**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

For the packaging type, Table 94: shows that the estimated prevalences in the category "Vacuum", "Modified atmosphere", "Normal atmosphere" and "Other (free text)" are 12.93%, 9.15%, 2.18% and 11.11% respectively. Merging packaging type as shown in Table 95: leads to about 10.47 % contaminated samples in the category "All other packaging types".

Table 94: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at end of shelf-life by Packaging type for all participating countries*

Packaging Type	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Vacuum	1 589	236	1 825	12.93
Modified atmosphere	526	53	579	9.15
Normal atmosphere	538	12	550	2.18
Other (free text)	88	11	99	11.11
Total	**2 741**	**312**	**3 053**	**10.22**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 95: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, at end of shelf-life by Packaging type[(c)] for all participating countries*

Packaging Type[(c)]	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Modified atmosphere	526	53	579	9.15
All other packaging types	2215	259	2474	10.47
Total	**2 741**	**312**	**3 053**	**10.22**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The number of contaminated samples by Country of production for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling is shown in Table 96: .

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 96: Number of samples contaminated and not contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life by the Country of production

Country of production	Number of samples not contaminated	Number of samples contaminated
Austria	27	1
Belarus	1	0
Belgium	7	2
Bulgaria	32	7
Canada	2	0
Croatia	3	0
Cyprus	11	3
Czech Republic	22	0
Denmark	161	15
Estonia	25	7
Faroe Islands		1
Finland	39	5
France	436	19
Germany	163	5
Greece	61	0
Greenland	3	2
Hungary	8	3
Ireland	28	1
Italy	52	23
Latvia	36	13
Lithuania	96	20
Luxembourg	1	0
Netherlands	47	8
Norway	217	29
Poland	440	107
Romania	57	3
Slovakia	8	1
Slovenia	5	1
Spain	187	13
Sweden	51	8
Switzerland	1	0
Turkey	47	2
Ukraine	1	0
United Kingdom	458	13
United States	3	0
Vietnam	5	0
Total	2741	312

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 97: shows that only one sample was not transported in line with the technical specifications.

Table 97: Prevalence of samples contaminated by *Listeria* monocytogenes in packaged (not frozen) hot or cold smoked or gravad fish samples, at end of shelf-life by transport protocol for all participating countries*

Transport Protocol	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Yes [a)]	2 740	312	3052	10.22
No [b)]	1	0	1	0.00
Total	**2 741**	**312**	**3 053**	**10.22**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) in line with technical specifications
b) not in line with technical specifications

The distribution of laboratory storage temperature for packaged (not frozen) hot or cold smoked or gravad fish is summarized for samples that are not contaminated and those that are contaminated at the end of shelf-life in Table 98: , Figure 24: and Figure 25: .

Table 98: Summary Statistics of Storage Temperature at Laboratory based on prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life for all participating countries*

Temperature at laboratory	Sample		Total
	Not contaminated	Contaminated	
n	2 741	312	3 053
mean	4.24	4.08	4.22
sd	1.27	1.36	1.28
min	0	1	0
lower whisker	4	2	4
Q1	4	3	4
median	4	4	4
Q3	4	4	4
Upper whisker	4	5	4
max	8	8	8
range (max-min)	8	7	8

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

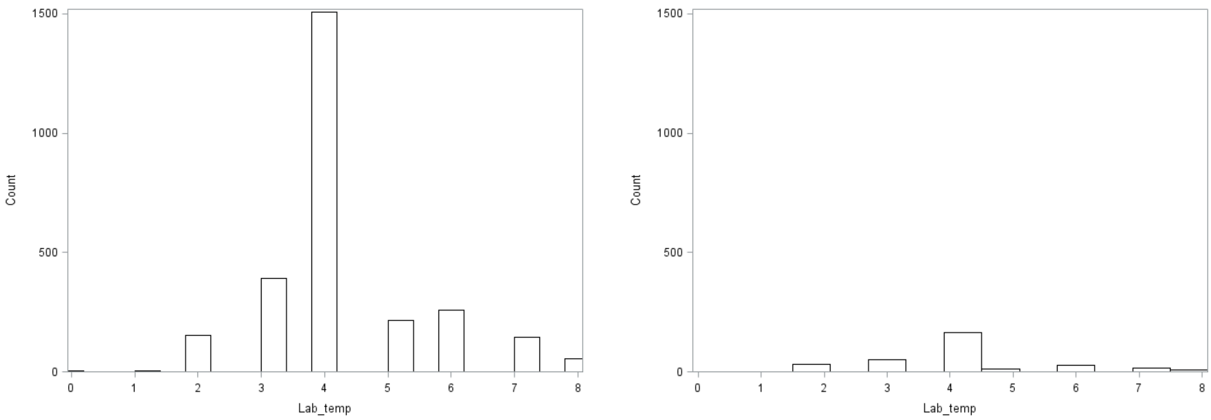


Figure 24: Histogram of storage temperature at laboratory for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life in all participating countries

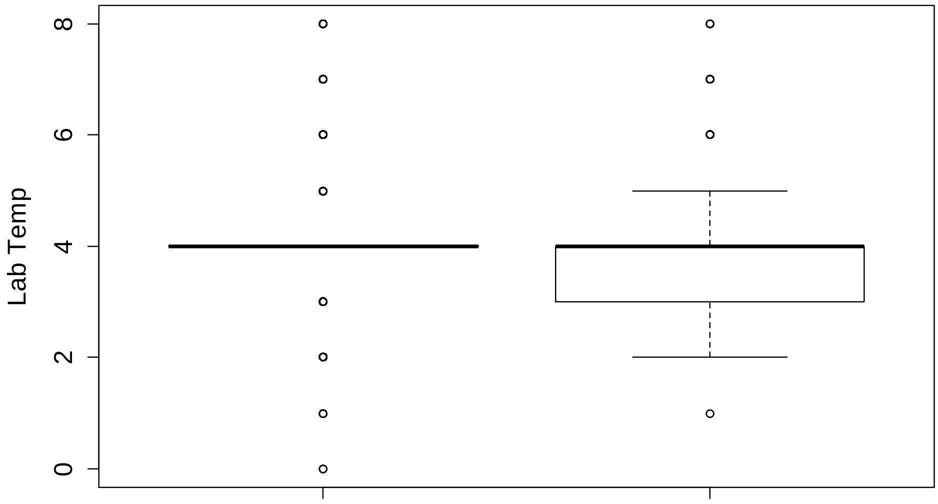


Figure 25: Boxplot[20] of Storage Temperature at Laboratory for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at end of shelf-life for all participating countries

The boxplot and histogram for the distribution of the remaining shelf-life in days are shown in Table 99: Figure 26: and Figure 27: .

[20] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 99: Summary Statistics of remaining shelf-life by outcome (contaminated/not contaminated/total) in packaged (not frozen) hot or cold smoked or gravad fish samples, at end of shelf-life for all participating countries*

Remaining shelf-life	Sample		Total
	Not contaminated	Contaminated	
n	2 741	312	3 053
mean	22.94	20.39	22.68
sd	38.47	13.96	36.73
min	1	1	1
lower whisker	1	1	1
Q1	9	9	9
median	14	16	15
Q3	23	29	23
Upper whisker	44	57	44
max	519	92	519
range (max-min)	518	91	518

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

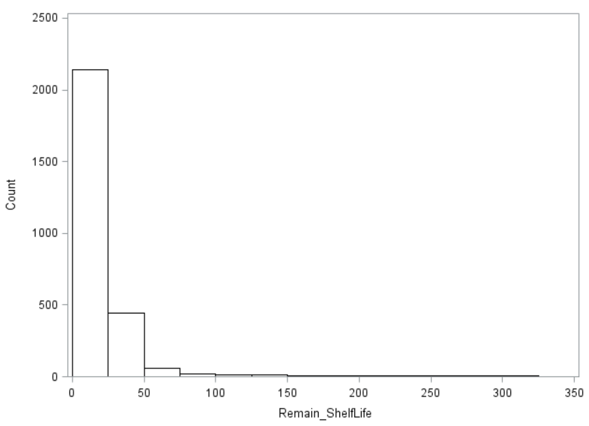


Figure 26: Histogram of remaining shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* at the end of shelf-life

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

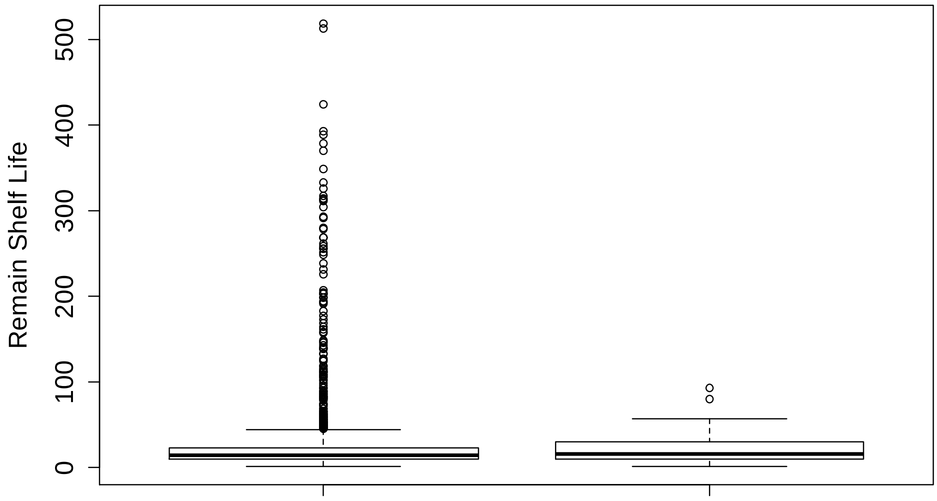


Figure 27: Boxplot[21]of remaining shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* at the end of shelf-life

For the “EC 2073/2005 NSG” indicator, Table 100: shows that in the category supporting growth there are 10.38% *Listeria monocytogenes* contaminated samples, whereas this percentage is only 8.10% in the category “EC 2073/2005 NSG”.

Table 100: Prevalence of samples contaminated by *Listeria monocytogenes* by “EC 2073/2005 NSG” indicator at end of shelf-life for all participating countries*.

“EC 2073/2005 NSG”	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
For samples not included in ‘EC 2073/2005 NSG’	2548	295	2843	10.38
For samples included in ‘EC 2073/2005 NSG ’	193	17	210	8.10
Total	**2 741**	**312**	**3 053**	**10.22**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

[21] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.2.1.2. Single-factor model

GEE (Ind) has been applied again to the single-factor model along with unweighted and weighted (based on sample planned and population) approaches. In the end a sensitivity analysis has been considered using logistic regression with Firth approach.

All variables in the dataset have been fitted in the single-factor model including the interaction with the "EC 2073/2005 NSG" indicator. Most of the single factor analyses for variables that have many categories did not converge , i.e. Country, the Code of the town , Date of testing, Use by date, Production date, Packaging date and Country of production. Others variables that were fitted in a single-factor model using Subtype of the fish product, Number of preservatives and acidity regulators and transport variable did not converge as well.

The result of the single-factor model ("single") may not be over-interpreted since this step of analysis is mainly serving as a preliminary analysis, proceeding the full analysis ("multiple analysis").

The result of single-factor model presents in the Appendix D.3.

5.2.1.3. Multiple-factors model

ANALYSIS WITH 'EC 2073/2005 NSG' INDICATOR

The same all subset model selection approach was used as before. All variables together with their interaction with the "EC 2073/2005 NSG" indicator were included in the model selection. The criterion used for subset selection was again AIC (Appendix C.2).

The selected model included Sampling season, Subtype of the fish product, Fish species, Number of preservatives and acidity regulators, Possible slicing, Packaging type(c), remaining shelf-life, "EC 2073/2005 NSG" indicator, the interactions outlet*"EC 2073/2005 NSG", Subtype of the fish product*"EC 2073/2005 NSG", Fish species*"EC 2073/2005 NSG", Number of preservatives and acidity regulators*"EC 2073/2005 NSG" and Storage temperature at laboratory*"EC 2073/2005 NSG". The interaction between Packaging type(c) and Storage temperature at retail as well as their main effects were included in the final model since they are considerd as biologically meaningful.

For further analysis, GEE (Ind) was used to analyse the selected model. After removing the non-significant effects from the model, the final model is shown in Table 101: and Table 102: .

Table 101: Wald Statistics For Type 3 GEE Analysis for final model Prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	17.09	0.00	3	14.02	0.00	3	14.34	0.00
Subtype of the fish product	3	10.10	0.02	3	12.25	0.01	3	9.31	0.03
Fish species	4	12.72	0.01	4	12.12	0.02	4	12.65	0.01
Preservatives and acidity	2	33.23	<.0001	2	8.81	0.01	2	5.73	0.06

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

regulators									
Possible slicing	1	2.70	0.10	1	1.03	0.31	1	1.00	0.32
Packaging type[(c)]	1	1.02	0.31	1	2.01	0.16	1	0.52	0.47
Temperature at laboratory	1	0.57	0.45	1	0.07	0.79	1	1.16	0.28
Type[(c)] **of retail outlet**	1	0.39	0.53	1	0.47	0.49	1	0.30	0.59
“EC 2073/2005 NSG”	1	5.34	0.02	1	4.20	0.04	1	5.50	0.02
“EC 2073/2005 NSG”*Type[(c)] **of retail outlet**	1	7.53	0.01	1	5.12	0.02	1	5.10	0.02
“EC 2073/2005 NSG” * Fish species	4	22.43	0.00	4	22.98	0.00	4	17.45	0.00
Temperature at laboratory * ”EC 2073/2005 NSG”	1	4.74	0.03	1	3.53	0.06	1	4.91	0.03
Temperature at laboratory * Packaging type[(c)]	1	1.26	0.26	1	2.66	0.10	1	0.53	0.47

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 102: Odds ratio of GEE (Ind) for final model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.13	0.06	0.28	<.0001	0.14	0.06	0.31	<.0001	0.16	0.06	0.37	<.0001
Sampling season a)	autumn	1.80	1.26	2.58	0.00	1.74	1.19	2.56	0.00	1.77	1.18	2.66	0.01
Sampling season	spring	0.96	0.64	1.45	0.86	0.97	0.63	1.47	0.87	0.94	0.60	1.47	0.77
Sampling season	summer	1.41	0.97	2.06	0.07	1.39	0.93	2.08	0.10	1.41	0.93	2.14	0.11
Subtype of the fish product b)	Gravad fish	0.90	0.55	1.45	0.65	0.95	0.58	1.55	0.83	0.85	0.51	1.41	0.52
Subtype of the fish product	Hot smoked fish	0.60	0.37	0.96	0.03	0.55	0.34	0.91	0.02	0.58	0.35	0.97	0.04
Subtype of the fish product	Unknown smoked fish	0.61	0.44	0.85	0.00	0.57	0.40	0.81	0.00	0.59	0.42	0.85	0.00
Fish species c)	Herring	1.05	0.55	2.02	0.88	0.97	0.52	1.84	0.94	1.11	0.56	2.20	0.76
Fish species	Mackerel	0.33	0.17	0.65	0.00	0.31	0.15	0.63	0.00	0.32	0.15	0.67	0.00
Fish species	Mixed Fish	0.67	0.41	1.09	0.11	0.70	0.42	1.15	0.16	0.63	0.37	1.08	0.09
Fish species	Other Fish	0.79	0.47	1.33	0.38	0.78	0.45	1.35	0.38	0.81	0.45	1.46	0.49
Preservatives and acidity regulators d)	1: Products with 1 AP+AR	0.59	0.20	1.69	0.32	0.50	0.18	1.44	0.20	0.61	0.19	1.96	0.41
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	7.31	3.66	14.61	<.0001	3.19	1.34	7.60	0.01	3.09	1.14	8.35	0.03
Possible slicing e)		1.43	0.93	2.20	0.10	1.25	0.81	1.94	0.31	1.28	0.79	2.07	0.32
Packaging type(c) f)	Modified atmosphere	1.92	0.54	6.78	0.31	2.45	0.71	8.45	0.16	1.62	0.44	6.05	0.47
Temperature at laboratory		0.95	0.83	1.09	0.45	0.98	0.86	1.12	0.79	0.93	0.81	1.06	0.28
Type(c) of retail outlet g)	All other types of retail outlet	1.33	0.54	3.27	0.53	1.40	0.53	3.69	0.49	1.28	0.52	3.15	0.59
"EC 2073/2005 NSG" h)		0.07	0.01	0.67	0.02	0.10	0.01	0.90	0.04	0.07	0.01	0.64	0.02
"EC 2073/2005 NSG" * Type(c) of retail outlet	All other types of retail outlet	144.16	4.14	5019.57	0.01	95.56	1.84	4964.66	0.02	167.75	1.97	14282.64	0.02
"EC 2073/2005 NSG" * Fish	Herring	0.13	0.03	0.60	0.01	0.12	0.03	0.58	0.01	0.13	0.02	0.77	0.03

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

species													
“EC 2073/2005 NSG” * Fish species	Mackerel	7.38	1.70	31.95	0.01	8.21	1.84	36.55	0.01	6.47	1.31	31.95	0.02
“EC 2073/2005 NSG” * Fish species	Mixed Fish	0.21	0.01	6.87	0.38	0.31	0.01	11.34	0.52	0.11	0.00	56.17	0.49
“EC 2073/2005 NSG” * Fish species	Other Fish	0.15	0.01	2.11	0.16	0.16	0.01	2.26	0.17	0.10	0.01	1.47	0.09
Temperature at laboratory * ”EC 2073/2005 NSG”		1.74	1.06	2.88	0.03	1.61	0.98	2.63	0.06	1.81	1.07	3.06	0.03
Temperature at laboratory * Packaging type(c)	Modified atmosphere	0.86	0.66	1.12	0.26	0.81	0.63	1.04	0.10	0.91	0.69	1.18	0.47

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is “winter”
b) : The reference category for Subtype of the fish product is “Cold smoked fish”
c) : The reference category for Fish Species “Salmon”
d) : The reference category for Preservatives and acidity regulators is “0: Products with no AP and AR”
e) : The reference category for Possible slicing is “Non-Sliced”
f) : The reference category for Packaging Type(c) is “All other packaging types”
g) : The reference category for Type(c) of retail outlet is “Supermarket or small shop”
h) : The reference category for ’EC 2073/2005 NSG’ is “not included in EC 2073/2005 NSG”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

However, there are huge OR estimates and huge ranges for confidence intervals for the interaction “EC 2073/2005 NSG” indicator and Type(c) of retail outlet. This problem is caused by sparseness, by the very low counts in the category “All other types of retail outlet” in both categories for the “EC 2073/2005 NSG” indicator (Table 103:). Thus, it was considered to drop this interaction from the model. Later on, the main effect of Type(c) of retail outlet was also dropped (not significant).

Table 103: Cross classification table among Type(c) of retail outlet, “EC 2073/2005 NSG” indicator and prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at end of shelf-life.

Type(c) of retail outlet	Not included in “EC 2073/2005 NSG”			Included in “EC 2073/2005 NSG”		
	Sample			Sample		
	Not contaminated	Contaminated	Total	Not contaminated	Contaminated	Total
Supermarket or small shop	2507	289	2796	192	16	208
All other types of retail outlet	41	6	47	1	1	2
Total	2548	295	2843	193	17	210

Table 104: and Table 105: show the result of the GEE fit, after removing the interaction between “EC 2073/2005 NSG” indicator and Type(c) of retail outlet.

The unweighted GEE(Ind) result shows that the main effects Sampling season, Subtype of the fish product, Fish species, Number of preservatives and acidity regulators, “EC 2073/2005 NSG” indicator and the interactions between “EC 2073/2005 NSG” indicator and Fish species, between Storage temperature at the laboratory and “EC 2073/2005 NSG” indicator have significant effects on the prevalence. Meanwhile Possible slicing and the interaction between Storage temperature at the laboratory and Packaging type(c) as well as the main effect of Packaging type(c) and Storage temperature at the laboratory were kept in the final model because of their biological expected relevance.

Table 105: summarizes the effects of each factor in the model in terms of the odds ratio. The odds for a contaminated sample in sliced fish is 1.39 times that of non-sliced fish. Thus, the risk of being contaminated by *Listeria monocytogenes* is estimated to be higher for sliced fish. That result however is statistically not significant.

The odds for a sample to be contaminated for “Products with 2 or more AP+AR” is 7.02 times the odds for “0: Products with no AP and AR” (Number of preservatives and acidity regulators).

The odds for a sample to be contaminated for autumn is 1.81 times higher than for the winter season.

The odds in samples included in “EC 2073/2005 NSG” is 0.06 times the odds in samples not included in “EC 2073/2005 NSG” for the reference species salmon, as well as for the herring, mixed fish and other Fish species (as the interaction terms are not significant). For mackerel however the odds for a sample to be contaminated is equal to 2.4(=0.32×7.43) the odds for salmon in the “EC 2073/2005 NSG” samples. The odds for mackerel equals 0.32 the odds for salmon in the samples not included in “EC 2073/2005 NSG”. So the effect of species (mackerel as compared to salmon) reverses with the “EC 2073/2005 NSG” indicator.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

GEE Analysis for final model

Table 104: Wald Statistics For Type 3 GEE Analysis for final model (after dropping Type(c) of retail outlet) for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	16.82	0.00	3	13.97	0.00	3	14.00	0.00
Subtype of the fish product	3	10.15	0.02	3	12.33	0.01	3	9.35	0.03
Fish species	4	13.24	0.01	4	12.69	0.01	4	13.22	0.01
Preservatives and acidity regulators	2	32.64	<.0001	2	8.69	0.01	2	5.73	0.06
Possible slicing	1	2.32	0.13	1	0.80	0.37	1	0.79	0.37
Packaging type(c)	1	0.92	0.34	1	1.85	0.17	1	0.43	0.51
Temperature at laboratory	1	0.50	0.48	1	0.04	0.83	1	1.06	0.30
“EC 2073/2005 NSG”	1	5.74	0.02	1	4.57	0.03	1	6.27	0.01
“EC 2073/2005 NSG” * Fish species	4	14.41	0.01	4	14.71	0.01	4	11.60	0.02
Temperature at laboratory * ”EC 2073/2005 NSG”	1	5.20	0.02	1	3.94	0.05	1	5.69	0.02
Temperature at laboratory * Packaging type(c)	1	1.16	0.28	1	2.52	0.11	1	0.45	0.50

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 105: Odds ratio of GEE (Ind) for final model prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.13	0.06	0.29	<.0001	0.14	0.06	0.31	<.0001	0.16	0.07	0.38	<.0001
Sampling season [a)]	autumn	1.81	1.26	2.59	0.00	1.75	1.20	2.57	0.00	1.79	1.19	2.67	0.00
Sampling season	spring	0.98	0.65	1.48	0.94	0.98	0.65	1.50	0.94	0.96	0.61	1.51	0.86
Sampling season	summer	1.41	0.96	2.05	0.08	1.39	0.93	2.07	0.11	1.40	0.92	2.13	0.11
Subtype of the fish product[b)]	Gravad fish	0.87	0.54	1.41	0.59	0.93	0.57	1.52	0.77	0.82	0.49	1.38	0.46
Subtype of the fish product	Hot smoked fish	0.60	0.38	0.97	0.04	0.56	0.34	0.91	0.02	0.59	0.36	0.98	0.04
Subtype of the fish product	Unknown smoked fish	0.61	0.44	0.84	0.00	0.57	0.40	0.80	0.00	0.59	0.41	0.84	0.00
Fish species [c)]	Herring	1.04	0.54	1.98	0.92	0.96	0.51	1.81	0.89	1.09	0.55	2.16	0.80
Fish species	Mackerel	0.32	0.16	0.64	0.00	0.30	0.15	0.61	0.00	0.31	0.15	0.65	0.00
Fish species	Mixed Fish	0.66	0.40	1.08	0.10	0.69	0.42	1.14	0.14	0.62	0.36	1.06	0.08
Fish species	Other Fish	0.78	0.47	1.32	0.36	0.78	0.45	1.34	0.36	0.80	0.45	1.44	0.46
Preservatives and acidity regulators [d)]	1: Products with 1 AP+AR	0.58	0.20	1.68	0.32	0.50	0.17	1.43	0.19	0.60	0.19	1.92	0.39
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	7.02	3.54	13.92	<.0001	3.11	1.32	7.35	0.01	3.01	1.13	8.04	0.03
Possible slicing [e)]		1.39	0.91	2.13	0.13	1.22	0.79	1.88	0.37	1.24	0.77	1.99	0.37
Packaging type[(c) f)]	Modified atmosphere	1.83	0.53	6.34	0.34	2.34	0.69	7.95	0.17	1.54	0.43	5.54	0.51
Temperature at laboratory		0.95	0.83	1.09	0.48	0.99	0.86	1.13	0.83	0.93	0.81	1.07	0.30
"EC 2073/2005 NSG" [g)]		0.06	0.01	0.60	0.02	0.09	0.01	0.82	0.03	0.06	0.01	0.55	0.01
"EC 2073/2005 NSG" * Fish species	Herring	0.26	0.02	2.86	0.27	0.22	0.02	2.23	0.20	0.32	0.03	3.66	0.36
"EC 2073/2005 NSG" * Fish	Mackerel	7.43	1.71	32.26	0.01	8.29	1.86	36.94	0.01	6.55	1.33	32.32	0.02

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

species													
"EC 2073/2005 NSG" * Fish species	Mixed Fish	0.48	0.05	4.55	0.52	0.69	0.07	6.58	0.75	0.77	0.08	6.92	0.81
"EC 2073/2005 NSG" * Fish species	Other Fish	0.15	0.01	2.16	0.16	0.15	0.01	2.29	0.17	0.10	0.01	1.48	0.09
Temperature at laboratory * "EC 2073/2005 NSG"		1.78	1.08	2.93	0.02	1.64	1.01	2.68	0.05	1.83	1.11	3.01	0.02
Temperature at laboratory * Packaging type(c)	Modified atmosphere	0.87	0.67	1.12	0.28	0.82	0.64	1.05	0.11	0.92	0.71	1.19	0.50

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is "winter"
b) : The reference category for Subtype of the fish product is "Cold smoked fish"
c) : The reference category for Fish Species "Salmon"
d) : The reference category for Preservatives and acidity regulators is "0: Products with no AP and AR"
e) : The reference category for Possible slicing is "Non-Sliced"
f) : The reference category for Packaging Type(c) is "All other packaging types"
g) : The reference category for 'EC 2073/2005 NSG' is "not included in EC 2073/2005 NSG"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

SENSITIVITY ANALYSES FOR FINAL MODEL

To get further insights in the stability of the final model, we investigate its sensitivity to some modifications:

- The weighted analyses as compared to the unweighted analyses.
- The use of Firth's method and exact logistic regression, as methods that can cope with sparseness to some larger extent. Exact logistic regression was computationally not feasible. It is extremely computer intensive and lead to memory problems.
- The deletion of the interaction of Storage temperature at retail and Packaging type(c)
- The use of the continuous variable expressing the no-growth probability instead of the "EC 2073/2005 NSG" indicator.

Weighted analyses versus unweighted analyses

Table 104: and Table 105: indicate that the analyses across different weighting schemes are consistent and that the model is quite robust for this issue.

Logistic regression with Firth's correction method for sparseness

Table 106: and Table 107: confirm the stability of the model. All results are in line, and inference remains consistent.

Table 106: Wald Statistics For Type 3 Firth Analysis for final model Prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	16.98	0.00	3	15.54	0.00	3	16.98	0.00
Subtype of the fish product	3	12.23	0.01	3	16.52	0.00	3	12.92	0.00
Fish species	4	13.35	0.01	4	14.54	0.01	4	14.92	0.00
Preservatives and acidity regulators	2	34.91	<.0001	2	16.28	0.00	2	13.05	0.00
Possible slicing	1	2.51	0.11	1	0.91	0.34	1	1.00	0.32
Packaging type(c)	1	1.11	0.29	1	2.09	0.15	1	0.54	0.46
Temperature at laboratory	1	0.60	0.44	1	0.04	0.84	1	1.25	0.26
"EC 2073/2005 NSG"	1	5.79	0.02	1	4.59	0.03	1	4.23	0.04
"EC 2073/2005 NSG" * Fish species	4	17.47	0.00	4	19.90	0.00	4	13.37	0.01
Temperature at laboratory * "EC 2073/2005 NSG"	1	6.30	0.01	1	4.76	0.03	1	5.15	0.02
Temperature at laboratory * Packaging type(c)	1	1.37	0.24	1	2.71	0.10	1	0.54	0.46

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 107: Odds ratio of Firth for final model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.13	0.06	0.27	<.0001	0.14	0.07	0.29	<.0001	0.16	0.08	0.34	<.0001
Sampling season a)	autumn	1.79	1.27	2.53	0.00	1.74	1.24	2.44	0.00	1.77	1.26	2.49	0.00
Sampling season	spring	0.98	0.66	1.47	0.93	0.99	0.66	1.47	0.94	0.96	0.64	1.44	0.85
Sampling season	summer	1.40	0.97	2.02	0.07	1.38	0.96	1.99	0.08	1.39	0.97	2.01	0.07
Subtype of the fish product b)	Gravad fish	0.88	0.55	1.40	0.59	0.93	0.58	1.50	0.78	0.83	0.51	1.35	0.46
Subtype of the fish product	Hot smoked fish	0.61	0.40	0.94	0.02	0.56	0.36	0.87	0.01	0.60	0.38	0.93	0.02
Subtype of the fish product	Unknown smoked fish	0.61	0.45	0.82	0.00	0.57	0.42	0.76	0.00	0.59	0.44	0.79	0.00
Fish species c)	Herring	1.06	0.59	1.93	0.84	0.98	0.55	1.77	0.95	1.12	0.63	2.00	0.70
Fish species	Mackerel	0.34	0.18	0.64	0.00	0.31	0.17	0.59	0.00	0.32	0.17	0.61	0.00
Fish species	Mixed Fish	0.67	0.42	1.09	0.10	0.70	0.43	1.15	0.16	0.63	0.38	1.06	0.08
Fish species	Other Fish	0.80	0.48	1.33	0.39	0.79	0.49	1.29	0.35	0.82	0.51	1.33	0.43
Preservatives and acidity regulators d)	1: Products with 1 AP+AR	0.65	0.24	1.76	0.40	0.56	0.21	1.52	0.26	0.67	0.25	1.76	0.42
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	6.77	3.54	12.95	<.0001	3.08	1.73	5.51	0.00	2.99	1.62	5.54	0.00
Possible slicing e)		1.38	0.93	2.05	0.11	1.21	0.82	1.80	0.34	1.23	0.82	1.85	0.32
Packaging type(c) f)	Modified atmosphere	1.87	0.58	6.02	0.29	2.38	0.73	7.73	0.15	1.58	0.47	5.33	0.46
Temperature at laboratory		0.95	0.85	1.08	0.44	0.99	0.88	1.11	0.84	0.93	0.83	1.05	0.26
"EC 2073/2005 NSG" g)		0.08	0.01	0.62	0.02	0.11	0.01	0.83	0.03	0.08	0.01	0.89	0.04
"EC 2073/2005 NSG" * Fish species	Herring	0.36	0.05	2.51	0.30	0.32	0.04	2.31	0.26	0.43	0.06	2.99	0.39
"EC 2073/2005 NSG" * Fish species	Mackerel	6.91	1.89	25.26	0.00	7.61	2.19	26.42	0.00	6.03	1.49	24.50	0.01

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

"EC 2073/2005 NSG" * Fish species	Mixed Fish	0.62	0.07	5.38	0.67	0.90	0.11	7.60	0.93	1.22	0.10	14.80	0.87
"EC 2073/2005 NSG" * Fish species	Other Fish	0.22	0.03	1.51	0.12	0.22	0.03	1.54	0.13	0.18	0.02	1.68	0.13
Temperature at laboratory * "EC 2073/2005 NSG"		1.74	1.13	2.68	0.01	1.61	1.05	2.46	0.03	1.77	1.08	2.90	0.02
Temperature at laboratory*Packaging type(c)	Modified atmosphere	0.87	0.68	1.10	0.24	0.82	0.64	1.04	0.10	0.91	0.72	1.16	0.46

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is "winter"
b) : The reference category for Subtype of the fish product is "Cold smoked fish"
c) : The reference category for Fish Species "Salmon"
d) : The reference category for Preservatives and acidity regulators is "0: Products with no AP and AR"
e) : The reference category for Possible slicing is "Non-Sliced"
f) : The reference category for Packaging Type(c) is "All other packaging types"
g) : The reference category for 'EC 2073/2005 NSG' is "not included in EC 2073/2005 NSG"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

GEE Analysis without the interaction of Storage temperature at retail and packaging type[(c)]

Table 108: and Table 109: show the same global picture after removing the biologically relevant but statistically insignificant factors Storage temperature at retail and Packaging type[(c)].

Table 108: Wald Statistics For Type 3 GEE Analysis for Prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	15.84	0.00	3	12.67	0.01	3	13.77	0.00
Subtype of the fish product	3	9.50	0.02	3	11.10	0.01	3	9.28	0.03
Fish species	4	13.19	0.01	4	12.59	0.01	4	13.27	0.01
Preservatives and acidity regulators	2	33.19	<.0001	2	8.50	0.01	2	5.61	0.06
Possible slicing	1	2.33	0.13	1	0.84	0.36	1	0.78	0.38
Temperature at laboratory	1	2.75	0.10	1	1.84	0.17	1	2.76	0.10
"EC 2073/2005 NSG"	1	5.99	0.01	1	4.85	0.03	1	6.30	0.01
"EC 2073/2005 NSG" * Fish species	4	14.29	0.01	4	14.49	0.01	4	11.53	0.02
Temperature at laboratory*"EC 2073/2005 NSG"	1	5.78	0.02	1	4.61	0.03	1	5.87	0.02

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 109: Parameter estimates of GEE (Ind) for Prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.15	0.07	0.32	<.0001	0.17	0.08	0.37	<.0001	0.17	0.08	0.39	<.0001
Sampling season a)	autumn	1.76	1.23	2.52	0.00	1.70	1.16	2.49	0.01	1.76	1.18	2.63	0.01
Sampling season	spring	0.98	0.65	1.47	0.91	0.98	0.64	1.49	0.92	0.96	0.61	1.51	0.86
Sampling season	summer	1.39	0.95	2.03	0.09	1.37	0.91	2.04	0.13	1.39	0.91	2.12	0.12
Subtype of the fish product b)	Gravad fish	0.86	0.53	1.40	0.55	0.91	0.56	1.49	0.71	0.82	0.49	1.37	0.45
Subtype of the fish product	Hot smoked fish	0.61	0.38	0.98	0.04	0.57	0.35	0.93	0.03	0.59	0.36	0.98	0.04
Subtype of the fish product	Unknown smoked fish	0.62	0.45	0.86	0.00	0.59	0.42	0.83	0.00	0.59	0.42	0.84	0.00
Fish species c)	Herring	1.05	0.55	2.01	0.88	0.98	0.52	1.86	0.96	1.10	0.56	2.19	0.78
Fish species	Mackerel	0.33	0.17	0.64	0.00	0.31	0.15	0.62	0.00	0.31	0.15	0.65	0.00
Fish species	Mixed Fish	0.65	0.40	1.06	0.08	0.67	0.41	1.11	0.12	0.62	0.36	1.05	0.08
Fish species	Other Fish	0.80	0.48	1.34	0.40	0.80	0.47	1.37	0.42	0.82	0.46	1.46	0.49
Preservatives and acidity regulators d)	1: Products with 1 AP+AR	0.60	0.20	1.77	0.36	0.52	0.18	1.54	0.24	0.61	0.19	2.02	0.42
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	7.15	3.61	14.17	<.0001	3.18	1.33	7.57	0.01	3.01	1.12	8.07	0.03
Possible slicing e)		1.39	0.91	2.12	0.13	1.22	0.80	1.88	0.36	1.24	0.77	1.98	0.38
Temperature at laboratory		0.91	0.82	1.02	0.10	0.93	0.84	1.03	0.17	0.91	0.82	1.02	0.10
"EC 2073/2005 NSG" f)		0.06	0.01	0.57	0.01	0.08	0.01	0.76	0.03	0.06	0.01	0.54	0.01
"EC 2073/2005 NSG" * Fish species	Herring	0.26	0.02	2.81	0.27	0.22	0.02	2.17	0.19	0.32	0.03	3.62	0.36
"EC 2073/2005 NSG" * Fish species	Mackerel	7.26	1.68	31.35	0.01	8.01	1.81	35.44	0.01	6.43	1.31	31.62	0.02

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

"EC 2073/2005 NSG" * Fish species	Mixed Fish	0.47	0.05	4.59	0.52	0.69	0.07	6.72	0.75	0.76	0.08	6.88	0.81
"EC 2073/2005 NSG" * Fish species	Other Fish	0.15	0.01	2.08	0.16	0.15	0.01	2.19	0.17	0.10	0.01	1.43	0.09
Temperature at laboratory * "EC 2073/2005 NSG"		1.84	1.12	3.02	0.02	1.72	1.05	2.81	0.03	1.85	1.13	3.05	0.02

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is "winter"
b) : The reference category for Subtype of the fish product is "Cold smoked fish"
c) : The reference category for Fish Species "Salmon"
d) : The reference category for Preservatives and acidity regulators is "0: Products with no AP and AR"
e) : The reference category for Possible slicing is "Non-Sliced"
f) : The reference category for 'EC 2073/2005 NSG' is "not included in EC 2073/2005 NSG"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Firth's method without the interaction of Storage temperature at retail and packaging type[(c)]

Table 110: and Table 111: are also in agreement with the earlier findings.

Table 110: Wald Statistics For Type 3 Firth Analysis for Prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	16.03	0.00	3	14.16	0.00	3	16.50	0.00
Subtype of the fish product	3	11.57	0.01	3	14.97	0.00	3	12.80	0.01
Fish species	4	13.29	0.01	4	14.35	0.01	4	14.93	0.00
Preservatives and acidity regulators	2	35.68	<.0001	2	16.71	0.00	2	13.05	0.00
Possible slicing	1	2.48	0.12	1	0.94	0.33	1	0.97	0.32
Temperature at laboratory	1	3.19	0.07	1	2.04	0.15	1	3.18	0.07
"EC 2073/2005 NSG"	1	6.19	0.01	1	5.06	0.02	1	4.33	0.04
"EC 2073/2005 NSG" * Fish species	4	17.31	0.00	4	19.62	0.00	4	13.30	0.01
Temperature at laboratory * "EC 2073/2005 NSG"	1	7.13	0.01	1	5.73	0.02	1	5.41	0.02

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 111: Odds ratio of Firth for Prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.15	0.08	0.31	<.0001	0.18	0.09	0.35	<.0001	0.18	0.09	0.35	<.0001
Sampling season [a)]	autumn	1.75	1.24	2.46	0.00	1.68	1.20	2.36	0.00	1.75	1.24	2.45	0.00
Sampling season	spring	0.98	0.65	1.46	0.91	0.98	0.66	1.46	0.91	0.96	0.64	1.44	0.84
Sampling season	summer	1.38	0.96	1.99	0.08	1.36	0.95	1.95	0.10	1.38	0.96	1.99	0.08
Subtype of the fish product [b)]	Gravad fish	0.87	0.55	1.38	0.55	0.91	0.57	1.47	0.71	0.83	0.51	1.35	0.44
Subtype of the fish product	Hot smoked fish	0.62	0.40	0.95	0.03	0.57	0.37	0.89	0.01	0.60	0.38	0.93	0.02
Subtype of the fish product	Unknown smoked fish	0.62	0.46	0.83	0.00	0.59	0.44	0.78	0.00	0.59	0.44	0.80	0.00
Fish species [c)]	Herring	1.08	0.59	1.96	0.81	1.01	0.56	1.81	0.98	1.13	0.63	2.02	0.68
Fish species	Mackerel	0.34	0.18	0.64	0.00	0.32	0.17	0.60	0.00	0.32	0.17	0.61	0.00
Fish species	Mixed Fish	0.66	0.41	1.07	0.09	0.69	0.42	1.12	0.13	0.63	0.38	1.05	0.08
Fish species	Other Fish	0.82	0.49	1.35	0.43	0.82	0.50	1.32	0.41	0.83	0.51	1.35	0.46
Preservatives and acidity regulators [d)]	1: Products with 1 AP+AR	0.67	0.25	1.81	0.44	0.59	0.22	1.59	0.30	0.68	0.26	1.80	0.44
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	6.91	3.62	13.21	<.0001	3.15	1.77	5.63	0.00	3.00	1.62	5.54	0.00
Possible slicing [e)]		1.38	0.92	2.05	0.12	1.22	0.82	1.80	0.33	1.23	0.82	1.85	0.32
Temperature at laboratory		0.91	0.83	1.01	0.07	0.93	0.84	1.03	0.15	0.91	0.83	1.01	0.07
"EC 2073/2005 NSG" [f)]		0.07	0.01	0.56	0.01	0.09	0.01	0.74	0.02	0.08	0.01	0.86	0.04
"EC 2073/2005 NSG" * Fish species	Herring	0.35	0.05	2.47	0.29	0.31	0.04	2.25	0.25	0.42	0.06	2.96	0.38
"EC 2073/2005 NSG" * Fish species	Mackerel	6.76	1.85	24.70	0.00	7.37	2.13	25.53	0.00	5.93	1.46	24.06	0.01
"EC 2073/2005 NSG" * Fish	Mixed Fish	0.62	0.07	5.40	0.66	0.91	0.11	7.69	0.93	1.21	0.10	14.74	0.88

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

species													
"EC 2073/2005 NSG" * Fish species	Other Fish	0.21	0.03	1.48	0.12	0.22	0.03	1.51	0.12	0.18	0.02	1.64	0.13
Temperature at laboratory * "EC 2073/2005 NSG"		1.80	1.17	2.78	0.01	1.68	1.10	2.58	0.02	1.80	1.10	2.94	0.02

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is "winter"
b) : The reference category for Subtype of the fish product is "Cold smoked fish"
c) : The reference category for Fish Species "Salmon"
d) : The reference category for Preservatives and acidity regulators is "0: Products with no AP and AR"
e) : The reference category for Possible slicing is "Non-Sliced"
f) : The reference category for 'EC 2073/2005 NSG' is "not included in EC 2073/2005 NSG"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

GEE Analysis for final model with continuous variable expressing the no–growth probability

The effect of replacing the "EC 2073/2005 NSG" indicator by the continuous variable expressing the no-growth probability is shown in Table 112: and Table 113: . Most factors are quite robust for this modification, except for Fish species, as its main effect and its interaction with the continuous variable expressing the no-growth probability are no longer significant. Also the interaction between Storage temperature at laboratory and the continuous variable expressing the no-growth probability is no longer significant.

Table 112: Wald Statistics For Type 3 GEE Analysis for Prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries* for continuous variable expressing the no-growth probability.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	15.85	0.00	3	13.86	0.00	3	14.67	0.00
Subtype of the fish product	3	10.45	0.02	3	12.65	0.01	3	10.34	0.02
Fish species	4	8.67	0.07	4	9.66	0.05	4	6.22	0.18
Preservatives and acidity regulators	2	26.51	<.0001	2	8.63	0.01	2	6.25	0.04
Possible slicing	1	2.38	0.12	1	0.79	0.37	1	0.80	0.37
Packaging type[(c)]	1	1.42	0.23	1	1.85	0.17	1	0.28	0.60
Temperature at laboratory	1	0.95	0.33	1	0.67	0.41	1	0.22	0.64
Continuous no-growth probability	1	1.93	0.16	1	0.85	0.36	1	0.00	0.98
Continuous no-growth probability * Fish species	4	6.95	0.14	4	8.59	0.07	4	4.55	0.34
Temperature at laboratory * Continuous no-growth probability	1	1.55	0.21	1	0.52	0.47	1	0.02	0.90
Temperature at laboratory * Packaging type[(c)]	1	1.78	0.18	1	2.54	0.11	1	0.29	0.59

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 113: Odds ratios of GEE (Ind) for final model for prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries* for continuous variable expressing the no-growth probability

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.04	0.01	0.26	0.00	0.06	0.01	0.40	0.00	0.16	0.02	1.13	0.07
Sampling season a)	autumn	1.72	1.22	2.44	0.00	1.70	1.18	2.45	0.00	1.78	1.20	2.63	0.00
Sampling season	spring	0.95	0.63	1.44	0.82	0.96	0.63	1.46	0.84	0.96	0.61	1.50	0.85
Sampling season	summer	1.37	0.95	1.99	0.10	1.36	0.92	2.01	0.12	1.41	0.93	2.12	0.11
Subtype of the fish product b)	Gravad fish	0.76	0.47	1.24	0.28	0.79	0.48	1.30	0.35	0.74	0.44	1.25	0.27
Subtype of the fish product	Hot smoked fish	0.57	0.36	0.92	0.02	0.52	0.32	0.86	0.01	0.54	0.32	0.91	0.02
Subtype of the fish product	Unknown smoked fish	0.60	0.44	0.83	0.00	0.55	0.38	0.78	0.00	0.57	0.39	0.82	0.00
Fish species c)	Herring	2.87	0.97	8.46	0.06	2.85	0.96	8.48	0.06	2.83	0.83	9.62	0.10
Fish species	Mackerel	0.51	0.15	1.66	0.26	0.44	0.13	1.48	0.19	0.55	0.16	1.92	0.35
Fish species	Mixed Fish	0.55	0.21	1.40	0.21	0.48	0.17	1.30	0.15	0.55	0.20	1.51	0.24
Fish species	Other Fish	0.93	0.31	2.73	0.89	0.88	0.30	2.59	0.82	0.76	0.24	2.39	0.64
Preservatives and acidity regulators d)	1: Products with 1 AP+AR	0.45	0.16	1.26	0.13	0.39	0.14	1.07	0.07	0.49	0.17	1.41	0.19
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	5.11	2.65	9.89	<.0001	2.48	1.10	5.60	0.03	2.60	1.03	6.58	0.04
Possible slicing e)		1.39	0.91	2.12	0.12	1.21	0.79	1.86	0.37	1.24	0.78	1.96	0.37
Packaging type (c) f)	Modified atmosphere	2.02	0.64	6.40	0.23	2.24	0.70	7.17	0.17	1.42	0.39	5.25	0.60
Temperature at laboratory		1.16	0.86	1.55	0.33	1.13	0.84	1.52	0.41	0.93	0.68	1.27	0.64
Continuous no-growth probability		3.44	0.60	19.69	0.16	2.31	0.39	13.77	0.36	0.97	0.15	6.25	0.98
Continuous no-growth probability *	Herring	0.19	0.05	0.69	0.01	0.17	0.05	0.62	0.01	0.22	0.05	0.95	0.04

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Fish species													
Continuous no-growth probability * Fish species	Mackerel	0.92	0.17	4.94	0.92	1.07	0.20	5.69	0.94	0.67	0.11	4.01	0.66
Continuous no-growth probability * Fish species	Mixed Fish	1.18	0.36	3.90	0.79	1.64	0.45	5.98	0.45	1.20	0.31	4.60	0.79
Continuous no-growth probability * Fish species	Other Fish	0.66	0.18	2.39	0.53	0.70	0.20	2.44	0.57	0.92	0.25	3.33	0.89
Temperature at laboratory * Continuous no-growth probability		0.82	0.60	1.12	0.21	0.89	0.65	1.22	0.47	1.02	0.73	1.43	0.90
Temperature at laboratory * Packaging type(c)	Modified atmosphere	0.85	0.67	1.08	0.18	0.82	0.65	1.05	0.11	0.93	0.71	1.21	0.59

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is "winter"
b) : The reference category for Subtype of the fish product is "Cold smoked fish"
c) : The reference category for Fish Species "Salmon"
d) : The reference category for Preservatives and acidity regulators is "0: Products with no AP and AR"
e) : The reference category for Possible slicing is "Non-Sliced"
f) : The reference category for Packaging Type(c) is "All other packaging types"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

<u>Firth's method for final model with continuous variable expressing the no-growth probability</u>

Table 114: and Table 115: show the same changes as the GEE analysis above.

Table 114: Wald Statistics For Logistic Regression (Firth Approach) Analysis of multiple-factors model Prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life for all participating countries* with continuous variable expressing the no-growth probability.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	15.38	0.00	3	14.71	0.00	3	17.03	0.00
Subtype of the fish product	3	12.27	0.01	3	17.37	0.00	3	14.36	0.00
Fish species	4	7.67	0.10	4	8.44	0.08	4	7.90	0.10
Preservatives and acidity regulators	2	28.50	<.0001	2	12.98	0.00	2	11.28	0.00
Possible slicing	1	2.50	0.11	1	0.86	0.35	1	0.95	0.33
Packaging type(c)	1	1.61	0.20	1	2.02	0.15	1	0.40	0.53
Temperature at laboratory	1	1.51	0.22	1	1.16	0.28	1	0.19	0.66
Continuous no-growth probability	1	2.71	0.10	1	1.35	0.24	1	0.01	0.94
Continuous no-growth probability * Fish species	4	5.63	0.23	4	6.97	0.14	4	4.97	0.29
Temperature at laboratory * Continuous no-growth probability	1	2.28	0.13	1	0.91	0.34	1	0.00	0.98
Temperature at laboratory * Packaging type(c)	1	2.00	0.16	1	2.67	0.10	1	0.41	0.52

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 115: Odds ratios of Logistic Regression (Firth Approach) of final model for multiple-factors model for Prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life for all participating countries* with continuous variable expressing the no-growth probability.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.04	0.01	0.20	<.0001	0.06	0.01	0.30	0.00	0.15	0.03	0.77	0.02
Sampling season [a)]	autumn	1.71	1.21	2.40	0.00	1.69	1.20	2.36	0.00	1.76	1.26	2.48	0.00
Sampling season	spring	0.95	0.64	1.42	0.82	0.96	0.65	1.43	0.84	0.96	0.64	1.43	0.84
Sampling season	summer	1.37	0.95	1.96	0.09	1.36	0.95	1.95	0.10	1.40	0.98	2.01	0.07
Subtype of the fish product [b)]	Gravad fish	0.77	0.49	1.22	0.27	0.80	0.50	1.27	0.35	0.76	0.47	1.23	0.26
Subtype of the fish product	Hot smoked fish	0.58	0.37	0.90	0.02	0.53	0.34	0.83	0.01	0.55	0.35	0.87	0.01
Subtype of the fish product	Unknown smoked fish	0.60	0.45	0.81	0.00	0.55	0.41	0.74	<.0001	0.57	0.42	0.77	0.00
Fish species [c)]	Herring	2.98	0.98	9.08	0.05	2.95	0.96	9.10	0.06	2.91	1.00	8.43	0.05
Fish species	Mackerel	0.55	0.19	1.53	0.25	0.48	0.17	1.40	0.18	0.59	0.22	1.63	0.31
Fish species	Mixed Fish	0.58	0.23	1.42	0.23	0.51	0.19	1.36	0.18	0.57	0.24	1.39	0.22
Fish species	Other Fish	0.99	0.34	2.87	0.99	0.94	0.33	2.72	0.91	0.82	0.28	2.38	0.71
Preservatives and acidity regulators[d)]	1: Products with 1 AP+AR	0.51	0.19	1.38	0.19	0.44	0.16	1.20	0.11	0.55	0.20	1.48	0.24
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	5.01	2.68	9.34	<.0001	2.48	1.40	4.38	0.00	2.60	1.42	4.77	0.00
Possible slicing [e)]		1.38	0.93	2.05	0.11	1.20	0.81	1.79	0.35	1.22	0.81	1.84	0.33
Packaging type[(c) f)]	Modified atmosphere	2.07	0.67	6.39	0.20	2.30	0.73	7.23	0.15	1.49	0.43	5.08	0.53
Temperature at laboratory		1.17	0.91	1.51	0.22	1.15	0.89	1.47	0.28	0.94	0.73	1.23	0.66
Continuous no-growth probability		3.67	0.78	17.24	0.10	2.48	0.54	11.50	0.24	1.06	0.22	5.02	0.94
Continuous no-growth probability * Fish species	Herring	0.19	0.05	0.80	0.02	0.17	0.04	0.73	0.02	0.22	0.05	0.89	0.03
Continuous no-growth probability *	Mackerel	0.88	0.23	3.38	0.85	1.00	0.26	3.81	1.00	0.65	0.17	2.54	0.54

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Fish species													
Continuous no-growth probability * Fish species	Mixed Fish	1.14	0.35	3.76	0.82	1.57	0.45	5.54	0.48	1.19	0.34	4.17	0.79
Continuous no-growth probability * Fish species	Other Fish	0.63	0.17	2.33	0.49	0.67	0.18	2.45	0.54	0.87	0.24	3.25	0.84
Temperature at laboratory * Continuous no-growth probability		0.81	0.62	1.06	0.13	0.88	0.67	1.15	0.34	1.00	0.76	1.33	0.98
Temperature at laboratory * Packaging type(c)	Modified atmosphere	0.85	0.67	1.07	0.16	0.82	0.65	1.04	0.10	0.92	0.72	1.18	0.52

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is "winter"
b) : The reference category for Subtype of the fish product is "Cold smoked fish"
c) : The reference category for Fish Species "Salmon"
d) : The reference category for Preservatives and acidity regulators is "0: Products with no AP and AR"
e) : The reference category for Possible slicing is "Non-Sliced"
f) : The reference category for Packaging Type(c) is "All other packaging types"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.2.1.4. Diagnostic Test

Goodness of fit test

Goodness of fit was investigated using the Hosmer and Lemeshow Chi-Square test. The result shows that there is lack of fit in the model (p-value 0.03). It is not clear why lack of fit is detected or how to improve the model. As mentioned in the methodology section, the test is developed for logistic regression only and not for GEE or Firth's method. Consequently it is not known what effect the clustered nature or the sparse nature of the data have on the validity of the test. All possible models have been investigated, and therefore it is not obvious how to extend or improve the current model. Nonlinear models were not feasible to fit. We also used the Deviance and the Pearson Chisquare goodness of fit, which both compare the current model with the saturated model (the most complicated model available for the data at hand). If necessary conditions for valid tests are met, both test results are expected to be close. In this case however the Deviance test does not reject (p-value 0.99) whereas the Pearson test does (p-value <0.001). This extreme difference between both tests is an indication that asymptotics are problematic in these goodness of fit tests. So, it seems that the distributional properties of the tests and consequently the conclusions derived from them are questionable in this setting. This typically happens in case the sample size is not large enough, a phenomenon that goes hand in hand with sparseness.

Table 116: Hosmer and Lemeshow Chi-Square test

Chi-Square	DF	P-value
17.22	8	0.03

Table 117: Goodness of fit test

Criterion	DF	Value	Value/DF
Deviance	763	579.10	0.76
Scaled Deviance	763	579.10	0.76
Pearson Chi-Square	763	929.05	1.22
Scaled Pearson X2	763	929.05	1.22

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Multicolinearity analysis

All VIF values are small to very small. So there do not seem to be any problems with multicollinearity.

Table 118: Variance Inflation Factor values

Variable	VIF
Sampling season	1.05
Subtype of the fish product	1.93
Fish species	3.69
Number of preservatives and acidity regulators	6.38
Possible slicing	1.75
Packaging type[c]	1.69
"EC 2073/2005 NSG"	2.64
Storage temperature at laboratory	1.20

Additional analysis about Number of preservatives and acidity regulators

The VIF of Number of preservatives and acidity regulators is larger than others, though the value is still considerably less than 10. In order to get some information about which covariates are correlated with the Number of preservatives and acidity regulators, the results of an ordinal logistic regression are presented in the following table. It shows that most of the covariates have a significant effect on the Number of preservatives and acidity regulators.

Table 119: Wald Statistics For Type 3 ordinal logistic regression Analysis

Variable	DF	Wald Chi-Square	P-value
Fish species	8	52.48	<.0001
Subtype of the fish product	6	138.11	<.0001
Sampling season	6	25.05	0.00
Possible slicing	2	36.42	<.0001
Packaging type[c]	2	6.20	0.05
Temperature at laboratory	2	61.82	<.0001
"EC 2073/2005 NSG"	2	4.38	0.11

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.2.1.5. Other Analysis

The explanation for the reversed effect of mackarel as compared to salmon can be derived from the following table. This descriptive analysis is fully in line with the GEE result.

Table 120: Cross classification table among Fish species, "EC 2073/2005 NSG" indicator and Prevalence of *Listeria monocytogenes* contaminated samples in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life.

Fish Species	Not included in "EC 2073/2005 NSG"				Included in "EC 2073/2005 NSG"			
	Sample				Sample			
	Not contaminated	Contaminated	Total	Prevalence of contaminated samples	Not contaminated	Contaminated	Total	Prevalence of contaminated samples
Herring	128	15	143	10.49	39	1	40	2.50
Mackerel	358	11	369	2.98	34	7	41	17.07
Mixed Fish	280	24	304	7.89	21	1	22	4.55
Salmon	1569	224	1793	12.49	59	7	66	10.61
Other Fish	213	21	234	8.97	40	1	41	2.44
Total	2548	295	2843	10.38	193	17	210	8.10

Table 121: Cross classification table for Mackerel samples contaminated by *Listeria monocytogenes* at the end of shelf-life.

Country	Number of City	Number of Outlet	"EC 2073/2005 NSG"		Total Sample per country
			Not Included	Included	
Bulgaria	4	2	3	5	8
Denmark	1	1	1	0	1
Estonia	3	3	1	2	3
Germany	2	2	2	0	2
Netherlands	1	1	1	0	1
Poland	2	3	3	0	3
Total	**13**	**12**	**11**	**7**	**18**

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.2.2. Proportion of smoked or gravad fish samples at end of shelf-life, with counts exceeding the level of 100 cfu/g

5.2.2.1. Description of the samples

The following tables and figures provide further insights for packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life. It is important to realize that the observed differences might be due to other factors, which is the reason for considering the multivariable analysis in the next section.

In total 3 053 samples of packaged (not frozen) hot or cold smoked or gravad fish were collected. For 1.7% of the samples, the result of the enumeration test at the end of shelf-life was above 100 cfu/g (Table 122:).

Table 122: Descriptive statistics of percentage of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100cfu/g at end of shelf-life for all participating countries*

	Frequency	Percentage of samples with counts exceeding 100 cfu/g
Samples with counts not exceeding the level of 100 cfu/g	3 001	98.3
Samples with counts exceeding the level of 100 cfu/g	52	1.7
Total	3 053	

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The following tables and figures provide further insights in the percentage of samples with a test result above 100 cfu/g at end of shelf-life with regard to possible factors.

For each participating country, the number of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is given in Table 123: . For many countries the number of collected samples is low.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 123: Number of samples in packaged (not frozen) hot or cold smoked or gravad fish with counts exceeding and not exceeding the level of 100 cfu/g at end of shelf-life by country

Country	Number of samples with counts not exceeding the level of 100 cuf/g	Number of samples with counts exceeding the level of 100 cuf/g
Austria	128	0
Belgium	27	0
Bulgaria	44	1
Cyprus	26	1
Czech Republic	12	0
Denmark	56	4
Estonia	29	1
Finland	62	1
France	390	1
Germany	468	6
Greece	59	0
Hungary	59	2
Ireland	31	0
Italy	367	22
Latvia	29	0
Lithuania	30	0
Luxembourg	21	1
Malta	36	0
Netherlands	66	0
Norway	59	0
Poland	193	7
Romania	60	0
Slovakia	60	0
Slovenia	27	2
Spain	200	2
Sweden	66	1
United Kingdom	396	0
Total	3 001	52

The percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is calculated for each Type of retail outlet in Table 124: . It shows that 1.63% of the samples collected from a supermarket or small shop had a *Listeria monocytogenes* count exceeding the level of 100 cfu/g. Meanwhile for Street market or farmers' market, Speciality delis and Other retail outlets there are 0%, 33.33% and 4.55% samples with a *Listeria monocytogenes* count exceeding the level of 100 cfu/g respectively. These percentages should not be over-interpreted because the total number of samples for Speciality delis and Street market or farmers' market is only 3 and 2 respectively.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 124: Percentage of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100 cfu/g at end of shelf-life by Type of retail outlet for all participating countries*

Type of retail outlet	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Supermarket or small shop	2955	49	3004	1.63
Speciality delis	2	1	3	33.33
Street market or farmers' market	2	0	2	0.00
Other (free text field)	42	2	44	4.55
Total	**3 001**	**52**	**3 053**	**1.70**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

As the sparseness of the data caused problems in the multiple-factors model especially with this variable, we also provide the percentages for the Type(c) of retail outlet after merging the last three categories. The percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g in the category "All other types of retail outlet" is equal to 6.12% (Table 125:).

Table 125: Percentage of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100 cfu/g at end of shelf-life by Type(c) of retail outlet for all participating countries*

Type(c) of retail outlet	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Supermarket or small shop	2955	49	3004	1.63
All other types of retail outlet	46	3	49	6.12
Total	**3 001**	**52**	**3 053**	**1.70**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

For every Sampling season, Table 126: shows the percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g. The percentages are highest and similar for autumn and summer (2.35% and 2.24%) and lowest for spring.

Table 126: Percentage of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100 cfu/g at end of shelf-life by Sampling season for all participating countries*

Sampling Season	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Autumn	916	22	938	2.35
Spring	672	3	675	0.44
Summer	743	17	760	2.24
Winter	670	10	680	1.47
Total	**3 001**	**52**	**3 053**	**1.70**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g are given for each Subtype of the fish product in Table 127: . It appears that 1.78% of the samples have a count exceeding the level of 100 cfu/g in the category "Unknown smoked fish" and 1.88% in the category "Cold smoked fish". Meanwhile for the category "Hot smoked fish" and "Gravad Fish" there are 1.68% and 0.79% samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g respectively.

Table 127: Percentage of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100 cfu/g at end of shelf-life by Subtype of the fish product for all participating countries*

Subtype of the fish product	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Unknown smoked fish	1 596	29	1 625	1.78
Cold smoked fish	628	12	640	1.88
Hot smoked fish	526	9	535	1.68
Gravad fish	251	2	253	0.79
Total	**3 001**	**52**	**3 053**	**1.70**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

In Table 128: we show the results for each Fish species. The percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is 2.04% in the category "Salmon" and 0.49% in the category "Mackerel". Meanwhile for category "Other Fish" , "Mixed Fish" and "Hering" there are 2.55% , 1.23% and 0.55% samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g respectively.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 128: Percentage of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100 cfu/g at end of shelf-life by Fish Species for all participating countries*

Fish Species	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Salmon	1 821	38	1 859	2.04
Mixed Fish	322	4	326	1.23
Mackerel	408	2	410	0.49
Herring	182	1	183	0.55
Other Fish	268	7	275	2.55
Total	**3 001**	**52**	**3 053**	**1.70**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The percentages of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g for each category of preservative and acidity regulators are shown in Table 129: . When 2 or more AP+AR are used, the percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is equal to 5.45%. When no AP+AR are used 1.68% of the samples has a count exceeding the level of 100 cfu/g .

Table 129: Percentage of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100 cfu/g at end of shelf-life by preservative and acidity regulators for all participating countries*

Preservatives and acidity regulators	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
0: Products with no AP and AR	2 866	49	2 915	1.68
1: Products with 1 AP+AR	83	0	83	0.00
2: Products with 2 or more AP+AR	52	3	55	5.45
Total	**3 001**	**52**	**3 053**	**1.70**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Some summary statistics and graphs for pH test result (on the arrival at the laboratory) are given in Table 130: , Figure 28: and Figure 29: . In the summary statistics we see that the mean and median pH test result are almost the same for samples with *Listeria monocytogenes* counts exceeding and not exceeding the level of 100 cfu/g at the end of shelf-life. The range of pH test result for the samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is smaller than the range for samples not with *Listeria monocytogenes* counts exceeding the level. The distribution of pH test result is similar for samples with *Listeria monocytogenes* counts exceeding and not exceeding the level, as can be seen in the box-whisker plots in Figure 29: . However, note that the pH measurement was done on the arrival at the laboratory, and the comparison in the plot is based on the prevalence at the end of shelf-life.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 130: Summary Statistics of pH test result (on the arrival at the laboratory) in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at the end of shelf-life

pH test result	Samples with counts exceeding 100 cfu/g		Total
	No	Yes	
N	3 001	52	3 053
Mean	6.03	6.05	6.03
Sd	0.34	0.29	0.34
Min	3.22	5.18	3.22
lower whisker	5.61	5.79	5.61
Q1	5.59	6	5.59
Median	6.05	6.08	6.05
Q3	6.18	6.205	6.18
Upper whisker	6.52	6.5	6.52
Max	7.6	6.7	7.6
range (max-min)	4.38	1.52	4.38

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

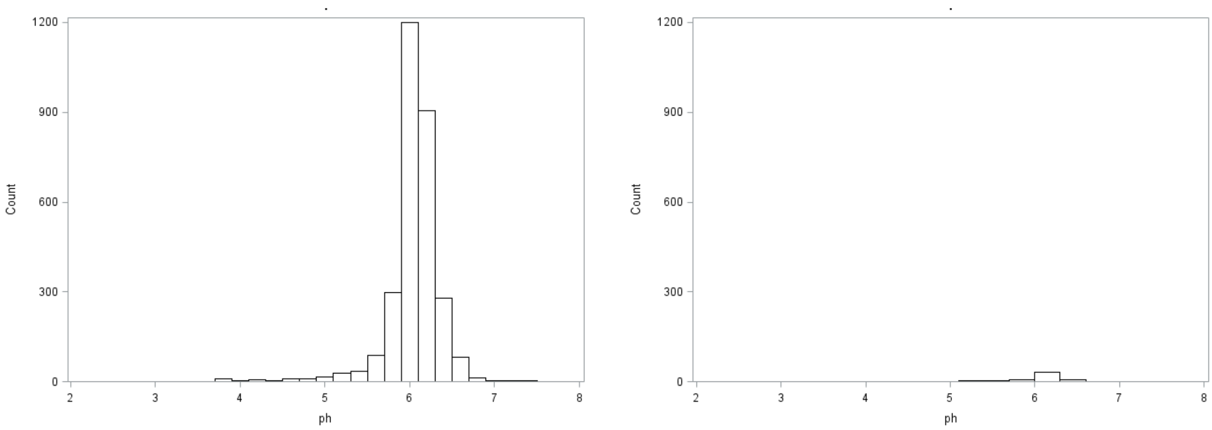


Figure 28: Histogram of pH test result (on the arrival at the laboratory) in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at the end of shelf-life

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

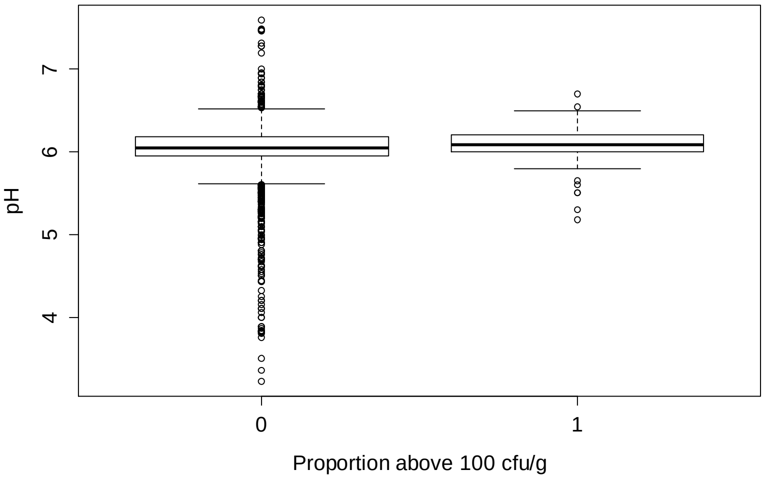


Figure 29: Boxplot[22] of pH test result (on the arrival at the laboratory) in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at the end of shelf-life

The distribution of water activity results is described in Table 131: , Figure 30: and Figure 31: for samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g or not. However, the water activity measurement was done at the arrival at the laboratory, and the comparison in the plot is based on the proportion at the end of shelf-life.

[22] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

All summary statistics are similar for samples with *Listeria monocytogenes* counts exceeding and those not exceeding the level of 100 cfu/g. The box-whisker plot of the samples not exceeding the level is wider compared to the samples with counts that do exceed the level, but both are symmetric.

Table 131: Summary Statistics of water activity result (on the arrival at the laboratory) in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at the end of shelf-life

Water activity result	Samples with counts exceeding 100 cfu/g		Total
	No	Yes	
N	3 001	52	3 053
Mean	0.96	0.96	0.96
Sd	0.02	0.01	0.02
Min	0.88	0.93	0.88
lower whisker	0.92	0.94	0.92
Q1	0.95	0.955	0.95
Median	0.96	0.96	0.96
Q3	0.97	0.97	0.97
Upper whisker	1	0.99	1
Max	1	0.99	1
range (max-min)	0.12	0.06	0.12

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

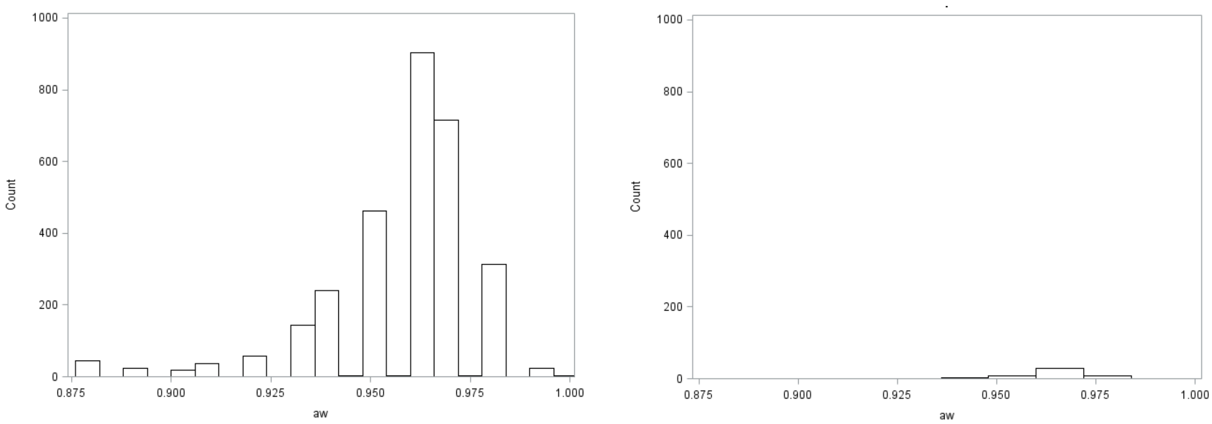


Figure 30: Histogram of water activity result (on the arrival at the laboratory) in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at the end of shelf-life

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

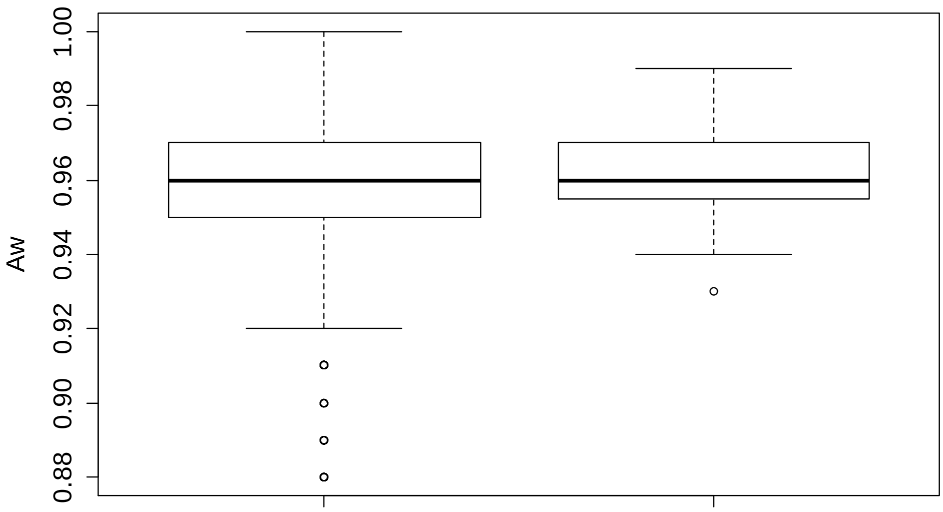


Figure 31: Boxplot[23] of water activity result (on the arrival at the laboratory) in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at time of the end of shelf-life

By comparing the percentage of samples with *Listeria monocytogenes* counts exceeding 100 cfu/g for sliced and non-sliced fish in Table 132: we see that the percentage is higher for sliced fish (2.02% vs. 0.77%).

Table 132: Percentage of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100 cfu/g at end of shelf-life by Possible slicing for all participating countries*

Possible slicing	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Sliced	2 229	46	2 275	2.02
Non-sliced	772	6	778	0.77
Total	**3 001**	**52**	**3 053**	**1.70**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

[23] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The percentage of samples with test result above 100 cfu/g is the largest for samples packaged in vacuum (Table 133:). By merging several categories (Table 134:), we see that 1.21% of the samples packaged in modified atmosphere have a count exceeding the level of 100 cfu/g while 1.82% of the other samples have a count exceeding the level of 100 cfu/g.

Table 133: Percentage of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100 cfu/g at end of shelf-life by for Packaging type for all participating countries*

Packaging Type	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Vacuum	1 784	41	1 825	2.25
Modified atmosphere	572	7	579	1.21
Normal atmosphere	547	3	550	0.55
Other (free text)	98	1	99	1.01
Total	**3 001**	**52**	**3 053**	**1.70**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 134: Percentage of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100 cfu/g at end of shelf-life by Packaging type[(c)] for all participating countries*

Packaging Type[(c)]	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Modified atmosphere	572	7	579	1.21
All other packaging types	2429	45	2474	1.82
Total	**3 001**	**52**	**3 053**	**1.70**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The results for every country of production are shown in Table 135: .

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 135: The number of samples with counts exceeding and not exceeding the level of 100cfu/g at the end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish by country of production

Country of production	Number of samples with counts not exceeding the level of 100 cuf/g	Number of samples with counts exceeding the level of 100 cuf/g
Austria	28	0
Belarus	1	0
Belgium	9	0
Bulgaria	39	0
Canada	2	0
Croatia	3	0
Cyprus	13	1
Czech Republic	22	0
Denmark	169	7
Estonia	31	1
Faroe Islands	1	0
Finland	43	1
France	452	3
Germany	167	1
Greece	61	0
Greenland	3	2
Hungary	11	0
Ireland	29	0
Italy	67	8
Latvia	49	0
Lithuania	111	5
Luxembourg	1	0
Netherlands	53	2
Norway	240	6
Poland	535	12
Romania	60	0
Slovakia	9	0
Slovenia	6	0
Spain	199	1
Sweden	59	0
Switzerland	1	0
Turkey	48	1
Ukraine	1	0
United Kingdom	470	1
United States	3	0
Vietnam	5	0
Total	3001	52

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Only one sample was not guaranteed to be transported in line with technical specifications. This sample was negative (Table 136:).

Table 136: Percentage of samples in packaged (not frozen) hot or cold smoked or gravad fish , with counts exceeding the level of 100 cfu/g at end of shelf-life by transport protocol for all participating countries*

Transport Protocol	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Yes [a)]	3000	52	3052	1.70
No [b)]	1	0	1	0.00
Total	**3 001**	**52**	**3 053**	**1.70**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) in line with technical specifications
b) not in line with technical specifications

Summary statistics and graphical representation of the temperature for storge in the laboratory are in Table 137: , Figure 32: and Figure 33: . The average storage temperature for the samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is 4.12°C, while the average temperature for the other samples is 4.22°C. Most samples are stored at 4°C, and this can also be seen in the histogram in Figure 32: and the box-whisker plot in Figure 33: .

Table 137: Summary Statistics of Storage temperature at laboratory by proportion of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100cfu/g at end of shelf-life for all participating countries*

Temperature at lab	Samples with counts exceeding 100 cfu/g		Total
	No	Yes	
n	3 001	52	3 053
mean	4.22	4.12	4.22
sd	1.28	1.28	1.28
min	0	2	0
lower whisker	4	4	4
Q1	4	4	4
median	4	4	4
Q3	4	4	4
Upper whisker	4	4	4
max	8	8	8
range (max-min)	8	6	8

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

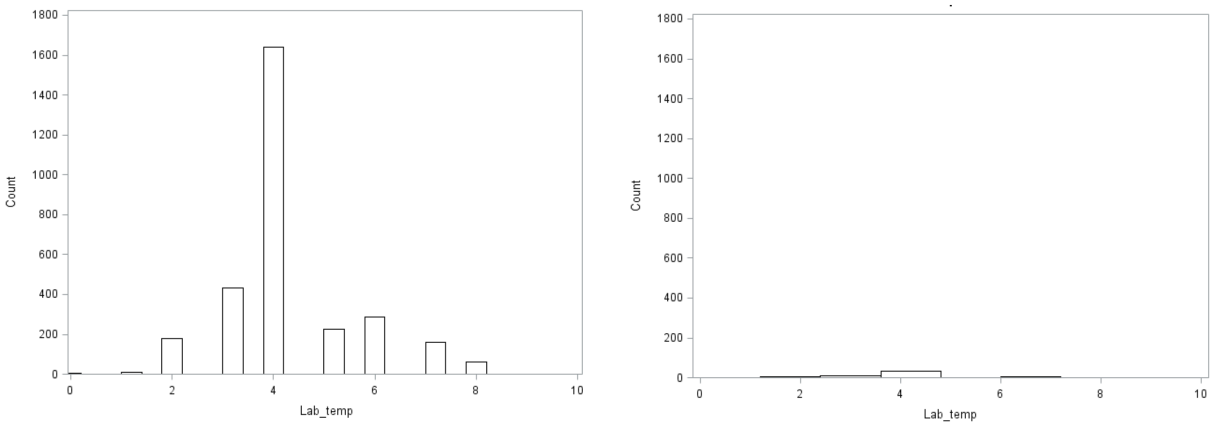


Figure 32: Histogram of Storage temperature at laboratory for samples with counts not exceeding (left) and exceeding (right) the level of 100 cfu/g at the end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish in all participating countries

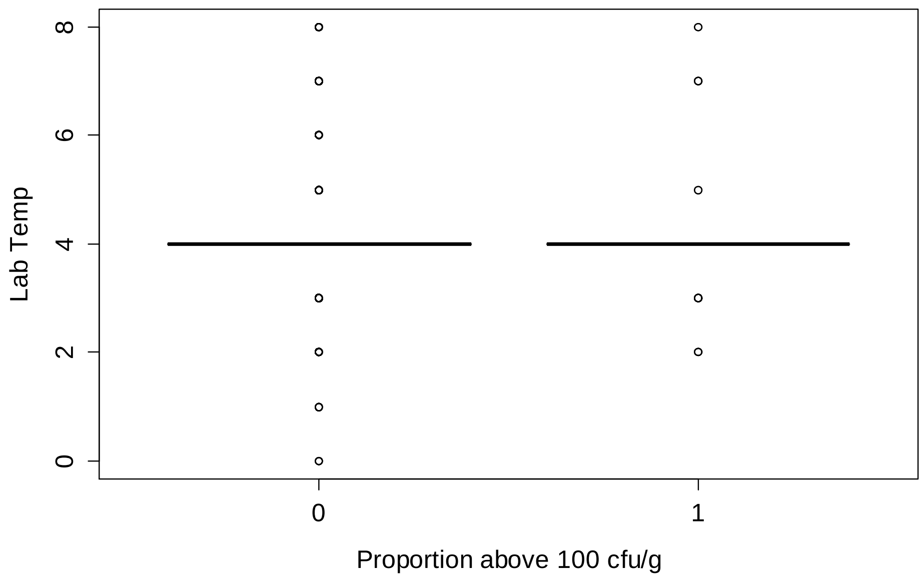


Figure 33: Boxplot[24] of Storage temperature at laboratory for samples with counts not exceeding (left) and exceeding (right) the level of 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries

The remaining shelf-life of the samples is described in Table 138: , Figure 34: and Figure 35: . We notice that the width of the box-whisker plot for samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is larger, while there are more outliers for the samples with *Listeria monocytogenes* counts not exceeding the level.

[24] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 138: Summary Statistics of Remaining shelf-life by proportion of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100cfu/g at end of shelf-life for all participating countries*

Remaining shelf-life	Samples with counts exceeding 100 cfu/g		Total
	No	Yes	
n	3 001	52	3 053
mean	22.69	22.13	22.68
sd	36.99	14.7	36.73
min	1	1	1
lower whisker	1	1	1
Q1	9	11	9
median	14	17.5	15
Q3	23	34.5	23
Upper whisker	44	57	44
max	519	57	519
range (max-min)	518	56	518

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

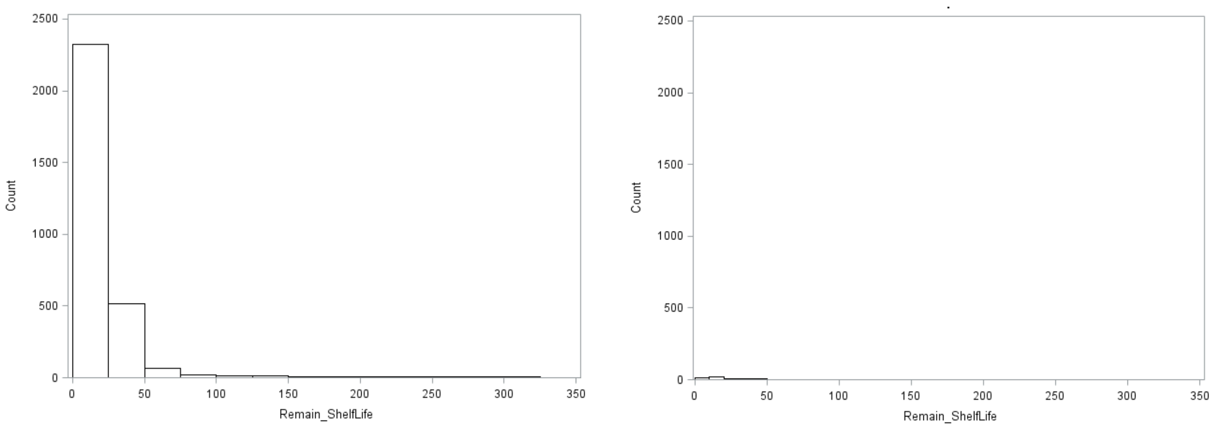


Figure 34: Histogram of remaining shelf-life in packaged (not frozen) hot or cold smoked or gravad fish , for samples with counts that do not exceed (left) and do exceed (right) 100 cfu/g at the end of shelf-life

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

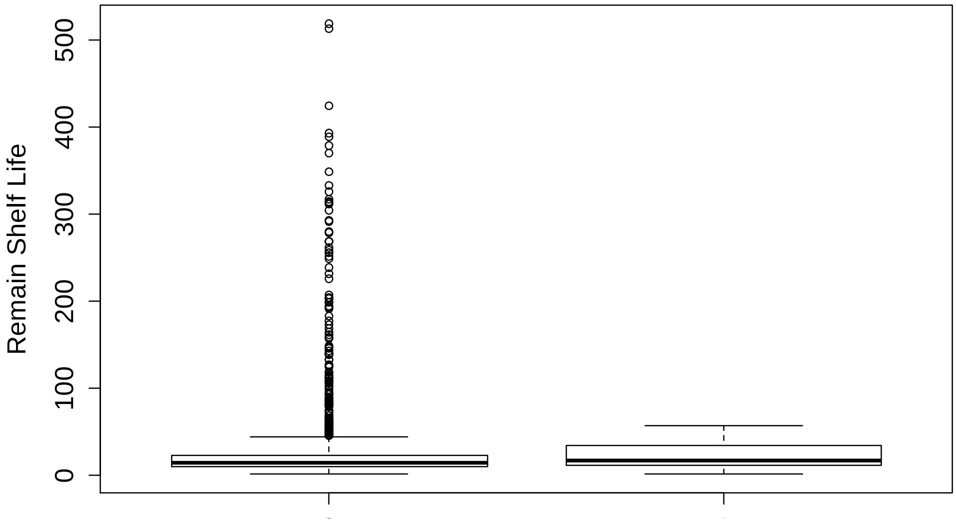


Figure 35: Boxplot[25] of remaining shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries, for samples with *Listeria monocytogenes* counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at the end of shelf-life

All samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g at the end of shelf-life are not included in 'EC 2073/2005 NSG' (Table 139:).

Table 139: Percentage of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100 cfu/g at end of shelf-life by **"EC 2073/2005 NSG"** for all participating countries*

"EC 2073/2005 NSG"	**Samples with counts exceeding 100 cfu/g**		**Total**	**Percentage of samples with counts exceeding 100 cfu/g**
	No	**Yes**		
For samples not included in 'EC 2073/2005 NSG'	2 791	52	2 843	1.83
For samples included in 'EC 2073/2005 NSG '	210	0	210	0.00
Total	**3 001**	**52**	**3 053**	**1.70**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

5.2.2.2. Single-factor model

All variables in the dataset have been fitted in the single-factor model with GEE (Ind), including the interaction with the "EC 2073/2005 NSG" indicator. However, none of these models converges, because there are no samples with a test result above 100 cfu/g that are included in 'EC 2073/2005 NSG' (Table 139:). This causes sparseness issues even if the no-supporting growth variable is included without the interaction with a risk factor.

[25] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

However, in order to get more information on the effect of each factor, the single-factor models without the 'EC 2073/2005 NSG' indicator (no main nor interaction effect) were fitted. The single-factor models for the Number of preservatives and acidity regulators and Transport protocol did not converge. The results are presented in the Appendix D.4.

5.2.2.3. Multiple-factors model

ANALYSIS WITH 'EC 2073/2005 NSG' INDICATOR

As described in the Material and Methods section, an "all subsets" model selection approach of multiple logistic regression was used for selecting variables. All variables together with their interactions and the "EC 2073/2005 NSG" indicator including interactions were included in the model selection. The AIC criterion (the lower the better) was used to select the model (Appendix C.2). The selected model includes the factors Type(c) of retail outlet, Sampling season, Fish species, Number of preservatives and acidity regulators, Possible slicing, Packaging type(c) and the "EC 2073/2005 NSG" variable.

After completion model selection using all variables mentioned above as well as accounting for the hierarchical nature of the data through GEE (Ind), the model did not converge. Non-convergence or computational problems in general can result in no output at all (no estimates) with an error or warning message, no estimates for some effects or unrealistic and excessive parameter estimates, possibly combined with the absence of standard error estimates. The reason is sparseness, because all samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g are not included in'EC 2073/2005 NSG' (Table 139:). To be able to gain insights in the factors related to the proportion of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g, we removed the "EC 2073/2005 NSG" indicator from the model. Next the biologically relevant interaction between Packaging type(c) and Storage temperature at laboratory (as well as the main effect of Storage temperature at laboratory) was added, although the effect is not significant. Weighted and unweighted analyses were applied for the final model as sensitivity analyses (Table 140: and Table 141:).

Table 140: Wald statistics For Type 3 GEE analysis for proportion of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100cfu/g at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type(c) of retail outlet	1	6.98	0.01	1	6.85	0.01	1	7.50	0.01
Sampling season	3	8.75	0.03	3	7.33	0.06	3	7.74	0.05
Possible slicing	1	4.41	0.04	1	5.23	0.02	1	2.45	0.12
Packaging type(c)	1	1.28	0.26	1	1.66	0.20	1	0.48	0.49
Temperature at laboratory	1	0.07	0.79	1	0.29	0.59	1	0.23	0.63
Temperature at laboratory * Packaging type(c)	1	1.94	0.16	1	2.41	0.12	1	0.83	0.36

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 141: Odds ratios of GEE (Ind) for proportion of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100cfu/g at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001	0.01	0.00	0.03	<.0001
Type(c) of retail outlet a)	All other types of retail outlet	7.07	1.66	30.15	0.01	6.95	1.63	29.70	0.01	8.03	1.81	35.67	0.01
Sampling season b)	autumn	1.49	0.70	3.17	0.30	1.46	0.68	3.12	0.33	1.40	0.63	3.12	0.40
Sampling season	spring	0.28	0.08	1.04	0.06	0.32	0.09	1.21	0.09	0.27	0.07	1.09	0.07
Sampling season	summer	1.50	0.69	3.30	0.31	1.59	0.72	3.49	0.25	1.42	0.61	3.29	0.41
Possible slicing c)		2.58	1.07	6.26	0.04	2.85	1.16	6.97	0.02	2.06	0.83	5.08	0.12
Packaging type(c) d)	Modified atmosphere	6.33	0.26	154.12	0.26	7.62	0.35	166.60	0.20	3.36	0.11	102.19	0.49
Temperature at laboratory		1.03	0.82	1.30	0.79	1.06	0.85	1.33	0.59	0.96	0.80	1.14	0.63
Temperature at laboratory * Packaging type(c)	Modified atmosphere	0.62	0.32	1.22	0.16	0.59	0.31	1.15	0.12	0.72	0.36	1.45	0.36

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

a) : The reference category for Type(c) of retail outlet is "Supermarket or small shop"

b) : The reference category for Sampling season is "winter"

c) : The reference category for Possible slicing is "Non-sliced"

d) : The reference category for Packaging Type(c) is "All other packaging types"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

However, the confidence interval for the the main effect of packaging type(c) was extremely wide, caused by the low count in the category "Modified atmosphere" for samples with count exceeding the level of 100 cfu/g (Table 134:). Thus, it was considered to drop this main effect as well as the interaction with Storage temperature at laboratory from the model, although the interaction between Storage temperature at laboratory and packaging type(c) has a meaningful biological interpretation.

The following tables show the result of GEE (Table 142: and Table 143:) along with the sensitivity analysis using Firth approach (Table 144: and Table 145:). The weighted and unweighted analyses were applied for this final model.

The unweighted GEE(Ind) result shows that the effect of Type(c) of retail outlet, Sampling season and Possible slicing have statistically significant effects on the proportion of samples with enumeration result above 100 cfu/g.

The odds ratio of a sample with counts exceeding the level of 100 cfu/g (compared to not exceeding the level) for Sampling season in spring compared to winter is equal to 0.28 (Table 143:). The odds ratio for slicing compared to no-slicing is 2.55. Meanwhile the odds ratio for "All other outlet types of retail outlet" compared to "Supermarket or small shop" is 4.29.

<u>GEE Analysis for final model</u>

Table 142: Wald statistics For Type 3 GEE analysis for final model (after dropping Packaging type(c)) of proportion of samples in in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100cfu/g at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type(c) of retail outlet	1	5.67	0.02	1	5.59	0.02	1	6.62	0.01
Sampling season	3	8.01	0.05	3	6.73	0.08	3	7.19	0.07
Possible slicing	1	4.49	0.03	1	5.23	0.02	1	2.63	0.10

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 143: Odds ratios of GEE (Ind) for proportion of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100cfu/g at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001
Type(c) of retail outlet[a)]	All other types of retail outlet	4.29	1.29	14.22	0.02	4.28	1.28	14.27	0.02	4.86	1.46	16.21	0.01
Sampling season [b)]	autumn	1.39	0.64	3.00	0.41	1.36	0.63	2.96	0.44	1.32	0.58	2.99	0.50
Sampling season	spring	0.28	0.08	1.02	0.05	0.32	0.09	1.20	0.09	0.28	0.07	1.08	0.06
Sampling season	summer	1.45	0.66	3.21	0.36	1.53	0.69	3.41	0.29	1.39	0.60	3.24	0.45
Possible slicing [c)]		2.55	1.07	6.05	0.03	2.78	1.16	6.69	0.02	2.07	0.86	4.97	0.10

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

a) : The reference category for Type(c) of retail outlet is "Supermarket or small shop"

b) : The reference category for Sampling season is "winter"

c) : The reference category for Possible slicing is "Non-sliced"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

SENSITIVITY ANALYSES FOR FINAL MODEL

To get further insights in the stability of the final model, we investigate its sensitivity to some modifications:

- The weighted analyses as compared to the unweighted analyses.
- The use of Firth's method and exact logistic regression, as methods that can cope with sparseness to some larger extent.
- The use of the continuous variable expressing the no-growth probability instead of the "EC 2073/2005 NSG" indicator.

Weighted analyses versus unweighted analyses

Table 142: and Table 143: indicate that the significance of Sampling season and Possible slicing changes for weighted analysis instead of unweighted. The corresponding odds ratios are still quite similar.

As both weights are merely proxy weights for unknown true weight (that would correct for over- or underrepresentation), it is not straightforward how to interpret these differences. Major conclusion is that one should be careful with formulating strong statements about those factors that are unstable across such unweighted and weighted analyses.

Logistic regression with Firth's correction method for sparseness

Table 144: and Table 145: indicate that the results of the GEE model are very close to that with the Firth method. This indicates and confirms that there are no major sparseness issues in our final GEE model.

Table 144: Wald statistics For Type 3 Firth analysis for final model proportion of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100cfu/g at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type(c) of retail outlet	1	6.94	0.01	1	6.24	0.01	1	8.31	0.00
Sampling season	3	7.57	0.06	3	7.24	0.06	3	6.59	0.09
Possible slicing	1	4.35	0.04	1	4.97	0.03	1	2.52	0.11

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 145: Odds ratios of Firth for final model proportion of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100cfu/g at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001
Type(c) of retail outlet a)	All other types of retail outlet	4.83	1.50	15.58	0.01	4.92	1.41	17.17	0.01	5.41	1.72	17.07	0.00
Sampling season b)	autumn	1.35	0.64	2.86	0.43	1.33	0.63	2.81	0.46	1.29	0.60	2.78	0.51
Sampling season	spring	0.31	0.09	1.04	0.06	0.36	0.11	1.14	0.08	0.31	0.09	1.08	0.07
Sampling season	summer	1.43	0.66	3.08	0.37	1.50	0.70	3.22	0.30	1.37	0.62	3.01	0.44
Possible slicing c)		2.37	1.05	5.35	0.04	2.58	1.12	5.93	0.03	1.93	0.86	4.35	0.11

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type(c) of retail outlet is "Supermarket or small shop"
b) : The reference category for Sampling season is "winter"
c) : The reference category for Possible slicing is "Non-sliced"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Exact logistic regression for final model

Exact logistic regression was performed to the final model with "EC 2073/2005 NSG" indicator. Most of the odds ratios are similar to the GEE(Ind) analysis. The main difference is that the effect of Type(c) of retail outlet is no longer significant, but the exact logistic regression ignores the hierarchical structure in the data.

Table 146: Odds ratios of Exact logistic regression for final model of proportion of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100cfu/g at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries* with "EC 2073/2005 NSG" indicator.

Source		OR	CL		P-Value
			LL	UL	
Type(c) of retail outlet a)	**All other types of retail outlet**	4.05	0.75	14.31	0.10
Sampling season b)	**autumn**	1.37	0.60	3.30	0.55
Sampling season	**spring**	0.28	0.05	1.10	0.07
Sampling season	**summer**	1.45	0.62	3.57	0.47
Possible slicing c)		2.36	0.99	6.80	0.05
"EC 2073/2005 NSG" d),**		0.22	0.00	0.97	0.09

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
**: indicates a median unbiased estimate
a) : The reference category for Type(c) of retail outlet is "Supermarket or small shop"
b) : The reference category for Sampling season is "winter"
c) : The reference category for Possible slicing is "Non-sliced"
d) : The reference category for 'EC 2073/2005 NSG' is not included in 'EC 2073/2005 NSG'

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

GEE Analysis for final model with continuous variable expressing the no-growth probability

Although the final model (Table 142: and Table 143:) does not contain the "EC 2073/2005 NSG" indicator, we present the results of this final model when including the continuous variable expressing the no-growth probability. The results in Table 147: up to Table 150: show that the risk factors are not influenced by the inclusion of the continuos variable expressing the no-growth probability, which appears to be not significant.

Table 147: Wald Statistics For Type 3 GEE Analysis for proportion of samples in packaged (not frozen) hot or cold smoked or gravad fish with counts exceeding the level of 100cfu/g at the end of shelf-life, with taking into account hierarchical structure (country, city, store) for all participating countries* for continuous variable expressing the no-growth probability.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type[(c)] of retail outlet	1	4.99	0.03	1	4.47	0.03	1	5.80	0.02
Sampling season	3	8.04	0.05	3	6.73	0.08	3	7.18	0.07
Possible slicing	1	4.52	0.03	1	5.34	0.02	1	2.62	0.11
Continuous no-growth probability	1	0.11	0.74	1	0.00	0.96	1	0.14	0.71

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 148: Odds ratios of GEE (Ind) for proportion of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100cfu/g at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries* for continuous variable expressing the no-growth probability.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001
Type(c) of retail outlet a)	All other types of retail outlet	4.64	1.21	17.82	0.03	4.34	1.11	16.90	0.03	5.28	1.36	20.48	0.02
Sampling season b)	autumn	1.39	0.64	3.01	0.40	1.36	0.63	2.96	0.44	1.33	0.59	3.00	0.50
Sampling season	spring	0.28	0.08	1.02	0.05	0.32	0.09	1.20	0.09	0.28	0.07	1.08	0.06
Sampling season	summer	1.45	0.66	3.21	0.36	1.53	0.69	3.41	0.29	1.39	0.60	3.23	0.45
Possible slicing c)		2.52	1.07	5.89	0.03	2.78	1.17	6.61	0.02	2.04	0.86	4.83	0.11
Continuous no-growth probability		1.15	0.51	2.57	0.74	1.02	0.45	2.32	0.96	1.16	0.53	2.55	0.71

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type(c) of retail outlet is “Supermarket or small shop”
b) : The reference category for Sampling season is “winter”
c) : The reference category for Possible slicing is “Non-sliced”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Firth's method for final model with continuous variable expressing the no-growth probability

Table 149: Wald Statistics For Type 3 Firth Analysis for proportion of samples in packaged (not frozen) hot or cold smoked or gravad fish with counts exceeding the level of 100cfu/g at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries* for continuous variable expressing the no-growth probability.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type[(c)] of retail outlet	1	6.54	0.01	1	5.42	0.02	1	7.78	0.01
Sampling season	3	7.65	0.05	3	7.30	0.06	3	6.66	0.08
Possible slicing	1	4.22	0.04	1	4.96	0.03	1	2.41	0.12
Continuous no-growth probability	1	0.07	0.79	1	0.00	0.99	1	0.08	0.77

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 150: Odds ratios of Firth for proportion of samples in packaged (not frozen) hot or cold smoked or gravad fish, with counts exceeding the level of 100cfu/g at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries* for continuous variable expressing the no-growth probability.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001
Type(c) of retail outlet a)	All other types of retail outlet	5.13	1.46	17.94	0.01	4.89	1.29	18.59	0.02	5.78	1.68	19.80	0.01
Sampling season b)	autumn	1.36	0.64	2.86	0.42	1.33	0.63	2.80	0.45	1.30	0.61	2.78	0.50
Sampling season	spring	0.31	0.09	1.04	0.06	0.36	0.11	1.14	0.08	0.31	0.09	1.07	0.06
Sampling season	summer	1.43	0.66	3.07	0.37	1.50	0.70	3.21	0.29	1.37	0.62	3.00	0.44
Possible slicing c)		2.34	1.04	5.26	0.04	2.57	1.12	5.89	0.03	1.90	0.85	4.27	0.12
Continuous no-growth probability		1.12	0.49	2.53	0.79	1.00	0.44	2.26	0.99	1.13	0.49	2.62	0.77

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type(c) of retail outlet is "Supermarket or small shop"
b) : The reference category for Sampling season is "winter"
c) : The reference category for Possible slicing is "Non-sliced"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.2.2.4. Diagnostic Test

Goodness of fit test for final model

Goodness of fit test was performed using the Hosmer-Lemeshow Chi-Square test. The result show that there is no lack of fit in the final model since p-value is larger than 5% alpha.

Table 151: Hosmer and Lemeshow test

Chi-Square	DF	p-value
2.83	6	0.83

Multicolinearity analysis

The VIF values calculated for the multicollinearity analysis among potentially associated factors that related to above final model is presents in the following table. This analysis showed that multicollinearity was not important for the full model since all the VIF values were very small.

Table 152: Variance Inflation Factor values for factors potentially related to Fish Product

Variable	VIF
Type[(c)] of retail outlet	3.05
Sampling season	1.04
Possible slicing	1.25

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.3. Results for packaged heat-treated meat products at the end of shelf-life for all participating countries

5.3.1. Prevalence for packaged heat-treated meat products

Samples were considered to be contaminated if at least one of detection or enumeration testing was positive (a positive enumeration test being a test result of at least 10 cfu/g).

5.3.1.1. Descriptions of the samples

The following tables and figures provide further insights for packaged heat-treated meat products at the end of shelf-life. It is important to realize that the observed differences might be due to other factors, which is the reason for considering the multivariable analysis in the next section.

In total 3 530 samples of packaged heat-treated meat products at the end of shelf-life were collected. 2.04% was contaminated by *Listeria monocytogenes* (Table 153:).

Table 153: Descriptive statistics of prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life for all participating countries*

Sample	Frequency	Percentage
Not contaminated	3 458	97.96
Contaminated	72	2.04
Total	3 530	

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

In the following tables and figures we describe the possible factors related to packaged heat-treated meat products at the end of shelf-life. These tables should be interpreted with caution because the observed differences might be due to other variables. Therefore multivariable models will be fit in the next section.

For each participating country, the number of contaminated and not contaminated samples is given in Table 154: . In many countries the total number of samples taken is small.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 154: Number of samples contaminated and not contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by country for all participating countries*

Country	Number of samples not contaminated	Number of samples contaminated
Austria	122	1
Belgium	27	0
Bulgaria	39	0
Cyprus	26	1
Czech Republic	60	0
Denmark	59	1
Estonia	29	1
Finland	66	0
France	384	5
Germany	897	18
Greece	58	2
Hungary	62	0
Ireland	31	1
Italy	395	8
Latvia	27	3
Lithuania	30	0
Luxembourg	26	0
Malta	22	0
Netherlands	50	6
Norway	60	0
Poland	194	6
Romania	60	0
Slovakia	59	0
Slovenia	30	2
Spain	188	13
Sweden	75	0
United Kingdom	382	4
Total	3 458	72

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

In Table 155: we show the number of samples for each participating country and the number of towns and outlet shops from which the samples were collected. The number of outlet shops varies from 2 to 693.

Table 155: Number of samples, towns, and outlet by country for packaged heat-treated meat products

Country	Number of Sample	Number of Town	Number of Outlet
Austria	123	7	115
Belgium	27	20	25
Bulgaria	39	4	2
Cyprus	27	5	7
Czech Republic	60	8	57
Denmark	60	4	37
Estonia	30	5	20
Finland	66	8	65
France	389	8	3
Germany	915	431	693
Greece	60	21	8
Hungary	62	17	16
Ireland	32	2	17
Italy	403	14	401
Latvia	30	7	19
Lithuania	30	3	27
Luxembourg	26	18	25
Malta	22	9	11
Netherlands	56	12	54
Norway	60	6	50
Poland	200	8	76
Romania	60	8	42
Slovakia	59	8	48
Slovenia	32	10	27
Spain	201	8	83
Sweden	75	8	71
United Kingdom	386	11	125
Total	3 530	670	2124

The prevalence of contaminated samples for each Type of retail outlet is given in Table 156: . Most samples are collected from supermarket or small shops, where 2.02% is contaminated with *Listeria monocytogenes.* As only a few samples are collected from other types of retail outlet and only 2 of these are contaminated, the other types of retail outlet are combined into one category. Table 157: shows that 3.13% of the samples in the category “All other types of retail outlet” are contaminated.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 156: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by Type of retail outlet for all participating countries*

Type of retail outlet	Sample		Total	Prevalence of contaminated samples
	Not Contaminated	Contaminated		
Supermarket or small shop	3 396	70	3 466	2.02
Speciality delis	10	1	11	9.09
Street market or farmers' market	6	0	6	0.00
Other (free text field)	46	1	47	2.13
Total	**3 458**	**72**	**3 530**	**2.04**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 157: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by Type[(c)] of retail outlet, for all participating countries*

Type[(c)] of retail outlet	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Supermarket or small shop	3 396	70	3 466	2.02
All other types of retail outlet	62	2	64	3.13
Total	**3 458**	**72**	**3 530**	**2.04**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

By ordering the samples according to the Sampling season, we observe that the prevalence of contaminated samples is similar in each season(Table 158:).

Table 158: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by Sampling season for all participating countries*

Sampling Season	Sample		Total	Prevalence of contaminated samples
	Not contaminated	contaminated		
Autumn	1 023	19	1 042	1.82
Spring	777	19	796	2.39
Summer	927	19	946	2.01
Winter	731	15	746	2.01
Total	**3 458**	**72**	**3 530**	**2.04**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

For every category in Animal species of the origin of the meat product, Table 159: shows the percentage of samples contaminated with *Listeria monocytogenes.* We observe that none of the samples of "other" animal species is contaminated. Only one sample is collected from Goose and this sample is not

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

contaminated. A summary of the data after merging several species is shown in Table 160: . The percentages of contaminated samples are quite similar: 2.06% for avian species and 2.04% for other species.

Table 159: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by Animal species of the origin of the meat product for all participating countries*

Animal Species	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Pork	2 516	50	2 566	1.95
Mixed	298	10	308	3.25
Broiler	88	4	92	4.35
Turkey	228	4	232	1.72
Poultry	207	3	210	1.43
Beef	104	1	105	0.95
Goose	1	0	1	0.00
Other	16	0	16	0.00
Total	**3 458**	**72**	**3 530**	**2.04**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 160: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by Animal species[(c)] of the origin of the meat product after merging some categories, for all participating countries*

Animal Species[(c)]	Sample		Total	Prevalene of contaminated samples
	Not contaminated	Contaminated		
Avian species	524	11	535	2.06
Other species	2 934	61	2 995	2.04
Total	**3 458**	**72**	**3 530**	**2.04**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The Type of the meat product is another possible factor for packaged heat-treated meat products. A summary of the contaminated samples for each Type of the meat product is shown in Table 161: . The highest percentage is observed for paté (4.93%), while for sausages 1.79% and for cold, cooked meat products 1.88% of the samples is contaminated.

Table 161: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by Type of meat product for all participating countries*

Type of the meat product	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Cold, cooked meat product	2 499	48	2 547	1.88
Paté	193	10	203	4.93
Sausage	766	14	780	1.79
Total	**3 458**	**72**	**3 530**	**2.04**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The percentage of samples contaminated by *Listeria monocytogenes* for each packaging place is given in Table 162: . Of the samples packaged at retail 1 out of 21 is contaminated, while 1.99% are contaminated in samples packaged by the producer. For 96 samples the packaging place is unknown and the percentage of contaminated samples equals 3.13%.

Table 162: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by Packaging place for all participating countries*

Packaging Place	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Packaged by the producer	3 345	68	3 413	1.99
Packaged at retail	20	1	21	4.76
Unknown	93	3	96	3.13
Total	**3 458**	**72**	**3 530**	**2.04**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Next to the packaging place, the type of packaging might be of influence for the contamination with *Listeria monocytogenes. Table 163:* shows the prevalence of contaminated samples for every packaging type. In Table 164: the categories are merged into Modified atmosphere and All other packaging types. The prevalence of contaminated samples is smaller for modified atmosphere (1.65%) compared to All other packaging types (2.55%).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 163: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by Packaging type for all participating countries*

Packaging Type	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Modified atmosphere	1 968	33	2 001	1.65
Vacuum	868	20	888	2.25
Normal atmosphere	532	16	548	2.92
Other (free text)	90	3	93	3.23
Total	**3 458**	**72**	**3 530**	**2.04**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 164: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by Packaging type(c) for all participating countries*

Packaging Type(c)	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Modified atmosphere	1 968	33	2 001	1.65
All other packaging types	1 490	39	1 529	2.55
Total	**3 458**	**72**	**3 530**	**2.04**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Small differences in the prevalence of contaminated packaged heat-treated meat products are observed with regard to sliced and non-sliced meat (Table 165:). For sliced meat, 2.13% of the samples are contaminated, while for non-sliced meat products 1.52% is contaminated.

Table 165: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by Possible slicing for all participating countries*

Possible slicing	Sample		Total	Prevalence of contaminated samples
	Not contaminated	Contaminated		
Sliced	2 941	64	3 005	2.13
Non-sliced	517	8	525	1.52
Total	**3 458**	**72**	**3 530**	**2.04**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 166: gives a summary of the contaminated samples for each country of production.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 166: Number of samples contaminated and not contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by Country of production for all participating countries*

Country of production	Number of samples not contaminated	Number of samples contaminated
Argentina	2	1
Austria	125	1
Belgium	65	1
Brazil	19	0
Bulgaria	37	0
Croatia	1	0
Cyprus	26	1
Czech Republic	87	0
Denmark	30	0
Estonia	36	2
European Union	1	0
Finland	62	0
France	374	6
Germany	972	19
Greece	59	2
Hungary	63	0
Ireland	37	0
Israel	2	0
Italy	431	9
Latvia	18	1
Lithuania	32	0
Luxembourg	14	0
Malta	5	0
Netherlands	45	6
Norway	59	0
Oman	1	0
Pakistan	1	0
Poland	194	6
Romania	45	0
Slovakia	18	0
Slovenia	12	0
Spain	190	14
Sweden	70	0
Thailand	8	0
United Kingdom	299	3
United States	18	0
Total	3458	72

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

In Table 167: we can see that the transport of 4 samples is not guaranteed to be in line with technical specifications. None of these samples were contaminated.

Table 167: Prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life by transport protocol for all participating countries*

Transport Protocol	Sample: Not contaminated	Sample: Contaminated	Total	Prevalence of contaminated samples
Yes [a)]	3 454	72	3 526	2.04
No [b)]	4	0	4	0.00
Total	**3 458**	**72**	**3 530**	**2.04**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) in line with technical specifications
b) not in line with technical specifications

Some summary statistics of the storage temperature of the lab are shown in Table 168: . A graphical representation of the storage temperatures is given in Figure 36: and Figure 37: .

The average temperature of the contaminated samples is 4.42°C, while the average temperature of the other samples is 4.51°C. The range of temperature for the contaminated samples is smaller than the range for the other samples. From the histogram in Figure 36: we see that most samples that are not contaminated have a storage temperature of 4°C. The box-whisker plots in Figure 37: show that the difference in storage temperature between contaminated and not contaminated samples are small.

Table 168: Summary Statistics of Storage Temperature at Lab by prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life for all participating countries*

Storage temperature	Sample: Not contaminated	Sample: Contaminated	Total
n	3 458	72	3 530
mean	4.51	4.42	4.51
sd	1.43	1.42	1.43
min	0	2	0
lower whisker	3	2	3
Q1	4	3.5	4
median	4	4	4
Q3	5	5	5
Upper whisker	6	7	6
max	18	8	18
range (max-min)	18	6	18

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

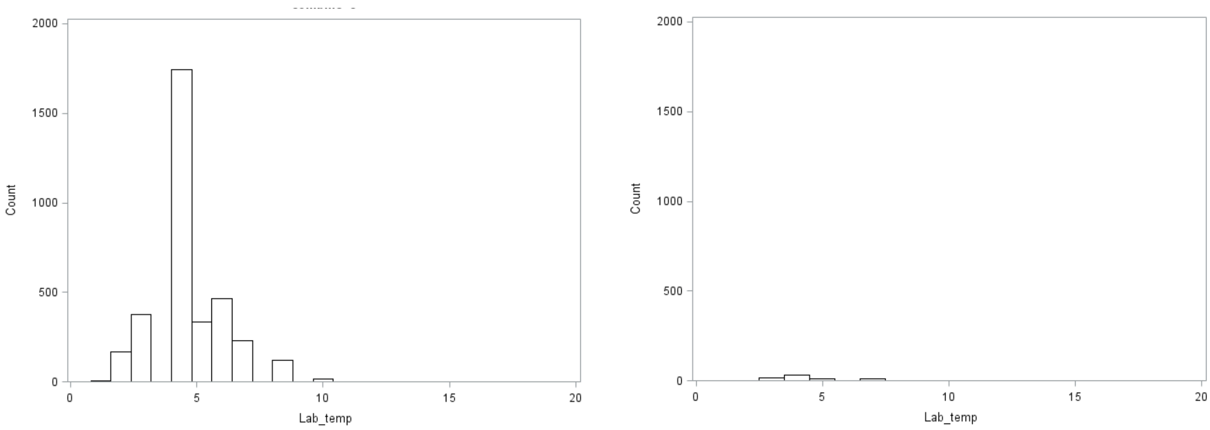


Figure 36: Histogram of storage temperature at laboratory for samples that are not contaminated (left) and contaminated (right) by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life for all participating countries

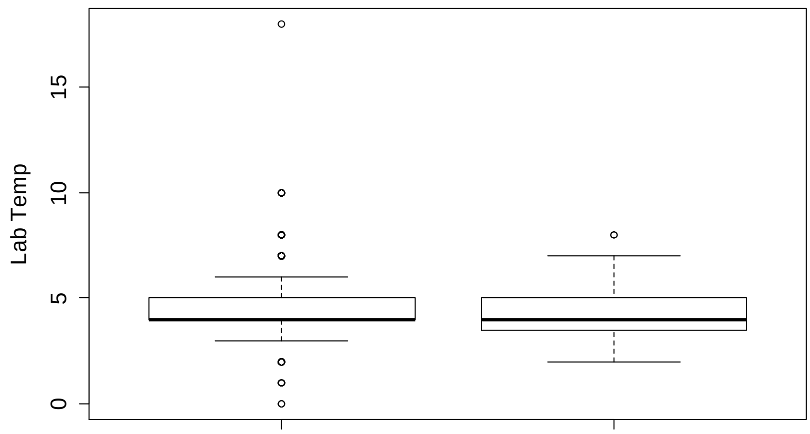


Figure 37: Boxplot[26] of storage temperature at laboratory up to the end of shelf-life for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life for all participating countries

Summary statistics of the remaining shelf-life are provided in Table 169: and a graphical representation is given in Figure 38: and Figure 39: .

[26] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

On average the remaining shelf-life is higher for the samples contaminated by *Listeria monocytogenes*. The range of the remaining shelf-life is smaller for contaminated samples compared to not contaminated samples. The box-whisker plots in Figure 39: show two similar boxplots, but there are less outliers for the contaminated samples.

Table 169: Summary Statistics of Remaining shelf-life by prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life for all participating countries*

Remaining shelf-life	Sample		Total
	Not contaminated	Contaminated	
N	3 458	72	3 530
mean	19.48	20.74	19.51
Sd	20.1	15.56	20.02
min	0	2	0
lower whisker	0	2	0
Q1	10	11	10
median	15	16	15
Q3	23	25	23
Upper whisker	42	46	42
max	427	86	427
range (max-min)	427	84	427

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

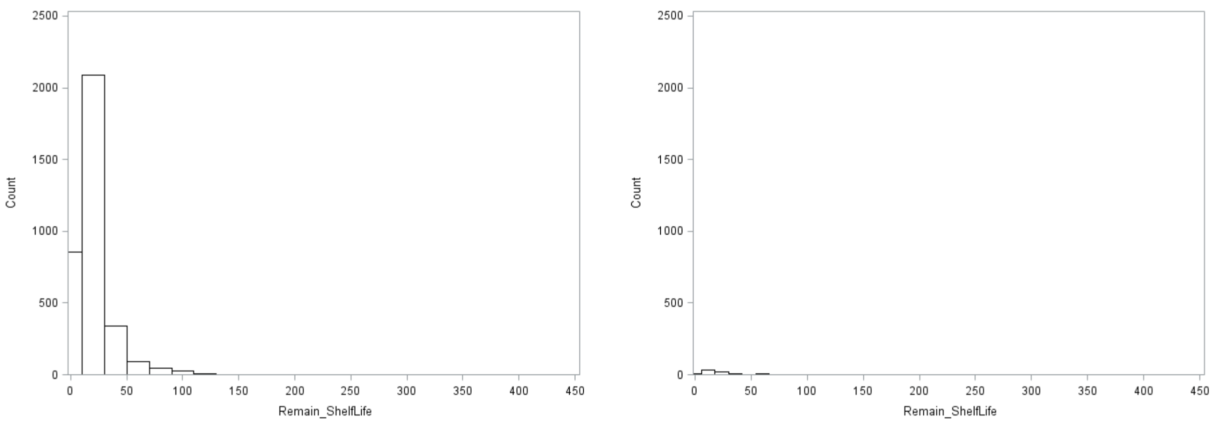


Figure 38: Histogram of remaining shelf-life for packaged heat-treated meat products for all participating countries, for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* at the end of shelf-life

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

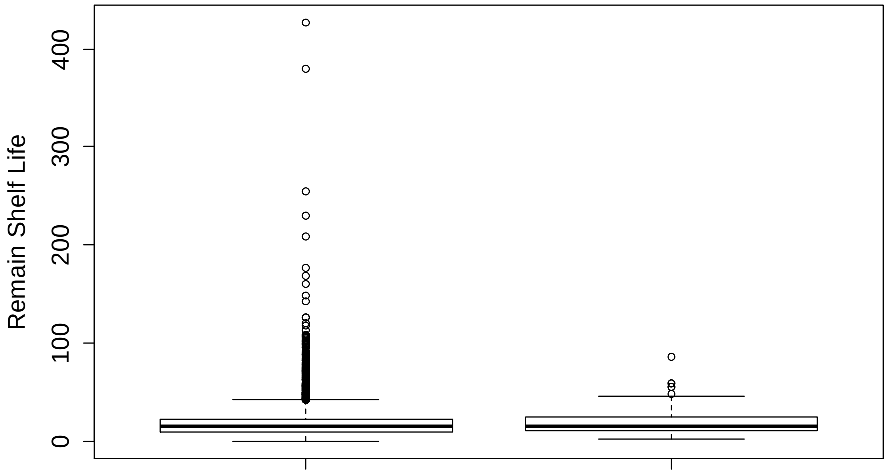


Figure 39: Boxplot[27] of remaining shelf-life for packaged heat-treated meat products for all participating countries, for samples not contaminated (left) and contaminated (right) by *Listeria monocytogenes* at the end of shelf-life

5.3.1.2. Single-factor model

As for the data on Fish species, a single-factor model was performed for packaged heat-treated meat products. The Wald statistics and corresponding odds ratios are available in Appendix D.5. The results should be interpreted with caution, because the observed effects could be due to confounding.

As before, some problems occurred while fitting models for a factor with many categories, such as country and country of production. Results were obtained for Type(c) of retail outlet, but not for Type of retail outlet. No results were obtained for the variable Transport protocol. No convergence was obtained for the model with date of testing, use by date, production date or packaging date.

5.3.1.3. Multiple-factors model

As described in the Material and Methods section, an all subsets model selection approach of multiple logistic regression was used for selecting variables. The AIC criterion (the lower the better) was used to select the model (Table 253: in Appendix C.3). The final model consists of the variables Animal species of the origin of the meat product, Type of the meat product, packaging type(c) and Possible slicing. The interaction between packaging type(c) and Storage temperature at laboratory as well as their main effects were included in the final model because of their biological relevance, even if not significant. Some convergence problems occurred, because no sample is contaminated by *Listeria monocytogenes* for some animal species (Table 159:). Therefore the variable Animal species(c) of the origin of the meat product is used. The effect of Animal species(c) is however not significant at 5% significance level and is therefore removed from the model.

[27] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

For further analysis, GEE (Ind) was used to analyse the selected model while accounting for the hierarchal nature of the data. After removing the non-significant effects from the GEE model, the final model is shown in Table 170: and Table 171: . Weighted and unweighted analyses were applied for the final model as sensitivity analyses.

The following tables show the result of GEE (Table 170: and Table 171:) along with the sensitivity analysis using the method of Firth (Table 172: and Table 173:).

The unweighted GEE(Ind) result shows statistical significance of Type of the meat product and borderline significance of Possible slicing. Although the p-value for Possible slicing is larger than 5%, the variable is not removed because of its biological relevance. The interaction effect between Storage temperature at laboratory and packaging type(c) is not significant.

Table 171: shows the effect of each risk factor in the final model, in terms of odd ratios. The odds ratio of being contaminated (compared to not being contaminated) for paté compared to cold, cooked meat products is 3.13, while there is no significant difference between sausage and cold, cooked meat product. The odds of being contaminated (compared to not being contaminated) for sliced meat is 2.19 the odds for non-sliced meat. Only minor differences exist between the odds ratios of the weighted models.

GEE Analysis for final model

Table 170: Wald Statistics For Type 3 GEE Analysis for final model for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type of the meat product	2	9.50	0.01	2	10.25	0.01	2	9.48	0.01
Possible slicing	1	3.52	0.06	1	5.01	0.03	1	6.07	0.01
Packaging type(c)	1	0.77	0.38	1	0.34	0.56	1	0.07	0.79
Temperature at laboratory	1	0.44	0.51	1	1.02	0.31	1	0.45	0.50
Temperature at laboratory * Packaging type(c)	1	2.39	0.12	1	1.35	0.25	1	0.63	0.43

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 171: Odds ratios of GEE (Ind) for final model for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.01	0.00	0.03	<.0001	0.01	0.00	0.02	<.0001	0.01	0.00	0.03	<.0001
Type of the meat product a)	Paté	3.13	1.47	6.65	0.00	2.96	1.38	6.36	0.01	2.57	1.16	5.72	0.02
Type of the meat product	Sausage	1.04	0.53	2.03	0.91	0.78	0.38	1.59	0.50	0.67	0.33	1.36	0.27
Possible slicing b)		2.19	0.97	4.98	0.06	2.63	1.13	6.14	0.03	2.95	1.25	6.98	0.01
Packaging type(c) c)	Modified atmosphere	2.06	0.41	10.40	0.38	1.67	0.30	9.37	0.56	1.29	0.20	8.51	0.79
Temperature at laboratory		1.09	0.85	1.40	0.51	1.15	0.88	1.50	0.31	1.12	0.81	1.54	0.50
Temperature at laboratory * Packaging type(c)	Modified atmosphere	0.76	0.54	1.08	0.12	0.80	0.55	1.17	0.25	0.84	0.55	1.29	0.43

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type of the meat product is “Cold, cooked meat product”
b) : The reference category for Possible slicing is “Non-sliced”
c) : The reference category for Packaging type(c) is “All other packaging types”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

SENSITIVITY ANALYSIS FOR FINAL MODEL

To get further insights in the stability of the final model, we investigate its sensitivity to some modifications:

- The weighted analyses as compared to the unweighted analyses.
- The use of Firth's method and exact logistic regression, as methods that can cope with sparseness to some larger extent. Exact logistic regression was computationally not feasible. It is extremely computer intensive and lead to memory problems.
- The deletion of the interaction of Storage temperature at retail and packaging type[c].

Weighted analyses versus unweighted analyses

Table 170: and Table 171: indicate that most of the factors are quite insensitive to the weighting. The only difference is that Possible slicing is borderline non-significant for the unweighted analysis while it is significant for the weighted analysis.

As both weights are merely proxy weights for unknown true weight (that would correct for over- or underrepresentation), it is not straightforward how to interpret these differences. Major conclusion is that one should be careful with formulating strong statements about those factors that are unstable across such unweighted and weighted analyses.

Logistic regression with Firth's correction method for sparseness

In the sensitivity analysis with the method of Firth (Table 172:) the p-values are almost the same as in the GEE model (Table 170:). The odds ratios in Table 173: are of the same magnitude as the odds ratios of the GEE model in Table 171: . This indicates and confirms that there are no major sparseness issues in our final GEE model.

Table 172: Wald Statistics of Logistic Regression (Firth Approach) Analysis for final model Prevalence of samples contaminated by *Listeria monocytogenes* with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type of the meat product	2	10.67	0.00	2	10.60	0.01	2	9.68	0.01
Possible slicing	1	3.57	0.06	1	5.18	0.02	1	5.59	0.02
Packaging type[c]	1	0.88	0.35	1	0.45	0.50	1	0.12	0.73
Temperature at laboratory	1	0.77	0.38	1	1.82	0.18	1	1.34	0.25
Temperature at laboratory * Packaging type[c]	1	2.71	0.10	1	1.82	0.18	1	1.26	0.26

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 173: Odds ratios of Logistic Regression (Firth Approach) for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.01	0.00	0.03	<.0001	0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001
Type of the meat product a)	Paté	3.22	1.57	6.60	0.00	3.06	1.48	6.32	0.00	2.65	1.31	5.37	0.01
Type of the meat product	Sausage	1.06	0.57	1.99	0.85	0.82	0.39	1.72	0.60	0.70	0.34	1.45	0.33
Possible slicing b)		2.08	0.97	4.45	0.06	2.49	1.14	5.48	0.02	2.76	1.19	6.38	0.02
Packaging type(c) c)	Modified atmosphere	2.09	0.45	9.84	0.35	1.68	0.37	7.57	0.50	1.28	0.32	5.17	0.73
Temperature at laboratory		1.10	0.89	1.37	0.38	1.16	0.93	1.45	0.18	1.13	0.92	1.38	0.25
Temperature at laboratory * Packaging type(c)	Modified atmosphere	0.76	0.54	1.05	0.10	0.80	0.58	1.11	0.18	0.84	0.63	1.14	0.26

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type of the meat product is “Cold, cooked meat product”
b) : The reference category for Possible slicing is “Non-sliced”
c) : The reference category for Packaging type(c) is “All other packaging types”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Note

In the previous model, the non-significant interaction between the Storage temperature at laboratory and Packaging type(c) is kept in the model. However, we also present the results of the model without the interaction term. The Storage temperature at laboratory appeared not to be significant and is therefore also removed from the model. The results are presented below.

GEE Analysis without interaction of Storage temperature at laboratory and packaging type(c)

The statistics and p-values of Type of the meat product and Possible slicing in Table 174: are almost the same as in the previous analysis. The effect of Packaging type(c) is borderline significant at 5% significance level (but not significant for the weighted analysis). The odds ratios of Type of the meat product and Possible slicing have not changed much compared to the GEE analysis. For packaging type(c) it is easier in this model to interpret the odds ratio. The odds for modified atmosphere is smaller than the odds of All other packaging types.

Table 174: Wald Statistics For Type 3 GEE Analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type of the meat product	2	8.90	0.01	2	9.79	0.01	2	8.99	0.01
Possible slicing	1	3.31	0.07	1	5.01	0.03	1	6.00	0.01
Packaging type(c)	1	3.92	0.05	1	2.73	0.10	1	2.84	0.09

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 175: Odds ratios of GEE (Ind) for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life with taking into account hierarchical structure (country, city, store) for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.01	0.01	0.03	<.0001	0.01	0.00	0.03	<.0001	0.01	0.00	0.03	<.0001
Type of the meat product a)	Paté	2.91	1.39	6.10	0.00	2.84	1.33	6.04	0.01	2.48	1.12	5.47	0.02
Type of the meat product	Sausage	0.97	0.52	1.82	0.93	0.78	0.39	1.55	0.48	0.67	0.35	1.29	0.23
Possible slicing b)		2.13	0.94	4.83	0.07	2.63	1.13	6.12	0.03	2.92	1.24	6.90	0.01
Packaging type(c) c)	Modified atmosphere	0.60	0.36	0.99	0.05	0.63	0.37	1.09	0.10	0.61	0.34	1.08	0.09

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type of the meat product is “Cold, cooked meat product”
b) : The reference category for Possible slicing is “Non-sliced”
c) : The reference category for Packaging type(c) is “All other packaging types”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Firth's method without the interaction of Storage temperature at retail and Packaging type(c)

Further comparison with Table 176: and Table 177: confirms the significanc of Type of the meat product and it confirms that Packaging type(c) is borderline significant, depending on which analysis (unweighted or weighted) is considered.

Table 176: Wald Statistics of Logistic Regression (Firth Approach) Analysis for Prevalence of samples contaminated by *Listeria monocytogenes* with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type of the meat product	2	9.82	0.01	2	9.88	0.01	2	9.12	0.01
Possible slicing	1	3.34	0.07	1	5.18	0.02	1	5.49	0.02
Packaging type(c)	1	4.35	0.04	1	3.44	0.06	1	4.62	0.03

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 177: Odds ratios of Logistic Regression (Firth Approach) for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.01	0.01	0.03	<.0001	0.01	0.01	0.03	<.0001	0.01	0.01	0.03	<.0001
Type of the meat product a)	Paté	3.01	1.48	6.13	0.00	2.94	1.42	6.06	0.00	2.57	1.27	5.19	0.01
Type of the meat product	Sausage	1.00	0.55	1.82	0.99	0.82	0.40	1.70	0.60	0.70	0.34	1.44	0.33
Possible slicing b)		2.04	0.95	4.37	0.07	2.50	1.14	5.51	0.02	2.74	1.18	6.36	0.02
Packaging type(c) c)	Modified atmosphere	0.60	0.37	0.97	0.04	0.63	0.39	1.03	0.06	0.61	0.39	0.96	0.03

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type of the meat product is “Cold, cooked meat product”
b) : The reference category for Possible slicing is “Non-sliced”
c) : The reference category for Packaging type(c) is “All other packaging types”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.3.1.4. Diagnostic Test

In this last section some last checks are performed, including an examination of the goodness of fit of the final model and a multicollinearity analysis of the factors appearing in the final model.

Goodness of fit test

The goodness of fit test (Hosmer-Lemeshow in Table 178:) shows that there is no lack of fit in the model since the p-value is larger than the 5% significance level.

Table 178: Hosmer and Lemeshow test

Chi-Square	DF	Pr > ChiSq
9.15	7	0.24

Multicolinearity analysis

The VIF between the factors in the final model of Table 170: , are given in Table 179: . All values are very small, so we conclude that there are no problems related to multicollinearity.

Table 179: Variance Inflation Factor values for factors potentially related to Packaged heat-treated meat products

Variable	VIF
Type of the meat product	2.37
Possible slicing	2.06
Packaging type[(c)]	1.13
Storage temperature at laboratory	1.09

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.3.1.5. Other Analysis

A cross classification table between the prevalence of the samples, Packaging type[(c)] and Type of the meat product is included in Table 180: .

Table 180: Cross classification table between prevalence, Packaging type[(c)] and Type of the meat product

Type of the meat product	Modified atmosphere				All other packaging types			
	Sample		Total	Prevalence of contaminated samples	Sample		Total	Prevalence of contamianted samples
	Not contaminated	Contaminated			Not contaminated	Contaminated		
Cold, cooked meat product	1584	26	1610	1.61	915	22	937	2.35
Paté	64	4	68	5.88	129	6	135	4.44
Sausage	320	3	323	0.93	446	11	457	2.41
Total	1968	33	2001	1.65	1490	39	1529	2.55

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.3.2. Proportion of packaged heat-treated meat products with counts exceeding the level of 100 cfu/g at the end of shelf-life

5.3.2.1. Description of the samples

The following tables and figures provide further insights for packaged heat-treated meat products at the end of shelf-life. It is important to realize that the observed differences might be due to other factors, which is the reason for considering the multivariable analysis in the next section.

In total 3 530 samples of packaged heat-treated meat products at the end of shelf-life were collected. For only 0.42% the *Listeria monocytogenes* count was exceeding the level of 100 cfu/g (Table 181:).

Table 181: Descriptive statistics of percentage of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g for all participating countries*

	Frequency	Percentage of samples with counts not exceeding the level of 100 cfu/g
Samples with counts not exceeding the level of 100 cfu/g	3 515	99.58
Samples with counts exceeding the level of 100 cfu/g	15	0.42
Total	3 530	

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The following tables and figures provide further insights into the factors related to packaged heat-treated meat products at the end of shelf-life, with regard to samples with *Listeria monocytogenes* counts exceeding and not exceeding the level of 100 cfu/g.

For each participating country, the number of samples with *Listeria monocytogenes* counts exceeding and not exceeding the level of 100 cfu/g is given in Table 182: .

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 182: Number of packaged heat-treated meat products at the end of shelf-life with counts exceeding and not exceeding the level of 100 cfu/g by country for all participating countries*

Country	Number of samples with counts not exceeding the level of 100 cuf/g	Number of samples with counts exceeding the level of 100 cuf/g
Austria	123	0
Belgium	27	0
Bulgaria	39	0
Cyprus	26	1
Czech Republic	60	0
Denmark	59	1
Estonia	30	0
Finland	66	0
France	388	1
Germany	914	1
Greece	60	0
Hungary	62	0
Ireland	32	0
Italy	401	2
Latvia	30	0
Lithuania	30	0
Luxembourg	26	0
Malta	22	0
Netherlands	54	2
Norway	60	0
Poland	199	1
Romania	60	0
Slovakia	59	0
Slovenia	32	0
Spain	196	5
Sweden	75	0
United Kingdom	385	1
Total	3 515	15

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 183: shows that 0.43% of the samples collected in supermarkets or small shops has a count exceeding the level of 100 cfu/g. The other types of retail outlet have no samples with count exceeding the level of 100 cfu/g and these types are merged in Table 184: .

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 183: Percentage of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g by Type of retail outlet for all participating countries*

Type of retail outlet	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Supermarket or small shop	3 451	15	3 466	0.43
Street market or farmers' market	6	0	6	0.00
Speciality delis	11	0	11	0.00
Other (free text field)	47	0	47	0.00
Total	**3 515**	**15**	**3 530**	**0.42**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 184: Percentage of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g by Type(c) of retail outlet, for all participating countries*

Type(c) of retail outlet	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Supermarket or small shop	3 451	15	3 466	0.43
All other types of retail outlet	64	0	64	0.00
Total	**3 515**	**15**	**3 530**	**0.42**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

We again order the samples according to the Sampling season and we observe small differences between the seasons, with highest percentage during the winter and smallest during the spring (Table 185:). However all percentages are low.

Table 185: Percentage of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g by Sampling season for all participating countries*

Sampling Season	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Autumn	1 038	4	1 042	0.38
Spring	794	2	796	0.25
Summer	942	4	946	0.42
Winter	741	5	746	0.67
Total	**3 515**	**15**	**3 530**	**0.42**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

For every category of Animal species of the origin of the meat product, Table 186: shows the percentage of samples for which the result of the enumeration test exceeds 100 cfu/g. We observe that none of the

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

samples of "other" animal species has a count exceeding the level of 100 cfu/g. Only one sample is collected from Goose and this sample has a count not exceeding the level of 100 cfu/g. A summary of the data after merging several species is shown in Table 187: . The percentages of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g are 0.93% for birds and 0.33% for other species.

Table 186: Percentage of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g by Animal species of the origin of the meat product for all participating countries*

Animal Species	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Pork	2 558	8	2 566	0.31
Poultry	208	2	210	0.95
Broiler	90	2	92	2.17
Turkey	231	1	232	0.43
Beef	104	1	105	0.95
Mixed	307	1	308	0.32
Goose	1	0	1	0.00
Other	16	0	16	0.00
Total	**3 515**	**15**	**3 530**	**0.42**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 187: Percentage of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g by Animal Species[(c)], for all participating countries*

Animal Species[(c)]	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Avian species	530	5	535	0.93
Other species	2 985	10	2 995	0.33
Total	**3 515**	**15**	**3 530**	**0.42**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

A summary of the samples exceeding the count of 100 cfu/g for each Type of the meat product is shown in Table 188: . The highest percentage is observed for paté (0.99%), while for sausages 0.13% and for cold, cooked meat products 0.47% of the samples has a count exceeding the level of 100 cfu/g.

Table 188: Percentage of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g by Type of meat product for all participating countries*

Type of the meat product	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Cold, cooked meat product	2 535	12	2 547	0.47
Paté	201	2	203	0.99
Sausage	779	1	780	0.13
Total	**3 515**	**15**	**3 530**	**0.42**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The percentage of samples with a count exceeding 100 cfu/g is given for each packaging place in Table 189: . All samples packaged at retail have a count not exceeding the level of 100 cfu/g, while 0.41% have a count exceeding the level in samples packaged by the producer. For 96 samples the packaging place is unknown and 1 of these samples has a count exceeding the level of 100 cfu/g.

Table 189: Percentage of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g by Packaging place for all participating countries*

Packaging Place	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Packaged by the producer	3 399	14	3 413	0.41
Packaged at retail	21	0	21	0.00
Unknown	95	1	96	1.04
Total	**3 515**	**15**	**3 530**	**0.42**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Next to the packaging place, the type of packaging might be of influence for the contamination with *Listeria monocytogenes.* Table 190: shows the percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g for every packaging type. In Table 191: the categories are merged into modified and All other packaging types. The percentage of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is smaller for Modified atmosphere (0.35%) compared to All other packaging types (0.52%).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 190: Percentage of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g by Packaging type for all participating countries*

Packaging Type	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Modified atmosphere	1 994	7	2 001	0.35
Vacuum	883	5	888	0.56
Normal atmosphere	546	2	548	0.36
Other (free text)	92	1	93	1.08
Total	**3 515**	**15**	**3 530**	**0.42**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 191: Percentage of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g by Packaging type(c) for all participating countries*

Packaging Type(c)	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Modified atmosphere	1 994	7	2 001	0.35
All other packaging types	1 521	8	1 529	0.52
Total	**3 515**	**15**	**3 530**	**0.42**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Small differences in the percentage of packaged heat-treated meat products with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g are observed with regard to sliced and non-sliced meat (Table 192:). For sliced meat, 0.47% of the samples have *Listeria monocytogenes* counts exceeding the level of 100 cfu/g , while this percentage is 0.19% for non-sliced meat products.

Table 192: Percentage of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g by Possible slicing for all participating countries*

Possible slicing	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Sliced	2 991	14	3 005	0.47
Non-sliced	524	1	525	0.19
Total	**3 515**	**15**	**3 530**	**0.42**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 193: gives a summary of the samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g for each country of production.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 193: Number of packaged heat-treated meat products at the end of shelf-life with counts exceeding and not exceeding the level of 100 cfu/g by Country of production for all participating countries*

Country of production	Number of samples with counts not exceeding the level of 100 cuf/g	Number of samples with counts exceeding the level of 100 cuf/g
Argentina	2	1
Austria	126	0
Belgium	65	1
Brazil	19	0
Bulgaria	37	0
Croatia	1	0
Cyprus	26	1
Czech Republic	87	0
Denmark	30	0
Estonia	38	0
European Union	1	0
Finland	62	0
France	379	1
Germany	989	2
Greece	61	0
Hungary	63	0
Ireland	37	0
Israel	2	0
Italy	438	2
Latvia	19	0
Lithuania	32	0
Luxembourg	14	0
Malta	5	0
Netherlands	49	2
Norway	59	0
Oman	1	0
Pakistan	1	0
Poland	199	1
Romania	45	0
Slovakia	18	0
Slovenia	12	0
Spain	200	4
Sweden	70	0
Thailand	8	0
United Kingdom	302	0
United States	18	0
Total	3515	15

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

In Table 194: we can see that the transport of 4 samples is not guaranteed to be in line with technical specifications. None of these have *Listeria monocytogenes* counts exceeding the level of 100 cfu/g .

Table 194: Percentage of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g by transport protocol for all participating countries*

Transport Protocol	Samples with counts exceeding 100 cfu/g		Total	Percentage of samples with counts exceeding 100 cfu/g
	No	Yes		
Yes [a)]	3 511	15	3 526	0.43
No [b)]	4	0	4	0.00
Total	**3 515**	**15**	**3 530**	**0.42**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
[a)] in line with technical specifications
[b)] not in line with technical specifications

Some summary statistics of the storage temperature of the lab are shown in Table 195: . A graphical representation of the storage temperatures is given in Figure 40: and Figure 41: .

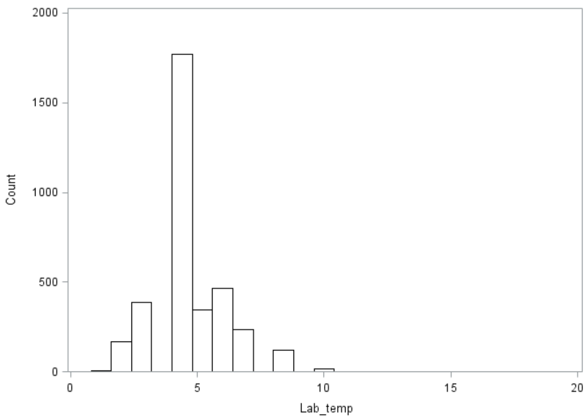
The average temperature of the samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is 4°C, while the average temperature of the other samples is 4.51°C. The range of temperature for the samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is smaller than the range for the negative samples. From the histogram in Figure 40: we see that most samples with *Listeria monocytogenes* counts not exceeding the level of 100 cfu/g have a storage temperature of 4°C. The box-whisker plots in Figure 41: show that the distribution of the storage temperatures between samples with *Listeria monocytogenes* counts exceeding and not exceeding the level of 100 cfu/g is quite different.

Table 195: Summary Statistics of Storage temperature at laboratory by proportion of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g for all participating countries*

Temperature at laboratory	Samples with counts exceeding 100 cfu/g		Total
	No	Yes	
n	3 515	15	3 530
mean	4.51	4	4.51
sd	1.43	1.36	1.43
min	0	3	0
lower whisker	3	3	3
Q1	4	3	4
median	4	4	4
Q3	5	4	5
Upper whisker	6	5	6
max	18	7	18
range (max-min)	18	4	18

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.



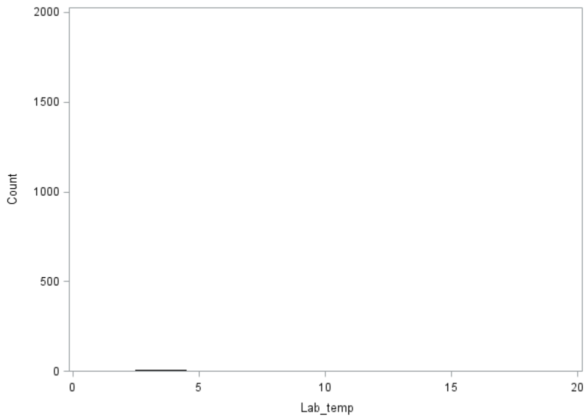


Figure 40: Histogram of Storage temperature at laboratory up to the end of shelf-life for samples with coutns not exceeding (left) and exceeding (right) the level of 100 cfu/g of packaged heat-treated meat products at the end of shelf-life for all participating countries

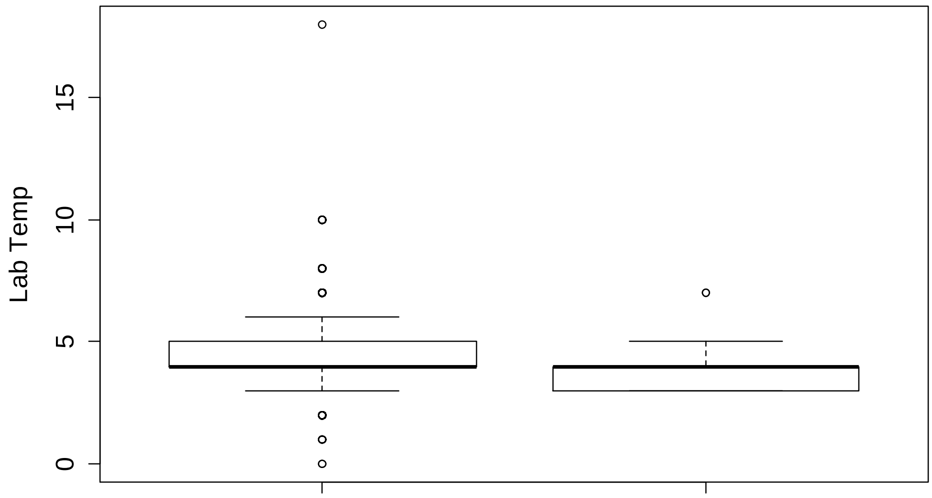


Figure 41: Boxplot[28] of Storage temperature at laboratory up to the end of shelf-life for samples with counts not exceeding (left) and exceeding (right) the level of 100 cfu/g of packaged heat-treated meat products at the end of shelf-life in all participating countries

[28] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Summary statistics of the remaining shelf-life are provided in Table 196: and a graphical representation is given in Figure 42: and Figure 43: .

On average the remaining shelf-life is higher for the samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g. The range of the remaining shelf-life is smaller for samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g compared to samples with *Listeria monocytogenes* counts not exceeding the level of 100 cfu/g. The box-whisker plots in Figure 43: show two similar boxplots, but at higher level for the samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g and with more outliers for the samples with *Listeria monocytogenes* counts not exceeding the level of 100 cfu/g.

Table 196: Summary Statistics of Remaining shelf-life by proportion of packaged heat-treated meat products at the end of shelf-life with counts exceeding the level of 100 cfu/g for all participating countries*

Remaining shelf-life	Samples with counts exceeding 100 cfu/g		Total
	No	Yes	
n	3 515	15	3 530
mean	19.46	29.53	19.51
sd	20.01	20.87	20.02
min	0	5	0
lower whisker	0	5	0
Q1	10	18.5	10
median	15	24	15
Q3	23	31	23
Upper whisker	42	46	42
max	427	86	427
range (max-min)	427	81	427

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

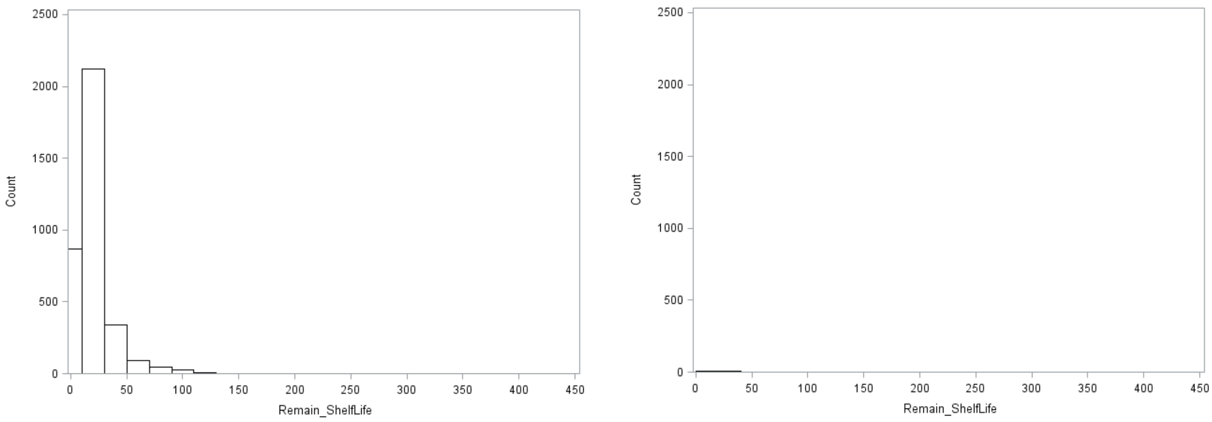


Figure 42: Histogram of remaining shelf-life for packaged heat-treated meat products for all participating countries, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at the end of shelf-life

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

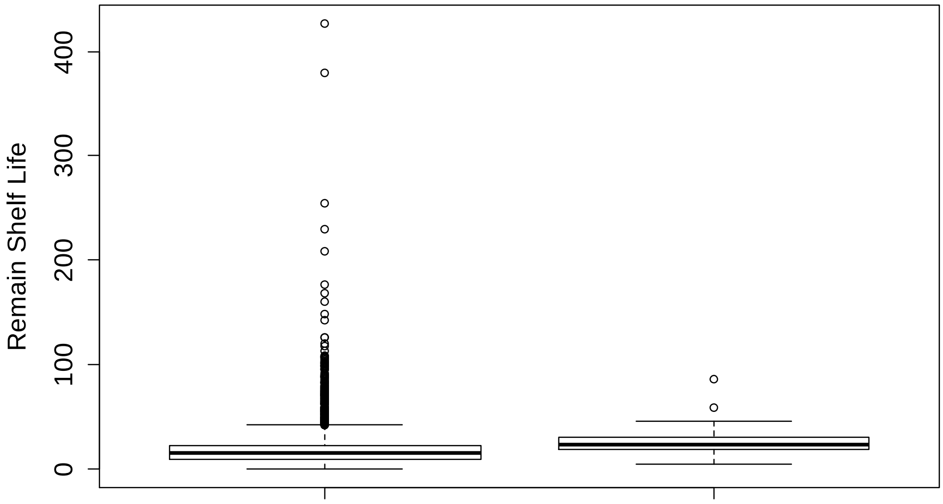


Figure 43: Boxplot[29] of remaining shelf-life for packaged heat-treated meat products for all participating countries, for samples with counts that do not exceed (left) and do exceed (right) the level of 100 cfu/g at the end of shelf-life

5.3.2.2. Single-factor model

GEE (Ind) has been applied to the analysis of single-factor model along with unweighted and weighted (based on planned sample and population sizes) approaches. In the end a sensitivity analysis has been considered using logistic regression with Firth approach. The results are presented in Appendix D.6. The results should be interpreted with caution, because the observed effects could be due to confounding.

All variables in the dataset have been fitted in the single-factor model. As before, some problems occurred while fitting models for a risk factor with many categories, such as country and country of production. Results were obtained for Type[(c)] of retail outlet, but not Type of retail outlet. No results were obtained for the variables packaging place and transport protocol. No convergence was obtained for the model with date of testing, use by date, production date or packaging date.

5.3.2.3. Multiple-factors model

As described in the Material and Methods section, an "all subsets" model selection approach of multiple logistic regression was used for selecting variables. The AIC criterion (the lower the better) was used to select the model (Table 254: in Appendix C.3). The final model consists of the variables Animal species of the origin of the meat product, Type of the meat product, Possible slicing and remaing shelf-life. The interaction between Packaging type[(c)] and Storage temperature at the laboratory as well as their main

[29] The lower whisker represent the lowest value, bottom of the box represents the first quartile of the distribution and the top the third quartile, whereas the bar inside the box represents the median. The upper whisker represent the maximum value or 1.5 times the difference between the third and the first quartile (interquartile range). Small circular symbols indicate extreme values, with a value larger than the upper whisker (217 extreme values).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

effects were included in the final model because of their biological relevance, even if not significant. Some convergence problems occurr for GEE (Ind) (hessian not positive definite), because no sample has a count exceeding the level of 100 cfu/g for some category of Animal species of the origin of the meat product (Table 186:). Therefore the variable Animal species(c) of the origin of the meat product was used. The effect of the Type of the meat product is no longer significant at 5% significance level and is therefore removed from the model. The final model is presented in the following tables.

The following tables show the result of GEE (Table 197: and Table 198:) along with the sensitivity analysis using the method of Firth (Table 199: and Table 200:).

The unweighted GEE(Ind) result shows statistical significance of Animal species(c) and the remaining shelf-life. The effect of Possible slicing and the interaction effect between Storage temperature at the laboratory and Packaging type(c) are not statistically significant.

Table 198: shows the odds ratios of each factor in the model. The odds ratio of having outcome above 100 cfu/g compared to outcome below 100 cfu/g is equal to 1.010 (CI: 1.004, 1.016) when increasing one day of remaining shelf-life. The odds ratio of having outcome above 100 cfu/g compared to outcome below 100 cfu/g for other species compared to avian species is equal to 0.37.

<u>GEE Analysis for final model</u>

Table 197: Wald Statistics For Type 3 GEE Analysis for final model for proportion of samples with counts exceeding the level of 100 cfu/g of *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life with taking into account hierarchical structure (country , city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Animal species(c)	1	4.12	0.04	1	3.72	0.05	1	6.41	0.01
Possible slicing	1	1.07	0.30	1	1.12	0.29	1	1.10	0.29
Remaining Shelf-life	1	11.62	0.00	1	10.40	0.00	1	10.58	0.00
Packaging type(c)	1	0.02	0.90	1	0.00	0.98	1	0.06	0.81
Temperature at laboratory	1	0.23	0.63	1	0.06	0.80	1	0.01	0.94
Temperature at laboratory * Packaging type(c)	1	0.15	0.70	1	0.05	0.82	1	0.00	1.00

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 198: Odds ratios of GEE (Ind) for final model Proportion of packaged heat-treated meat products at end of shelf-life with counts exceeding the level of 100 cfu/g with taking into account hierarchical structure (country, city, store) for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.00	0.00	0.06	0.00	0.00	0.00	0.07	0.00	0.00	0.00	0.08	0.00
Animal species(c) a)	Other species	0.37	0.14	0.97	0.04	0.39	0.15	1.01	0.05	0.30	0.12	0.76	0.01
Possible slicing b)		3.39	0.33	34.49	0.30	3.55	0.34	37.15	0.29	3.53	0.34	36.95	0.29
Remaining Shelf-life		1.010	1.004	1.016	0.001	1.009	1.004	1.015	0.001	1.011	1.004	1.018	0.001
Packaging type(c) c)	Modified atmosphere	1.28	0.02	68.21	0.90	1.04	0.02	71.77	0.98	0.58	0.01	49.00	0.81
Temperature at laboratory		0.86	0.46	1.60	0.63	0.91	0.45	1.85	0.80	0.97	0.45	2.09	0.94
Temperature at laboratory * Packaging type(c)	Modified atmosphere	0.83	0.33	2.12	0.70	0.89	0.32	2.43	0.82	1.00	0.35	2.82	1.00

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Animal species(c) is “Avian species”
b) : The reference category for Possible slicing is “Non-sliced”
c) : The reference category for Packaging type(c) is “All other packaging types”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

SENSITIVITY ANALYSIS FOR FINAL MODEL

To get further insights in the stability of the final model, we investigate its sensitivity to some modifications:

- The weighted analyses as compared to the unweighted analyses.
- The use of Firth's method and exact logistic regression, as methods that can cope with sparseness to some larger extent. Exact logistic regression was computationally not feasible. It is extremely computer intensive and lead to memory problems.
- The deletion of the interaction of Storage temperature at retail and Packaging type(c).

Weighted analyses versus unweighted analyses

Table 197: and Table 198: indicate that most of the factors are quite insensitive to the weighting.

Logistic regression with Firth's correction method for sparseness

The differences in p-values between the model fit with the method of Firth (Table 199:) and the GEE model are small. The odds ratios in Table 200: are similar to the odds ratios in the GEE model.

Table 199: Wald Statistics of Logistic Regression (Firth Approach) Analysis for final model of the proportion of samples with counts exceeding the level of 100 cfu/g with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Animal species(c)	1	4.11	0.04	1	4.20	0.04	1	7.94	0.00
Possible slicing	1	1.12	0.29	1	1.53	0.22	1	1.44	0.23
Remaining Shelf-life	1	8.06	0.00	1	8.17	0.00	1	7.75	0.01
Packaging type(c)	1	0.03	0.86	1	0.00	0.97	1	0.16	0.69
Temperature at laboratory	1	0.16	0.69	1	0.02	0.90	1	0.01	0.93
Temperature at laboratory * Packaging type(c)	1	0.24	0.63	1	0.10	0.75	1	0.00	0.99

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 200: Odds ratios of Logistic Regression (Firth Approach) for Proportion of packaged heat-treated meat products at end of shelf-life with counts exceeding the level of 100 cfu/g for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.00	0.00	0.04	<.0001	0.00	0.00	0.03	<.0001	0.00	0.00	0.02	<.0001
Animal species(c) a)	Other species	0.36	0.13	0.97	0.04	0.38	0.15	0.96	0.04	0.29	0.12	0.69	0.00
Possible slicing b)		2.44	0.47	12.73	0.29	2.69	0.56	12.83	0.22	2.59	0.55	12.21	0.23
Remaining Shelf-life		1.012	1.004	1.020	0.005	1.011	1.003	1.018	0.004	1.013	1.004	1.022	0.005
Packaging type(c) c)	Modified atmosphere	1.34	0.05	32.81	0.86	1.05	0.05	21.26	0.97	0.59	0.04	7.89	0.69
Temperature at laboratory		0.90	0.55	1.49	0.69	0.97	0.60	1.58	0.90	1.02	0.68	1.53	0.93
Temperature at laboratory * Packaging type(c)	Modified atmosphere	0.83	0.39	1.76	0.63	0.89	0.44	1.80	0.75	1.00	0.56	1.78	0.99

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Animal species(c) is “Avian species”
b) : The reference category for Possible slicing is “Non-sliced”
c) : The reference category for Packaging type(c) is “All other packaging types”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Note

In the previous model, the non-significant interaction between the Storage temperature at laboratory and Packaging type(c) is kept in the model. However, we also present the results of the model without the interaction term. The Storage temperature at laboratory and Packaging type(c) appeared not to be significant and are therefore also removed from the model. The results are presented below.

GEE Analysis without interaction between Storage temperature at laboratory and packaging type(c)

A comparison of the p-values in Table 201: and in the previous GEE model reveals only small differences. The odds ratios in Table 202: are similar to the odds ratios in the GEE model. The odds ratio of sliced versus non-sliced meat is 2.61, compared to an odds ratio of 3.39 in the GEE model.

Table 201: Wald Statistics For Type 3 GEE Analysis for proportion of samples with counts exceeding the level of 100 cfu/g of *Listeria monocytogenes* in packaged heat-treated meat products at the end of shelf-life with taking into account hierarchical structure (country , city, store) for all participating countries*

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Animal species(c)	1	4.07	0.04	1	3.56	0.06	1	5.45	0.02
Possible slicing	1	0.83	0.36	1	0.99	0.32	1	0.94	0.33
Remaining Shelf-life	1	13.93	0.00	1	11.61	0.00	1	12.09	0.00

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 202: Odds ratios of GEE (Ind) for Proportion of packaged heat-treated meat products at end of shelf-life with counts exceeding the level of 100 cfu/g with taking into account hierarchical structure (country, city, store) for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.00	0.00	0.02	<.0001	0.00	0.00	0.03	<.0001	0.00	0.00	0.03	<.0001
Animal species(c) a)	Other species	0.35	0.13	0.97	0.04	0.37	0.14	1.04	0.06	0.29	0.10	0.82	0.02
Possible slicing b)		2.61	0.33	20.53	0.36	2.86	0.36	22.56	0.32	2.81	0.35	22.69	0.33
Remaining Shelf-life		1.010	1.005	1.016	0.000	1.009	1.004	1.014	0.001	1.011	1.005	1.018	0.001

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Animal species(c) is "Avian species"
b) : The reference category for Possible slicing is "Non-sliced"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

<u>Firth's method without the interaction of Storage temperature at retail and packaging type(c)</u>

The p-values and odds ratios of the analysis with the method of Firth are slightly different, but as no major differences occur, we conclude that there are no major sparseness problems in the variables of the final model.

Table 203: Wald Statistics of Logistic Regression (Firth Approach) Analysis for proportion of samples with counts exceeding the level of 100 cfu/g with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Animal species(c)	1	4.30	0.04	1	4.28	0.04	1	7.78	0.01
Possible slicing	1	0.52	0.47	1	0.90	0.34	1	0.82	0.37
Remaining Shelf-life	1	8.34	0.00	1	8.40	0.00	1	7.97	0.00

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 204: Odds ratios of Logistic Regression (Firth Approach) for Proportion of packaged heat-treated meat products at end of shelf-life with counts exceeding the level of 100 cfu/g for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.00	0.00	0.03	<.0001	0.00	0.00	0.03	<.0001	0.01	0.00	0.03	<.0001
Animal species(c) a)	Other species	0.34	0.12	0.94	0.04	0.36	0.14	0.95	0.04	0.29	0.12	0.69	0.01
Possible slicing b)		1.84	0.35	9.65	0.47	2.13	0.45	10.11	0.34	2.05	0.43	9.73	0.37
Remaining Shelf-life		1.012	1.004	1.020	0.004	1.010	1.003	1.018	0.004	1.013	1.004	1.021	0.005

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Animal species(c) is "Avian species"
b) : The reference category for Possible slicing is "Non-sliced"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.3.2.4. Diagnostic Test

In this last section some checks are performed, including an examination of the goodness of fit of the final model and a multicollinearity analysis of the factors appearing in the final model.

Goodness of fit test

The goodness of fit test (Hosmer-Lemeshow in Table 205:) shows that there is no lack of fit in the model since the p-value is larger than the 5% significance level.

Table 205: Hosmer and Lemeshow test

Chi-Square	DF	P-value
8.76	8	0.36

Multicolinearity analysis

The VIF between the factors in the final modelin Table 197: , are given in Table 206: . All values are very small, so we conclude that there are no problems related to multicollinearity.

Table 206: Variance Inflation Factor values for factors potentially related to meat product

Variable	VIF
Animal species(c)	1.71
Possible slicing	1.98
Packaging type(c)	1.15
Remaining Shelf-life	1.08
Storage temperature at laboratory	1.04

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

5.3.2.5. Other Analysis

A cross classification table of Packaging type[(c)] and Type of the meat product, together with the proportion of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g is presented in Table 207: .

Table 207: Cross classification table between proportion of samples with counts exceeding the level of 100 cfu/g, Packaging type[(c)] and Type of the meat product

Type of the meat product	Modified atmosphere			All other packaging types		
	Samples with counts exceeding the level of 100 cfu/g		Total	Samples with counts exceeding the level of 100 cfu/g		Total
	No	Yes		No	Yes	
Cold, cooked meat product	1604	6	1610	931	6	937
Paté	67	1	68	134	1	135
Sausage	323	0	323	456	1	457
Total	1994	7	2001	1521	8	1529

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

6. Summary tables

Table 208: Summary of the model using GEE(Ind)

Variable	Fish at the time of sampling				Fish at the end of shelf-life				Meat at the end of shelf-life			
	Prevalence		Proportion of samples with counts exceeding the level of 100 cfu/g		Prevalence		Proportion of samples with counts exceeding the level of 100 cfu/g		Prevalence		Proportion of samples with counts exceeding the level of 100 cfu/g	
	Single Analysis	Multiple Analysis	Single Analysis	Multiple Analysis	Single Analysis	Multiple Analysis	Single Analysis	Multiple Analysis	Single Analysis	Multiple Analysis	Single Analysis	Multiple Analysis
main effect:												
Type of retail outlet												
Type(c) of retail outlet	NS	D	NC	D	NS	D	S	S	NS	D	NC	D
Date of sampling												
Sampling season	S	D	NC	S	S	S	S	S	NS	D	NS	D
Subtype of the fish product	S	S	NC	D	NC	S	NS	D				
Fish species	S	S	NC	D	S	S	NsS	D				
Preservatives and acidity regulators	S	S	NC	D	NC	S	NC	D				
Animal species of the origin of the meat product												
Animal species(c) of the origin of the meat product									NS	D	S	S
Type of the meat product									S	S	NS	D
Packaging place for meat									NS	D	NC	D
Possible slicing	S	S	NC	NS	S	NS	S	S	NS	NS	NS	NS
Packaging type												
Packaging type(c)	S	NS	NC	NS	NS	NS	NS	D	NS	NS	NS	NS
Storage temperature at retail	NS	NS	NS	NS								

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Transport protocol	NC	D	NC	D	NC	D	NC	D	NC	D	NC	D
Storage temperature at laboratory up to the end of shelf-life					S	NS	NS	D	NS	NS	NC	NS
remaining shelf-life	NS	S	NS	D	NS	D	NS	D	NS	D	S	S
Country of production	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC	NC
"EC 2073/2005 NSG" indicator		NS		NS		S						
Interaction with "EC 2073/2005 NSG" indicator :												
Type[(c)] of retail outlet	NS	D	NC	D	NS	D						
Sampling season	NS	D	NC	D	NS	D						
Subtype of the fish product	NS	S	NC	D	NC	D						
Fish species	S	D	NC	D	S	S						
Preservatives and acidity regulators	NS	D	NC	D	NC	D						
Possible slicing	NS	D	NC	D	NS	D						
Packaging type[(c)]	NS	D	NC	D	NS	D						
Storage temperature at retail	NS	D	S	D		D						
Transport protocol	NC	D	NC	D	NC	D						
Storage temperature at laboratory up to the end of shelf-life		D		D	S	S						
Remaining shelf-life	S	D	S	D	NS	D						
Other interaction												
Temperature * Packaging type[(c)]		NS		NS		NS				NS		NS

S : Significant effect (alpha 5%)

NS : Not Significant

NC : Not Converging

D : Dropped from model selection

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

DISCUSSION & CONCLUSIONS

The results of the statistical analyses of all potential factors for the prevalence of *Listeria monocytogenes* for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling for all participating countries showed statistically significant effects (at 5% level) for the factors Subtype of the fish product, Fish species, Number of preservatives and acidity regulators, Possible slicing, remaining shelf-life and the interaction between the ‘‘EC 2073/2005 NSG’’ indicator and Fish species. The biologically relevant interaction between Storage temperature at retail and Packaging type[c] appeared to be not significant. For the proportion of samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling for all participating countries, it is shown that there is only a statistically significant effect (at 5% level) for the Sampling season with an increase in the odds (for a sample with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g) with a factor 4.5 when comparing summer to winter.

The results of the statistical analyses of all potential factors for the prevalence of *Listeria monocytogenes* for packaged (not frozen) hot or cold smoked or gravad fish at end of shelf-life for all participating countries showed statistically significant effects (at 5% level) for the factors Sampling season, Subtype of the fish product, Fish species, Number of preservatives and acidity regulators, ‘‘EC 2073/2005 NSG’’ indicator and the interactions between ‘‘EC 2073/2005 NSG’’ indicator and Fish species, between Storage temperature at laboratory and ‘‘EC 2073/2005 NSG’’ indicator have significant effects on the prevalence. For the proportion samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g for packaged (not frozen) hot or cold smoked or gravad fish at end of shelf-life for all participating countries, statistically significant effects (at 5% level) are identified for the factors Type[c] of retail outlet, Sampling season and Possible slicing. For this model the ‘‘EC 2073/2005 NSG’’ indicator was not included due to sparseness issues.

The results of the statistical analyses of all potential factors for the prevalence of *Listeria monocytogenes* for packaged heat-treated meat products at end of shelf-life for all participating countries showed statistically significant effects (at 5% level) for Type of the meat product. The final model also included the non-significant factors Possible slicing, Storage temperature at laboratory, Packaging type[c] and an interaction between Storage temperature at laboratory and Packaging type[c]. For the proportion samples with *Listeria monocytogenes* counts exceeding the level of 100 cfu/g for packaged heat-treated meat products at end of shelf-life for all participating countries, it is shown that there are statistically significant effects (at 5% level) for the factors Animal species[c] of the origin of the meat product and remaining shelf-life.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

REFERENCES

Aerts, M., Geys, H., Molenberghs, G. and Ryan, L. (2002). Topics in Modelling of Clustered Data. Chapman & Hall, London.

Agresti, A. (2013). *Categorical Data Analysis*. Wiley, Hoboken, New Jersey.

Firth, D. (1993). Bias reduction of maximum likelihood estimates. *Biometrika*, **80**, 27-38.

Hirji, K.F., Mehta, C.R. and Patel, N.R. (1987). Computing distributions for exact logistic regression. *J. Amer. Statist. Assoc.*, **82**, 1110-1117.

Liang, K.Y. and Zeger, S.L. (1986). Longitudinal data analysis using generalized linear models. *Biometrika*, **73**, 13-22.

Molenberghs, G. and Verbeke, G., 2005. Models for Discrete Longitudinal Data. New York: Springer-Verlag.

Rakhmawati T W, Nysen R, Aerts M, 2013. Statistical analysis of the *Listeria monocytogenes* EU-wide baseline survey in certain ready-to-eat foods Part A: *Listeria monocytogenes* prevalence estimates. EFSA supporting publication 2013:EN-441, 114 pp. (http://www.efsa.europa.eu/en/supporting/pub/441e.htm?wtrl=01)

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

PART II: PREDICTIVE MODELS FOR GROWTH OF LISTERIA MONOCYTOGENES

7. Materials and Methods

7.1. Predictive models for microbial growth

In the next sextion, we will first discuss the data and define some "eligible" subsets, depending on the type of model. Given the nature of the data, three types of predictive models for microbial growth of *L. monocytogenes* will be developed and/or applied, using the enumeration data from the surveys in packaged (not frozen) hot or cold smoked or gravad fish at two different time points (at the date of testing on the arrival at the laboratory and at the end of shelf-life), and the effect of temperature, pH and water activity will be addressed:

- Statistical models for the enumeration data at both time points, accounting for different sources of variability and heterogeneity.

- Existing predictive deterministic models based on parameter values as known from literature, modeling the enumeration data of a batch at the date of testing at the end of shelf-life, given the enumeration value at the date of testing on the arrival at the laboratory.

- Statistical models for the "change rate" in a batch, defined as the batch-difference between the enumeration counts (on log scale) at both time points relative to the duration of time between both time points.

All three types of models reflect the association between the enumeration data from the same batch at both time points. The statistical models for the enumeration data use random batch effects to do so, whereas the deterministic models predict the enumeration value for a batch at the date of testing at the end of shelf-life from the value of the same batch (though other sample) at the date of testing on the arrival at the laboratory. Finally, the statistical models for the change rate focus already at the batch-difference, and moreover condition on the count at date of testing on the arrival at the laboratory.

7.2. Materials

The technical specifications for the survey on *Listeria monocytogenes* in selected categories of ready-to-eat food at retail in the EU are described in the Commission Decision 2010/678/EU. In sub-survey 1 for smoked or gravid fish the survey was designed to have 2 samples per batch, at the sample collection and at the end of shelf-life. Related to the nature of the design, we have :

1. Two repeated test results from the same batch, though from different samples. Explorative analyses show high within batch variability, which also turns part of the data "ineligible" for microbial growth models (see definition of eligible subsets below).

2. Each sample or in extension each batch follows its individual growth process. This implies that the batches have their individual time scale for the growth process. In order to develop the statistical models for the enumeration data and in order to fit them, the time scales for the different batches are aligned to some common point of time and, in this way they estimate an "averaged" growth curve. In Figure 44: the data for the same batch were connected with a line, and were, across all batches, aligned at the first time point (date of testing on arrival at

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

the laboratory). Of course batches have evolved differently through their individual growth process and reached different stadia at the point of sampling.

In summary, based on these considerations, we applied three different approaches:

1. Approach 1 (statistical approach). A statistical model is developed for the correlation between the results of the same batch as well as the different sources of variability and heterogeneity. We implement a statistical manner to align the different individual time scales of growth to a common time scale, which allows us to define and fit models to all data at both time points.

2. Approach 2 (deterministic approach). Existing growth models, with parameter values taken from literature, are applied to predict the result at the date of testing at the end of shelf-life, given the result at the date of testing on arrival at the laboratory.

3. Approach 3 (statistical approach). A statistical model is developed of the relative rate of change within a batch.

As mentioned above, depending on the type of model, we might need to exclude some ineligible data and in the sequel we will use different subsets of the data.

We consider data of a batch (a pair of samples) to be "eligible" (***eligible subset 1***) in case

- Outcome at the date of testing at the end of shelf-life is positive, i.e. above the limit of detection 10 cfu's

- Outcome at the date of testing at the end of shelf-life not less than the outcome at the date of testing on the arrival at the laboratory, i.e. we assume that the count does not decrease

- Date of testing at the end of the shelf-life beyond date of testing on the arrival at the laboratory, i.e. the samples cannot be tested on the same day twice.

Plotting batch profiles for our data at both occasions reveals that there is only a limited amount of "eligible" data. The *Listeria monocytogenes* count is non-decreasing for 84 batches (see Figure 44: .), but one of these batches was tested twice on the same day. Therefore subset 1 contains 83 batches. 2 out of 83 batches are included in "EC 2073/2005 NSG". The subset of size 83 is labelled as ***subset 1a*** (see left panel of Figure 46:); the exclusion of the two batches that are included in "EC 2073/2005 NSG" leads to ***subset 1b*** (of size 81).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

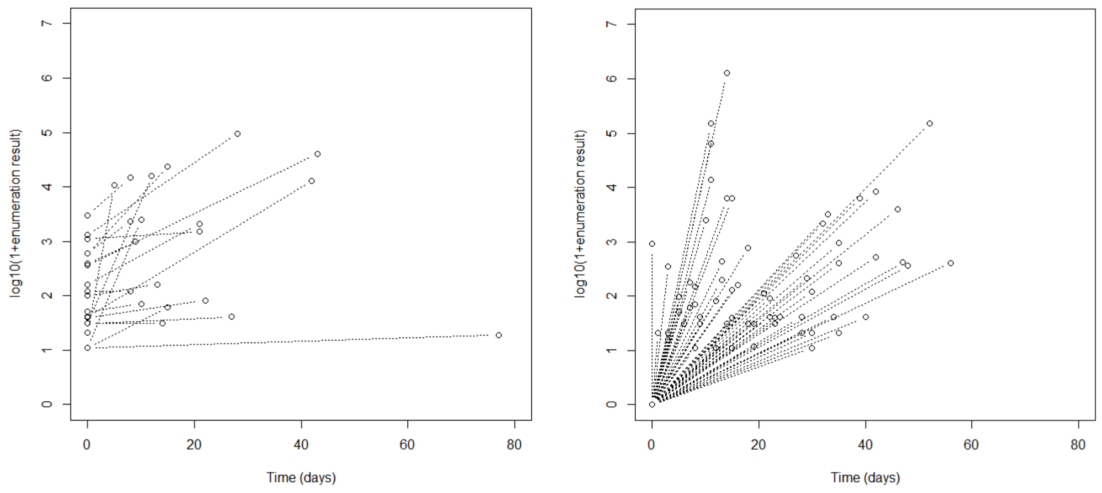


Figure 44: Graphical representation of the batches with an increasing count. Left panel: initial count positive (20 batches). Right panel: initial count negative (64 batches).

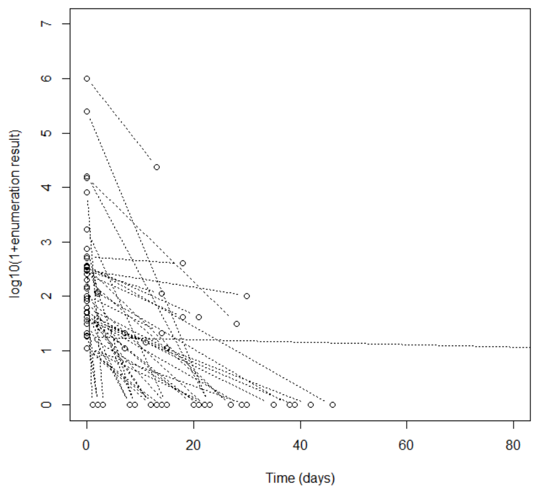


Figure 45: Graphical representation of the batches with a decreasing count (46 batches).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

20 batches are non-decreasing and positive at the date of testing on the arrival at the laboratory and at the date of testing at the end of shelf-life (see left panel of Figure 44:). 19 of these are not included in "EC 2073/2005 NSG". We denote the 19 batches by ***eligible subset 2*** *(see right panel of Figure 46:).*

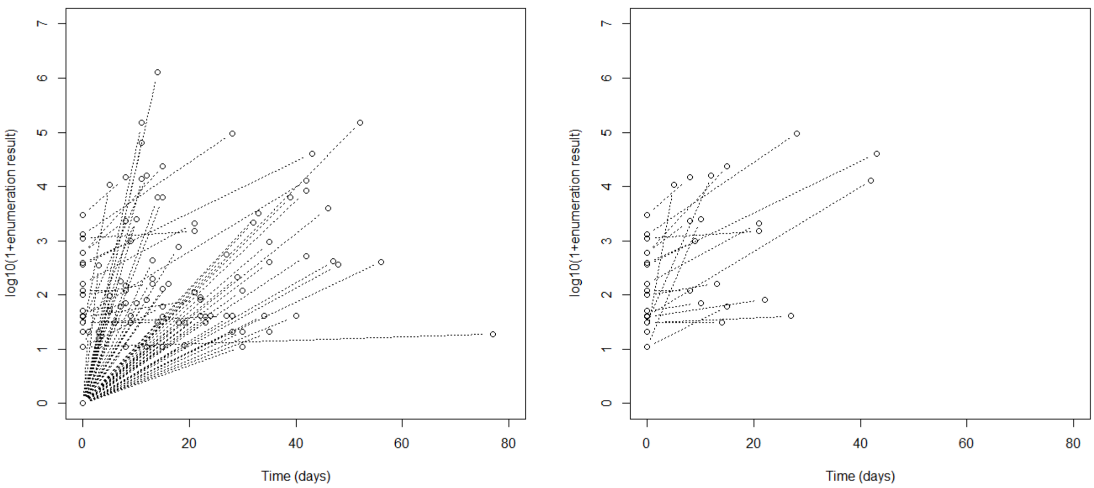


Figure 46: Graphical representation of eligible subset 1a (left panel) and eligible subset 2 (right panel).

7.3. Approach 1: Statistical models.

For this part we consider eligible subsets 1b and 2.

Let y_{cibs} denote the level of contamination by *L. monocytogenes* in samples from country *c*, instance *i*, batch b, sample s, and corresponding covariates x_{ibs} (such as calendar date, temperature, pH, ...).

As an example, let us start with an additive model for $\log_{10}(y_{cibs}+1)$, only including time

$$\log_{10}(y_{cibs}+1) = \mu_c(t_{ibs}) + u_i + v_{ib} + w_{ibs} + \varepsilon_{ibs} ,$$

with $\mu(t)$ the mean growth, u_i the "instance" effect, v_{ib} the effect of batch b at instance i, and w_{ibs} the effect of sample *s* within batch *b* at instance *i* and error term ε_{ibs}. The different effects can be represented through random or fixed effects, but the most natural choice would be

- Fixed effects u_i for the instance
- Random effects $v_{ib} \sim N(0,\sigma_b^2)$ for batch effect
- Random effects $w_{ibs} \sim N(0,\sigma_s^2)$ for sample effect.

The error term can be taken as $\varepsilon_{ibs} \sim N(0,\sigma^2)$

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

For our design and data at hand, it seems necessary and/or recommendable to further simplify this model:

- Given the limited number of eligible data, it seems not feasible to estimate any country effect, implying that $\mu_c(t_{ibs}) = \mu(t_{ibs})$. For simplicity the subscript *c* will be deleted in the sequel.
- Given the limited number of eligible data and as there is no particular instance effected to be expected, it seems natural to absorb the term u_i in the last error term.
- A batch effect is necessary, but as it concerns the same batch at both instances, we can simplify $v_{ib} = v_b$.
- As only one single sample is taken from batch *b* at instance *i*, the sample effect w_{ibs} at a fixed instance cannot be identified, and needs to be simplified to w_{is} . Furthermore, given that there are only two instances (two points in time to evaluate the growth) and only two samples, one at each instance, the effect of instance cannot be disentangled from any time effect, incorporated in the function $\mu(t_{ibs})$. This hampers a more accurate estimation of the growth model $\mu(t_{ibs})$, and for the model formulation the only option is to absorb the term w_{is} in the last error term. For the same reason, we can simplify $t_{ibs} = t_{ib}$
- As only one sample *s* is taken for each batch at each instance, the subscript *s* can be deleted everywhere.

Applying these simplifications to the above model formulation results in the model

$$\log_{10}(y_{ib} + 1) = \mu(t_{ib}) + v_b + \varepsilon_{ib} .$$

Next, time t_{ib}, the time-scale on which bacteria grow on the sample on instance *i* of batch *b*, is batch-specific. All data however should be transferred to a common time scale in order to fit the above model. By using the calendar dates to put all batches to one and the same time point, and adding a batch-specific time-shift Δ_b, one could shift all batches on one and the same time scale

$$t_{ib} = \tau_{ib} + \Delta_b ,$$

with

$$\tau_{ib} = \tau + (d_{2b} - d_{1b})I(i = 2) ,$$

where τ reflects any starting point, such as $\tau = 0$ (taking instance 1) and $(d_{2b} - d_{1b})$ is the difference in dates of testing at the end of shelf-life and date of testing on the arrival at the laboratory, so the time duration between the two measurements of the same batch, and $I(i = 2)$ an indicator that equals 1 for the second occasion and 0 otherwise. In simpler formulas, we have $t_{1b} = \Delta_b$ and $t_{2b} = (d_{2b} - d_{1b}) + \Delta_b$. Note that we observe or know τ_{ib}, but we do not observe the batch-specific time-shift Δ_b; it is a latent parameter.

Inserting the above time-alignment into the model leads to

$$\log_{10}(y_{ib} + 1) = \mu((d_{2b} - d_{1b})I(i = 2) + \Delta_b) + v_b + \varepsilon_{ib} .$$

The next step is to specify the mean function $\mu(.)$ that incorporates the time effect. In the next sections we will specify the mean function in a linear way and a non-linear way.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

7.3.1. Linear model

As only two measurements in time are available for the same batch, we are limited to a two-parameter batch specific model. With a further reduction of eligible data to those that are positive at both instances (eligible subset 2), we can use a straight line model, as the middle part of the "three-line-model", resulting in the following model (for that subset of eligible data), with t_{ib} defined as above

$$\log_{10}(y_{ib}+1) = \beta_0 + \beta_1(\tau_{ib} + \Delta_b) + v_b + \varepsilon_{ib} ,$$

which can be rewritten as

$$\log_{10}(y_{ib}+1) = \beta_0 + b_0 + \beta_1\tau_{ib} + \varepsilon_{ib} ,$$

with

$$b_0 = \beta_1\Delta_b + v_b \ .$$

Assuming a random time-shift effect $\Delta_b \sim (0, \sigma_\Delta^2)$, independent from the batch effect $v_b \sim N(0, \sigma_b^2)$, we have that

$$b_0 \sim N(0,\ \beta_1^2\sigma_\Delta^2 + \sigma_b^2)\ .$$

This is nothing else than a linear mixed model with a random intercept b_0. This random intercept accounts for the time alignment together with the batch effect, and depends on the growth rate β_1; these three components can however not be disentangled. But the main parameter, the slope β_1 characterizes the average bacterial growth

$$E(\log_{10}(y_{ib}+1)) = \beta_0 + \beta_1\tau_{ib}\ .$$

The batch effects b_0 can be estimated from the data (e.g. empirical Bayes estimates), but cannot be decomposed in its two components $\beta_1\Delta_b$ and v_b. Consequently we cannot determine $t_{ib} = \tau_{ib} + \Delta_b$ and no batch-specific plots can be plotted on a common time scale. As shown in the results section, observed and fitted plots can be depicted on the same graph by aligning profile on for instance the time of sample collection.

Interpreting the variance component of the random effect b_0 (equal to $\beta_1^2\sigma_\Delta^2 + \sigma_b^2$) is bit problematic, as well as assessing the goodness of fit of the mean model (the straight line), as alignment and model structure are inherently connected.

Growth starts at the time where the sloping straight line intersects the time-axis, so for $t = -\beta_0/\beta_1$. In principle this could be used to extend the mean function to a broken line model

$$\log_{10}(y_{ib}+1) = \begin{cases} 0 & t_{ib} < -\beta_0/\beta_1 \\ \beta_0 + \beta_1 t_{ib} + v_b + \varepsilon_{ib} & t_{ib} \geq -\beta_0/\beta_1 \end{cases}$$

and to extend the analysis with data from eligible subset 2 to the larger subset 1. But since the condition $t_{ib} < -\beta_0/\beta_1$ cannot be tested, this is not feasible.

7.3.2. Non-linear models

Another option is a non-linear, typically sigmoidal function and there are many possibilities. This has the advantage that all eligible data (subset 1) can be used. However there is no reason to believe that

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

growth reaches its maximum for any of the batches (as they are expected not to reach such a maximum before end of shelf-life time). A first model would be

$$\mu(t_{ib}) = \beta_0 e^{\beta_1 t_{ib}} \quad (1)$$

which continues growing exponentially (only likely for a relative short time range), or by a logistic function

$$\mu(t_{ib}) = \frac{M}{1+\beta_0 e^{-\beta_1 t_{ib}}}. \quad (2)$$

which flattens out if time grows, with a horizontal asymptote $y = M$. However, as this model has three parameters, it is not identifiable. Pragmatic options are to take M equal to the highest value observed over all batches or to perform different analyses with different sensible choices.In this report we have chosen for the first option and the results can be found in Section 8.1.

Another choice is the Gompertz model

$$\mu(t_{ib}) = M e^{(-\beta_0 e^{-\beta_1 t_{ib}})} \quad (3)$$

The full **exponential growth model** (see Equation (1)) becomes

$$\log_{10}(y_{ib}+1) = \beta_0 e^{\beta_1(\tau_{ib}+\Delta_b)} + v_b + \varepsilon_{ib} = b_0 e^{\beta_1 \tau_{ib}} + v_b + \varepsilon_{ib},$$

with multiplicative batch-specific random effect $b_0 = \beta_0 e^{\beta_1 \Delta_b}$.

For the logistic growth curve, we obtain the following full **logistic growth model** (see Equation (2))

$$\log_{10}(y_{ib}+1) = \frac{M}{1+\beta_0 e^{-\beta_1(\tau_{ib}+\Delta_b)}} + v_b + \varepsilon_{ib} = \frac{M}{1+b_0 e^{-\beta_1 \tau_{ib}}} + v_b + \varepsilon_{ib},$$

and for the full **Gompertz growth model** (see Equation (3))

$$\log_{10}(y_{ib}+1) = M e^{(-\beta_0 e^{-\beta_1(\tau_{ib}+\Delta_b)})} + v_b + \varepsilon_{ib} = M e^{(-b_0 e^{-\beta_1 \tau_{ib}})} + v_b + \varepsilon_{ib},$$

where now $b_0 = \beta_0 e^{-\beta_1 \Delta_b}$ acts as a multiplicative batch-specific random effect.

The nonlinearity of the mean function implies that Δ_b and v_b can now not be collapsed into one single random effect. The exponential, logistic and Gompertz model can be fitted without the batch effect v_b (absorbed in the last error term). In any case, the fact that both random effects do not collapse into one random effect for these non-linear models has the advantage that these models allow the estimation of the batch-specific time-shifts Δ_b. More specifically, for the exponential model it holds that $\Delta_b = \frac{1}{\beta_1}\log\frac{b_0}{\beta_0}$ and for the logistic and Gompertz model $\Delta_b = -\frac{1}{\beta_1}\log\frac{b_0}{\beta_0}$.

In the next section we investigate the effect of temperature and pH on the growth of *Listeria monocytogenes*.

7.3.3. Extending growth models with factors affecting growth

As introduced before, let x_{ib} denote the value of factor *x* for the single sample at instance *i* of batch *b*. Some factors are instance specific (such as temperature), others are only available at one instance (e.g. pH was only measured on the arrival at the laboratory). The effect of a factor can be incorporated in

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

the above linear and non-linear models by "varying coefficients", i.e. one or more model parameters may vary with the factor *x*, or in other words may depend on *x*.

7.3.3.1. Linear model

Consider the linear model, with the intercept β_0 now depending on covariate or factor *x*, so for instance in a simple linear way (assuming *x* is a continuous or at least ordinal variable):

$$\beta_0(x) = \beta_0 + \beta_{0x}x ,$$

then the linear model extends to

$$\log_{10}(y_{ib}+1) = (\beta_0 + \beta_{0x}x_{ib}) + b_0 + \beta_1\tau_{ib} + \varepsilon_{ib} = \beta_0 + b_0 + \beta_1\tau_{ib} + \beta_{0x}x_{ib} + \varepsilon_{ib} ,$$

showing that the linear model just extends with an additional term $\beta_x x$. The dependency on *x* can be extended to other parameters. For instance, also the slope $\beta_1$can depend on *x* e.g. in a linear way $\beta_1(x) = \beta_1 + \beta_{1x}x$, leading to a linear model with a time×factor interaction term

$$\begin{aligned}\log_{10}(y_{ib}+1) &= (\beta_0 + \beta_{0x}x_{ib}) + b_0 + (\beta_1 + \beta_{1x}x)\tau_{ib} + \varepsilon_{ib} \\ &= \beta_0 + b_0 + \beta_1\tau_{ib} + \beta_{0x}x_{ib} + \beta_{1x}x \times \tau_{ib} + \varepsilon_{ib}.\end{aligned}$$

In principle this dependency can be extended to more covariates $x_1, x_2, \ldots$, but feasibility depends on the size of the sample at hand.

7.3.3.2. Non-linear model

The similar concept can be applied to the non-linear models. Letting the intercept depend on *x* in these models boils down to:

- For the **exponential growth model**

$$\log_{10}(y_{ib}+1) = \beta_0 e^{\beta_1(\tau_{ib}+\Delta_b)} + v_b + \varepsilon_{ib} = b_0 e^{\beta_{0x}x_{ib}+\beta_1\tau_{ib}} + v_b + \varepsilon_{ib},$$

- For the **logistic growth model**

$$\log_{10}(y_{ib}+1) = \frac{M}{1+\beta_0 e^{-\beta_1(\tau_{ib}+\Delta_b)}} + v_b + \varepsilon_{ib} = \frac{M}{1+b_0 e^{-(\beta_{0x}x_{ib}+\beta_1\tau_{ib})}} + v_b + \varepsilon_{ib},$$

- For the **Gompertz growth model**

$$\log_{10}(y_{ib}+1) = Me^{(-\beta_0 e^{-\beta_1(\tau_{ib}+\Delta_b)})} + v_b + \varepsilon_{ib} = Me^{(-b_0 e^{-(\beta_{0x}x_{ib}+\beta_1\tau_{ib})})} + v_b + \varepsilon_{ib}.$$

Extending the model further with the slope β_1 depending on *x* is in principle more complicated as it also implies an interaction term with the batch specific time-shift (next to an interaction term with time). One could however consider to extend the model only with an interaction term with time, as e.g. for the logistic growth model

$$\log_{10}(y_{ib}+1) = \frac{M}{1+\beta_0 e^{-\beta_1(\tau_{ib}+\Delta_b)}} + v_b + \varepsilon_{ib} = \frac{M}{1+b_0 e^{-(\beta_{0x}x_{ib}+\beta_1\tau_{ib}+\beta_{1x}x\times\tau_{ib})}} + v_b + \varepsilon_{ib},$$

and again this idea can be applied to several covariates $x_1, x_2, \ldots$, with feasibility depending on the size of the sample at hand.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Finally note that the effect of a continuous factor *x* can be extended with more flexible models, such as polynomials models, or fractional polynomials, etc, and in case the factor *x* is nominal/categorical, one needs to apply the same ideas using dummy variables (one less as the number of categories).

The statistical models described above will be fitted with the SAS procedure NLMIXED. For testing hypotheses and corresponding p-values, NLMIXED uses a *t*-distribution with number of degrees of freedom equal to the number of "subjects" (here batches) minus the n umber of random effects. And as stated in Molenberghs and Verbeke (2005) the reported p-values for variance components should be interpreted with great care, due to possible occurrence of boundary problems.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

7.4. Approach 2: Deterministic models.

The main difference with the previous section, is the way we handle the concentration at the date of testing on the arrival at the laboratory. In the previous section, both concentrations are estimated. The current section estimates the concentration at the date of testing at the end of shelf-life, conditional on the concentration at the date of testing on the arrival at the laboratory. Now we consider the data from subset 1a.

For the design and data at hand, it seems necessary and/or recommendable to make the following assumptions:

- Although two different samples are taken from one batch, it is assumed that there is no difference between the samples and they can be considered as two tests on the same sample.

- For samples negative for *Listeria monocytogenes* at the date of testing on the arrival at the laboratory, the concentration should be assumed as <0.04 CFU/g (the value 0 is replaced by 0.04) or assumed as <0.02 CFU/g.

- Another approach is to replace the count of all samples at date of testing on the arrival at the laboratory with the median, 5th and 95th percentiles of the initial concentration of the positive samples at date of testing on the arrival at the laboratory for all 83 samples.

We will evaluate several secondary models that predict the growth rate μ of *L. monocytogenes*, based on storage temperature (at the laboratory), product pH, water activity (a_w), lactate, phenol and nitrite. Based on the growth rate, we predict the concentration of *L. monocytogenes* at date of testing at the end of shelf-life using a simple two-phase primary model:

$$E(N_{ESL}|\mathrm{N}_S, \text{other covariates}) = \begin{cases} N_S & \text{for } t \leq \text{lag} \\ N_S e^{\mu(t-\text{lag})} & \text{for } t > \text{lag} \end{cases} \quad (4)$$

where N_S is the concentration at date of testing on the arrival at the laboratory, N_{ESL} is the concentration at date of testing at the end of shelf-life, t is the time between the two tests, lag is the lag phase of *L. monocytogenes* and μ is the growth rate predicted by a model (see section *7.4.1* for the square-root model, section *7.4.2* for the Mejlholm-Dalgaard model and *7.4.3* for the model of Augustin et al. (2005)).

Another primary model can be applied, but it will typically influence the results only a little. Another primary model used for the current data is the logistic equation with delay (with maximum concentration 10^7) as described in Augustin and Carlier (2000).

Some of the secondary models use information on lactate, nitrite and phenol. We will assume that the negative samples have value zero for all three, while the positive samples have 0.70% lactate, 6 ppm phenol and 0 ppm nitrite (inspired by Uyttendaele et al. (2009)). We will use this information for all samples, although it is typical for cold-smoked salmon.

In the initial study, we will assume that there is no lag phase (lag=0).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

7.4.1. Square-root model

The square-root model includes only the effect of temperature. The growth rate is estimated by

$$\mu = \begin{cases} 0 & \text{for } T \leq T_{\min} \\ \mu_{\text{ref}} \dfrac{(T - T_{\min})^2}{(T_{\text{ref}} - T_{\min})^2} & \text{for } T > T_{\min} \end{cases} \tag{5}$$

where T is the temperature, $T_{\min}$ is the theoretical minimum temperature (°C) preventing growth of *L. monocytogenes* and μ_{ref} is equal to the maximum specific growth rate at the reference temperature T_{ref}.

Delignette-Muller et al. (2006)[30] estimated μ_{ref} and $T_{\min}$ values of 6.24/d (or 0.26/h) and -2.86°C respectively. The reference temperature is 25°C.

Vermeulen et al. (2011) estimate μ_{ref} and $T_{\min}$ values of 0.248 $\log_{10}$/d (equal to 0.010 $\log_{10}$/h or 0.571 ln/d or 0.024 ln/h) and -2°C respectively. The reference temperature is 8°C.

Although other reference values exist, we will only use the above two settings. As information from more potential factors, i.e. more covariates, is included, the models of Mejlholm-Dalgaard and Augustin et al (see below) are supposed to be more accurate and it is therefore considered not worthwhile to investigate the square-root model in much detail.

7.4.2. Mejlholm-Dalgaard model

The second model under consideration is the cardinal parameter model of Mejlholm and Dalgaard model (Mejlholm and Dalgaard, 2009). It includes the effect of temperature, pH and water activity and interaction effects.

Other possible effects in the model are phenol, nitrite, CO_2, acetic acid, benzoic acid, citric acid, diacetate, lactic acid and sorbic acid, but these are omitted from the model (multiply with factor 1 in μ and add 0 in ψ) because no information is available from the survey.

The model is constructed as follows:

$$\begin{aligned} \mu = \mu_{\text{ref}} \left[\frac{T + 2.83}{T_{\text{ref}} + 2.83}\right]^2 \frac{a_w - 0.923}{1 - 0.923} \left[1 - 10^{4.97 - pH}\right] \\ \cdot \left(1 - \frac{LAC_U}{3.79}\right) \frac{32.0 - P}{32.0} \left[\frac{350 - NIT}{350}\right]^2 \xi, \end{aligned} \tag{6}$$

with

$$\xi = \begin{cases} 1 & \text{for } \psi \leq 0.5 \\ 2(1 - \psi) & \text{for } 0.5 < \psi < 1 \\ 0 & \text{for } \psi \geq 1 \end{cases}$$

and

[30] The values of the parameters are taken from Mejlholm et al. (2010).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

$$\psi = \sum_i \frac{\varphi_{e_i}}{2\prod_{j\neq i}(1-\varphi_{e_j})},$$

$$\varphi_T = \left\{1 - \frac{T + 2.83}{T_{\mathrm{ref}} + 2.83}\right\}^2,$$

$$\varphi_{a_w} = \left\{1 - \sqrt{\frac{a_w - 0.923}{1 - 0.923}}\right\}^2,$$

$$\varphi_{pH} = \left\{1 - \sqrt{1 - 10^{4.97 - pH}}\right\}^2,$$

$$\varphi_{LAC_U} = \left\{1 - (1 - \sqrt{\frac{LAC_U}{3.79}})\right\}^2,$$

$$\varphi_P = \left\{1 - \sqrt{\frac{32.0 - P}{32.0}}\right\}^2,$$

$$\varphi_{NIT} = \left\{1 - \frac{350 - NIT}{350}\right\}^2.$$

The parameter T_{ref} is equal to the reference temperature of 25°C and the reference growth rate μ_{ref} is equal to 10.06 ln/d (or 0.419 ln/h).

The unit of lactate in the model is different from the unit in the data. Therefore we use the transformation

$$\mathrm{LAC_U} = (\mathrm{LAC_{\%}} * 104/90.08)/(1 + 10\mathrm{pH} - 3.86).$$

7.4.3. Model of Augustin et al. (2005)

The third model under consideration is the model of Augustin et al. (2005)[31]. Like the Mejlholm-Dalgaard model, it includes the effect of temperature, pH and water activity and interaction effects.

$$\mu = \mu_{ref} CM_2(T) CM_1(pH) \left(\frac{a_w - a_{w,min}}{a_{w,opt} - a_{w,min}}\right)\left(1 - \frac{NIT}{NIT_{MIC}}\right)\left(1 - \frac{P}{P_{MIC}}\right)\xi \qquad (7)$$

,

with

[31] The values of the parameters are taken from Mejlholm et al. (2010).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

$$CM_1(pH) = \frac{(pH - pH_{max})(pH - pH_{min})}{(pH_{opt} - pH_{min})(pH - pH_{opt}) + (pH_{opt} - pH_{max})(pH - pH_{min})}$$

$$if\ pH_{min} < pH < pH_{max}$$

$$CM_2(T) = \frac{(T - T_{max})(T - T_{min})^2}{(T_{opt} - T_{min})\{(T_{opt} - T_{min})(T - T_{opt}) - (T_{opt} - T_{max})[T_{opt} + T_{min} - 2T]\}}$$

$$if\ T_{min} < T < T_{max}$$

$$\xi = \begin{cases} 1 & \text{for } \psi \leq 0.5 \\ 2(1-\psi) & \text{for } 0.5 < \psi < 1 \\ 0 & \text{for } \psi \geq 1 \end{cases}$$

and

$$\psi = \sum_i \frac{\varphi_{e_i}}{2\prod_{j \neq i}(1 - \varphi_{e_j})},$$

$$\varphi(X) = \left(\frac{X_{opt} - X}{X_{opt} - X_{min}}\right)^3,$$

where X is T, pH or a_w and

$$\varphi(NIT, P) = 1 - \left(1 - \frac{NIT}{NIT_{MIC}}\right)\left(1 - \frac{P}{P_{MIC}}\right).$$

The values of the parameters are as follows:

- temperature: minimum -1.72, optimal 37.0, maximum 45.5
- pH: minimum 4.26, optimal 7.10, maximum 9.61
- a_w: minimum 0.913, optimal 0.997, maximum 1
- Nitrite: MIC 25
- Phenol: MIC 31.9
- μ_{ref} 0.565/h (or 13.56/d)

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

7.4.4. Evaluation of the models

The models are evaluated by comparing the observed and predicted growth rates. If we consider the two-phase primary model , the observed growth rate equals

$$\mu_{\text{obs}} = \frac{\ln(N_{\text{ESL}}/N_{\text{S}})}{t}. \quad (8)$$

The comparison of observed and predicted growth rates (μ) was carried out by calculation of bias (9) and accuracy factors (10) (Ross, 1996):

$$\text{Bias factor}(\mu) = 10^{\sum \log_{10}(\mu_{\text{pred}}/\mu_{\text{obs}})/n} \quad (9)$$

$$\text{Accuracy factor}(\mu) = 10^{\sum |\log_{10}(\mu_{\text{pred}}/\mu_{\text{obs}})|/n} \quad (10)$$

The bias factor indicates a systematic over- or underestimation of growth, and the accuracy factor is a measure of the average difference between observed and predicted μ values. The closer the values of bias and accuracy factor are to 1, the better the model performs. In the (unrealistic) case that observed and predicted growth rates are identical, both factors are exactly equal to 1. In all other cases the accuracy factor takes values larger than 1. The higher the value of the accuracy factor, the poorer the performance of the model. The bias factor can take values below and above 1. The bias factor is calculated so that numbers greater than 1 indicate that predicted growth on average is faster than observed growth. As an example, a bias factor of 1.15 indicates that predicted growth on average is 15% faster than observed growth.

If the predicted growth rate equals zero or if the concentration of *L. monocytogenes* at date of testing on the arrival at the laboratory and at date of testing at the end of shelf-life are equal, the bias and accuracy factor cannot be computed and therefore that batch is omitted.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

7.5. Approach 3: Including information of samples with 'decreasing growth'

A lot of samples in the survey are excluded from eligible subset 1. We could include these batches with a decreasing count, by investigating the factors related to the change rate.

The change rate in (log10 of) count is defined by

$$\frac{\log_{10}(\text{count at date 2}) - \log_{10}(\text{count at date 1})}{\text{time between tests}}$$

We examine the relation to the risk factors by means of a GEE model with a Gaussian distribution for the change rate and an identity link function.

We will consider several potential factors: temperature, pH, water activity and preservatives and acidity regulators. Also the count at date of testing on the arrival at the laboratory is included in the models.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

8. Results

This section shows the results of the methods discussed in section 7.3 and 7.4 for the data obtained from the European Union-wide survey, as discussed in section 7.2.

8.1. Approach 1: Statistical models

8.1.1. Linear model

The batch effects b_0 can be estimated from the data (e.g. empirical Bayes estimates), but cannot be decomposed in its two components $\beta_1\Delta_b$ and v_b. Consequently we cannot determine $t_{ib} = \tau_{ib} + \Delta_b$ and no batch-specific plots can be plotted on a common time scale. As shown in Figure 47: , observed and fitted concentrations can be depicted on the same graph by aligning the profile on for instance the time of sample collection.

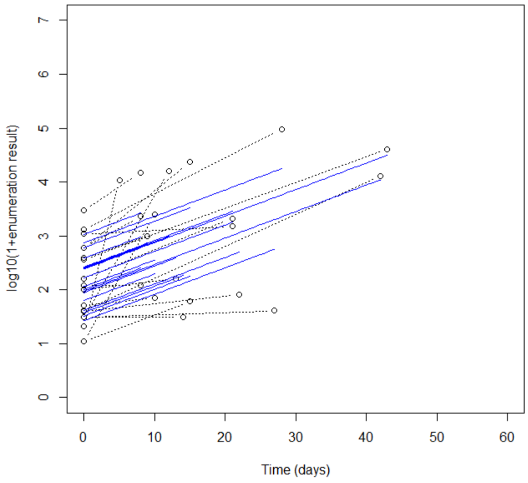


Figure 47: Eligible subset 2. Dots represent the observed concentrations (joined by dotted straight line). The estimated bacterial growth, based on the linear growth model (blue full line).

The parameter estimates of the linear growth model are shown in Table 209: . The estimate of the slope is positive, as expected, and highly significant.

Table 209: Parameter estimates in the linear growth model.

	Estimate	Std.err.	p-value
Exponential growth model			
β_0	2.1809	0.2016	<0.0001
β_1	0.04911	0.0107	0.0002
σ	0.7099	0.1153	0.0001
σ_b	0.5959	0.1793	0.0038

Interpreting the variance component of the random effect b_0 (equal to $\beta_1^2\sigma_\Delta^2 + \sigma_b^2$) is bit problematic, as well as assessing the goodness of fit of the mean model (the straight line), as alignment and model structure are inherently connected.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

8.1.2. Non-linear models

In Table 210: we compare the non-linear models with regard to AIC, while the parameter estimates and standard errors are listed in Table 211: .

The parameter M in the logistic and Gompertz model is fixed at 6.1139, the maximum (log-transformed) concentration. We consider models with and without batch effect. In both cases, the Gompertz model is the best model according to AIC.

Table 210: Comparison of non-linear models with regard to AIC.

	AIC
Models without batch effect v_b	
Exponential	537.6
Logistic (M = 6.1139)	525.3
Gompertz (M = 6.1139)	519.9
Models with batch effect v_b	
Exponential	539.4
Logistic (M = 6.1139)	527.3
Gompertz (M = 6.1139)	521.9

The parameter estimates (see Table 211:) between the models with and without batch effect are nearly the same, because the batch effect is clearly not significant. The slope in the Gompertz model is positive and is highly significant.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 211: Parameter estimates in the non-linear growth models.

	Without batch effect			**With batch effect**		
	Estimate	**Std.err.**	**p-value**	**Estimate**	**Std.err.**	**p-value**
Exponential growth model						
β_0	0.9497	0.1162	<0.0001	0.9402	0.1180	<0.0001
β_1	0.0323	0.004484	<0.0001	0.03270	0.004584	<0.0001
σ	1.0640	0.08935	<0.0001	1.0570	0.08833	<0.0001
σ_Δ	12.9303	2.2761	<0.0001	13.1562	2.2820	<0.0001
σ_b				1.2E-6	0.2054	1.0000
Logistic growth model (M = 6.1139)						
β_0	6.9303	1.2829	<0.0001	6.9303	1.2829	<0.0001
β_1	0.06189	0.007940	<0.0001	0.06189	0.007940	<0.0001
σ	0.9779	0.07863	<0.0001	0.9780	0.07863	<0.0001
σ_Δ	12.4500	1.8397	<0.0001	12.4498	1.8397	<0.0001
σ_b				0.000029	0.1885	0.9999
Gompertz growth model (M = 6.1139)						
β_0	2.1693	0.2036	<0.0001	2.1693	0.2036	<0.0001
β_1	0.03774	0.004525	<0.0001	0.03774	0.004525	<0.0001
σ	0.9682	0.07862	<0.0001	0.9682	0.07862	<0.0001
σ_Δ	11.1581	1.8122	<0.0001	11.1581	1.8122	<0.0001
σ_b				1.7E-6	0.2150	1.0000

Figure 48: and Figure 49: show the estimated profiles of the non-linear models (respectively without and with batch effect). As the batch effect is not significant, there are hardly any differences between the figures. For each batch, the estimated profile (coloured lines) is compared to the observed profile (black dots and dashed lines). The latter is represented by a straight line because only two concentrations are measured. We can see that the batch-specific time-shifts are quite well estimated by the model, because the observed and predicted profiles almost overlap.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

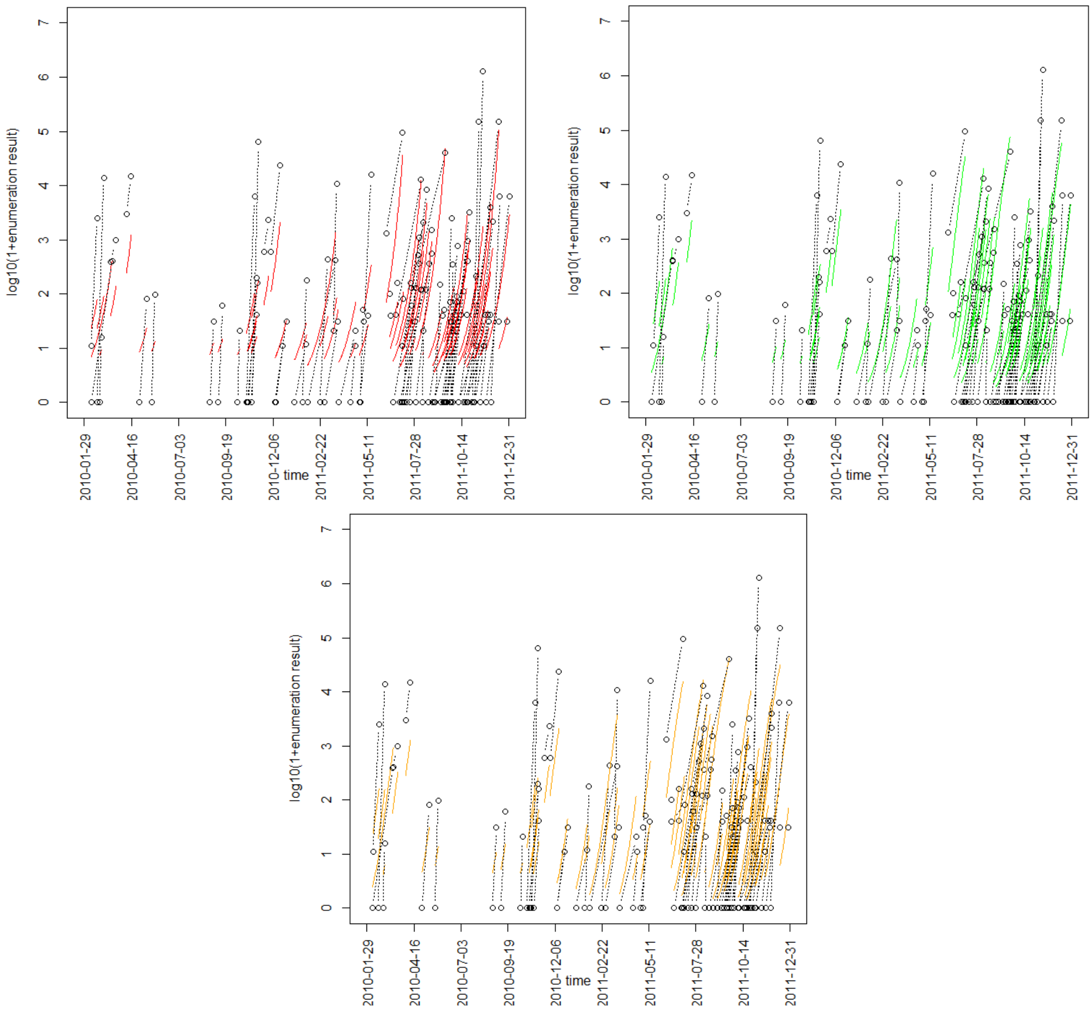


Figure 48: Eligible subset 1b. Graphical representation of the data with respect to the calendar dates. Δ_b is estimated in each of the non-linear models (without batch effect v_b) to account for the time shift. Profiles are shown for the exponential (red), logistic (green) and Gompertz (orange) model.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

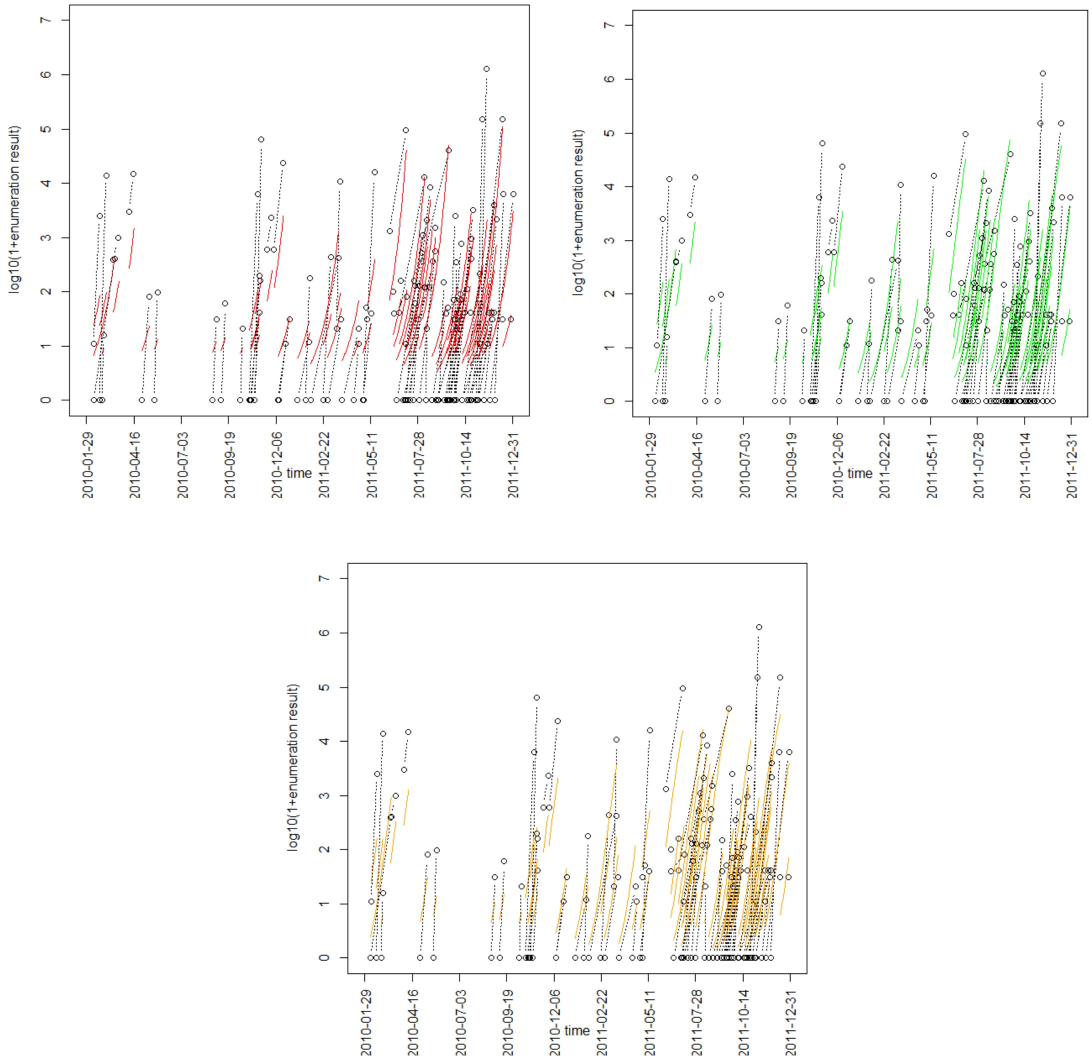


Figure 49: Eligible subset 1b. Graphical representation of the data with respect to the calendar dates. Δ_b is estimated in each of the non-linear models (with batch effect v_b) to account for the time shift. Profiles are shown for the exponential (red), logistic (green) and Gompertz (orange) model.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Figure 50: shows the fitted population-averaged growth model, after integration over the random effects. The figure compares the pattern of each model, but the initial date of testing is fixed. In the previous figures all lines seem practically linear, but in this figure you can see the differences more clearly. Note that the integration over the random effects is straightforward for the linear model, but needs numerical integration for the non-linear models. For instance for the Gompertz model, the fitted population-averaged growth model equals

$$E(\log_{10}(y_{ib}+1)) = E(Me^{(-b_0 e^{-\beta_1 \tau_{ib}})} + v_b + \varepsilon_{ib})$$

$$= ME(e^{(-b_0 e^{-\beta_1 \tau_{ib}})}) + 0 + 0) = M\int_0^\infty e^{(-x e^{-\beta_1 \tau_{ib}})} f(x)dx \ .$$

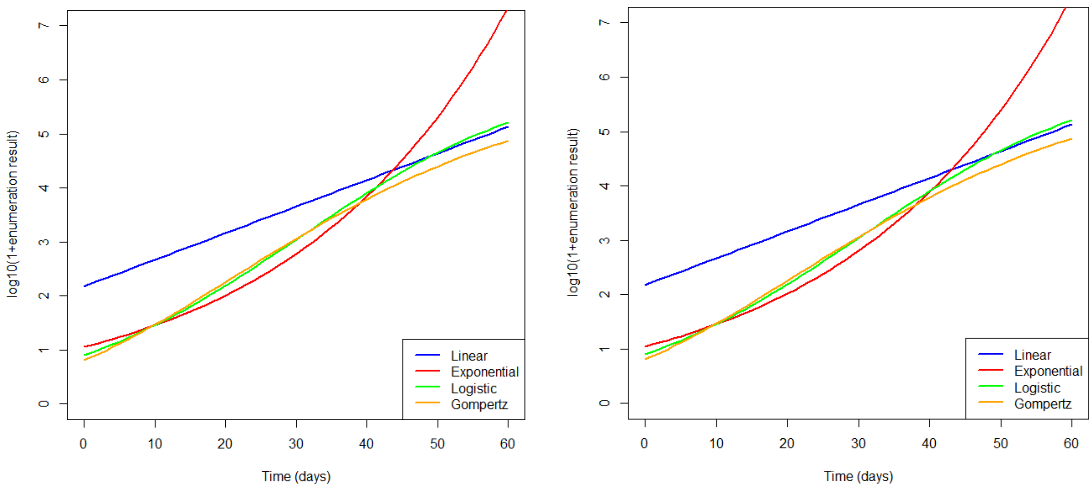


Figure 50: Population-averaged growth models for the linear (blue), exponential (red), logistic (green) and Gompertz (orange) model. Left panel: without batch effect v_b; Right panel: with batch effect v_b.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

8.1.3. Extending growth models with factors affecting growth

8.1.3.1. Temperature

The temperature of the batch was measured twice. In Figure 51: we match the temperature at the retail store with the date of testing on the arrival at the laboratory (this is the temperature that can possibly have an effect on the count of *Listeria monocytogenes* at the arrival at the laboratory) and we match the temperature at the laboratory with the date of testing at the end of shelf-life.

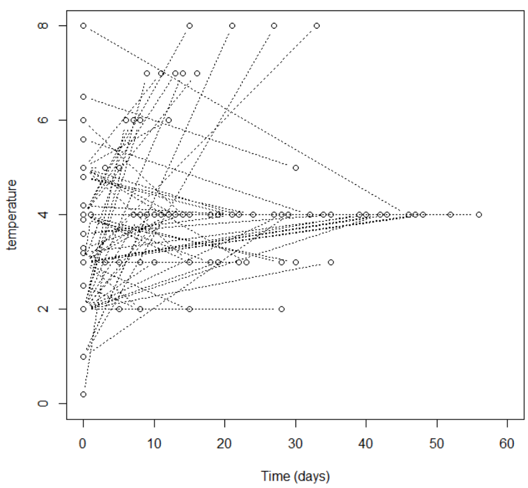


Figure 51: Changes in temperature for the 81 eligible batches.

The parameter estimates for the linear model with covariate temperature are given in Table 212: . The effect of temperature is negative, but not significant. If we extend the model with an interaction between time between the two tests and temperature, the interaction is not significant (see Table 213:).

Table 212: Parameter estimates in the linear growth model adjusted for temperature in a simple linear way.

	Estimate	Std.err.	p-value
Linear growth model			
β_0	2.3027	0.3263	<0.0001
β_1	0.0516	0.0119	0.0004
β_{0x}	-0.0425	0.0897	0.6413
σ	0.7102	0.1157	<0.0001
σ_b	0.5892	0.1802	0.0043

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 213: Parameter estimates in the linear growth model adjusted for temperature with interaction term.

	Estimate	Std.err.	p-value
Linear growth model			
β_0	1.7434	0.4412	0.0009
β_1	0.1129	0.0358	0.0055
β_{0x}	0.1427	0.1334	0.2989
β_{1x}	-0.0162	0.0091	0.0900
σ	0.6499	0.1075	<0.0001
σ_b	0.6303	0.1709	0.0017

As shown in Table 214: , including the temperature in the linear model, does not improve AIC.

Table 214: Comparison of linear growth models adjusted for temperature.

	AIC
Unadjusted	106.5
Adjusted in simple linear way	108.3
Adjusted with interaction term	107.2

Compared to the exponential and logistic model, the Gompertz model again fits the data best. AIC of all three models is shown in Table 215: .

Table 215: Comparison of non-linear growth models adjusted for temperature in a simple linear way.

	AIC
Models without batch effect v_b	
Exponential	537.3
Logistic (M = 6.1139)	524.8
Gompertz (M = 6.1139)	519.6
Models with batch effect v_b	
Exponential	539.3
Logistic (M = 6.1139)	526.8
Gompertz (M = 6.1139)	521.6

The parameter estimates for the non-linear models with temperature as the single covariate, are given in Table 216: . Like AIC already indicated, the effect of the temperature is not significant.

Table 216: Parameter estimates in the non-linear growth models adjusted for temperature in a simple linear way.

	Without batch effect	With batch effect

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

	Estimate	Std.err.	p-value	Estimate	Std.err.	p-value
Exponential growth model						
β_0	0.7214	0.1659	<0.0001	0.7214	0.1659	<0.0001
β_1	0.03266	0.004599	<0.0001	0.03266	0.004599	<0.0001
β_{0x}	0.06600	0.04514	0.1477	0.06600	0.04514	0.1477
σ	1.0341	0.08761	<0.0001	1.0341	0.08761	<0.0001
σ_Δ	13.7347	2.3045	<0.0001	13.7347	2.3045	<0.0001
σ_b				-6.9E-6	0.2094	1.0000
Logistic growth model (M = 6.1139)						
β_0	10.6848	3.7123	0.0051	10.6848	3.7123	0.0051
β_1	0.06178	0.007862	<0.0001	0.06178	0.007862	<0.0001
β_{0x}	0.1085	0.06971	0.1235	0.1085	0.06971	0.1236
σ	0.9526	0.07719	<0.0001	0.9526	0.07718	<0.0001
σ_Δ	13.1062	1.8969	<0.0001	13.1063	1.8969	<0.0001
σ_b				-0.00002	0.1855	0.9999
Gompertz growth model (M = 6.1139)						
β_0	2.7285	0.5143	<0.0001	2.7285	0.5143	<0.0001
β_1	0.03776	0.004511	<0.0001	0.03776	0.004511	<0.0001
β_{0x}	0.05739	0.03899	0.1450	0.05739	0.03899	0.1450
σ	0.9401	0.07755	<0.0001	0.9401	0.07755	<0.0001
σ_Δ	11.9129	1.8585	<0.0001	11.9130	1.8585	<0.0001
σ_b				-2E-6	0.2038	1.0000

By comparing Table 215: and Table 217: , we can say that there is no benefit of including an interaction term in the non-linear models.

Table 217: Comparison of non-linear growth models adjusted for temperature with interaction term.

	AIC
Models without batch effect v_b	
Exponential	539.3
Logistic (M = 6.1139)	526.8
Gompertz (M = 6.1139)	521.4
Models with batch effect v_b	
Exponential	541.3
Logistic (M = 6.1139)	528.8
Gompertz (M = 6.1139)	523.4

The parameter estimates in Table 218: also show that the interaction is not significant.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 218: Parameter estimates in the non-linear growth models adjusted for temperature with interaction term.

	Without batch effect			With batch effect		
	Estimate	**Std.err.**	**p-value**	**Estimate**	**Std.err.**	**p-value**
Exponential growth model						
β_0	0.7371	0.2236	0.0015	0.7371	0.2236	0.0015
β_1	0.03101	0.01586	0.0541	0.03101	0.01586	0.0541
β_{0x}	0.06043	0.06836	0.3793	0.06043	0.06836	0.3793
β_{1x}	0.000407	0.003753	0.9139	0.000407	0.003753	0.9139
σ	1.0348	0.08796	<0.0001	1.0348	0.08796	<0.0001
σ_Δ	14.4330	7.2144	0.0488	14.4330	7.2143	0.0489
σ_b				-0.00001	0.2084	1.0000
Logistic growth model (M = 6.1139)						
β_0	10.0023	4.3977	0.0256	10.0025	4.3979	0.0257
β_1	0.05574	0.02607	0.0356	0.05574	0.02607	0.0356
β_{0x}	0.09150	0.09892	0.3578	0.09150	0.09892	0.3578
β_{1x}	0.001486	0.006140	0.8094	0.001485	0.006140	0.8095
σ	0.9545	0.07785	<0.0001	0.9545	0.07785	<0.0001
σ_Δ	14.4358	6.4657	0.0284	14.4357	6.4655	0.0284
σ_b				-3.5E-6	0.1850	1.0000
Gompertz growth model (M = 6.1139)						
β_0	2.5546	0.6014	<0.0001	2.5545	0.6014	<0.0001
β_1	0.03111	0.01520	0.0440	0.03111	0.01520	0.0440
β_{0x}	0.04042	0.05375	0.4543	0.04042	0.05375	0.4543
β_{1x}	0.001636	0.003593	0.6501	0.001636	0.003593	0.6502
σ	0.9444	0.07876	<0.0001	0.9444	0.07875	<0.0001
σ_Δ	14.2293	6.6107	0.0344	14.2292	6.6105	0.0344
σ_b				-0.00003	0.2043	0.9999

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

8.1.3.2. pH

The pH of the batch was measured only on the arrival at the laboratory. We assume that pH remains constant over the rest of the shelf-life. The following tables show that the effect of pH on concentration in the linear and non-linear models is not significant.

Table 219: Parameter estimates in the linear growth model adjusted for pH in a simple linear way.

	Estimate	Std.err.	p-value
Exponential growth model			
β_0	-2.6796	2.8902	0.3661
β_1	0.04888	0.01062	0.0002
β_{0x}	0.8115	0.4813	0.1090
σ	0.7100	0.1154	<0.0001
σ_b	0.5252	0.1812	0.0096

Table 220: Parameter estimates in the linear growth model adjusted for pH with interaction term.

	Estimate	Std.err.	p-value
Exponential growth model			
β_0	-9.2967	9.1564	0.3234
β_1	1.9218	1.5180	0.2217
β_{0x}	2.1884	2.7280	0.4329
β_{1x}	-0.3462	0.4527	0.4544
σ	1.0052	0.1713	<0.0001
σ_b	0.1534	0.8494	0.8587

Based on AIC, the model adjusted for pH in a simple linear way is preferred over the unadjusted. Including the interaction term does not improve the model.

Table 221: Comparison of linear growth models adjusted for pH

	AIC
Unadjusted	106.5
Adjusted in simple linear way	105.9
Adjusted with interaction term	107.5

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

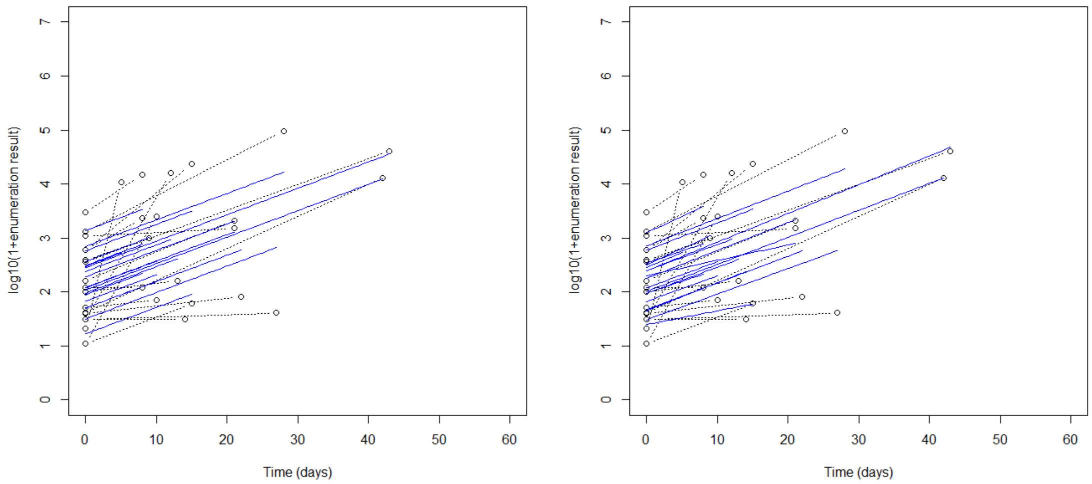


Figure 52: Eligible subset 2: Profiles of eligible batches, with estimated bacterial growth adjusted for pH. Left panel: in a simple linear way. Right panel: with interaction effect.

We could also include pH in the non-linear growth models. The following tables and figures show the results for the non-linear growth models. The Gompertz model is the best model based on AIC, both for models with and without batch effect.

Table 222: Comparison of non-linear growth models adjusted for pH in a simple linear way

	AIC
Models without batch effect v_b	
Exponential	537.6
Logistic (M = 6.1139)	525.6
Gompertz (M = 6.1139)	520.2
Models with batch effect v_b	
Exponential	539.6
Logistic (M = 6.1139)	527.6
Gompertz (M = 6.1139)	522.2

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 223: Parameter estimates in the non-linear growth models adjusted for pH in a simple linear way.

	Without batch effect			With batch effect		
	Estimate	**Std.err.**	**p-value**	**Estimate**	**Std.err.**	**p-value**
Exponential growth model						
β_0	0.09082	0.1620	0.5766	0.09082	0.1620	0.5766
β_1	0.03293	0.004554	<0.0001	0.03293	0.004554	<0.0001
β_{0x}	0.3872	0.2928	0.1898	0.3872	0.2928	0.1898
σ	1.0557	0.08725	<0.0001	1.0557	0.08725	<0.0001
σ_Δ	12.7833	2.2482	<0.0001	12.7833	2.2482	<0.0001
σ_b				-1.7E-6	0.2088	1.0000
Logistic growth model (M = 6.1139)						
β_0	249.80	688.33	0.7176	249.83	688.41	0.7176
β_1	0.06205	0.007925	<0.0001	0.06205	0.007925	<0.0001
β_{0x}	0.5948	0.4531	0.1930	0.5948	0.4531	0.1930
σ	0.9795	0.07904	<0.0001	0.9795	0.07904	<0.0001
σ_Δ	12.1156	1.8496	<0.0001	12.1156	1.8496	<0.0001
σ_b				-3.55E-6	0.1942	1.0000
Gompertz growth model (M = 6.1139)						
β_0	15.1169	22.6077	0.5056	15.1167	22.6074	0.5057
β_1	0.03785	0.004515	<0.0001	0.03785	0.004515	<0.0001
β_{0x}	0.3221	0.2462	0.1945	0.3221	0.2462	0.1945
σ	0.9700	0.07919	<0.0001	0.9700	0.07919	<0.0001
σ_Δ	10.8403	1.8352	<0.0001	10.8403	1.8352	<0.0001
σ_b				-0.00005	0.2227	0.9998

If we include an interaction term in the non-linear growth models, the AIC does not improve.

Table 224: Comparison of non-linear growth models adjusted for pH with interaction term

	AIC
Models without batch effect v_b	
Exponential	539.5
Logistic (M = 6.1139)	527.5
Gompertz (M = 6.1139)	522.0
Models with batch effect v_b	
Exponential	541.5
Logistic (M = 6.1139)	529.5
Gompertz (M = 6.1139)	524.0

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 225: Parameter estimates in the non-linear growth models adjusted for pH with interaction term.

	Without batch effect			With batch effect		
	Estimate	**Std.err.**	**p-value**	**Estimate**	**Std.err.**	**p-value**
Exponential growth model						
β_0	0.04859	0.1254	0.6995	0.04858	0.1254	0.6995
β_1	0.06600	0.09608	0.4941	0.06600	0.09608	0.4941
β_{0x}	0.4917	0.4270	0.2530	0.4917	0.4270	0.2530
β_{1x}	-0.00553	0.01604	0.7310	-0.00553	0.01604	0.7310
σ	1.0626	0.09054	<0.0001	1.0626	0.09054	<0.0001
σ_Δ	6.2200	9.5611	0.5172	6.2199	9.5607	0.5172
σ_b				5.5E-6	0.2150	1.0000
Logistic growth model (M = 6.1139)						
β_0	198.41	716.23	0.7825	194.40	716.21	0.7825
β_1	0.04684	0.1554	0.7639	0.04684	0.1554	0.7640
β_{0x}	0.5564	0.5973	0.3544	0.5564	0.5973	0.3544
β_{1x}	0.002543	0.02597	0.9222	0.002544	0.02597	0.9222
σ	0.9781	0.08017	<0.0001	0.9781	0.08017	<0.0001
σ_Δ	16.1206	54.2259	0.7670	16.1221	54.2353	0.7670
σ_b				4.6E-6	0.1932	1.0000
Gompertz growth model (M = 6.1139)						
β_0	10.3989	19.1335	0.5883	10.3999	19.1355	0.5883
β_1	0.009048	0.08509	0.9156	0.009050	0.08509	0.9156
β_{0x}	0.2598	0.3044	0.3959	0.2598	0.3044	0.3959
β_{1x}	0.004816	0.01422	0.7358	0.004815	0.01422	0.7358
σ	0.9661	0.07945	<0.0001	0.9661	0.07945	<0.0001
σ_Δ	45.8536	432.59	0.9159	45.8396	432.33	0.9158
σ_b				6.5E-6	0.2203	1.0000

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

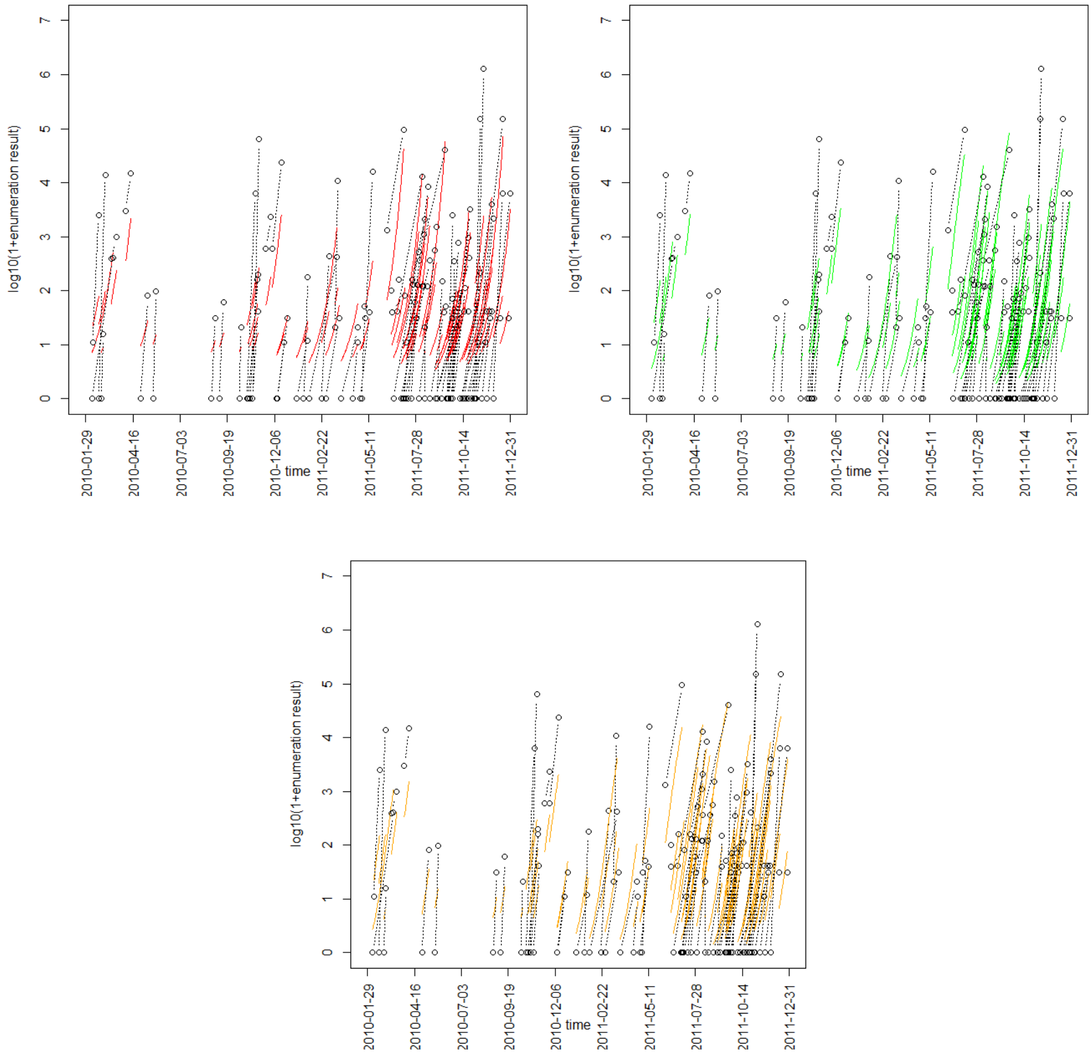


Figure 53: Graphical representation of the data with respect to the calendar dates. Δ_b is estimated in each of the non-linear models (without batch effect v_b) to account for the time shift. Adjusted for pH in a simple linear way.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

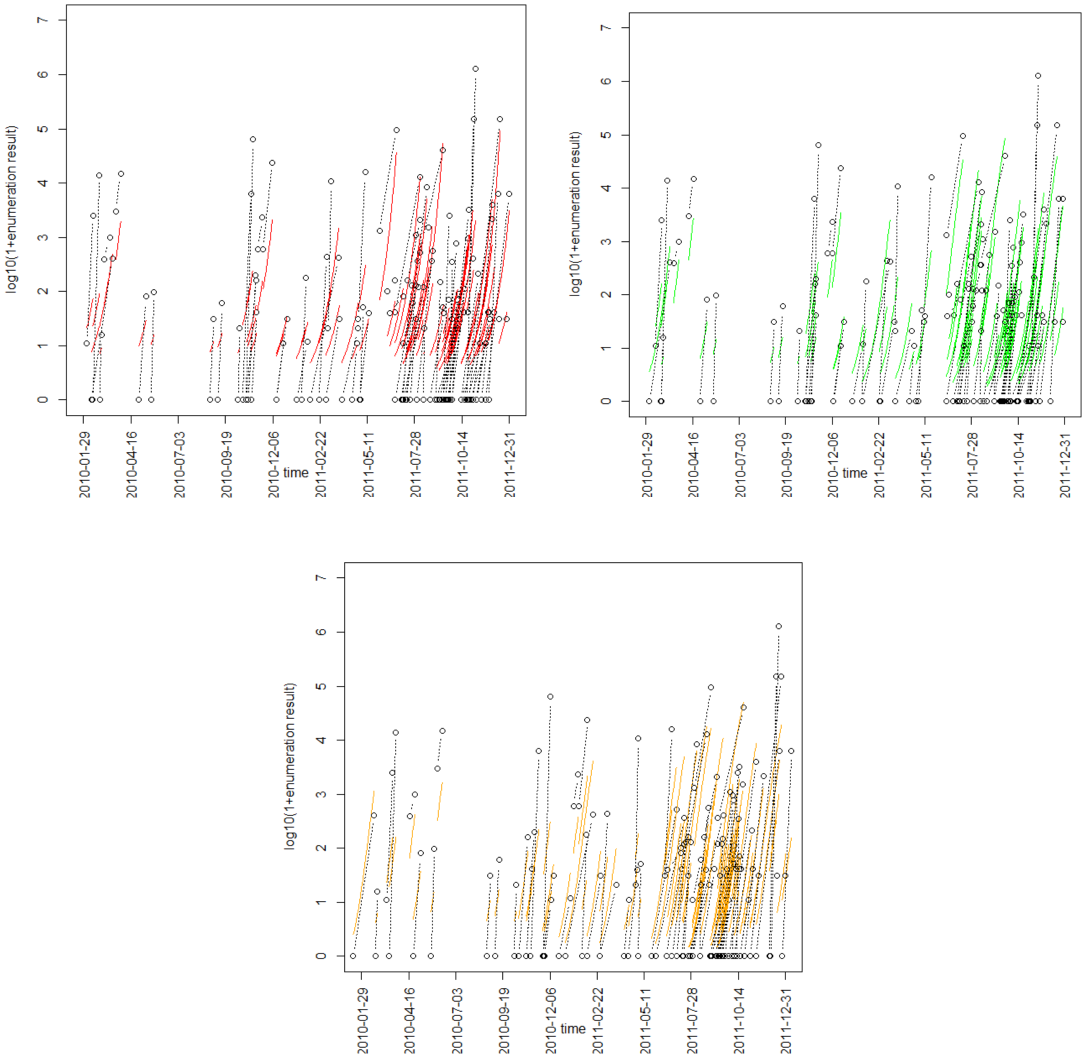


Figure 54: Graphical representation of the data with respect to the calendar dates. Δ_b is estimated in each of the non-linear models (without batch effect v_b) to account for the time shift. Adjusted for pH with interaction term.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

8.1.3.3. Water activity

The water activity of the batch was measured only on the arrival at the laboratory. We assume that the water activity remains constant over the rest of the shelf-life. The following tables show that the effect of water activity on concentration in the linear models is not significant.

Table 226: Parameter estimates in the linear growth model adjusted for a_w in a simple linear way.

	Estimate	Std.err.	p-value
Exponential growth model			
β_0	-8.4131	19.4917	0.6711
β_1	0.0489	0.0107	0.0002
β_{0x}	10.9888	20.2167	0.5934
σ	0.7100	0.1154	<0.0001
σ_b	0.5878	0.1795	0.0042

Table 227: Parameter estimates in the linear growth model adjusted for a_w with interaction term.

	Estimate	Std.err.	p-value
Exponential growth model			
β_0	-6.7556	21.9202	0.7615
β_1	-0.1213	1.0296	0.9075
β_{0x}	9.2711	22.7314	0.6882
β_{1x}	0.1763	1.0663	0.8705
σ	0.7094	0.1153	<0.0001
σ_b	0.5883	0.1793	0.0042

Based on AIC, the model adjusted for water activity in a simple linear way is preferred over the unadjusted. Including the interaction term does not improve the model.

Table 228: Comparison of linear growth models adjusted for a_w

	AIC
Unadjusted	106.5
Adjusted in simple linear way	108.2
Adjusted with interaction term	110.2

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

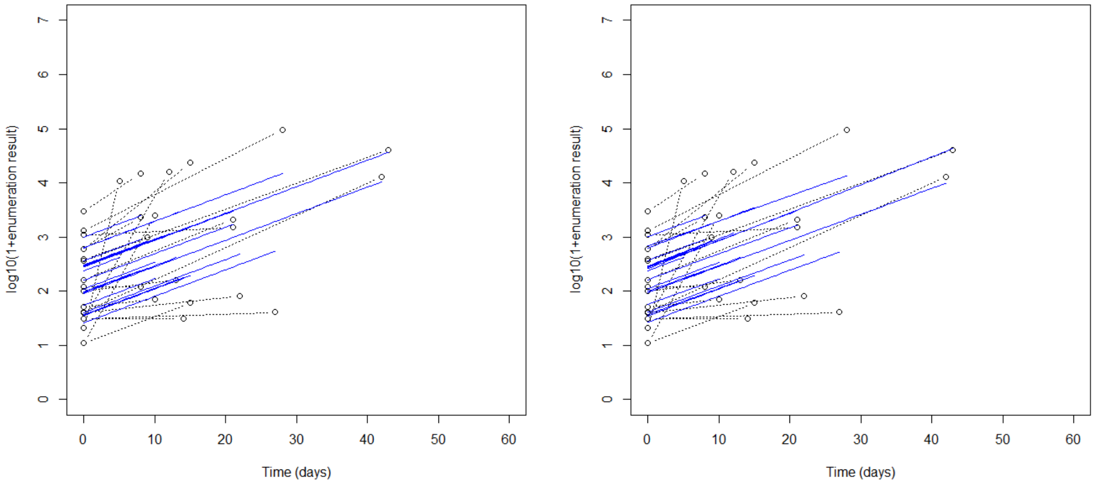


Figure 55: Eligible subset 2: Profiles of eligible batches, with estimated bacterial growth adjusted for a_w. Left panel: in a simple linear way. Right panel: with interaction effect.

We could also include water activity in the non-linear growth models. The following tables and figures show the results for the non-linear growth models. The Gompertz model is again the best model based on AIC, both for models with and without batch effect. The effect of water activity on the intercept is significant in the Gompertz model.

Table 229: Comparison of non-linear growth models adjusted for a_w in a simple linear way

	AIC
Models without batch effect v_b	
Exponential	535.8
Logistic (M = 6.1139)	522.7
Gompertz (M = 6.1139)	517.5
Models with batch effect v_b	
Exponential	537.6
Logistic (M = 6.1139)	524.7
Gompertz (M = 6.1139)	519.5

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 230: Parameter estimates in the non-linear growth models adjusted for a_w in a simple linear way.

	Without batch effect			With batch effect		
	Estimate	**Std.err.**	**p-value**	**Estimate**	**Std.err.**	**p-value**
Exponential growth model						
β_0	0.0000	0.0001	0.8584	0.0000	0.0001	0.8603
β_1	0.0336	0.0046	<.0001	0.0340	0.0047	<.0001
β_{0x}	11.0583	5.7678	0.0588	11.1945	5.8466	0.0592
σ	1.0501	0.0878	<.0001	1.0438	0.0867	<.0001
σ_Δ	12.3048	2.1533	<.0001	12.5026	2.1575	<.0001
σ_b				0.0000	0.2011	1.0000
Logistic growth model (M = 6.1139)						
β_0	3.2 E9	3.1 E10	0.9167	3.2 E9	3.1 E10	0.9167
β_1	0.0641	0.0081	<.0001	0.0641	0.0081	<.0001
β_{0x}	20.6995	9.8451	0.0387	20.6996	9.8451	0.0387
σ	0.9669	0.0767	<.0001	0.9669	0.0767	<.0001
σ_Δ	11.7833	1.7511	<.0001	11.7833	1.7511	<.0001
σ_b				0.0000	0.1872	1.0000
Gompertz growth model (M = 6.1139)						
β_0	1.2 E5	6.2 E5	0.8514	1.2 E5	6.2 E5	0.8513
β_1	0.0389	0.0046	<.0001	0.0389	0.0046	<.0001
β_{0x}	11.2966	5.4985	0.0432	11.2898	5.4979	0.0433
σ	0.9568	0.0768	<.0001	0.9569	0.0768	<.0001
σ_Δ	10.6846	1.7169	<.0001	10.6844	1.7170	<.0001
σ_b				0.0000	0.2094	1.0000

If we include an interaction term in the non-linear growth models, the AIC does not improve, except for the exponential model with batch effect.

Table 231: Comparison of non-linear growth models adjusted for a_w with interaction term

	AIC
Models without batch effect v_b	
Exponential	537.4
Logistic (M = 6.1139)	523.3
Gompertz (M = 6.1139)	517.1
Models with batch effect v_b	
Exponential	525.4
Logistic (M = 6.1139)	525.3
Gompertz (M = 6.1139)	519.9

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 232: Parameter estimates in the non-linear growth models adjusted for a_w with interaction term.

	Without batch effect			**With batch effect**		
	Estimate	**Std.err.**	**p-value**	**Estimate**	**Std.err.**	**p-value**
Exponential growth model						
β_0	0.00025	0.00199	0.9002	0.000361	0.002864	0.8999
β_1	-0.08041	0.244	0.7426	-0.08832	0.2438	0.7182
β_{0x}	8.527	8.2324	0.3034	8.1469	8.2132	0.3243
β_{1x}	0.1191	0.2542	0.6407	0.1273	0.2541	0.6177
σ	1.0395	0.08656	<.0001	1.0397	0.08663	<.0001
σ_Δ	-5.336	16.0879	0.741	-4.8554	13.3075	0.7162
σ_b				-4.65E-06	0.1983	1
Logistic growth model (M = 6.1139)						
β_0	3.54E+05	4.18E+06	0.9329	3.54E+05	4.18E+06	0.9329
β_1	-0.4256	0.4139	0.3069	-0.4256	0.4139	0.307
β_{0x}	11.2243	12.2715	0.3631	11.2243	12.2715	0.3631
β_{1x}	0.5102	0.432	0.241	0.5102	0.432	0.2411
σ	0.9593	0.07602	<.0001	0.9593	0.07602	<.0001
σ_Δ	-1.7906	1.7378	0.3059	-1.7906	1.7379	0.306
σ_b				9.64E-06	0.185	1
Gompertz growth model (M = 6.1139)						
β_0	456.97	2813.29	0.8714	330.62	2029.5	0.871
β_1	-0.3259	0.2385	0.1756	-0.333	0.2383	0.1662
β_{0x}	5.5376	6.3835	0.3883	5.2019	6.3657	0.4163
β_{1x}	0.3803	0.249	0.1307	0.3876	0.2488	0.1233
σ	0.9468	0.0759	<.0001	0.947	0.07595	<.0001
σ_Δ	-1.2789	0.9533	0.1835	-1.2511	0.9122	0.1741
σ_b				0.000058	0.2099	0.9998

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

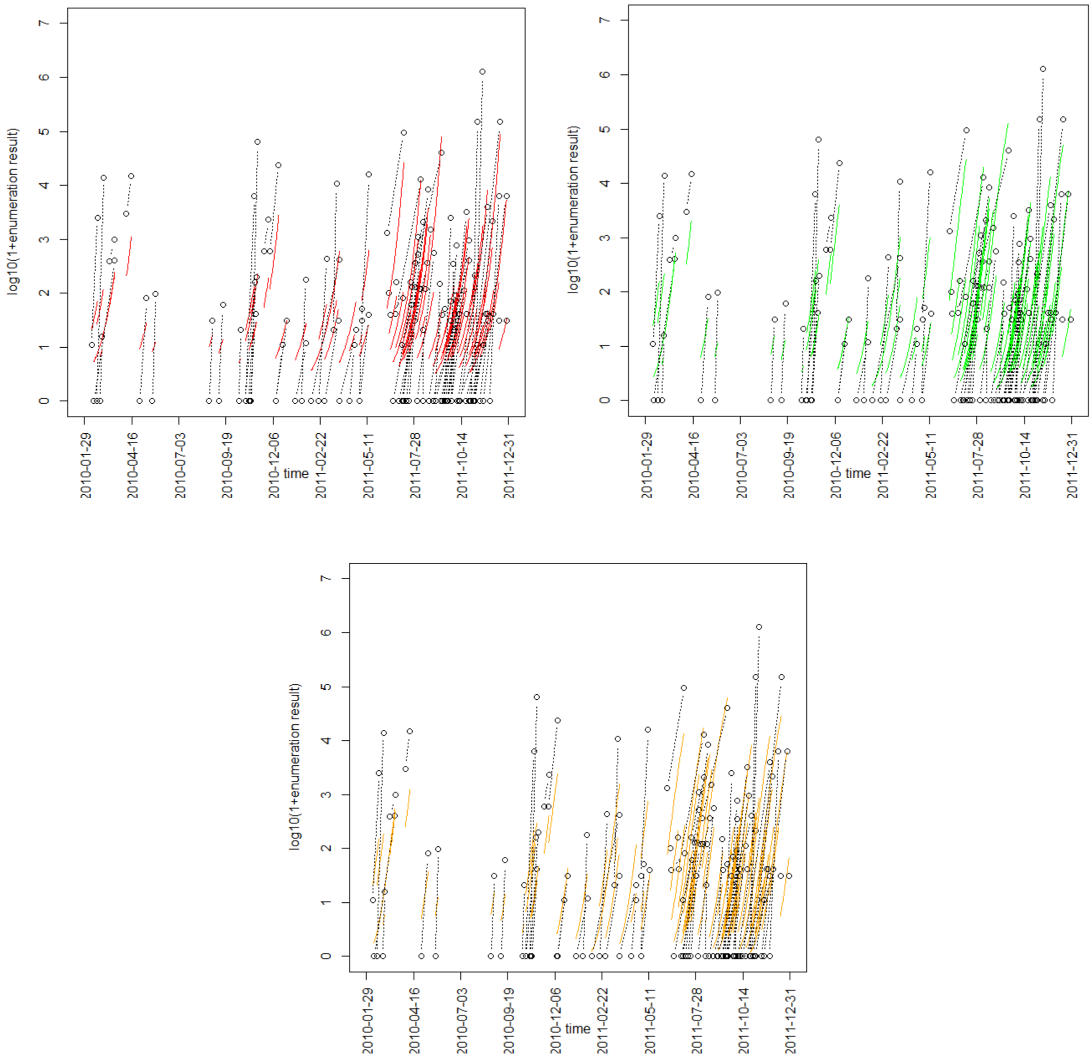


Figure 56: Graphical representation of the data with respect to the calendar dates. Δ_b is estimated in each of the non-linear models (without batch effect v_b) to account for the time shift. Adjusted for a_w in a simple linear way.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

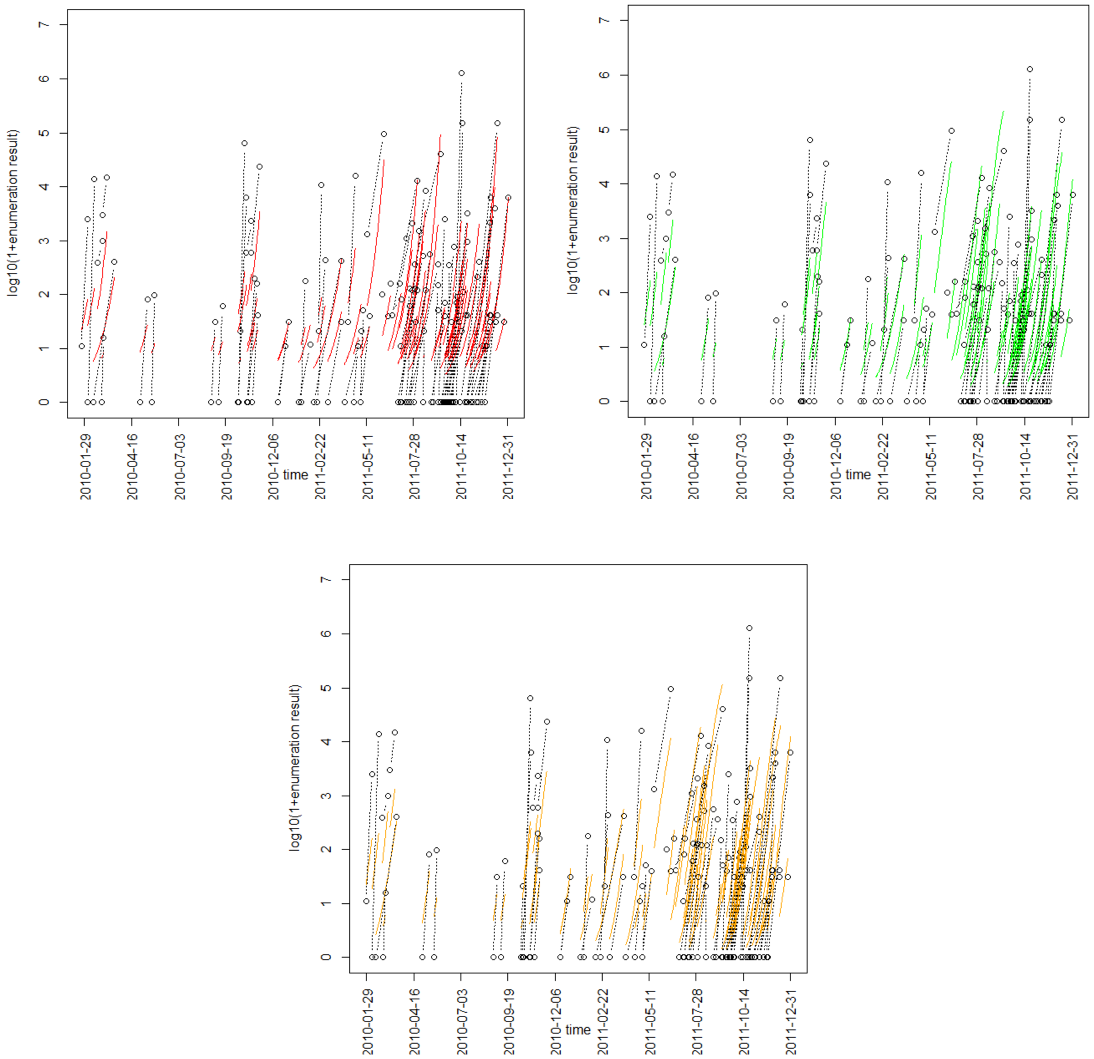


Figure 57: Graphical representation of the data with respect to the calendar dates. Δ_b is estimated in each of the non-linear models (without batch effect v_b) to account for the time shift. Adjusted for a_w with interaction term.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

8.2. Approach 2: Deterministic models

Two batches have equal concentration of *L. monocytogenes* at the date of testing on the arrival at the laboratory and at the date of testing at the end of shelf-life; both are positive. These batches are omitted when computing the bias and accuracy factor, resulting in a total of 81 batches. The figures include all batches. The predicted counts of *Listeria monocytogenes* are sometimes larger than 10^7, due to the lack of a stationary phase in the models. Because such high values of the count are unlikely, the graphs of the predicted counts are truncated at $\log_{10}(10^7)$ or equivalently the counts are equal to the minimum of 10^7 and the prediction from the model.

Table 233: shows the bias and accuracy of the models discussed in section 7.4. In the upper part the counts of negative samples have been replaced by 0.04CFU/g or 0.02CFU/g. Comparing the values of the bias and accuracy factors to the ideal value of 1, the model of Delignette and Muller seems to perform best when using all samples, taking over by the model of Augustin et al and Mejholm et al when using only the samples that are positive at the date of testing on the arrival at the laboratory. In the lower part the count of all samples at the date of testing on the arrival at the laboratory is replaced by a percentile of the positive samples at the date of testing on the arrival at the laboratory. Now the model of Augustin et al performs best using all samples, while the model of Mejlholm et al performs mostly better when using only the samples that are positive at the date of testing on the arrival at the laboratory.

Table 233: Bias and accuracy for primary model (4), based on all samples (all) or only the samples positive at the date of testing on the arrival at the laboratory. The first column shows how the concentrations at the date of testing on the arrival at the laboratory are dealt with: for the first two cases the negative concentrations are replaced by a detection limit (0.04) or half this value; for the last case all concentrations at the date of testing on the arrival at the laboratory are replaced by the 5%, 50% or 95% percentile.

		Exponential growth with base e					
		all			positives		
		bias	accuracy	number	bias	accuracy	number
Negative samples replaced by 0.04	Delignette and Muller	1.112	2.319	81	3.751	5.180	18
	Vermeulen	0.603	2.737	81	2.012	3.947	18
	Mejlholm et al.	0.687	2.673	76	2.402	3.753	16
	Mejlholm et al. [(a)]	0.620	2.583	75	1.561	3.234	15
	Mejlholm et al. [(b)]	0.421	3.521	75	1.561	3.234	15
	Augustin et al.	0.505	3.100	71	1.502	3.207	16
	Augustin et al. [(a)]	0.405	3.316	64	0.722	5.312	9
	Augustin et al. [(b)]	0.254	5.703	41	0.722	5.312	9
Negative samples replaced by 0.02	Delignette and Muller	1.042	2.342	81	3.751	5.180	18
	Vermeulen	0.565	2.876	81	2.012	3.947	18
	Mejlholm et al.	0.643	2.788	76	2.402	3.753	16
	Mejlholm et al. [(a)]	0.580	2.696	75	1.561	3.234	15
	Mejlholm et al. [(b)]	0.394	3.715	75	1.561	3.234	15
	Augustin et al.	0.473	3.262	71	1.502	3.207	16
	Augustin et al. [(a)]	0.376	3.508	64	0.722	5.312	9
	Augustin et al. [(b)]	0.239	5.989	41	0.722	5.312	9
All samples	Mejlholm et al.	1.438	2.764	74	0.873	2.546	18

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

replaced by 5% percentile	Mejlholm et al. [(a)]	1.340	2.832	73	0.627	2.811	17
	Mejlholm et al. [(b)]	0.921	2.779	73	0.627	2.811	17
	Augustin et al.	1.021	2.664	69	0.525	3.488	18
	Augustin et al. [(a)]	1.004	2.789	61	0.277	5.718	10
	Augustin et al. [(b)]	0.473	3.400	39	0.277	5.718	10
All samples replaced by median	Mejlholm et al.	2.378	3.651	49	1.372	2.817	15
	Mejlholm et al. [(a)]	2.189	3.637	48	0.993	2.979	14
	Mejlholm et al. [(b)]	1.486	3.434	48	0.993	2.979	14
	Augustin et al.	1.662	3.769	45	0.801	3.542	15
	Augustin et al. [(a)]	1.541	3.990	38	0.295	4.400	8
	Augustin et al. [(b)]	0.831	3.917	28	0.295	4.400	8
All samples replaced by 95% percentile	Mejlholm et al.	5.265	6.147	22	3.093	3.914	9
	Mejlholm et al. [(a)]	4.564	5.677	22	2.181	3.222	9
	Mejlholm et al. [(b)]	3.564	5.071	22	2.181	3.222	9
	Augustin et al.	4.016	5.496	21	2.059	3.359	9
	Augustin et al. [(a)]	2.725	6.602	17	0.323	4.224	5
	Augustin et al. [(b)]	1.349	6.219	15	0.323	4.224	5

[(a)] covariates induced for samples positive at date of testing on the arrival at the laboratory
[(b)] covariates induced for all samples

The next sections show some figures with the results of the models. Each dot represents the growth rate of one batch. Red dots represent growth rates from 20 batches where the prevalence at the date of testing on the arrival at the laboratory is positive. Blue cross indicates that for this batch at least one preservative was reported. As an overall conclusion the predicted concentrations seem to be closer to the observed concentrations for those batches with a positive value for the prevalence at sampling time.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

8.2.1. Square-root model

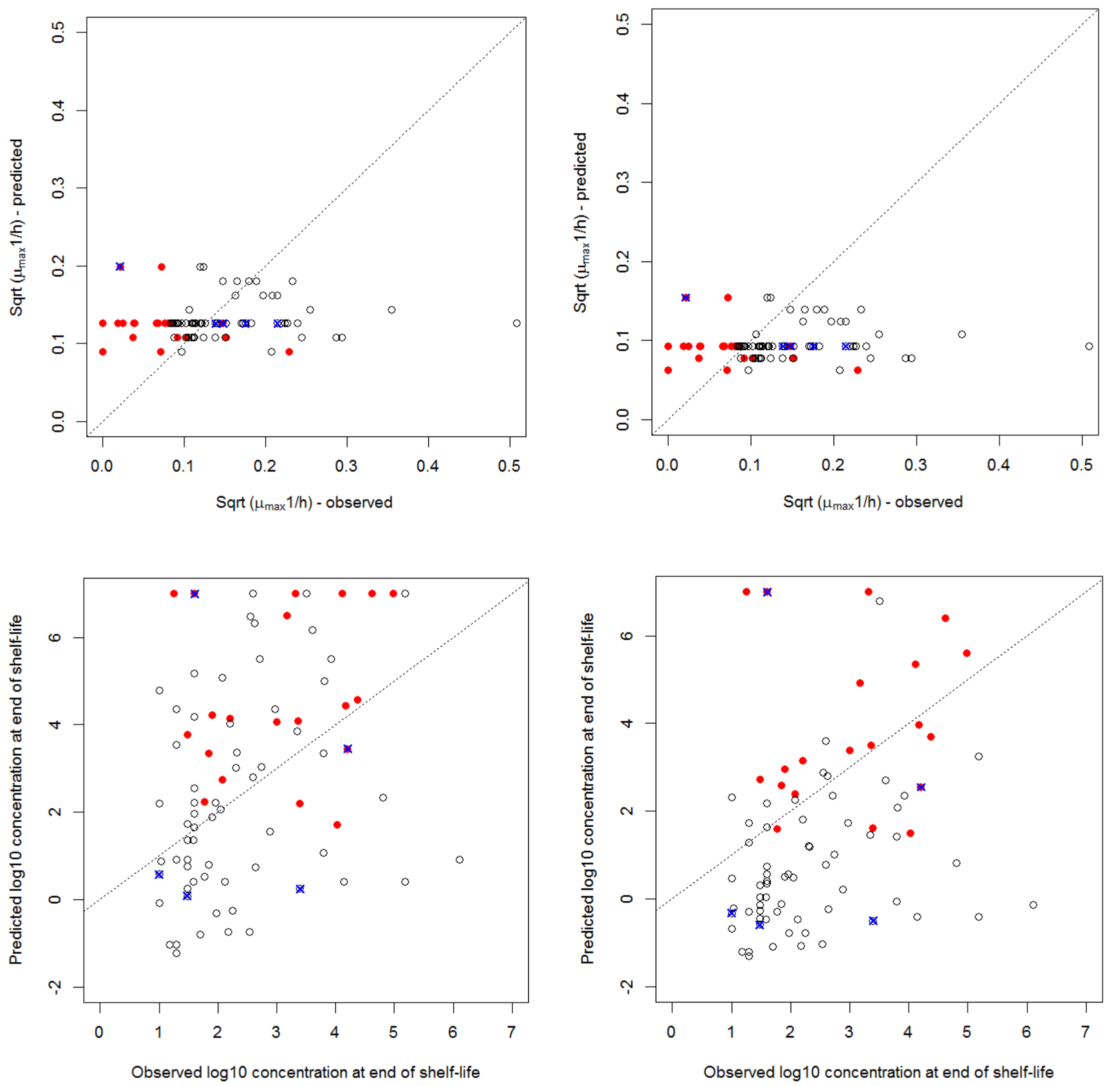


Figure 58: (Based on primary model (4), concentrations negative at the date of testing on the arrival at the laboratory replaced by 0.04) Upper panels: Square-root of observed and estimated growth rates. Lower panels: Observed and estimated $\log_{10}$ counts at end of shelf-life. Left panels: Delignette-Muller model. Right panels: model of Vermeulen et al..

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

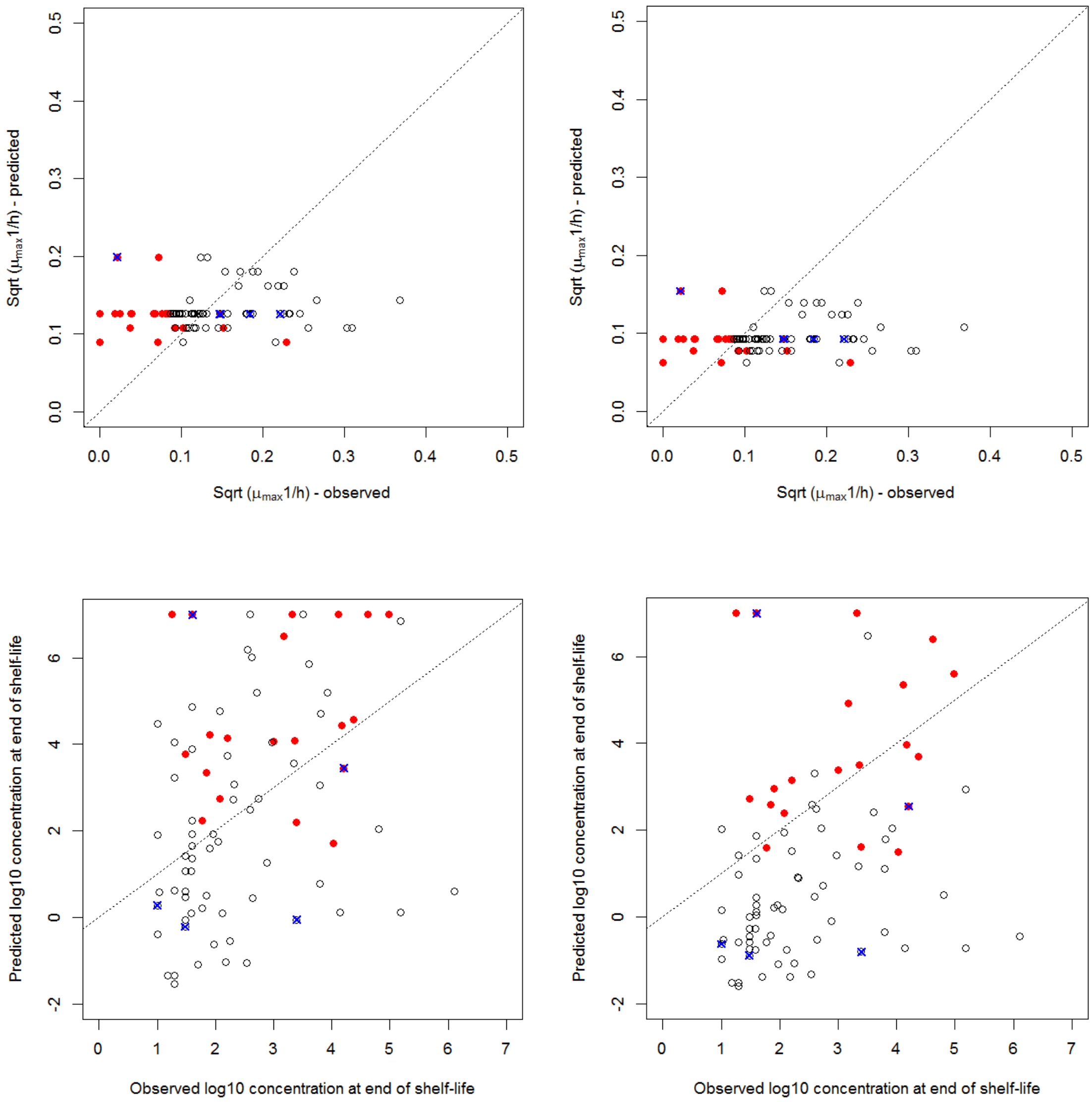


Figure 59: (Based on primary model (4), concentrations negative at the date of testing on the arrival at the laboratory replaced by 0.02) Upper panels: Square-root of observed and estimated growth rates. Lower panels: Observed and estimated $\log_{10}$ counts at end of shelf-life. Left panels: Delignette-Muller model. Right panels: model of Vermeulen et al..

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

8.2.2. Mejlholm-Dalgaard model

The estimated growth rate of three batches is zero, because the interaction has value 0 ($\psi \geq 1$). Two batches have a water activity of 0.89 and 0.91 resulting in a negative estimate for the growth rate. Although this is a strange result, it could be expected because such small values for water activity do not support the growth of *L. monocytogenes*.

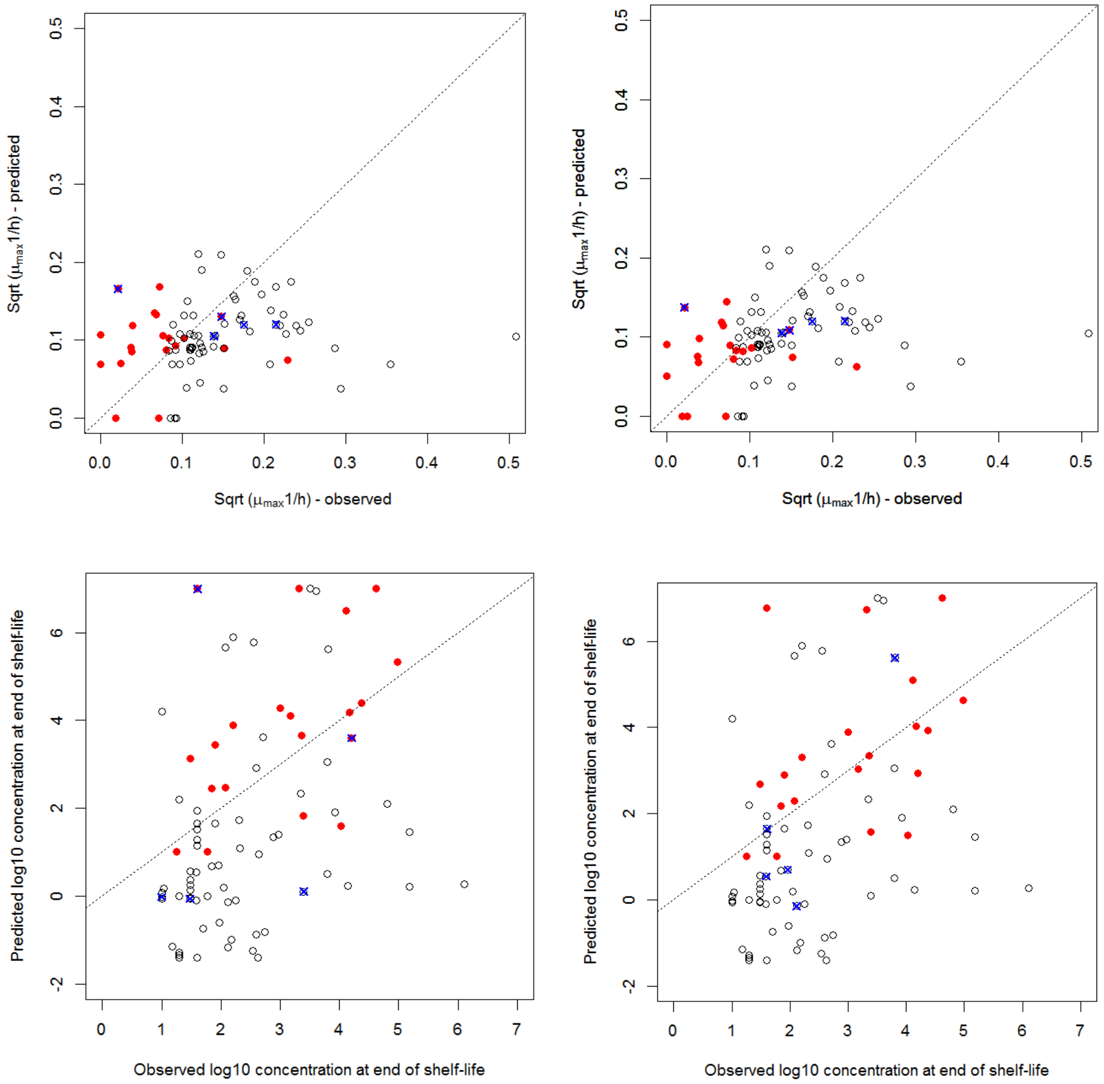


Figure 60: (Based on primary model (4), concentrations negative at the date of testing on the arrival at the laboratory replaced by 0.04) Upper panels: Square-root of observed and estimated growth rates in the Mejlholm-Dalgaard model. Lower panels: Observed and estimated $\log_{10}$ counts at end of shelf-life. Left panels: no information on lactate, phenol and nitrite; right panels: information on lactate, phenol and nitrite induced for samples positive at the date of testing on the arrival at the laboratory.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

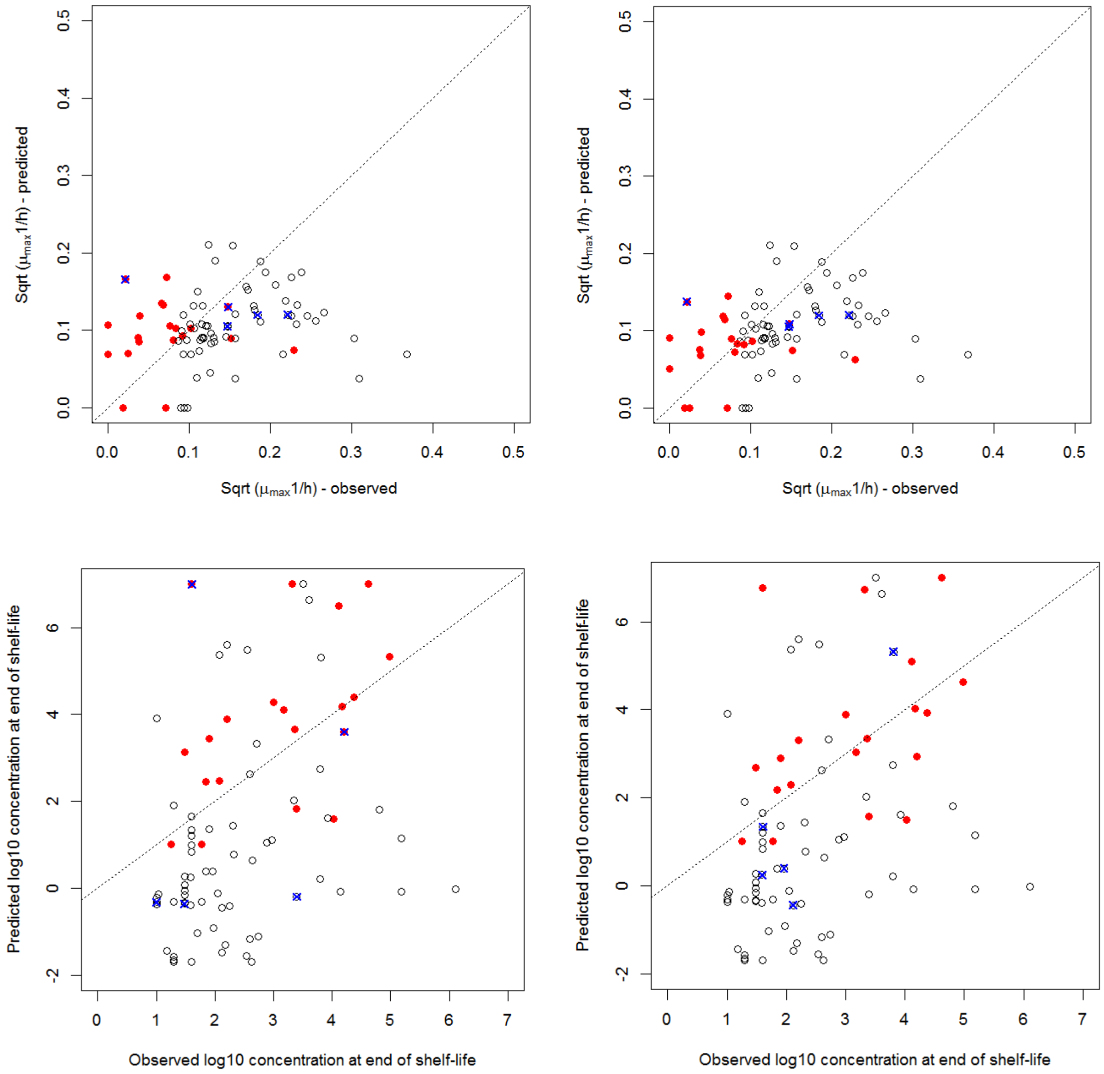


Figure 61: (Based on primary model (4), concentrations negative at the date of testing on the arrival at the laboratory replaced by 0.02) Upper panels: Square-root of observed and estimated growth rates in the Mejlholm-Dalgaard model. Lower panels: Observed and estimated $\log_{10}$ counts at end of shelf-life. Left panels: no information on lactate, phenol and nitrite; right panels: information on lactate, phenol and nitrite induced for samples positive at the date of testing on the arrival at the laboratory.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The second part of the results is based on the data after replacing the count of all samples at time of sampling with the percentiles of the count of the samples positive at the date of testing on the arrival at the laboratory. The figures show the median in the middle and the 5% and 95% percentiles at the ends of the bars.

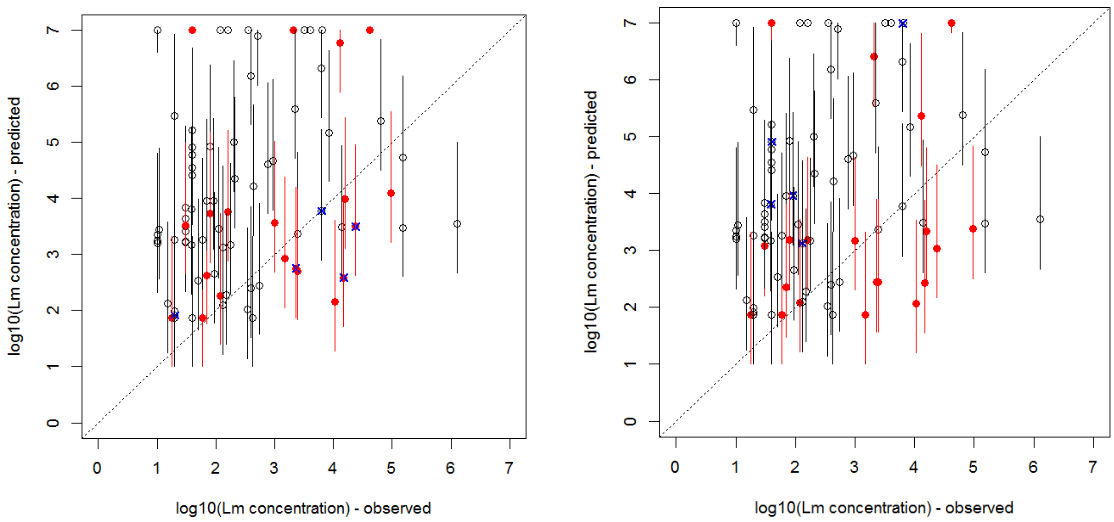


Figure 62: (Based on primary model (4), concentrations at the date of testing on the arrival at the laboratory replaced by 5%, 50% or 95% percentiles) Logarithm (base 10) of concentrations in the Mejlholm-Dalgaard model. Left panel: no information on lactate, phenol and nitrite; right panel: information induced for samples positive at the date of testing on the arrival at the laboratory. For the concentration at the date of testing on the arrival at the laboratory we use the median concentration of the samples positive at the date of testing on the arrival at the laboratory (dot) and the 5% and 95% percentile (bar).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

8.2.3. Model of Augustin et al. (2005)

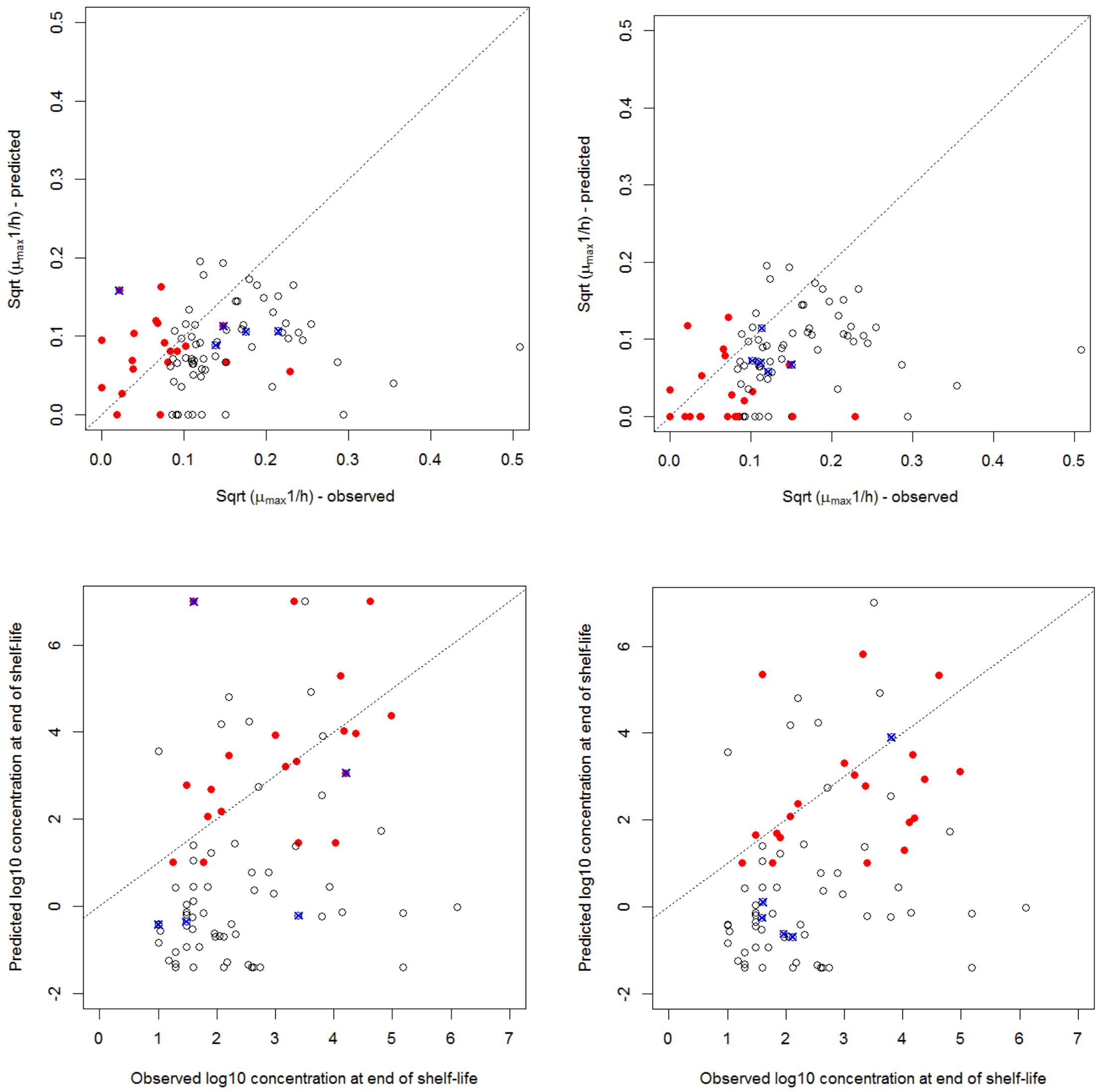


Figure 63: (Based on primary model (4), concentrations negative at the date of testing on the arrival at the laboratory replaced by 0.04) Upper panels: Square-root of observed and estimated growth rates in the model of Augustin et al. (2005). Lower panels: Observed and estimated $\log_{10}$ counts at end of shelf-life. Left panels: no information on lactate, phenol and nitrite; right panels: information on lactate, phenol and nitrite induced for samples positive at the date of testing on the arrival at the laboratory.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

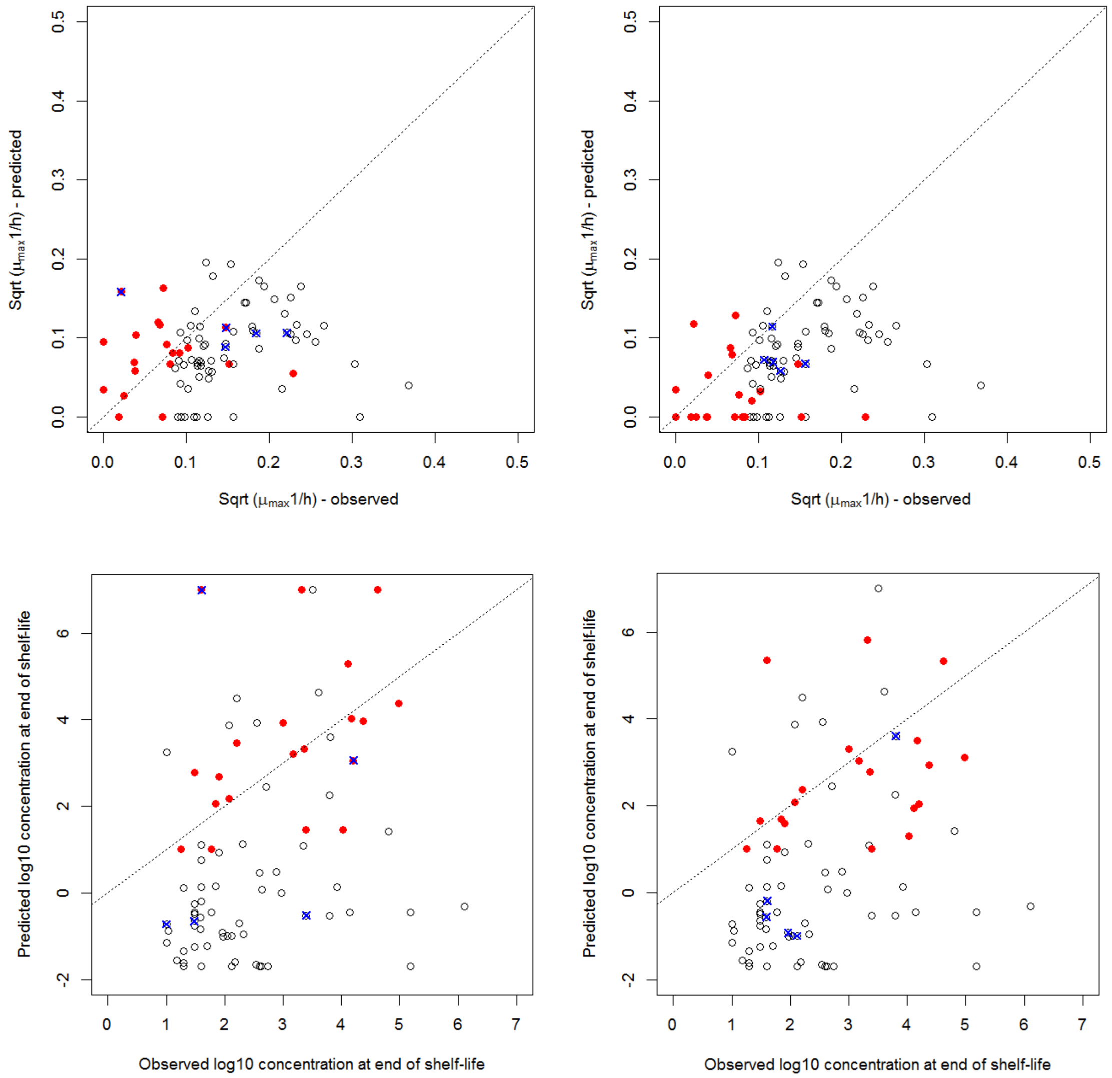


Figure 64: (Based on primary model (4), concentrations negative at the date of testing on the arrival at the laboratory replaced by 0.02) Square-root of observed and estimated growth rates in the model of Augustin et al. (2005). Left panel: no information on lactate, phenol and nitrite; right panel: information on lactate, phenol and nitrite induced for samples positive at the date of testing on the arrival at the laboratory.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

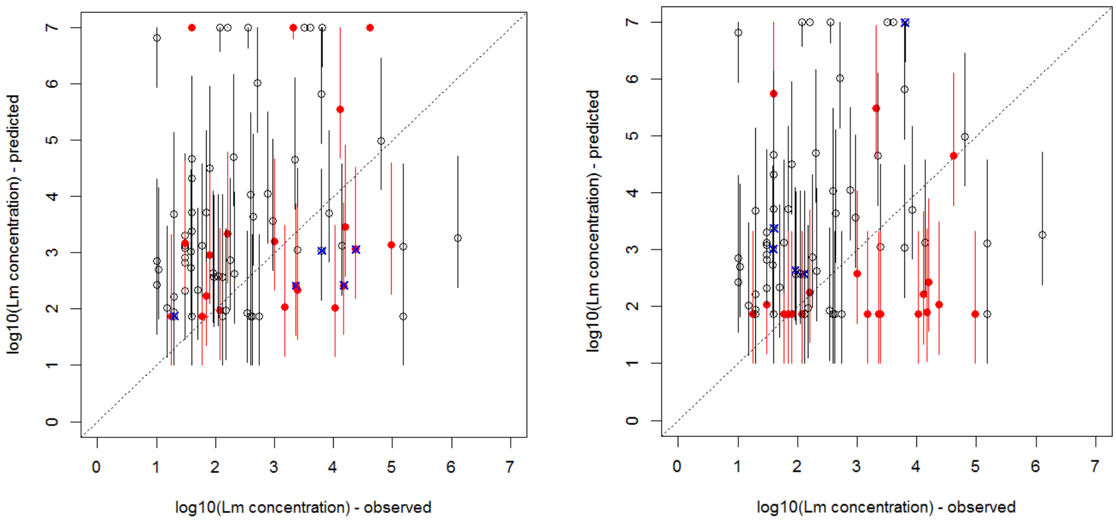


Figure 65: (Based on primary model (4), concentrations at the date of testing on the arrival at the laboratory replaced by 5%, 50% or 95% percentiles) Logarithm (base 10) of concentrations in the model of Augustin et al. (2005). Left panel: no information on lactate, phenol and nitrite; right panel: information induced for samples positive at the date of testing on the arrival at the laboratory. For the concentration at the date of testing on the arrival at the laboratory we use the median concentration of the samples positive at the date of testing on the arrival at the laboratory (dot) and the 5% and 95% percentile (bar).

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

8.3. Approach 3: Including information of samples with 'decreasing growth'

We build a model for the change rate in the $\log_{10}$ count of *Listeria monocytogenes*. For 13 samples the tests were performed on the same day (time is 0 days); these samples are not used in the present analysis. The $\log_{10}$ count of the negative samples is replaced by $\log_{10}$ 0.04.

A graphical representation of the growth rates is given in Figure 66: . Most growth rates (2965 out of 3040) are in the range -0.125 to 0.125. The samples that are included in "EC 2073/2005 NSG" have growth rates between -0.31 and 0.09.

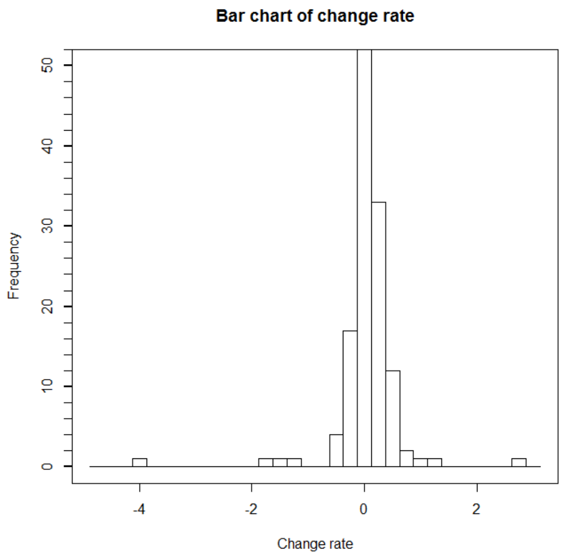


Figure 66: Bar chart of the change rate for all samples. The bar around zero contains 2965 samples.

The significance of every risk factor (temperature, pH, water activity and preservatives) is given in Table 234: . The model also includes the ^{10}log count of *Listeria monocytogenes* at the date of testing on the arrival at the laboratory, because it is highly likely that the growth rate depends on the initial concentration.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 234: Wald Statistics For Type 3 GEE Analysis for model of change rate of *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, with taking into account hierarchical structure (country, city, store) for all participating countries*

Source	GEE		
	DF	Chi-Square	P-Value
log_{10}Log count at the date of testing on the arrival at the laboratory	1	8.74	0.0031
Temperature	1	0.52	0.4719
pH	1	1.68	0.1945
Water activity	1	2.72	0.0988
Preservatives and acidity regulators	2	3.25	0.1967

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

There is only one significant variable in the model, i.e. the count at the date of testing on the arrival at the laboratory. A backward model selection procedure can be applied by deleting, one by one, the non-significant factors, starting with the least significant. This procedure results in the model containing only the count at the date of testing on the arrival at the laboratory. It seems that the potential risk factors envisaged do not have a significant effect on the growth rate.

Table 235: Estimates of GEE (Ind) model of change rate of *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish samples, with taking into account hierarchical structure (country, city, store) for all participating countries*

Source		GEE (Ind)			
		estimate	CL		P-Value
			LL	UL	
Intercept		-0.1386	-0.2466	-0.0307	0.0118
log_{10}log count at the date of testing on the arrival at the laboratory		-0.0606	-0.1008	-0.0204	0.0031
Temperature		-0.0013	-0.0048	0.0022	0.4719
pH		0.0038	-0.0097	0.0020	0.1945
Water activity		0.0931	-0.0174	0.2037	0.0988
Preservatives and acidity regulators [a)]	Products with 1 AP+AR	0.0042	-0.0110	0.0025	0.2213
	Products with 2 or more AP+AR	0.0181	-0.0162	0.0524	0.3000

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category is " Products with no AP and AR"

If we don't include the initial count of *Listeria monocytogenes* in the model, then again all risk factors are not significant. The backward model selection procedure deletes every potential risk factor step by step, resulting in a model with only the intercept.

We tried to include a quadratic effect of temperature in the model, but the effect is not significant.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

DISCUSSION & CONCLUSIONS

In this report we have developed and applied statistical and deterministic predictive models for microbial growth of *Listeria monocytogenes*.The first type of models are statistical growth models, modeling the mean level of the enumeration counts (on log10 scale, at both dates of testing) as a function of time in terms of fixed effects, and with a random effect for batch (representing the correlation between the levels for samples of the same batch) and with random error terms to represent the remaining heterogeneity. All statistical models showed a statistically increasing growth effect over time and provided a quantification of microbial growth. The Gompertz model was fitting best. The extension of the statistical models with factors affecting growth did identify water activity as a statistically significant factor in the Gompertz model, while taking into account the different sources of variability and uncertainty in the data.

Deterministic growth models with parameter values as available from scientific literature, were applied to predict the concentration at the date of testing at the end of shelf-life, based on the model and on the concentration at the date of testing on the arrival at the laboratory. Then the different deterministic models were evaluated by comparing the observed with the predicted growth rates. There was no single model outperforming the others throughout. Depending on the subset of samples under consideration, depending on how negative samples were treated, and depending on scenarios of sensitivity on the concentrations at the date of testing on the arrival at the laboratory, different models appeared to be the best.

A final statistical approach, based on a model for the change rate in the $\log_{10}$ count of *L. monocytogenes*, including samples with decreasing growth, did not identify any factor affecting growth to be significant, except for the concentration at the date of testing at the arrival at the laboratory.

RECOMMENDATIONS

While studying and applying both statistical and deterministic growth models, it became clear that it might be worthwhile to set up a power study, optimizing the characteristics of a survey design in order to furher develop predictive models for microbial growth of *L. monocytogenes* under various storage conditions. Such a study should shed more insights on questions such as: i) what additional production data are needed (date of production, date of transport to retail...), ii) when and how often should which measurements be taken on samples from the same batch, and how many batches should be included in order to identify different sources of heterogeneity, and in order to estimate certain parameters of interest, such as the growth rate, with a predefined accuracy and preassigned coverage, etc.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

REFERENCES

Aerts, M., Geys, H., Molenberghs, G. and Ryan, L.M., 2002. Topics in Modelling of Clustered data. Chapman & Hall, London.

Augustin, J.-C. and Carlier, V., 2000. Mathematical modeling of the growth rate and lag time for *Listeria monocytogenes*. International Journal of Food Microbiology 56, 29-51.

Augustin, J.-C., Zuliani, V., Cornu, M., Guillier, L., 2005. Growth rate and growth probability of *Listeria monocytogenes* in dairy, meat and seafood products in suboptimal conditions. Journal of Applied Microbiology 99, 1019-1042.

Delignette-Muller, M. L., Cornu, M., Pouillot, R., Denis, J.-B., 2006. Use of Bayesian modelling in risk assessment: Application to growth of *Listeria monocytogenes* and food flora in cold-smoked salmon. International Journal of Food Microbiology 106, 195-208.

Mejlholm O, Dalgaard P. 2009. Development and validation of an extensive growth and growth boundary model for *Listeria monocytogenes* in lightly preserved and ready-to-eat shrimp. Journal of Food Protection 72(10), 2132-43.

Mejlholm O., Gunvig, A., Borggaard, C., Blom-Hanssen, J., Mellefont, L,. Ross, T,. Leroi, F., Else, T., Visser, D., Dalgaard, P. 2010. Predicting growth rates and growth boundary of *Listeria monocytogenes* - An international validation study with focus on processed and ready-to-eat meat and seafood. International Journal of Food Microbiology, 141, 137-150.
Ross, T. 1996. Indices for performance evaluation of predictive models in food microbiology. Journal of Applied Bacteriology 81, 501–508.

Molenberghs, G. and Verbeke, G. (2005). Models for Discrete Longitudinal Data. New York: Springer-Verlag.

Uyttendaele, M., Busschaert, P., Valero, A., Geeraerd, A.H., Vermeulen, A., Jacxsens, L., Goh, K.K., De Loy, A., Van Impe, J.F., Devlieghere, F. (2009) Prevalence and challenge tests of *Listeria monocytogenes* in Belgian produced and retailed mayonnaise-based deli-salads, cooked meat products and smoked fish between 2005 and 2007. International Journal of Food Microbiology, 133, 94-104.

Vermeulen, A., Devlieghere, F., De Loy-Hendrickx, A., Uyttendaele, M. 2011. Critical evaluation of the EU-technical guidance on shelf-life studies for *L. monocytogenes* on RTE-foods: A case study for smoked salmon. International Journal of Food Microbiology 145, 176-185

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

PART III: PREDICTIVE MODELS FOR COMPLIANCE WITH LISTERIA MONOCYTOGENES

9. Materials and Methods

Generally speaking 'compliance' means conforming to a rule, such as a specification, policy, standard or law. According to the definition in Article 2 of the Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs (referred to the Regulation in the sequel), 'compliance with microbiological criteria' means obtaining satisfactory or acceptable results set in Annex I of the Regulation when testing against the values set for the criteria through the taking of samples, the conduct of analyses and the implementation of corrective action, in accordance with food law and the instructions given by the competent authority. A 'microbiological criterion' means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch.

In 1999, the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) issued a separate opinion on *Listeria monocytogenes*, recommending the objective to keep the concentration of *Listeria monocytogenes* in food below 100 cfu/g. The Scientific Committee on Food (SCF) agreed with these recommendations in its opinion of 22 June 2000.

In Article 3 the Regulation states the general requirement that the food business operators responsible for the manufacture of the product shall conduct studies in accordance with Annex II of the Regulation in order to investigate compliance with the criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods that are able to support the growth of *Listeria monocytogenes* and that may pose a *Listeria monocytogenes* risk for public health.

One of the food safety criteria, as described in Chapter 1 of Annex I of the Regulation, for ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes, state that out of n=5 number of units comprising the sample c=0 number of sample units should give values over 100 cfu/g. This criterion (referred to as "FSC100" hereinafter) applies on the stage when products are placed on the market during their shelf-life.

A 'sample' is defined as a set composed of one or several units or a portion of matter selected by different means in a population or in an important quantity of matter, which is intended to provide information on a given characteristic of the studied population or matter and to provide a basis for a decision concerning the population or matter in question or concerning the process which has produced it.

The scope of this exercise is the development of predictive models for the compliance with the *L. monocytogenes* FSC100 criterion. The purpose of the model-based approach is to assess whether the **observed prevalence estimates** of *L. monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish, in soft or semi-soft cheeses and in packaged heat-treated meat products **at the end of the shelf-life are compatible with the *L. monocytogenes*** FSC100 criterion. Detailed results and summary tables and graphs of the data should be provided, when necessary.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Following the above mentioned FSC100 criterion, the probability of compliance is defined as the probability that no single sample unit, out of n=5 sample units comprising the sample, exceeds the limit of 100 cfu/g. [32]

9.1. Predictive models for compliance

Denote

- n the number of sample units comprising the sample
- π the probability for a random sample unit from a random sample to exceed the limit of 100 cfu/g
- ρ the within sample correlation for samples with $n > 1$, i.e. any two randomly selected sample units originating from the same sample might be correlated in their test value to be above 100 cfu/g. The correlation quantifies the tendency of any two units from the same sample to have either simultaneously a test value above 100 cfu/g or both not. In the extreme case that $\rho = 1$, all units from the same sample have values above 100 cfu/g, or none of them has. In case $\rho = 0$, the event that one unit from the sample has a value above 100 cfu/g is independent of the event that any other unit exceeds the value of 100 cfu/g.

In case of a single unit ($n = 1$), the probability of compliance depends in a straightforwardly way on the probability π through the formula

$$C(\pi) = 1 - \pi.$$

In case two or more units are inspected ($n > 1$) within the same sample, compliance not only depends on the probability π but also on the within sample correlation ρ. A well-established probability model for clustered binary data is the beta-binomial model, extending the binomial model for independent units to correlated units (see e.g. Aerts *et al* 2002). Using the beta-binomial probability model, the probability of compliance can be modelled as

$$C(\pi,\rho) = P(\text{compliance}) = P\left(0 \text{ out of n exceed } 100\frac{\text{cfu}}{\text{g}}\right)$$

$$C(\pi,\rho) = (1 - \pi)\left(1 - \pi + \frac{\pi\rho}{1}\right)\left(1 - \pi + \frac{2\pi\rho}{1+\rho}\right)\dots\left(1 - \pi + \frac{(n-1)\pi\rho}{1+(n-2)\rho}\right). \qquad (11)$$

Figure 67: shows how the compliance probability depends on the proportion π, for different values of ρ. The red segments represent that part of the curve corresponding to values for the proportion π in the range (0,0.04).

[32] The terminology “sample unit” and “sample” is the one used in the Regulation 2073/2005. It leaves the possibility that the units originate from the same batch or rather from different batches. The terminology of samples within batches was used in Report A.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

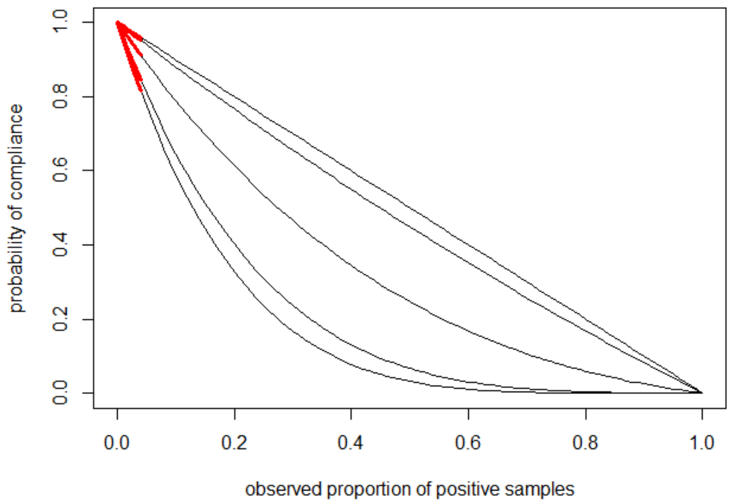


Figure 67: The probability of compliance as a function of the proportion π and for within sample correlation ρ equal to 0, 0.1, 0.5, 0.9 to 1 (lower to upper curves, respectively).

Note that

- If the sample units are independent, then Equation (11) becomes:

$$C(\pi, 0) = (1 - \pi)^n,$$

which is the well-known binomial expression. The binomial model was applied in the simulation-based assessment of microbial criteria on Salmonella in poultry meat in EFSA(2011). Low values for ρ, close to 0, could be applicable for the case, for example, when the units comprising the sample are taken from different food products and even from different manufacturers.

- If the sample units are perfectly correlated

$$C(\pi, 1) = 1 - \pi.$$

High values for ρ, closer to 1, could be applicable for the case where all units are taken from one unique location, of the same food product.

- For a given ρ, $C(\pi, \rho)$ is monotone in π, meaning that, as expected, compliance decreases if the probability that a random selected unit (from the population of all units) has a count exceeding the level of 100 cfu/g.

- For a given π, $C(\pi, \rho)$ is monotone in ρ, meaning that, as expected, compliance increases if all units have the tendency to all jointly have counts not exceeding the level of 100 cfu/g.

The function $C(\pi, \rho)$ is flexible enough to allow for an easy estimation of the compliance probability for any particular case. Given a point estimate or confidence interval for its input parameters π and ρ, one can easily derive an estimate for the compliance probability.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Typically, one has a point estimate and a confidence interval for π from, e.g. a EU-wide baseline survey, while information about ρ is harder to get. In effect, the only way to have such information would be to set up a survey collecting test values of units from the same foodstuff, from the same manufacturer, etc. Let us first assume that ρ is known. In that case, starting from

- estimate $\hat{\pi}$ for proportion π
- 95% Confidence interval $(\hat{\pi}_l, \hat{\pi}_u)$

one can easily derive a point estimate and a confidence interval for the compliance probability

- point estimate $\mathrm{C}(\hat{\pi}, \rho)$ for compliance $\mathrm{C}(\pi, \rho)$
- 95% Confidence interval $(C(\hat{\pi}_u, \rho), C(\hat{\pi}_l, \rho))$.

In case one has knowledge about a range of plausible values for ρ, say the interval $(\rho_{\min}, \rho_{\max})$, and using the monotonicity of $\mathrm{C}(\pi, \rho)$ as a function of ρ, one can take the uncertainty about ρ into account by taking the confidence interval

$$(C(\hat{\pi}_u, \rho_{\min}), C(\hat{\pi}_l, \rho_{\max}))$$

In case there is completely no knowledge of ρ, one can use the confidence interval $(C(\hat{\pi}_u, 0), C(\hat{\pi}_l, 1))$.

In case one has an estimate $\hat{\rho}$ and a confidence interval $(\hat{\rho}_l, \hat{\rho}_u)$ for ρ, the point estimate $\mathrm{C}(\hat{\pi}, \hat{\rho})$ can be used to estimate the compliance $\mathrm{C}(\pi, \rho)$, and a confidence interval can be derived from the delta method. More details and justification of this approach is given in section 9.2.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

9.2. Technical details concerning confidence interval for compliance

For a given ρ, the 95% confidence interval $(C(\hat{\pi}_u,\rho), C(\hat{\pi}_l,\rho))$ is based on the following probability statement

$$P\{C(\hat{\pi}_u,\rho) \leq \mathrm{C}(\pi,\rho) \leq C(\hat{\pi}_l,\rho)\} = 0.95$$

In case one has knowledge about a range of plausible values for ρ, say the interval $(\rho_{\min},\rho_{\max})$, the monotonicity of the function $\mathrm{C}(\pi,\rho)$ implies that

$$\min_{\rho_{\min}\leq\rho\leq\rho_{\max}} C(\hat{\pi}_u,\rho) = C(\hat{\pi}_u,\rho_{\min}) \leq C(\hat{\pi}_u,\rho)$$

and

$$C(\hat{\pi}_l,\rho) \leq \max_{\rho_{\min}\leq\rho\leq\rho_{\max}} C(\hat{\pi}_l,\rho) = C(\hat{\pi}_l,\rho_{\max})$$

So, independent of the value of ρ, we get the following probability statement

$$P\{C(\hat{\pi}_u,\rho_{\min}) \leq \mathrm{C}(\pi,\rho) \leq C(\hat{\pi}_l,\rho_{\max})\} \geq 0.95$$

The 95% interval

$$(C(\hat{\pi}_u,\rho_{\min}), C(\hat{\pi}_l,\rho_{\max}))$$

accounts for

- sampling variability from the baseline survey
- uncertainty about the true value of the within sample correlation

The only "price to pay" is that this interval might be a bit "conservative", in the sense that the coverage probability might be above 0.95.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

10. Results

Estimates for the proportion of samples with counts exceeding the level of 100 cfu/g for several ready-to-eat foods were estimated in the external Scientific EFSA Report "Statistical analysis of the *Listeria monocytogenes* EU-wide baseline survey in certain ready-to-eat foods Part A: *Listeria monocytogenes* prevalence estimates[33]. Based on the estimates for the proportion, we will estimate the compliance rate for several ready-to-eat foods.

10.1. Fish at the date of testing at the end of shelf-life

The proportion of smoked and gravad fish samples with counts exceeding the level of 100 cfu/g was estimated to be 1.7% at the date of testing at the end of shelf-life. Based on the method from section 9.1, we can estimate the compliance rate for packaged (not frozen) hot or cold smoked or gravad fish.

The results are shown in Table 236: .

If we assume that the sample units are independent ($\rho = 0$), the compliance is estimated by 91.8% (95% CI [89.0,93.7]) at the end of shelf-life. However, if the sample units are perfectly correlated, the compliance rate increases to 98.3%.

If no information is available on the correlation, we follow the conservative approach and conclude that the point estimate for the compliance is in between 91.8% and 98.3% at the end of shelf-life. The confidence interval is composed by the minimal and maximal limits of all confidence intervals. In general the compliance at the date of testing on the arrival at the laboratory is higher than the compliance at the end of shelf-life.

Table 236: Point estimate and 95% confidence interval of compliance of fish at end of shelf-life for a range of within sample correlations.

At date of testing at the end of shelf-life $\hat{\pi} = 1.7\%$ $(\hat{\pi}_l, \hat{\pi}_u) = (1.3, 2.3)$		
ρ	$C(\hat{\pi}, \rho)$	$(C(\hat{\pi}_u, \rho), C(\hat{\pi}_l, \rho))$
0.0	0.918	(0.890,0.937)
0.1	0.931	(0.908,0.947)
0.5	0.962	(0.948,0.971)
0.9	0.979	(0.972,0.984)
1.0	0.983	(0.977,0.987)
-	(0.918,0.983)	(0.890,0.987)

A graphical representation of the results is provided in Figure 68: . We can see clearly that the point estimates for the compliance are higher for higher within sample correlation and that the confidence intervals become narrower.

[33] http://www.efsa.europa.eu/en/supporting/doc/441e.pdf

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

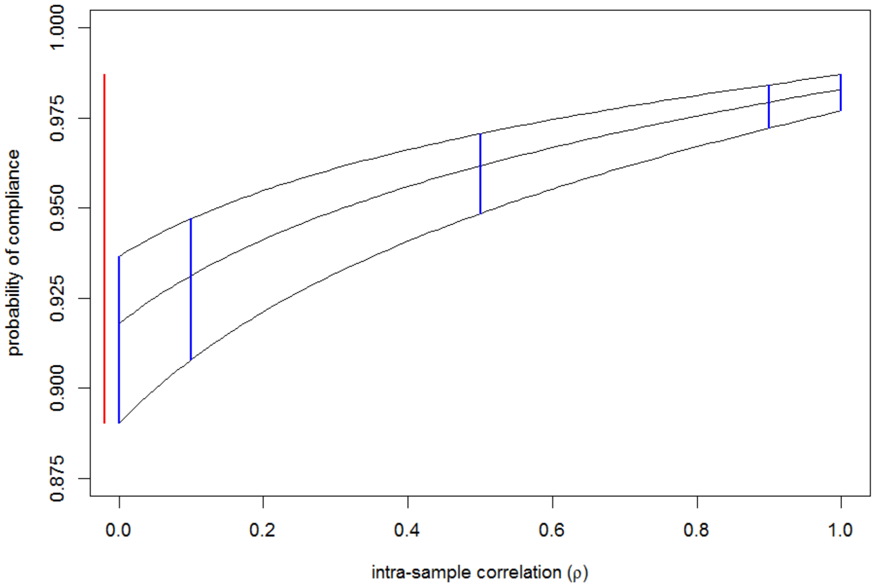


Figure 68: Point estimate and 95% confidence interval for compliance of fish, based on prevalence estimated from the EU-wide baseline survey.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

10.2. Meat

Compared to the compliance of the smoked and gravad fish, the compliance of the packaged heat-treated meat products is higher. If we can assume that the meat samples are uncorrelated, the compliance equals 97.9% (95% CI [96.4,98.7]) and it increases as the samples are more correlated. If no information on the correlation is available, the compliance lies between 97.9% and 99.6%.

Table 237: Point estimate and 95% confidence interval for compliance of packaged heat-treated meat products at date of testing at the end of shelf-life for a range of within sample correlations.

At end of shelf-life $\hat{\pi} = 0.432\%$ $(\hat{\pi}_l, \hat{\pi}_u) = (0.253, 0.738)$		
ρ	$C(\hat{\pi}, \rho)$	$(C(\hat{\pi}_u, \rho), C(\hat{\pi}_l, \rho))$
0.0	0.979	(0.964,0.987)
0.1	0.982	(0.970,0.990)
0.5	0.990	(0.983,0.994)
0.9	0.995	(0.991,0.997)
1.0	0.996	(0.993,0.997)
-	(0.979,0.996)	(0.964,0.997)

A graphical representation of the results is given in Figure 69: .

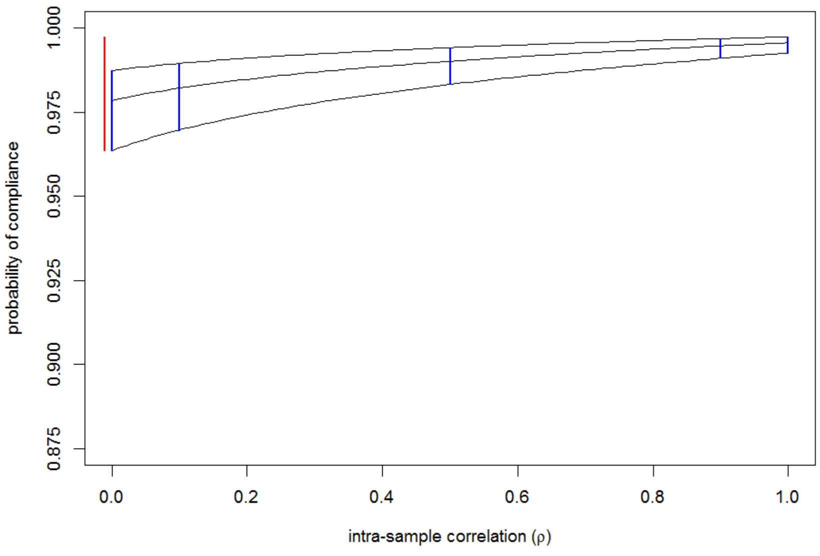


Figure 69: Point estimate and 95% confidence interval for compliance of meat, based on prevalence estimated from the EU-wide baseline survey.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

10.3. Cheese

The compliance estimate for cheese products is even higher than the compliance estimate for packaged heat-treated meat products. Even if the samples are not correlated, the compliance is 99.7% (95% CI [98.8,99.9]).

Table 238: Point estimate and 95% confidence interval for compliance of cheese products at date of testing at the end of shelf-life for a range of within sample correlations.

At end of shelf-life $\hat{\pi} = 0.059\%$ $(\hat{\pi}_l, \hat{\pi}_u) = (0.015, 0.236)$		
ρ	$C(\hat{\pi}, \rho)$	$(C(\hat{\pi}_u, \rho), C(\hat{\pi}_l, \rho))$
0.0	0.997	(0.988,0.999)
0.1	0.998	(0.990,0.999)
0.5	0.999	(0.995,1.000)
0.9	0.999	(0.997,1.000)
1.0	0.999	(0.998,1.000)
-	(0.997,0.999)	(0.988,1.000)

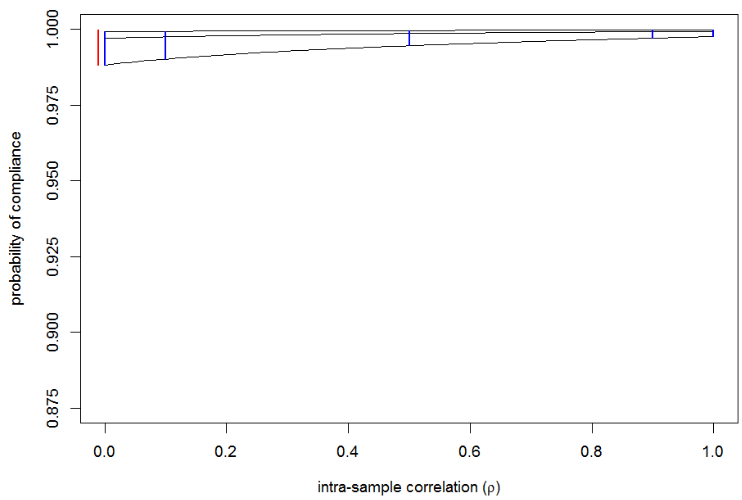


Figure 70: Point estimate and 95% confidence interval for compliance of cheese, based on prevalence estimated from the EU-wide baseline survey.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

DISCUSSION & CONCLUSIONS

It is shown how a predictive model for compliance can be developed. Based on the well-known beta-binomial distribution for clustered binary data, a probability for a sample to be compliant according to the criteria laid down in Regulation (EC) No 2073/2005 is defined. This probability can be interpreted as the proportion of ready-to-eat food samples of a particular category that are compliant at the EU level. The methodology allows to evaluate the effect of different sampling designs and corresponding correlation structure in the units comprising the sample on the probability to be compliant. Designs can vary from units comprising the sample originating from the same batch (correlated units) to units from different batches, which might be considered as independent units (e.g. batches from different producers) or correlated (but to a lesser extent as compared to originating from the same batch, e.g. batches from the same producer). According to the design, the correlation parameter ρ will vary from values close to 0 to values close to 1.

The compliance probability can be estimated and confidence intervals can be constructed using estimates for the proportion of samples with counts exceeding the level of 100 cfu/g for several ready-to-eat foods as estimated in the external Scientific EFSA Report "Statistical analysis of the *Listeria monocytogenes* EU-wide baseline survey in certain ready-to-eat foods Part A: *Listeria monocytogenes* prevalence estimates".

The results show that the proportion compliant to the European Union food safety criteria as laid down in the Regulation (EC) No 2073/2005, at the date of testing at the end of shelf-life, is highest for cheese (with 95% above 0.988), followed by meat (95% CI (0.964, 0.997)) and by fish (95% CI (0.890, 0.987)). In any situation, compliance increases with the level of correlation.

RECOMMENDATIONS

As the proportion of compliant samples depends on the correlation between the units comprising the sample, it would be worthwhile to include more specifications about how the units comprising the sample are expected to be collected. In relation to this issue, it seems also a worthwhile modification of the *Listeria monocytogenes* EU-wide baseline survey in certain ready-to-eat foods to test more than one sample from the same batch, at each occasion (at the date of testing on the arrival at the laboratory, and at the date of testing at the end of shelf-life). In this way the intrabatch correlation can be also estimated from the data, and more accurate confidence intervals for the compliance probability can be constructed.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

REFERENCES

Aerts, M., Geys, H., Molenberghs, G. and Ryan, L.M., 2002. Topics in Modelling of Clustered data. Chapman & Hall, London.

Augustin, J.-C. and Carlier, V., 2000. Mathematical modeling of the growth rate and lag time for *Listeria monocytogenes*. International Journal of Food Microbiology 56, 29-51.

Augustin, J.-C., Zuliani, V., Cornu, M., Guillier, L., 2005. Growth rate and growth probability of *Listeria monocytogenes* in dairy, meat and seafood products in suboptimal conditions. Journal of Applied Microbiology 99, 1019-1042.

Delignette-Muller, M. L., Cornu, M., Pouillot, R., Denis, J.-B., 2006. Use of Bayesian modelling in risk assessment: Application to growth of *Listeria monocytogenes* and food flora in cold-smoked salmon. International Journal of Food Microbiology 106, 195-208.

Mejlholm O, Dalgaard P. 2009. Development and validation of an extensive growth and growth boundary model for *Listeria monocytogenes* in lightly preserved and ready-to-eat shrimp. Journal of Food Protection 72(10), 2132-43.

Mejlholm O., Gunvig, A., Borggaard, C., Blom-Hanssen, J., Mellefont, L,. Ross, T,. Leroi, F., Else, T., Visser, D., Dalgaard, P. 2010. Predicting growth rates and growth boundary of *Listeria monocytogenes* - An international validation study with focus on processed and ready-to-eat meat and seafood. International Journal of Food Microbiology, 141, 137-150.
Ross, T. 1996. Indices for performance evaluation of predictive models in food microbiology. Journal of Applied Bacteriology 81, 501–508.

Vermeulen, A., Devlieghere, F., De Loy-Hendrickx, A., Uyttendaele, M. 2011. Critical evaluation of the EU-technical guidance on shelf-life studies for *L. monocytogenes* on RTE-foods: A case study for smoked salmon. International Journal of Food Microbiology 145, 176-185

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

APPENDIX/APPENDICES

PART I: ANALYSIS OF FACTORS RELATED TO THE PREVALENCE OF LISTERIA MONOCYTOGENES

A. ILLUSTRATION OF SPARSENESS AND ALTERNATIVE METHODS

The next example illustrates sparseness, its consequences as well as some alternative methods of inference and more pragmatic remedial actions.

Table 4: Table 239: cross-classifies the indicator of prevalence of samples contaminated by *Listeria monocytogenes* against one single factor "(original) Type of retail outlet" while accounting for the "EC 2073/2005 NSG" indicator. This three-way table clearly shows sparseness for the Type of retail outlet "Speciality delis" and "Street market or farmers' market" (observed frequencies mostly 0 or 1, and not exceeding 3).

Table 239: Cross classification table between original Type of retail outlet and EC 2073/2005 NSG indicator of prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling for all participating countries*

"EC 2073/2005 NSG"	Type of retail outlet	Sample		Total	Prevalence of contaminated samples
		Not contaminated	Contaminated		
Samples not included in "EC 2073/2005 NSG"	Speciality delis	2	1	3	33.33
	Street market or farmers' market	1	1	2	50.00
	Supermarket or small shop	2506	290	2796	10.37
	Other (free text field)	40	2	42	4.76
0 Total		***2549***	***294***	***2843***	***10.34***
Samples included in "EC 2073/2005 NSG"	Speciality delis	0	0	0	-
	Street market or farmers' market	0	0	0	-
	Supermarket or small shop	190	18	208	8.65
	Other (free text field)	1	1	2	50.00
1 Total		***191***	***19***	***210***	***9.05***
Total		**2740**	**313**	**3053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

How does this obvious case of sparseness affect the results of the logistic regression analysis? As no data are available for samples included in "EC 2073/2005 NSG" for the outlet categories "Speciality delis" and "street market or farmers' market", the interactions terms of outlet category with EC 2073/2005 NSG are not identifiable and cannot be estimated. This results in the lines of OR estimates fully filled up with the value "1". These are not estimates and cannot be interpreted. Firth's or the exact method cannot rectify anything here, as these effects are not identifiable and cannot be estimated in any way (no information at all).

Next consider the effect of outlet category "other" as compared to the reference category "supermarket or small shop". The estimate for the prevalence for this reference category equals 10.37% for samples

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

not included in EC 2073/2005 NSG, and 8.65% for samples included in EC 2073/2005 NSG. When turning to the category "other" the change in the prevalence depends on the status of EC 2073/2005 NSG. Indeed for samples not included in EC 2073/2005 NSG, we observe a reduction to 4.76% whereas for samples included in EC 2073/2005 NSG, we observe a huge increase up to 50%! This appears to be a clear interaction effect, but the problem is that it is based on only 2 observations, one positive and one negative. Changing one single observation could turn this into 0% or 100%! Obviously this instability originating from the lack of observations has to manifest itself in the estimates, confidence intervals and p-values. Indeed the corresponding lines of output in Table 241: show high to very high OR estimates, very broad confidence intervals and disagreeing p-values across traditional logistic regression, Firth's reduced method, and exact logistic regression. Highest confidence in this situation should be assigned to the exact approach, as this is a quite extreme case.

Nevertheless we also recommend to not interpret these results and to consider the more pragmatic option of collapsing or merging categories with low frequencies up to an acceptable level, while maintaining the possibility to have a sensible interpretation for such a collapsed category (if possible at least).

The four original categories of Type of retail outlet were merged into two categories ("Supermarket or small shop" and "All other types of retail outlet". Table 4: simplifies to Table 5:). The combinations and corresponding cell with 0 counts disappear and consequently all effects are technically identifiable (not implying that estimates are accurate of course). The frequencies for "All other types of retail outlet" combined with "samples included in EC 2073/2005 NSG" are still very low (equal to 1).

As shown in Table 242: all ORs are estimated. As there is still a huge increase to 50% when turning to "All other types of retail outlet" for samples included in "EC 2073/2005 NSG", the estimated interaction effect is still very high. But inference across the different methods has stabilized and is in agreement (from a qualitative point of view). The fact that the interaction effect needs to be estimated on an extremely low number of observations is reflected in wide confidence intervals and larger p-values. We recommend to use the estimates from Firth's and the exact method. The point estimates are very similar. As expected, the exact method is more conservative (inherent in its discrete nature) and leads to wider intervals and higher p-values.

Table 240: Cross classification table between Type of retail outlet and EC 2073/2005 NSG indicator of prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling for all participating countries*

"EC 2073/2005 NSG"	Type of retail outlet	Sample		Total	Prevalence of contaminated samples
		Not contaminated	Contaminated		
Samples not included in "EC 2073/2005 NSG"	Supermarket or small shop	2506	290	2796	10.37
	All other types of retail outlet	43	4	47	8.51
0 Total		***2549***	***294***	***2843***	***10.34***
Samples included in "EC 2073/2005 NSG"	Supermarket or small shop	190	18	208	8.65
	All other types of retail outlet	1	1	2	50.00
1 Total		***191***	***19***	***210***	***9.05***
Total		**2740**	**313**	**3053**	**10.25**

*: Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 241: Logistic regression models for the prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish, at time of

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

sampling for all participating countries* when including the Type of retail outlet and EC 2073/2005 NSG (with interaction)

Source		Logistic				Logistic - Firth				Exact Method			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.116	0.102	0.131	<.0001	0.116	0.115	0.116	<.0001				
Type of retail outlet [a)]	**Street market or farmers' market**	**8.642**	**0.539**	**138.518**	**0.128**	**176167309043.981**	**0.000**	**	**0.992**	**8.628**	**0.110**	**678.575**	**0.394**
Type of retail outlet	Speciality delis	4.321	0.391	47.794	0.233	5.169	4.882	5.472	<.0001	4.317	0.073	83.159	0.561
Type of retail outlet	Other (free text field)	0.432	0.104	1.797	0.249	0.583	0.567	0.600	<.0001	0.432	0.050	1.682	0.355
"EC 2073/2005 NSG" [b)]		0.819	0.497	1.348	0.431	0.851	0.841	0.861	<.0001	0.819	0.468	1.354	0.513
"EC 2073/2005 NSG" * Type of retail outlet	**Street market or farmers' market**	**1**	**1**	**1**	**.**	**1**	**1**	**1**	**.**				
"EC 2073/2005 NSG" * Type of retail outlet	**Speciality delis**	**1**	**1**	**1**	**.**	**1**	**1**	**1**	**.**				
"EC 2073/2005 NSG" * Type of retail outlet	**Other (free text field)**	**24.430**	**1.043**	**572.435**	**0.047**	**54.697**	**50.542**	**59.193**	**<.0001**	**19.738**	**0.197**	**>999.999**	**0.234**

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type of retail outlet is "Supermarket or small shop"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'
**) : Undefined

Table 242: Logistic regression models for the prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish, at time of sampling for all participating countries* by Type[(c)] of retail outlet and "EC 2073/2005 NSG" indicator (with interaction)

Source		Logistic				Logistic - Firth				Exact Method			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.116	0.102	0.131	<.0001	0.116	0.103	0.131	<.0001				
Type[(c)] of retail outlet [a)]	All other types of retail outlet	0.804	0.286	2.256	0.678	0.893	0.332	2.398	0.822	0.804	0.208	2.236	0.911
"EC 2073/2005 NSG" [b)]		0.819	0.497	1.348	0.431	0.838	0.511	1.373	0.483	0.819	0.468	1.354	0.513
"EC 2073/2005 NSG" * Type[(c)] of retail outlet	All other types of retail outlet	13.131	0.656	262.907	0.092	11.562	0.586	227.944	0.108	11.612	0.127	>999.999	0.345

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type[(c)] of retail outlet is "Supermarket or small shop"
b) : The reference category for 'EC 2073/2005 NSG' is "not included in EC 2073/2005 NSG"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

B. EXAMINATION OF THE SUPPORTING GROWTH VARIABLES

In the previous analyses, the"EC 2073/2005 NSG" indicator has been used. From a statistical point of view, the choice between both versions of the not-supporting growth variable ("EC 2073/2005 NSG" indicator and continuous variable expressing the no-growth probability) can be based on statistical goodness-of-fit measures (such as AIC). But the statistical arguments might not be the only ones. In the following sections we compare both versions in a case study: the analysis of factor for packaged (not frozen) hot or cold smoked or gravad fish at the time of sampling.

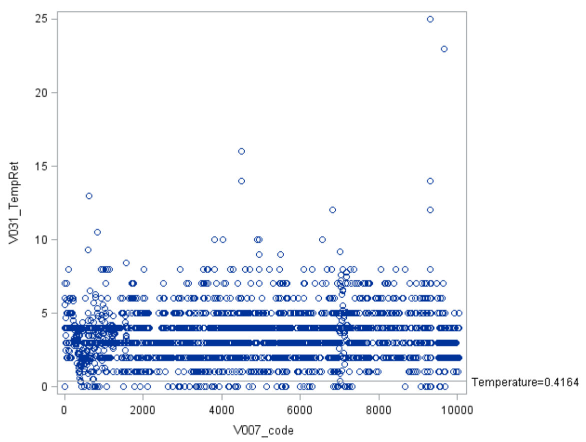
B.1. Supplementary facts on the continuous variable expressing the no-growth probability

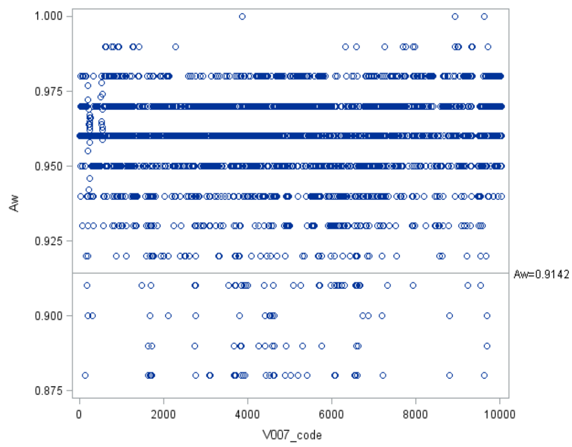
In the definition of the continuous variable expressing the no-growth probability, all samples with temperature, pH or water activity (on the arrival at the laboratory) below the minimum values, receive value 1. In total there are 220 samples with these extreme temperatures, pH or water activity measures. Table 243: shows that some of them are not included in "EC 2073/2005 NSG" while most of them are included.

Table 243: Number and percentage of samples with temperature, pH test results or water activity result (on the arrival at the laboratory) below the minimum value in the definition of the continuous variable expressing the no-growth probability, for samples included and not included in "EC 2073/2005 NSG".

	Frequency	Percent
For samples 'not included in EC 2073/2005 NSG'	129	58.64
For samples included in 'EC 2073/2005 NSG '	91	41.36

Figure 71: shows the distribution of the temperature, water activity and pH for all samples.





The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

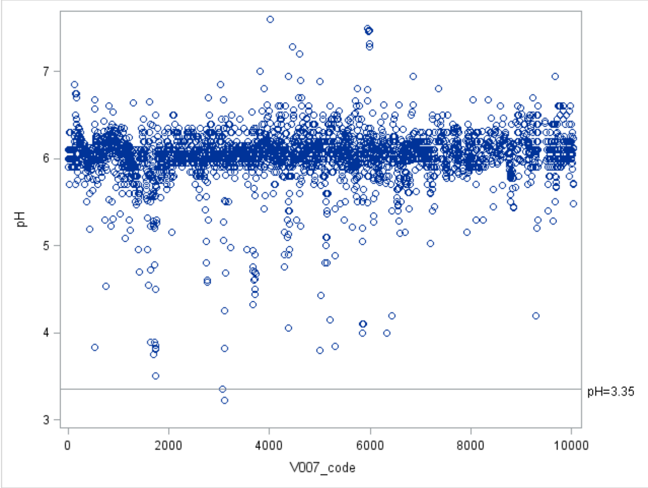


Figure 71: Distribution of temperature (upper left), water activity measure (upper right) and pH (below) for all samples. On horizontal axis is the sample identification number. The horizontal line corresponds to the minimum temperature, respectively water activity measure and pH.

B.2. Relation between the "EC 2073/2005 NSG" indicator and the continuous variable expressing the no-growth probability

Table 244: shows that the majority of the samples (93.12%) is not included in "EC 2073/2005 NSG". This is highly unbalanced and might cause sparseness problems.

Table 244: Number and percentage of samples included and not included in "EC 2073/2005 NSG".

Continuous no-growth probability	Frequency	Percent
For samples 'not included in EC 2073/2005 NSG'	2843	93.12
For samples included in 'EC 2073/2005 NSG '	210	6.88

In Figure 72: we present a graphical representation of the continuous variable expressing the no-growth probability versus the "EC 2073/2005 NSG" indicator . This scatterplot shows that about half of the samples support growth and half do not support growth, based on the continuous variable expressing the no-growth probability. So, if one would use a threshold on the continuous scale to reproduce the binary variable, one would end up with a threshold close to 0.99 (above this threshold corresponds to being included in "EC 2073/2005 NSG", also see Table 245:). This is very unusual from a statistical point of view. So, it would not be surprising that there are some differences when using the "EC 2073/2005 NSG" indicator and the continuous variable expressing the no-growth probability.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

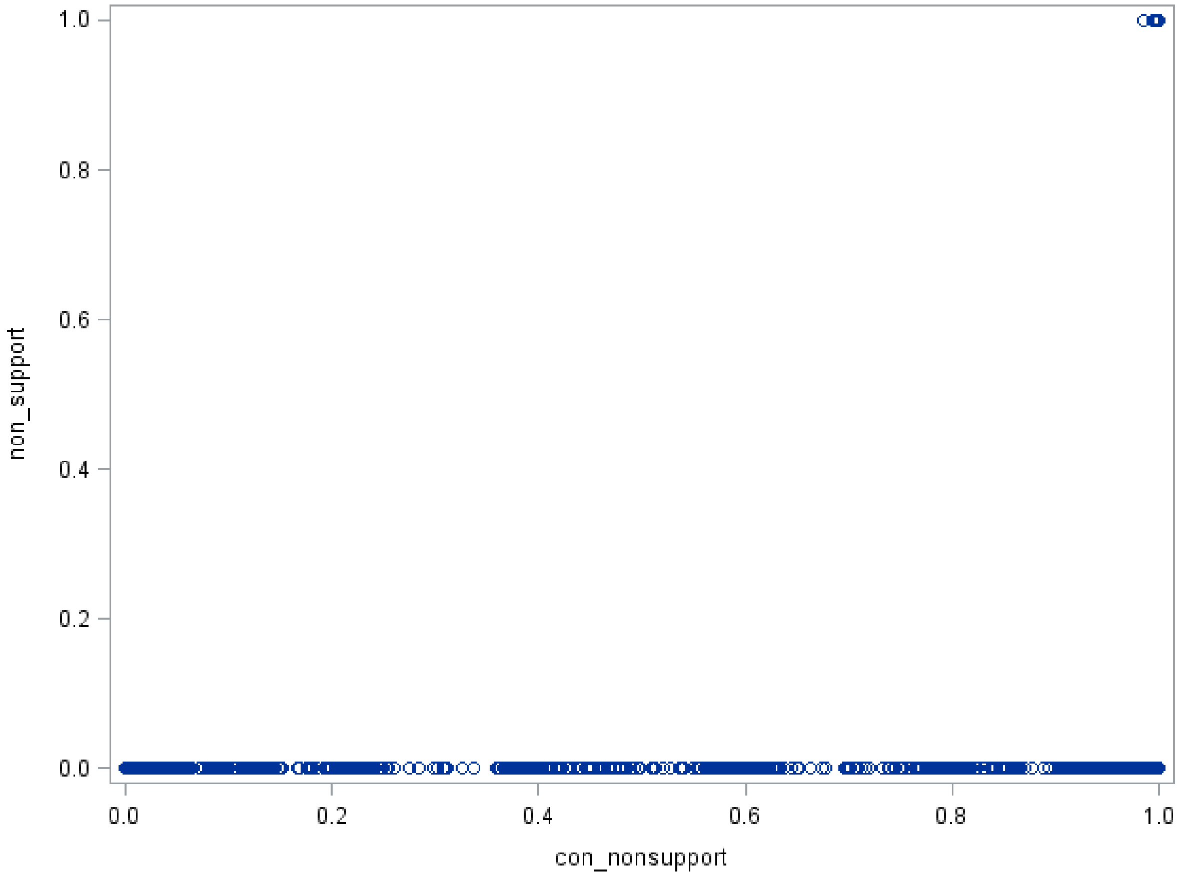


Figure 72: Relationship between “EC 2073/2005 NSG” indicator and continuous variable expressing the no-growth probability. The horizontal axis shows the continuous variable expressing the no-growth probability. The vertical axis represents the “EC 2073/2005 NSG” indicator and can be 1 (for samples included in ‘EC 2073/2005 NSG ’) or 0 (for samples ‘not included in EC 2073/2005 NSG’)

Also the box plot of the continuous variable expressing the no-growth probability in Figure 73: indicates that about 75% of the values are above a 60% probability.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

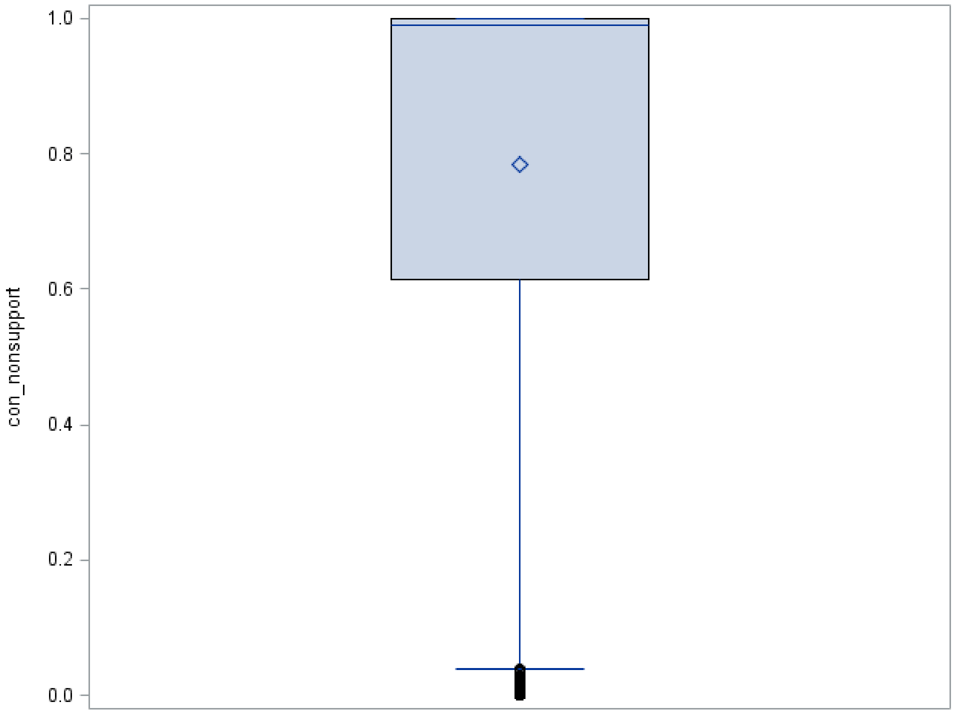


Figure 73: Boxplot representing the continuous variable expressing the no-growth probability.

Some descriptive statistics of the continuous variable expressing the no-growth probability for each value of the“EC 2073/2005 NSG” indicator is given in Table 245: . The minimum probability expressing the no-growth is 99% for the samples included in “EC 2073/2005 NSG”.

Table 245: Summary statistics for continuous variable expressing the no-growth probability for each value of the “EC 2073/2005 NSG” indicator.

Continuous no-growth probability	N	Mean	Std Dev	Minimum	Maximum
For samples ‘not included in EC 2073/2005 NSG’	2 843	0.77	0.343	0.00	1
For samples included in ‘EC 2073/2005 NSG’	210	1.00	0.001	0.99	1

Using logistic regression we obtain a measure for the association between the“EC 2073/2005 NSG” indicator (response) and the continuous variable expressing the no-growth probability:

Table 246: Modelling the relationship between the“EC 2073/2005 NSG” indicator and the continuous variable expressing the no-growth probability, using logistic regression.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	P-value
Intercept	1	-630.4	116.4	29.3219	<.0001
Continuous no-growth probability	1	628.8	116.4	29.1664	<.0001

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

There is a significant effect of the continuous variable expressing the no-growth probability on the "EC 2073/2005 NSG" indicator. The extremely low intercept reflects the fact that if the probability to not support growth (continuous) is not large (i.e. conditions do support growth) then the probability that the "EC 2073/2005 NSG" indicator equals 1 (i.e. included in "EC 2073/2005 NSG") is expit(-630.4)≈0%. If the probability to not support growth (continuous) is close to one (i.e. conditions do not support growth) then the probability that "EC 2073/2005 NSG" indicator equals 1 (i.e. included in "EC 2073/2005 NSG") is expit(-630.4+628.8)=16.8%.

This raises a major question: which version to choose. The continuous one seems to indicate that the majority of samples have a high to very high probability to not support growth. Is that what one believes or expects? In Appendix B.3 the continuous variable expressing the no-growth probability is used for the all subsets model selection approach.

B.3. Model building based on continuous variable expressing the no-growth probability

In this section we do model selection with the all subset regression approach, first by using the "EC 2073/2005 NSG" indicator (model A) and second by using the continuous variable expressing the no-growth probability (model B). In the final models we replace the "EC 2073/2005 NSG" indicator with the continuous variable expressing the no-growth probability and vice versa, leading to 4 different models. These models are compared based on the QIC criterion.

These are the results of the 4 models:

A. The model selected using the "EC 2073/2005 NSG" indicator:

   A1. model with the "EC 2073/2005 NSG" indicator: QIC=1916.2318,

   A2. model with the continuous variable expressing the no-growth probability: QIC=1922.8883

B. Model selected with the continuous variable expressing the no-growth probability:

   B1. model with the "EC 2073/2005 NSG" indicator: QIC=1919.7388,

   B2. model with thecontinuous variable expressing the no-growth probability: QIC=1918.2227

The model selection, based on the two different versions of the not-supporting growth variable ("EC 2073/2005 NSG" indicator and continuous variable expressing the no-growth probability), leads to a different final model. The main effect of the variables Possible slicing, Remaining Shelf-life, Subtype of the fish product, Fish Species, Number of preservatives and acidity regulators and Packaging Type[(c)] appear in both final models. In both models the biologically relevant interaction of Storage temperature at retail and Packaging type[(c)] is included. However the main effect of remaining shelf and the interaction effect for Fish species appear only in the model built with the "EC 2073/2005 NSG" indicator. The following tables summarize the results:

Table 247: Model A, built with the "EC 2073/2005 NSG" indicator

Source	"EC 2073/2005 NSG" indicator	Continuous variable expressing the no-growth probability

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

	DF	Chi-Square	P-value	DF	Chi-Square	P-value
Subtype of the fish product	3	13.81	0.0032	3	14.71	0.0021
Fish species	4	10.68	0.0304	4	2.35	0.6723
Preservatives and acidity regulators	2	42.96	<.0001	2	43.03	<.0001
Possible slicing	1	4.04	0.0444	1	4.1	0.0428
Packaging type(c)	1	0.04	0.8493	1	0.02	0.9014
Remaining Shelf-life	1	3.95	0.0468	1	4.84	0.0279
Temperature at retail	1	0.71	0.3989	1	0.1	0.7464
"EC 2073/2005 NSG"	1	1.72	0.1901			
"EC 2073/2005 NSG" * Fish species	4	15.15	0.0044			
Continuous no-growth probability				1	0.13	0.7139
Continuous no-growth probability * Fish species				4	2.66	0.6168
Temperature at retail * Packaging type(c)	1	0.57	0.4486	1	0.74	0.3891

Table 248: Model B, built with the continuous variable expressing the no-growth probability

Source	**"EC 2073/2005 NSG" indicator**			**Continuous variable expressing the no-growth probability**		
	DF	**Chi-Square**	**P-value**	**DF**	**Chi-Square**	**P-value**
Subtype of the fish product	3	14.71	0.0021	3	14.16	0.0027
Fish species	4	8.5	0.0747	4	8.82	0.0657
Preservatives and acidity regulators	2	40.99	<.0001	2	41.71	<.0001
Possible slicing	1	3.79	0.0515	1	3.99	0.0458
Packaging type(c)	1	0.03	0.8539	1	0.03	0.8693
Temperature at retail	1	0.99	0.3208	1	0.37	0.5418
"EC 2073/2005 NSG"	1	0.78	0.3767			
Continuous no-growth probability				1	0.02	0.8786
Temperature at retail * Packaging type(c)	1	0.53	0.4655	1	0.5	0.4803

From this exercise we learn that:

1) model selection can lead to different models
2) model B has less interaction terms
3) QIC indicates the differences are quite limited in goodness of fit. This goodness-of-fit measure also indicates that the "EC 2073/2005 NSG" indicator in the model selected with the "EC 2073/2005 NSG" indicator fits best.

General conclusion & possible recommendation: the continuous variable expressing the no-growth probability attains many values on the higher probability scale, which is a bit surprising, as compared to the "EC 2073/2005 NSG" indicator. An explorative analysis indicates minor differences, and indicates a slight preference for the "EC 2073/2005 NSG" indicator.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

C. Model Selection Summary

C.1. Model selection for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling

Table 249: Model Selection Multiple logistic Regression for prevalence

Number of Variables	Score Chi-Square	AIC	Variables Included in Model
1	75.43	1976.61	additive1
6	137.37	1919.06	fish_subtype1 fish_subtype3 additive1 slicing packaging2 slicing*non_support
7	142.86	1914.81	fish_subtype1 fish_subtype2 fish_subtype3 fish_species3 additive1 slicing packaging2
8	148.36	1912.93	fish_subtype1 fish_subtype3 additive1 slicing packaging2 non_support outlet*non_support fish_species2*non_support
9	153.52	1907.79	fish_subtype1 fish_subtype3 fish_species3 additive1 slicing packaging2 non_support outlet*non_support fish_species2*non_support
10	157.75	1904.79	fish_subtype1 fish_subtype3 fish_species2 fish_species3 additive1 slicing packaging2 non_support outlet*non_support fish_species2*non_support
11	**161.20**	**1902.86**	**fish_subtype1 fish_subtype3 fish_species2 fish_species3 additive1 slicing packaging2 Remain_ShelfLife non_support outlet*non_support fish_species2*non_support**
12	164.26	1903.00	fish_subtype1 fish_subtype2 fish_subtype3 fish_species2 fish_species3 additive1 slicing packaging2 Remain_ShelfLife non_support outlet*non_support fish_species2*non_support
13	165.89	1903.45	fish_subtype1 fish_subtype2 fish_subtype3 fish_species2 fish_species3 additive1 slicing packaging2 Remain_ShelfLife non_support outlet*non_support fish_species2*non_support packaging1*non_support
14	167.30	1904.39	fish_subtype1 fish_subtype2 fish_subtype3 fish_species2 fish_species3 additive1 slicing packaging2 Remain_ShelfLife non_support outlet*non_support fish_species2*non_support packaging1*non_support packaging3*non_support
15	168.34	1902.60	fish_subtype1 fish_subtype2 fish_subtype3 fish_species2 fish_species3 additive1 slicing packaging1 packaging2 packaging3 Remain_ShelfLife non_support outlet*non_support fish_species2*non_support packaging1*non_support
16	169.36	1903.93	fish_subtype1 fish_subtype2 fish_subtype3 fish_species2 fish_species3 additive1 slicing packaging1 packaging2 packaging3 Remain_ShelfLife non_support outlet*non_support fish_species2*non_support packaging1*non_support packaging3*non_support
17	169.94	1905.19	fish_subtype1 fish_subtype2 fish_subtype3 fish_species2 fish_species3 additive1 slicing packaging1 packaging2 packaging3 Retail_temp Remain_ShelfLife non_support outlet*non_support fish_species2*non_support packaging1*non_support packaging3*non_support
18	170.40	1906.60	fish_subtype1 fish_subtype2 fish_subtype3 fish_species2 fish_species3 fish_species4 additive1 slicing packaging1 packaging2 packaging3 Retail_temp Remain_ShelfLife non_support outlet*non_support fish_species2*non_support packaging1*non_support packaging3*non_support

Table 250: Model selection multiple logistic regression for proportion of samples with counts exceeding the level of 100 cfu/g

Number of Variables	Score Chi-Square	AIC	Variables Included in Model
2	17.23	324.60	sampling_season3 packaging2
3	22.83	321.25	sampling_season3 fish_subtype1 packaging2
4	25.80	318.84	sampling_season3 fish_subtype1 slicing packaging2
5	29.59	317.62	sampling_season3 fish_subtype1 fish_species4 slicing packaging2
6	33.03	317.21	sampling_season3 fish_subtype1 fish_species4 slicing packaging2 fish_subtype3*non_support
7	37.12	313.93	sampling_season3 fish_subtype1 fish_species4 slicing packaging2 fish_subtype3*non_support slicing*non_support
8	**39.67**	**311.86**	**sampling_season3 fish_subtype1 fish_species4 slicing packaging2 non_support fish_subtype3*non_support fish_species2*non_support**
9	40.81	312.20	sampling_season3 fish_subtype1 fish_species4 slicing packaging2 Retail_temp non_support fish_subtype3*non_support fish_species2*non_support
10	41.98	313.12	outlet sampling_season3 fish_subtype1 fish_species4 slicing packaging2 Retail_temp non_support fish_subtype3*non_support fish_species2*non_support
11	42.57	313.76	outlet sampling_season3 fish_subtype1 fish_species4 additive2 slicing packaging2 Retail_temp non_support fish_subtype3*non_support fish_species2*non_support
12	43.09	315.76	outlet sampling_season3 fish_subtype1 fish_species4 additive2 slicing packaging2 Retail_temp non_support fish_subtype1*non_support fish_subtype3*non_support fish_species2*non_support

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

C.2. Model selection for packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life

Table 251: Model Selection Multiple logistic Regression for prevalence

Number of Variables	Score Chi-Square	AIC	Variables Included in Model
7	142.39	1900.39	sampling_season1 fish_species2 additive1 packaging2 fish_subtype1*non_support fish_species2*non_support additive1*non_support
8	149.07	1891.87	sampling_season1 additive1 slicing packaging1 packaging2 fish_subtype1*non_support fish_species2*non_support additive1*non_support
9	156.50	1884.05	sampling_season1 fish_species2 fish_species3 additive1 packaging1 packaging2 fish_subtype1*non_support fish_species2*non_support additive1*non_support
10	162.14	1879.45	sampling_season1 fish_species2 fish_species3 additive1 packaging1 packaging2 outlet*non_support fish_subtype1*non_support fish_species2*non_support additive1*non_support
11	167.53	1873.13	sampling_season1 fish_species2 fish_species3 additive1 slicing packaging1 packaging2 outlet*non_support fish_subtype1*non_support fish_species2*non_support additive1*non_support
12	170.94	1866.67	sampling_season1 fish_species2 fish_species3 additive1 slicing packaging1 packaging2 packaging3 outlet*non_support fish_subtype1*non_support fish_species2*non_support additive1*non_support
13	173.66	1865.05	sampling_season1 fish_species2 fish_species3 additive1 slicing packaging1 packaging2 packaging3 Remain_ShelfLife outlet*non_support fish_subtype1*non_support fish_species2*non_support additive1*non_support
14	176.24	1864.07	sampling_season1 sampling_season3 fish_species2 fish_species3 additive1 slicing packaging1 packaging2 packaging3 Remain_ShelfLife outlet*non_support fish_subtype1*non_support fish_species2*non_support additive1*non_support
15	178.15	1863.62	sampling_season1 fish_species2 fish_species3 additive1 slicing packaging1 packaging2 packaging3 Remain_ShelfLife non_support outlet*non_support fish_subtype1*non_support fish_species2*non_support additive1*non_support Lab_temp*non_support
16	180.67	1862.62	sampling_season1 sampling_season3 fish_species2 fish_species3 additive1 slicing packaging1 packaging2 packaging3 Remain_ShelfLife non_support outlet*non_support fish_subtype1*non_support fish_species2*non_support additive1*non_support Lab_temp*non_support
17	**182.39**	**1862.07**	**sampling_season1 sampling_season3 fish_subtype1 fish_species2 fish_species3 additive1 slicing packaging1 packaging2 packaging3 Remain_ShelfLife non_support outlet*non_support fish_subtype1*non_support fish_species2*non_support additive1*non_support Lab_temp*non_support**
18	184.32	1863.20	sampling_season1 sampling_season3 fish_subtype1 fish_subtype3 fish_species2 fish_species3 additive1 slicing packaging1 packaging2 packaging3 Remain_ShelfLife non_support outlet*non_support fish_subtype1*non_support fish_species2*non_support additive1*non_support Lab_temp*non_support
19	185.91	1864.18	sampling_season1 sampling_season3 fish_subtype1 fish_subtype3 fish_species2 fish_species3 additive1 slicing packaging1 packaging2 packaging3 Remain_ShelfLife non_support outlet*non_support fish_subtype1*non_support fish_subtype2*non_support fish_species2*non_support additive1*non_support Lab_temp*non_support

Table 252: Model Selection Multiple logistic Regression for proportion of samples with counts exceeding the level of 100 cfu/g

Number of Variables	Score Chi-Square	AIC	Variables Included in Model
4	27.62	506.39	outlet sampling_season2 slicing packaging2
5	32.35	503.07	outlet sampling_season2 additive1 packaging2 non_support
6	35.46	501.44	outlet sampling_season2 additive1 slicing packaging2 non_support
7	**38.51**	**500.48**	**outlet sampling_season2 fish_species4 additive1 slicing packaging2 non_support**
8	40.34	502.48	outlet sampling_season2 fish_species4 additive1 slicing packaging2 non_support additive1*non_support
9	41.45	503.45	outlet sampling_season2 fish_species4 additive1 additive2 slicing packaging2 additive1*non_support packaging2*non_support
10	42.31	504.39	outlet sampling_season2 fish_subtype2 fish_species4 additive1 additive2 slicing packaging2 additive1*non_support packaging2*non_support
11	42.91	505.50	outlet sampling_season2 fish_subtype2 fish_species4 additive1 additive2 slicing packaging1 packaging2 additive1*non_support packaging2*non_support

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

C.3. Model selection for packaged heat-treated meat products at the end of shelf-life

Table 253: Model Selection Multiple logistic Regression for prevalence

Number of Variables	Score Chi-Square	AIC	Variables Included in Model
1	8.98	700.40	meat_type1
2	11.59	700.38	animal_species2 meat_type1
3	15.94	697.79	meat_type1 slicing packaging1
4	**18.81**	**697.53**	**animal_species2 meat_type1 slicing packaging1**
5	20.42	698.44	animal_species2 animal_species4 meat_type1 slicing packaging1
6	21.09	699.97	animal_species2 animal_species4 meat_type1 meat_packaging_place1 slicing packaging1
7	21.75	701.07	animal_species2 animal_species4 animal_species5 meat_type1 meat_packaging_place1 slicing packaging1
8	22.17	702.68	animal_species2 animal_species4 animal_species5 meat_type1 meat_packaging_place1 meat_packaging_place2 slicing packaging1
9	22.61	704.16	animal_species2 animal_species4 animal_species5 meat_type1 meat_packaging_place1 slicing packaging1 packaging2 Remain_ShelfLife
10	23.00	705.84	animal_species2 animal_species4 animal_species5 meat_type1 meat_packaging_place1 meat_packaging_place2 slicing packaging1 packaging2 Remain_ShelfLife

Table 254: Model Selection Multiple logistic Regression for proportion of samples with counts exceeding the level of 100 cfu/g

Number of Variables	Score Chi-Square	AIC	Variables Included in Model
1	6.83	194.24	animal_species2
2	10.60	194.41	animal_species2 Remain_ShelfLife
3	12.65	194.83	animal_species2 animal_species6 Remain_ShelfLife
4	15.01	194.89	animal_species2 meat_type1 slicing Remain_ShelfLife
5	**16.89**	**195.48**	**animal_species2 animal_species6 meat_type1 slicing Remain_ShelfLife**
6	18.08	196.49	animal_species1 animal_species2 animal_species6 meat_type1 slicing Remain_ShelfLife
7	19.24	197.51	animal_species1 animal_species2 animal_species6 meat_type1 slicing packaging3 Remain_ShelfLife
8	20.24	197.62	animal_species1 animal_species2 animal_species6 meat_type1 slicing packaging3 Lab_temp Remain_ShelfLife
9	21.00	199.03	animal_species1 animal_species2 animal_species6 meat_type1 slicing packaging2 packaging3 Lab_temp Remain_ShelfLife

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

D. SINGLE-FACTOR MODEL

D.1. Single-factor model of prevalence for packaged (not frozen) hot or cold smoked or gravad fish at time of sampling

- ***Type of retail outlet***

Table 255: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (Type of retail outlet) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type of retail outlet	3	5.72	0.13	3	47.91	<.0001	3	7.41	0.06
“EC 2073/2005 NSG”	1	0.42	0.52	1	0.32	0.57	1	0.26	0.61
“EC 2073/2005 NSG” * Type of retail outlet	1	4.16	0.04	1	4.11	0.04	1	4.06	0.04

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 256: Odds ratio GEE (Ind) Analysis of single risk factor (Type of retail outlet) analysis with interaction of “EC 2073/2005 NSG” indicator for prevalence for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.12	0.10	0.13	<.0001	0.13	0.11	0.15	<.0001	0.12	0.10	0.14	<.0001
Type of retail outlet [a)]	Other (free text field)	0.43	0.13	1.41	0.16	0.40	0.12	1.29	0.13	0.42	0.13	1.39	0.16
Type of retail outlet	Street market or farmers’ market	8.64	0.54	138.66	0.13	12470.24	776.66	200225.60	<.0001	17.31	1.08	277.94	0.04
Type of retail outlet	Speciality delis	4.32	0.39	47.85	0.23	3.63	0.33	40.32	0.29	4.03	0.36	44.68	0.26
“EC 2073/2005 NSG” [b)]		0.82	0.45	1.50	0.52	0.83	0.44	1.57	0.57	0.83	0.42	1.67	0.61

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

"EC 2073/2005 NSG"* Type of retail outlet	Other (free text field)	24.43	1.13	526.37	0.04	24.08	1.11	522.49	0.04	23.99	1.09	526.89	0.04
"EC 2073/2005 NSG"* Type of retail outlet	Street market or farmers' market	1.00	1.00	1.00	.	1.00	1.00	1.00	.	1.00	1.00	1.00	.
"EC 2073/2005 NSG"* Type of retail outlet	Speciality delis	1.00	1.00	1.00	.	1.00	1.00	1.00	.	1.00	1.00	1.00	.

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type of retail outlet is "Supermarket or small shop"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

The huge range of CI for Type of retail outlet is due to zero counts in the category "Street market or farmers' market" and "Speciality delis" for the samples included in "EC 2073/2005 NSG". To deal with these issues, the binary variable Type(c) of retail outlet was defined.

Table 257: Cross classification table between Type of retail outlet, support the growth and prevalence of *Listeria monocytogenes*.

Type of retail outlet	Not included in "EC 2073/2005 NSG"			Included in "EC 2073/2005 NSG"		
	Sample		Total	Sample		Total
	Not contaminated	Contaminated		Not contaminated	Contaminated	
Street market or farmers' market	1	1	**2**	0	0	**0**
Supermarket or small shop	2 506	290	**2 796**	190	18	**208**
Speciality delis	2	1	**3**	0	0	**0**
Other (free text field)	40	2	**42**	1	1	**2**
Total	**2 549**	**294**	**2 843**	**191**	**19**	**210**

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

GEE Analysis

Table 258: Odds ratio of GEE (Ind) Analysis of single risk factor (Type of retail outlet) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.12	0.10	0.13	<.0001	0.13	0.11	0.15	<.0001	0.12	0.10	0.14	<.0001
Type(c) of retail outlet a)	All other types of retail outlet	0.80	0.30	2.16	0.67	0.86	0.30	2.46	0.78	0.79	0.29	2.13	0.64
"EC 2073/2005 NSG" b)		0.82	0.45	1.50	0.52	0.83	0.44	1.57	0.57	0.83	0.42	1.67	0.61
"EC 2073/2005 NSG"*Type(c) of retail outlet	All other types of retail outlet	13.13	0.65	264.01	0.09	11.09	0.54	229.27	0.12	12.86	0.63	263.59	0.10

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type(c) of retail outlet is "Supermarket or small shop"
b) : The reference category for 'EC 2073/2005 NSG' is "not included in EC 2073/2005 NSG"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sensitivity Analysis

Table 259: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Type of retail outlet) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.12	0.10	0.13	<.0001	0.13	0.11	0.14	<.0001	0.12	0.10	0.13	<.0001
Type of retail outlet [a)]	All other types of retail outlet	0.89	0.33	2.40	0.82	0.96	0.35	2.62	0.93	0.87	0.33	2.29	0.78
"EC 2073/2005 NSG" [b)]		0.84	0.51	1.37	0.48	0.85	0.53	1.35	0.49	0.86	0.50	1.47	0.58
"EC 2073/2005 NSG"*Type of retail outlet	All other types of retail outlet	11.56	0.59	227.94	0.11	9.75	0.40	238.63	0.16	11.27	0.62	205.55	0.10

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type of retail outlet is "Supermarket or small shop"
b) : The reference category for 'EC 2073/2005 NSG' is "not included in EC 2073/2005 NSG"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Sampling season***

GEE Analysis

Table 260: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (Sampling season) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	8.39	0.04	3	9.73	0.02	3	7.80	0.05
“EC 2073/2005 NSG”	1	0.90	0.34	1	1.14	0.29	1	2.08	0.15
“EC 2073/2005 NSG” * Sampling season	3	0.96	0.81	3	1.11	0.78	3	2.41	0.49

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis

Table 261: Odds ratio GEE (Ind) Analysis of single risk factor (Sampling season) analysis with interaction of “EC 2073/2005 NSG” indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.12	0.10	0.16	<.0001	0.14	0.10	0.18	<.0001	0.13	0.09	0.18	<.0001
Sampling season [a)]	autumn	1.03	0.73	1.44	0.88	1.02	0.71	1.47	0.91	1.02	0.69	1.50	0.92
Sampling season	spring	0.63	0.42	0.94	0.02	0.59	0.39	0.91	0.02	0.61	0.39	0.95	0.03
Sampling season	summer	1.01	0.70	1.45	0.98	1.00	0.68	1.49	0.98	0.99	0.65	1.50	0.96
“EC 2073/2005 NSG” [b)]		0.59	0.20	1.75	0.34	0.55	0.18	1.65	0.29	0.42	0.13	1.37	0.15
“EC 2073/2005 NSG”*Sampling season	autumn	1.55	0.34	7.14	0.58	1.76	0.35	8.88	0.50	2.37	0.43	13.10	0.32
“EC 2073/2005 NSG”*Sampling season	spring	2.14	0.47	9.87	0.33	2.27	0.48	10.73	0.30	3.45	0.66	18.02	0.14

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

"EC 2073/2005 NSG"*Sampling season	summer	1.46	0.33	6.40	0.62	1.67	0.37	7.59	0.51	2.48	0.53	11.71	0.25

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category Sampling season is "winter"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

Sensitivity Analysis

Sensitivity analysis using Firth approach was fitted from GEE final model. The results are in the following table:

Table 262: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single risk factor (Sampling season) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	**Firth**			**Firth - weighted sample planned**			**Firth - weighted population**		
	DF	**Chi-Square**	**P-Value**	**DF**	**Chi-Square**	**P-Value**	**DF**	**Chi-Square**	**P-Value**
Sampling season	3	7.95	0.05	3	9.90	0.02	3	8.84	0.03
"EC 2073/2005 NSG"	1	0.67	0.41	1	1.06	0.30	1	1.28	0.26
"EC 2073/2005 NSG" * Sampling season	3	1.07	0.78	3	1.38	0.71	3	2.03	0.57

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 263: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Sampling season) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.13	0.10	0.16	<.0001	0.14	0.11	0.18	<.0001	0.13	0.10	0.16	<.0001
Sampling season [a)]	autumn	1.02	0.74	1.42	0.89	1.02	0.74	1.40	0.90	1.02	0.74	1.39	0.91
Sampling season	spring	0.63	0.43	0.93	0.02	0.60	0.40	0.88	0.01	0.61	0.42	0.90	0.01
Sampling season	summer	1.00	0.71	1.41	0.98	1.00	0.72	1.40	0.98	0.99	0.71	1.38	0.95
"EC 2073/2005 NSG" [b)]		0.66	0.24	1.79	0.41	0.60	0.23	1.58	0.30	0.50	0.15	1.67	0.26
"EC 2073/2005 NSG"*Sampling season	autumn	1.49	0.40	5.55	0.55	1.69	0.48	5.94	0.41	2.16	0.47	9.84	0.32
"EC 2073/2005 NSG"*Sampling season	spring	2.13	0.51	8.94	0.30	2.28	0.55	9.43	0.25	3.29	0.61	17.73	0.17
"EC 2073/2005 NSG"*Sampling season	summer	1.43	0.37	5.57	0.61	1.62	0.45	5.89	0.46	2.26	0.49	10.39	0.30

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category Sampling season is "winter"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Subtype of the fish product***

GEE Analysis

Table 264: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (Subtype of the fish product) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Subtype of the fish product	3	34.85	<.0001	3	42.32	<.0001	3	38.78	<.0001
"EC 2073/2005 NSG"	1	0.13	0.72	1	0.21	0.64	1	0.00	0.96
"EC 2073/2005 NSG" * Subtype of the fish product	3	2.74	0.43	3	2.66	0.45	3	2.76	0.43

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 265: Odds ratio of GEE (Ind) Analysis of single risk factor (Subtype of the fish product) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.20	0.16	0.26	<.0001	0.26	0.20	0.35	<.0001	0.24	0.18	0.32	<.0001
Subtype of the fish product [a)]	Gravad fish	0.72	0.44	1.15	0.17	0.59	0.36	0.98	0.04	0.54	0.32	0.92	0.02
Subtype of the fish product	Hot smoked fish	0.32	0.20	0.49	<.0001	0.27	0.17	0.43	<.0001	0.27	0.17	0.43	<.0001
Subtype of the fish product	Unknown smoked fish	0.49	0.36	0.66	<.0001	0.38	0.27	0.53	<.0001	0.39	0.28	0.55	<.0001
"EC 2073/2005 NSG" [b)]		0.87	0.40	1.89	0.72	0.83	0.38	1.81	0.64	1.02	0.45	2.32	0.96
"EC 2073/2005 NSG" * Subtype of the fish product	Gravad fish	0.82	0.29	2.32	0.71	0.81	0.31	2.17	0.68	0.65	0.24	1.74	0.39

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

“EC 2073/2005 NSG”* Subtype of the fish product	Hot smoked fish	2.00	0.36	11.19	0.43	1.83	0.32	10.36	0.49	1.81	0.29	11.23	0.52
“EC 2073/2005 NSG”* Subtype of the fish product	Unknown smoked fish	0.36	0.07	1.89	0.23	0.35	0.07	1.82	0.21	0.37	0.07	2.00	0.25

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Subtype of the fish product is “Cold smoked fish”
b) : The reference category “EC 2073/2005 NSG” is ‘not included in EC 2073/2005 NSG’

Sensitivity Analysis

Table 266: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single risk factor (Subtype of the fish product) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Subtype of the fish product	3	39.33	<.0001	3	63.86	<.0001	3	60.32	<.0001
“EC 2073/2005 NSG”	1	0.07	0.79	1	0.19	0.67	1	0.03	0.87
“EC 2073/2005 NSG” * Subtype of the fish product	3	3.09	0.38	3	2.83	0.42	3	2.79	0.43

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 267: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Subtype of the fish product) analysis with interaction of “EC 2073/2005 NSG” indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.20	0.16	0.25	<.0001	0.26	0.21	0.33	<.0001	0.24	0.20	0.30	<.0001
Subtype of the fish product [a)]	Gravad fish	0.73	0.45	1.17	0.19	0.60	0.37	0.98	0.04	0.55	0.33	0.91	0.02
Subtype of the fish product	Hot smoked fish	0.32	0.21	0.49	<.0001	0.27	0.18	0.41	<.0001	0.27	0.18	0.42	<.0001

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Subtype of the fish product	Unknown smoked fish	0.49	0.37	0.64	<.0001	0.38	0.29	0.49	<.0001	0.39	0.30	0.51	<.0001
"EC 2073/2005 NSG" b)		0.90	0.44	1.88	0.79	0.86	0.43	1.71	0.67	1.07	0.49	2.34	0.87
"EC 2073/2005 NSG" * Subtype of the fish product	Gravad fish	0.83	0.26	2.69	0.76	0.83	0.27	2.56	0.74	0.68	0.18	2.56	0.56
"EC 2073/2005 NSG" * Subtype of the fish product	Hot smoked fish	2.30	0.47	11.17	0.30	2.15	0.44	10.47	0.34	2.18	0.38	12.61	0.38
"EC 2073/2005 NSG" * Subtype of the fish product	Unknown smoked fish	0.43	0.10	1.89	0.26	0.42	0.10	1.85	0.25	0.44	0.10	1.94	0.28

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Subtype of the fish product is "Cold smoked fish"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

- ***Fish Species***

GEE Analysis

Table 268: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (Fish species) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Fish species	4	23.96	<.0001	4	24.11	<.0001	4	27.92	<.0001
"EC 2073/2005 NSG"	1	1.31	0.25	1	1.79	0.18	1	0.41	0.52
"EC 2073/2005 NSG" * Fish species	4	17.48	0.00	4	22.60	0.00	4	13.57	0.01

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 269: Odds ratio of GEE (Ind) Analysis of single risk factor (Fish species) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)	GEE (Ind) - weighted sample planned	GEE (Ind) - weighted population

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.14	0.12	0.17	<.0001	0.16	0.13	0.19	<.0001	0.15	0.12	0.18	<.0001
Fish species [a)]	Herring	0.83	0.45	1.51	0.53	0.77	0.42	1.41	0.40	0.77	0.40	1.49	0.44
Fish species	Mackerel	0.34	0.19	0.60	0.00	0.33	0.18	0.61	0.00	0.32	0.17	0.57	0.00
Fish species	Mixed Fish	0.44	0.27	0.73	0.00	0.41	0.24	0.69	0.00	0.34	0.19	0.60	0.00
Fish species	Other Fish	0.69	0.41	1.16	0.17	0.65	0.38	1.10	0.11	0.59	0.33	1.05	0.07
"EC 2073/2005 NSG" [b)]		0.58	0.23	1.48	0.25	0.52	0.20	1.35	0.18	0.72	0.26	1.99	0.52
"EC 2073/2005 NSG"*Fish species	Herring	0.78	0.13	4.57	0.78	0.85	0.14	5.09	0.86	0.87	0.14	5.49	0.89
"EC 2073/2005 NSG"*Fish species	Mackerel	7.39	1.94	28.06	0.00	9.12	2.44	34.08	0.00	5.98	1.40	25.63	0.02
"EC 2073/2005 NSG"*Fish species	Mixed Fish	4.35	0.88	21.51	0.07	4.98	0.99	25.01	0.05	3.93	0.73	21.10	0.11
"EC 2073/2005 NSG"*Fish species	Other Fish	0.90	0.16	5.12	0.91	1.05	0.19	5.97	0.95	0.66	0.11	4.16	0.66

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Fish Species "Salmon"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

Sensitivity Analysis

Table 270: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single risk factor (Fish species) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth DF	Firth Chi-Square	Firth P-Value	Firth - weighted sample planned DF	Firth - weighted sample planned Chi-Square	Firth - weighted sample planned P-Value	Firth - weighted population DF	Firth - weighted population Chi-Square	Firth - weighted population P-Value
Fish species	4	25.80	<.0001	4	30.10	<.0001	4	33.99	<.0001
"EC 2073/2005 NSG"	1	1.05	0.31	1	1.47	0.23	1	0.26	0.61
"EC 2073/2005 NSG" * Fish species	4	13.08	0.01	4	16.40	0.00	4	9.96	0.04

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 271: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Fish species) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.14	0.12	0.16	<.0001	0.16	0.14	0.18	<.0001	0.15	0.13	0.17	<.0001
Fish species a)	Herring	0.85	0.49	1.46	0.55	0.79	0.46	1.35	0.38	0.79	0.46	1.36	0.40
Fish species	Mackerel	0.35	0.21	0.58	<.0001	0.34	0.21	0.55	<.0001	0.32	0.20	0.53	<.0001
Fish species	Mixed Fish	0.45	0.28	0.74	0.00	0.42	0.25	0.70	0.00	0.35	0.20	0.61	0.00
Fish species	Other Fish	0.71	0.44	1.13	0.15	0.66	0.42	1.03	0.07	0.60	0.38	0.96	0.03
"EC 2073/2005 NSG" b)		0.63	0.26	1.53	0.31	0.57	0.23	1.41	0.23	0.78	0.31	1.99	0.61
"EC 2073/2005 NSG"*Fish species	Herring	0.86	0.16	4.50	0.85	0.92	0.18	4.67	0.92	0.94	0.18	5.05	0.95
"EC 2073/2005 NSG"*Fish species	Mackerel	6.97	1.92	25.28	0.00	8.49	2.44	29.55	0.00	5.67	1.46	22.09	0.01
"EC 2073/2005 NSG"*Fish species	Mixed Fish	4.42	0.95	20.60	0.06	5.05	1.05	24.41	0.04	4.38	0.67	28.61	0.12
"EC 2073/2005 NSG"*Fish species	Other Fish	1.00	0.20	5.11	1.00	1.13	0.24	5.44	0.88	0.77	0.13	4.39	0.77

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Fish Species "Salmon"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Preservatives and acidity regulators***

GEE Analysis

Table 272: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (Number of preservatives and acidity regulators) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Preservatives and acidity regulators	2	46.89	<.0001	2	26.96	<.0001	2	24.75	<.0001
"EC 2073/2005 NSG"	1	0.57	0.45	1	0.34	0.56	1	0.05	0.82
"EC 2073/2005 NSG"*Preservatives and acidity regulators	2	0.54	0.76	2	0.56	0.76	2	1.86	0.39

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 273: Odds ratio of GEE (Ind) Analysis of single risk factor (Number of preservatives and acidity regulators) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.11	0.09	0.13	<.0001	0.12	0.10	0.14	<.0001	0.11	0.09	0.13	<.0001
Preservatives and acidity regulators [a)]	1: Products with 1 AP+AR	0.54	0.17	1.68	0.29	0.48	0.15	1.49	0.20	0.50	0.14	1.75	0.28
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	9.14	4.81	17.38	<.0001	8.43	3.66	19.40	<.0001	10.93	4.15	28.78	<.0001
"EC 2073/2005 NSG" [b)]		0.78	0.40	1.50	0.45	0.82	0.41	1.62	0.56	0.92	0.45	1.89	0.82

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

"EC 2073/2005 NSG"*Preservatives and acidity regulators	1: Products with 1 AP+AR	0.78	0.10	5.91	0.81	0.94	0.13	6.69	0.95	0.74	0.09	5.80	0.77
"EC 2073/2005 NSG"*Preservatives and acidity regulators	2: Products with 2 or more AP+AR	0.64	0.17	2.37	0.51	0.60	0.15	2.38	0.47	0.39	0.09	1.63	0.20

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Preservatives and acidity regulators is "0: Products with no AP and AR"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

Sensitivity Analysis

Table 274: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single risk factor (Number of preservatives and acidity regulators) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Preservatives and acidity regulators	2	47.99	<.0001	2	62.22	<.0001	2	69.67	<.0001
"EC 2073/2005 NSG"	1	0.57	0.45	1	0.39	0.53	1	0.02	0.88
"EC 2073/2005 NSG"*Preservatives and acidity regulators	2	0.38	0.83	2	0.59	0.74	2	1.32	0.52

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 275: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Number of preservatives and acidity regulators) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	OR	CL	P-Value	OR	CL	P-	OR	CL	P-Value

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

			LL	UL			LL	UL	Value		LL	UL	
Intercept		0.11	0.10	0.12	<.0001	0.12	0.10	0.13	<.0001	0.11	0.10	0.12	<.0001
Preservatives and acidity regulators [a)]	1: Products with 1 AP+AR	0.62	0.21	1.86	0.39	0.56	0.18	1.70	0.30	0.56	0.20	1.54	0.26
Preservatives and acidity regulators	2: Products with 2 or more AP+AR	9.13	4.85	17.18	<.0001	8.42	4.93	14.40	<.0001	10.88	6.17	19.20	<.0001
"EC 2073/2005 NSG" [b)]		0.80	0.45	1.42	0.45	0.84	0.49	1.45	0.53	0.95	0.52	1.75	0.88
"EC 2073/2005 NSG" * Preservatives and acidity regulators	1: Products with 1 AP+AR	0.96	0.12	7.69	0.97	1.06	0.15	7.41	0.96	0.92	0.12	6.95	0.93
"EC 2073/2005 NSG" * Preservatives and acidity regulators	2: Products with 2 or more AP+AR	0.65	0.17	2.54	0.54	0.61	0.17	2.20	0.45	0.41	0.09	1.89	0.25

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Preservatives and acidity regulators is "0: Products with no AP and AR"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

- ***Possible slicing***

GEE Analysis

Table 276: Odds ratio of GEE (Ind) Analysis of single risk factor (Possible slicing) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.06	0.04	0.08	<.0001	0.06	0.04	0.09	<.0001	0.05	0.04	0.08	<.0001
Possible slicing [a)]	2.47	1.68	3.63	<.0001	2.46	1.62	3.72	<.0001	2.59	1.69	3.97	<.0001

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

"EC 2073/2005 NSG" b)	1.82	0.78	4.24	0.17	1.96	0.86	4.49	0.11	2.32	0.98	5.49	0.05
Possible slicing * "EC 2073/2005 NSG"	0.40	0.15	1.05	0.06	0.35	0.14	0.87	0.02	0.29	0.11	0.77	0.01

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Possible slicing is "No Sliced"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

Sensitivity Analysis

Table 277: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Possible slicing) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.06	0.04	0.08	<.0001	0.06	0.04	0.08	<.0001	0.05	0.04	0.08	<.0001
Possible slicing a)	2.45	1.71	3.50	<.0001	2.43	1.71	3.45	<.0001	2.56	1.76	3.70	<.0001
"EC 2073/2005 NSG" b)	1.89	0.86	4.15	0.11	2.03	0.98	4.17	0.06	2.42	1.08	5.43	0.03
Possible slicing * "EC 2073/2005 NSG"	0.40	0.15	1.09	0.07	0.35	0.14	0.91	0.03	0.29	0.10	0.85	0.02

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Possible slicing is "No Sliced"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Packaging Type***(c)

GEE Analysis

Table 278: Odds ratio of GEE (Ind) Analysis of single risk factor (Packaging type(c)) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.12	0.11	0.14	<.0001	0.13	0.11	0.16	<.0001	0.12	0.10	0.15	<.0001
Packaging type(c) a)	Modified atmosphere	0.70	0.49	1.00	0.05	0.66	0.46	0.96	0.03	0.72	0.50	1.06	0.09
"EC 2073/2005 NSG" b)		0.81	0.43	1.52	0.51	0.82	0.42	1.59	0.56	0.84	0.41	1.72	0.64
"EC 2073/2005 NSG" * Packaging type(c)	Modified atmosphere	1.44	0.29	7.27	0.66	1.33	0.26	6.86	0.73	1.40	0.25	7.84	0.70

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Packaging Type(c) is "All other packaging types"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

Sensitivity Analysis

Table 279: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Packaging type(c)) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.12	0.11	0.14	<.0001	0.13	0.12	0.15	<.0001	0.12	0.11	0.14	<.0001

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Packaging type(c) a)	Modified atmosphere	0.70	0.50	0.98	0.04	0.67	0.48	0.95	0.02	0.73	0.52	1.02	0.06
"EC 2073/2005 NSG" b)		0.83	0.50	1.38	0.47	0.84	0.52	1.36	0.47	0.87	0.50	1.51	0.61
"EC 2073/2005 NSG" * Packaging type(c)	Modified atmosphere	1.70	0.39	7.36	0.48	1.59	0.36	7.13	0.54	1.70	0.34	8.45	0.51

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Packaging Type(c) is "All other packaging types"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

- ***Storage temperature at retail***

<u>GEE Analysis</u>

Table 280: Odds ratio of GEE (Ind) Analysis of single risk factor (storage temperature at retail) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.14	0.11	0.18	<.0001	0.15	0.11	0.20	<.0001	0.14	0.11	0.19	<.0001
Temperature at retail	0.95	0.89	1.01	0.10	0.95	0.89	1.02	0.16	0.94	0.88	1.02	0.12
"EC 2073/2005 NSG" a)	0.83	0.16	4.24	0.82	1.05	0.17	6.47	0.96	0.91	0.16	5.11	0.91
Temperature at retail * "EC 2073/2005 NSG"	1.02	0.69	1.50	0.94	0.95	0.62	1.46	0.81	1.00	0.67	1.48	1.00

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sensitivity Analysis

Table 281: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (storage temperature at retail) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.14	0.11	0.18	<.0001	0.15	0.11	0.19	<.0001	0.14	0.11	0.19	<.0001
Temperature at retail	0.95	0.89	1.02	0.17	0.95	0.89	1.02	0.17	0.94	0.88	1.01	0.12
"EC 2073/2005 NSG" a)	0.84	0.27	2.54	0.75	1.05	0.36	3.12	0.93	0.92	0.27	3.11	0.89
Temperature at retail * "EC 2073/2005 NSG"	1.02	0.77	1.36	0.86	0.96	0.72	1.27	0.77	1.01	0.74	1.38	0.95

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

- ***Remaining shelf-life***

GEE Analaysis

Table 282: Odds ratio of GEE (Ind) Analysis of single risk factor (remaining shelf-life) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.12	0.10	0.14	<.0001	0.13	0.11	0.15	<.0001	0.12	0.10	0.14	<.0001
Remaining Shelf-life	1.00	1.00	1.00	0.83	1.00	1.00	1.00	0.78	1.00	1.00	1.00	0.92

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

"EC 2073/2005 NSG" [a)]	1.28	0.73	2.23	0.39	1.24	0.71	2.16	0.46	1.35	0.73	2.50	0.33
Remaining Shelf-life * "EC 2073/2005 NSG"	0.99	0.98	1.00	0.04	0.99	0.98	1.00	0.06	0.99	0.98	1.00	0.05

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

Sensitivity Analysis

Table 283: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (remaining shelf-life) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.12	0.10	0.13	<.0001	0.13	0.11	0.15	<.0001	0.12	0.10	0.14	<.0001
Remaining Shelf-life	1.00	1.00	1.00	0.94	1.00	1.00	1.00	0.99	1.00	1.00	1.01	0.78
"EC 2073/2005 NSG" [a)]	1.25	0.69	2.27	0.45	1.22	0.69	2.16	0.50	1.34	0.68	2.62	0.40
Remaining Shelf-life * "EC 2073/2005 NSG"	0.99	0.98	1.00	0.18	0.99	0.98	1.00	0.20	0.99	0.98	1.00	0.20

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

D.2. Single-factor model of proportion of samples with counts exceeding the level of 100 cfu/g of fish at time of sampling

- ***Storage temperature at retail***

GEE Analysis

Table 284: Odds ratio of GEE (Ind) Analysis of single risk factor (storage temperature at retail) analysis with interaction of "EC 2073/2005 NSG" indicator for Proportion of enumeration above 100 cfu/g for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.02	0.01	0.03	<.0001	0.02	0.01	0.04	<.0001	0.01	0.01	0.03	<.0001
Temperature at retail	0.86	0.71	1.04	0.13	0.87	0.71	1.05	0.14	0.82	0.66	1.03	0.09
"EC 2073/2005 NSG" a)	0.20	0.02	1.68	0.14	0.19	0.02	1.59	0.12	0.12	0.01	1.07	0.06
Temperature at retail * "EC 2073/2005 NSG"	1.29	1.04	1.59	0.02	1.29	1.04	1.60	0.02	1.37	1.07	1.76	0.01

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

Sensitivity Analysis

Table 285: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (storage temperature at retail) analysis with interaction of "EC 2073/2005 NSG" indicator for proportion of enumeration above 100cfu/g for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.02	0.01	0.04	<.0001	0.02	0.01	0.04	<.0001	0.02	0.01	0.04	<.0001
Temperature at retail	0.87	0.69	1.09	0.23	0.87	0.70	1.09	0.23	0.83	0.64	1.08	0.16

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

"EC 2073/2005 NSG" a)	0.20	0.01	6.81	0.37	0.17	0.01	5.91	0.33	0.13	0.00	9.53	0.35
Temperature at retail * "EC 2073/2005 NSG"	1.50	0.72	3.09	0.28	1.51	0.73	3.10	0.26	1.72	0.74	4.00	0.21

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

- ***Remaining shelf-life***

<u>GEE Analysis</u>

Table 286: Odds ratio of GEE (Ind) Analysis of single risk factor (remaining shelf-life) analysis with interaction of "EC 2073/2005 NSG" indicator for Proportion of enumeration above 100 cfu/g for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept	0.01	0.01	0.02	<.0001	0.01	0.01	0.02	<.0001	0.01	0.00	0.01	<.0001
Remaining Shelf-life	1.00	0.99	1.01	0.93	1.00	0.99	1.01	0.96	1.00	1.00	1.01	0.50
"EC 2073/2005 NSG" a)	1.13	0.15	8.46	0.90	1.15	0.15	8.61	0.89	1.04	0.14	7.86	0.97
Remaining Shelf-life * "EC 2073/2005 NSG"	0.97	0.96	0.98	<.0001	0.96	0.95	0.98	<.0001	0.96	0.95	0.97	<.0001

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sensitivity Analysis

Table 287: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (remaining shelf-life) analysis with interaction of "EC 2073/2005 NSG" indicator for proportion of enumeration above 100cfu/g for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.01	0.01	0.01	<.0001	0.01	0.01	0.02	<.0001	0.01	0.00	0.01	<.0001
Remaining Shelf-life	1.00	1.00	1.01	0.37	1.00	1.00	1.01	0.35	1.01	1.00	1.02	0.16
"EC 2073/2005 NSG" a)	0.74	0.12	4.76	0.75	0.69	0.11	4.35	0.69	0.69	0.06	7.47	0.76
Remaining Shelf-life * "EC 2073/2005 NSG"	1.00	0.99	1.01	0.99	1.00	0.99	1.01	0.99	1.00	0.98	1.02	0.98

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

D.3. Single-factor model of prevalence for packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life

- ***Type of retail outlet***

GEE Analysis

Table 288: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (Type of retail outlet) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type of retail outlet	1	0.34	0.56	1	0.62	0.43	1	0.44	0.51
“EC 2073/2005 NSG”	1	1.09	0.30	1	0.68	0.41	1	0.83	0.36
“EC 2073/2005 NSG” * Type of retail outlet	1	2.24	0.13	1	1.91	0.17	1	2.20	0.14

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 289: Odds ratio of GEE (Ind) Analysis of single risk factor (Type of retail outlet) analysis with interaction of “EC 2073/2005 NSG” indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.12	0.10	0.13	<.0001	0.12	0.10	0.14	<.0001	0.11	0.10	0.13	<.0001
Type of retail outlet [a)]	All other types of retail outlet	1.27	0.57	2.82	0.56	1.38	0.62	3.09	0.43	1.31	0.59	2.90	0.51
“EC 2073/2005 NSG” [b)]		0.72	0.39	1.33	0.30	0.76	0.40	1.45	0.41	0.72	0.35	1.46	0.36
“EC 2073/2005 NSG”*Type	All other types of	9.45	0.50	179.61	0.13	8.01	0.42	153.55	0.17	9.45	0.49	183.68	0.14

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

of retail outlet	retail outlet			

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type of retail outlet is "Supermarket or small shop"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

Sensitivity Analysis

Sensitivity analysis using Firth approach was fitted from GEE final model. The results are in the following table:

Table 290: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single risk factor (Type of retail outlet) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type of retail outlet	1	0.50	0.48	1	0.77	0.38	1	0.62	0.43
"EC 2073/2005 NSG"	1	1.27	0.26	1	0.95	0.33	1	0.98	0.32
"EC 2073/2005 NSG" * Type of retail outlet	1	2.05	0.15	1	1.51	0.22	1	2.16	0.14

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 291: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Type of retail outlet) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.12	0.10	0.13	<.0001	0.12	0.11	0.13	<.0001	0.11	0.10	0.13	<.0001
Type of retail outlet [a)]	All other types of retail outlet	1.36	0.58	3.16	0.48	1.48	0.62	3.57	0.38	1.39	0.61	3.17	0.43

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

"EC 2073/2005 NSG" [b)]		0.74	0.44	1.25	0.26	0.78	0.48	1.28	0.33	0.74	0.41	1.33	0.32
"EC 2073/2005 NSG" * Type of retail outlet	All other types of retail outlet	8.58	0.45	162.57	0.15	7.27	0.31	172.00	0.22	8.57	0.49	150.94	0.14

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type of retail outlet is "Supermarket or small shop"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

- ***Sampling season***

GEE Analysis

Table 292: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (Sampling season) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	15.85	0.00	3	14.33	0.00	3	16.57	0.00
"EC 2073/2005 NSG"	1	0.11	0.74	1	0.24	0.62	1	2.16	0.14
"EC 2073/2005 NSG" * Sampling season	3	0.31	0.96	3	0.42	0.94	3	1.31	0.73

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 293: Odds ratio of GEE (Ind) Analysis of single risk factor (Sampling season) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.09	0.06	0.12	<.0001	0.09	0.07	0.13	<.0001	0.09	0.06	0.12	<.0001

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sampling season a)	autumn	1.73	1.20	2.50	0.00	1.72	1.18	2.51	0.00	1.78	1.20	2.64	0.00
Sampling season	spring	0.96	0.63	1.47	0.86	0.98	0.64	1.50	0.93	0.93	0.59	1.46	0.76
Sampling season	summer	1.34	0.91	2.00	0.14	1.35	0.91	2.02	0.14	1.36	0.89	2.07	0.15
“EC 2073/2005 NSG” b)		0.83	0.28	2.48	0.74	0.76	0.25	2.28	0.62	0.42	0.13	1.34	0.14
“EC 2073/2005 NSG”*Sampling season	autumn	0.92	0.21	3.98	0.91	1.19	0.26	5.34	0.82	1.94	0.40	9.48	0.41
“EC 2073/2005 NSG”*Sampling season	spring	0.67	0.11	4.07	0.66	0.69	0.11	4.27	0.69	1.55	0.22	10.76	0.66
“EC 2073/2005 NSG”*Sampling season	summer	1.09	0.21	5.59	0.92	1.23	0.22	6.92	0.82	2.69	0.48	14.98	0.26

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is “winter”
b) : The reference category “EC 2073/2005 NSG” is ‘not included in EC 2073/2005 NSG’

Sensitivity Analysis

Sensitivity analysis using Firth approach was fitted from GEE final model. The results are in the following table:

Table 294: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single risk factor (Sampling season) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	15.49	0.00	3	14.70	0.00	3	18.14	0.00
“EC 2073/2005 NSG”	1	0.03	0.87	1	0.12	0.73	1	0.77	0.38
“EC 2073/2005 NSG” * Sampling season	3	0.23	0.97	3	0.31	0.96	3	0.94	0.82

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 295: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Sampling season) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.09	0.07	0.12	<.0001	0.09	0.07	0.12	<.0001	0.09	0.07	0.12	<.0001
Sampling season a)	autumn	1.72	1.22	2.43	0.00	1.71	1.22	2.41	0.00	1.78	1.26	2.49	0.00
Sampling season	spring	0.96	0.64	1.45	0.86	0.98	0.65	1.47	0.93	0.93	0.62	1.40	0.74
Sampling season	summer	1.34	0.92	1.94	0.12	1.35	0.93	1.95	0.11	1.36	0.94	1.96	0.10
"EC 2073/2005 NSG" b)		0.92	0.33	2.52	0.87	0.84	0.31	2.28	0.73	0.53	0.13	2.17	0.38
"EC 2073/2005 NSG"*Sampling season	autumn	0.89	0.24	3.31	0.86	1.13	0.32	4.07	0.85	1.65	0.31	8.78	0.56
"EC 2073/2005 NSG"*Sampling season	spring	0.74	0.14	3.90	0.72	0.78	0.14	4.17	0.77	1.58	0.21	12.22	0.66
"EC 2073/2005 NSG"*Sampling season	summer	1.07	0.27	4.20	0.92	1.19	0.31	4.55	0.80	2.27	0.42	12.16	0.34

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is "winter"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Fish Species***

GEE Analysis

Table 296: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (Fish species) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Fish species	4	25.44	<.0001	4	24.05	<.0001	4	26.59	<.0001
"EC 2073/2005 NSG"	1	0.21	0.65	1	0.22	0.64	1	0.03	0.86
"EC 2073/2005 NSG" * Fish species	4	12.75	0.01	4	14.16	0.01	4	10.87	0.03

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 297: Odds ratio of GEE (Ind) Analysis of single risk factor (Fish species) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.14	0.12	0.17	<.0001	0.15	0.13	0.18	<.0001	0.14	0.12	0.17	<.0001
Fish species [a)]	Herring	0.82	0.48	1.41	0.48	0.79	0.46	1.36	0.39	0.86	0.48	1.54	0.61
Fish species	Mackerel	0.22	0.11	0.42	<.0001	0.22	0.11	0.43	<.0001	0.21	0.11	0.43	<.0001
Fish species	Mixed Fish	0.60	0.39	0.93	0.02	0.58	0.36	0.93	0.02	0.50	0.30	0.81	0.01
Fish species	Other Fish	0.69	0.41	1.16	0.16	0.67	0.39	1.14	0.14	0.65	0.37	1.16	0.14

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

“EC 2073/2005 NSG” b)		0.83	0.37	1.85	0.65	0.83	0.37	1.84	0.64	0.92	0.38	2.24	0.86
“EC 2073/2005 NSG” * Fish species	Herring	0.26	0.03	2.40	0.24	0.21	0.02	1.92	0.17	0.31	0.03	3.05	0.32
“EC 2073/2005 NSG” * Fish species	Mackerel	8.06	1.80	36.17	0.01	9.38	2.01	43.76	0.00	7.00	1.28	38.23	0.02
“EC 2073/2005 NSG” * Fish species	Mixed Fish	0.67	0.07	5.99	0.72	0.70	0.08	6.33	0.75	0.66	0.07	6.27	0.72
“EC 2073/2005 NSG” * Fish species	Other Fish	0.31	0.03	2.76	0.29	0.28	0.03	2.59	0.26	0.17	0.02	1.62	0.12

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Fish Species “Salmon”
b) : The reference category “EC 2073/2005 NSG” is ‘not included in EC 2073/2005 NSG’

Sensitivity Analysis

Table 298: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single risk factor (Fish species) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Fish species	4	27.93	<.0001	4	29.70	<.0001	4	31.39	<.0001
“EC 2073/2005 NSG”	1	0.10	0.75	1	0.11	0.74	1	0.00	0.98
“EC 2073/2005 NSG” * Fish species	4	16.57	0.00	4	20.75	0.00	4	13.45	0.01

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Table 299: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Fish species) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.14	0.12	0.16	<.0001	0.15	0.13	0.17	<.0001	0.14	0.12	0.16	<.0001
Fish species a)	Herring	0.84	0.49	1.46	0.54	0.81	0.47	1.40	0.45	0.88	0.51	1.50	0.64
Fish species	Mackerel	0.22	0.12	0.41	<.0001	0.22	0.12	0.40	<.0001	0.22	0.12	0.40	<.0001
Fish species	Mixed Fish	0.61	0.39	0.94	0.03	0.59	0.37	0.95	0.03	0.51	0.31	0.83	0.01
Fish species	Other Fish	0.70	0.44	1.12	0.14	0.68	0.43	1.08	0.10	0.67	0.42	1.05	0.08
"EC 2073/2005 NSG" b)		0.88	0.40	1.92	0.75	0.88	0.40	1.92	0.74	0.99	0.41	2.37	0.98
"EC 2073/2005 NSG" * Fish species	Herring	0.36	0.05	2.39	0.29	0.30	0.04	2.16	0.23	0.41	0.06	2.82	0.37
"EC 2073/2005 NSG" * Fish species	Mackerel	7.69	2.18	27.13	0.00	8.85	2.63	29.76	0.00	6.66	1.70	26.15	0.01
"EC 2073/2005 NSG" * Fish species	Mixed Fish	0.91	0.13	6.11	0.92	0.96	0.14	6.67	0.97	1.13	0.11	11.46	0.92
"EC 2073/2005 NSG" * Fish species	Other Fish	0.42	0.06	2.73	0.36	0.39	0.06	2.51	0.32	0.29	0.03	2.51	0.26

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

a) : The reference category for Fish Species "Salmon"

b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Possible slicing***

GEE Analysis

Table 300: Odds ratio of GEE (Ind) Analysis of single risk factor (Possible slicing) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.06	0.04	0.08	<.0001	0.06	0.04	0.09	<.0001	0.06	0.04	0.08	<.0001
Possible slicing [a)]	2.40	1.67	3.46	<.0001	2.23	1.53	3.26	<.0001	2.33	1.57	3.45	<.0001
"EC 2073/2005 NSG" [b)]	1.53	0.52	4.49	0.44	1.63	0.53	5.00	0.40	1.87	0.61	5.80	0.28
Possible slicing* "EC 2073/2005 NSG"	0.43	0.12	1.54	0.20	0.40	0.11	1.48	0.17	0.30	0.08	1.20	0.09

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Possible slicing is "No Sliced"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

Sensitivity Analysis

Table 301: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Possible slicing) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Intercept	0.06	0.04	0.08	<.0001	0.06	0.05	0.09	<.0001	0.06	0.04	0.08	<.0001
Possible slicing [a)]	2.38	1.67	3.39	<.0001	2.21	1.56	3.13	<.0001	2.30	1.60	3.31	<.0001
"EC 2073/2005 NSG" [b)]	1.60	0.71	3.64	0.26	1.69	0.79	3.61	0.17	1.97	0.85	4.59	0.12
Possible slicing* "EC 2073/2005 NSG"	0.43	0.15	1.21	0.11	0.40	0.15	1.08	0.07	0.31	0.10	0.97	0.04

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Possible slicing is "No Sliced"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

- ***Packaging type***[(c)]

GEE Analysis

Table 302: Odds ratio of GEE (Ind) Analysis of single risk factor (Packaging type[(c)]) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.12	0.10	0.14	<.0001	0.12	0.10	0.14	<.0001	0.12	0.10	0.14	<.0001
Packaging type[(c) a)]	Modified atmosphere	0.84	0.61	1.16	0.29	0.84	0.61	1.16	0.29	0.90	0.65	1.25	0.55
"EC 2073/2005 NSG" [b)]		0.73	0.38	1.37	0.32	0.77	0.39	1.50	0.44	0.74	0.35	1.55	0.42
"EC 2073/2005 NSG" * Packaging type[(c)]	Modified atmosphere	1.37	0.27	6.88	0.70	1.23	0.24	6.31	0.80	1.38	0.25	7.71	0.71

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Packaging Type[(c)] is "All other packaging types"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sensitivity Analysis

Table 303: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Packaging type(c)) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.12	0.10	0.14	<.0001	0.12	0.11	0.14	<.0001	0.12	0.10	0.13	<.0001
Packaging type(c) a)	Modified atmosphere	0.85	0.62	1.17	0.31	0.85	0.61	1.18	0.33	0.91	0.66	1.25	0.56
"EC 2073/2005 NSG" b)		0.75	0.44	1.28	0.29	0.79	0.47	1.31	0.36	0.77	0.42	1.40	0.38
"EC 2073/2005 NSG" * Packaging type(c)	Modified atmosphere	1.61	0.37	7.02	0.53	1.47	0.33	6.62	0.62	1.67	0.33	8.38	0.54

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Packaging Type(c) is "All other packaging types"
b) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

- ***Storage temperature at laboratory up to the end of shelf-life***

GEE Analysis

Table 304: Odds ratio of GEE (Ind) Analysis of single risk factor (storage temperature at laboratory up to the end of shelf-life) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept	0.20	0.12	0.32	<.0001	0.19	0.12	0.30	<.0001	0.19	0.12	0.30	<.0001

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Temperature at laboratory	0.88	0.78	0.98	0.02	0.89	0.80	1.00	0.04	0.88	0.79	0.98	0.02
"EC 2073/2005 NSG" a)	0.10	0.02	0.58	0.01	0.13	0.02	0.72	0.02	0.13	0.02	0.87	0.04
Temperature at laboratory * "EC 2073/2005 NSG"	1.60	1.12	2.28	0.01	1.54	1.09	2.18	0.01	1.51	1.02	2.23	0.04

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

Sensitivity Analysis

Table 305: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (storage temperature at laboratory up to the end of shelf-life) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.20	0.13	0.30	<.0001	0.19	0.12	0.29	<.0001	0.19	0.13	0.29	<.0001
Temperature at laboratory	0.88	0.79	0.97	0.01	0.90	0.81	0.99	0.03	0.88	0.80	0.97	0.01
"EC 2073/2005 NSG" a)	0.11	0.02	0.57	0.01	0.13	0.03	0.66	0.01	0.13	0.02	0.86	0.03
Temperature at laboratory * "EC 2073/2005 NSG"	1.61	1.13	2.30	0.01	1.55	1.09	2.20	0.01	1.53	1.03	2.27	0.04

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Remaining shelf-life***

GEE Analysis

Table 306: Odds ratio of GEE (Ind) Analysis of single risk factor (remaining shelf-life) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.116	0.100	0.135	<.0001	0.118	0.101	0.138	<.0001	0.110	0.093	0.130	<.0001
Remaining Shelf-life	1.000	0.997	1.003	0.998	1.000	0.998	1.003	0.762	1.002	0.998	1.005	0.422
"EC 2073/2005 NSG" a)	1.114	0.628	1.974	0.712	1.141	0.646	2.014	0.650	1.184	0.623	2.250	0.606
Remaining Shelf-life * "EC 2073/2005 NSG"	0.991	0.983	1.000	0.045	0.992	0.983	1.000	0.053	0.990	0.979	1.000	0.050

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category "EC 2073/2005 NSG" is 'not included in EC 2073/2005 NSG'

Sensitivity Analysis

Table 307: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (remaining shelf-life) analysis with interaction of "EC 2073/2005 NSG" indicator for prevalence of samples contaminated by *Listeria monocytogenes* in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.115	0.099	0.133	<.0001	0.117	0.101	0.136	<.0001	0.109	0.093	0.127	<.0001

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Remaining Shelf-life	1.000	0.996	1.005	0.834	1.001	0.997	1.005	0.686	1.002	0.997	1.007	0.429
“EC 2073/2005 NSG” [a)]	1.093	0.590	2.026	0.777	1.124	0.616	2.051	0.704	1.166	0.571	2.381	0.674
Remaining Shelf-life * “EC 2073/2005 NSG”	0.993	0.983	1.004	0.198	0.993	0.983	1.003	0.181	0.992	0.980	1.004	0.175

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

a) : The reference category “EC 2073/2005 NSG” is ‘not included in EC 2073/2005 NSG’

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

D.4. Single-factor model of proportion of samples with counts exceeding the level of 100 cfu/g for packaged (not frozen) hot or cold smoked or gravad fish at the end of shelf-life

- ***Type of retail outlet***

GEE Analysis

Table 308: Odds ratio of GEE (Ind) Analysis of single- factor (Type of retail outlet) analysis for proportion of enumeration above 100 cfu/g at the end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.017	0.012	0.022	<.0001	0.017	0.013	0.023	<.0001	0.015	0.011	0.021	<.0001
Type[(c)] of retail outlet [a)]	All other types of retail outlet	3.933	1.134	13.643	0.031	3.773	1.087	13.093	0.037	4.378	1.259	15.229	0.020

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type[(c)] of retail outlet is "Supermarket or small shop"

Sensitivity Analysis

Sensitivity analysis using Firth approach was fitted from GEE final model. The results are in the following table:

Table 309: Odds ratio of Logistic Regression (Firth Approach) of single- factor (Type[(c)] of retail outlet) analysis for proportion of enumeration above 100 cfu/g at the end of shelf-life packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.02	0.01	0.02	<.0001	0.02	0.01	0.02	<.0001	0.02	0.01	0.02	<.0001
Type[(c)] of retail outlet [a)]	All other types of retail outlet	4.49	1.45	13.95	0.01	4.41	1.32	14.77	0.02	4.96	1.64	15.01	0.00

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type[(c)] of retail outlet is "Supermarket or small shop"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Sampling season***

GEE Analysis

Table 310: Wald Statistics For Type 3 GEE (Ind) Analysis of single-factor (Sampling season) analysis for for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	9.11	0.0278	3	7.69	0.0528	3	8.1	0.0439

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 311: Odds ratio of GEE (Ind) Analysis of single-factor (Sampling season) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.015	0.008	0.028	<.0001	0.015	0.008	0.028	<.0001	0.014	0.007	0.027	<.0001
Sampling season a)	autumn	1.609	0.753	3.437	0.219	1.601	0.750	3.421	0.224	1.555	0.696	3.473	0.281
Sampling season	spring	0.299	0.083	1.083	0.066	0.357	0.098	1.308	0.120	0.304	0.079	1.166	0.083
Sampling season	summer	1.533	0.699	3.360	0.286	1.658	0.755	3.639	0.208	1.467	0.638	3.375	0.368

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is “winter”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sensitivity Analysis

Sensitivity analysis using Firth approach was fitted from GEE final model. The results are in the following table:

Table 312: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single- factor (Sampling season) analysis for for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	8.2931	0.0403	3	7.8602	0.049	3	7.0561	0.0701

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 313: Odds ratio of Logistic Regression (Firth Approach) of single- factor (Sampling season) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.016	0.009	0.029	<.0001	0.016	0.008	0.029	<.0001	0.015	0.008	0.027	<.0001
Sampling season a)	autumn	1.568	0.748	3.285	0.234	1.561	0.744	3.274	0.239	1.517	0.714	3.227	0.279
Sampling season	spring	0.332	0.099	1.120	0.076	0.391	0.121	1.260	0.116	0.341	0.098	1.188	0.091
Sampling season	summer	1.503	0.694	3.255	0.301	1.624	0.756	3.488	0.214	1.442	0.653	3.187	0.365

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is “winter”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Fish Species***

GEE Analysis

Table 314: Wald Statistics For Type 3 GEE (Ind) Analysis of single- factor (Fish species) analysis for for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Fish species	4	6.86	0.143	4	7.93	0.094	4	5.35	0.253

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 315: Odds ratio of GEE (Ind) Analysis of single- factor (Fish species) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.140	0.120	0.170	<.0001	0.150	0.130	0.180	<.0001	0.140	0.120	0.170	<.0001
Fish species [a)]	Herring	0.820	0.480	1.410	0.480	0.790	0.460	1.360	0.390	0.860	0.480	1.540	0.610
Fish species	Mackerel	0.220	0.110	0.420	<.0001	0.220	0.110	0.430	<.0001	0.210	0.110	0.430	<.0001
Fish species	Mixed Fish	0.600	0.390	0.930	0.020	0.580	0.360	0.930	0.020	0.500	0.300	0.810	0.010
Fish species	Other Fish	0.690	0.410	1.160	0.160	0.670	0.390	1.140	0.140	0.650	0.370	1.160	0.140

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Fish Species “Salmon”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sensitivity Analysis

Table 316: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single- factor (Fish species) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Fish species	4	6.113	0.191	4	6.511	0.164	4	4.651	0.325

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 317: Odds ratio of Logistic Regression (Firth Approach) of single- factor (Fish species) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.021	0.015	0.029	<.0001	0.022	0.016	0.031	<.0001	0.019	0.014	0.027	<.0001
Fish species a)	Herring	0.389	0.075	2.010	0.260	0.361	0.070	1.855	0.223	0.490	0.103	2.335	0.371
Fish species	Mackerel	0.290	0.080	1.047	0.059	0.233	0.060	0.911	0.036	0.326	0.092	1.147	0.081
Fish species	Mixed Fish	0.660	0.247	1.768	0.409	0.714	0.265	1.920	0.504	0.613	0.201	1.866	0.389
Fish species	Other Fish	1.322	0.597	2.924	0.491	1.206	0.549	2.649	0.641	1.175	0.509	2.711	0.705

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Fish Species “Salmon”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Subtype of the fish product***

GEE Analysis

Table 318: Wald Statistics For Type 3 GEE (Ind) Analysis of single- factor (Fish species) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Subtype of the fish product	3	1.35	0.718	3	1.43	0.699	3	1.78	0.619

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 319: Odds ratio of GEE (Ind) Analysis of single- factor (Fish species) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.019	0.010	0.035	<.0001	0.021	0.011	0.038	<.0001	0.017	0.009	0.033	<.0001
Subtype of the fish product a)	Gravad fish	0.417	0.091	1.911	0.260	0.395	0.086	1.824	0.234	0.375	0.077	1.814	0.222
Subtype of the fish product	Hot smoked fish	0.895	0.378	2.123	0.802	0.853	0.354	2.055	0.723	1.077	0.433	2.682	0.873
Subtype of the fish product	Unknown smoked fish	0.951	0.463	1.953	0.891	0.884	0.429	1.821	0.737	0.940	0.428	2.060	0.876

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Subtype of the fish product is “Cold smoked fish”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sensitivity Analysis

Table 320: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single- factor (Fish species) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Subtype of the fish product	3	1.006	0.800	3	1.096	0.778	3	1.103	0.776

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 321: Odds ratio of Logistic Regression (Firth Approach) of single- factor (Fish species) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.020	0.011	0.035	<.0001	0.022	0.012	0.038	<.0001	0.018	0.010	0.033	<.0001
Subtype of the fish product [a)]	Gravad fish	0.500	0.127	1.963	0.321	0.478	0.119	1.914	0.297	0.481	0.103	2.255	0.354
Subtype of the fish product	Hot smoked fish	0.907	0.387	2.127	0.823	0.867	0.366	2.057	0.746	1.085	0.447	2.637	0.857
Subtype of the fish product	Unknown smoked fish	0.929	0.476	1.812	0.829	0.863	0.445	1.674	0.663	0.913	0.448	1.859	0.801

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Subtype of the fish product is "Cold smoked fish"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Possible slicing***

GEE Analysis

Table 322: Odds ratio of GEE (Ind) Analysis of single- factor (Possible slicing) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.008	0.003	0.017	<.0001	0.008	0.003	0.017	<.0001	0.009	0.004	0.019	<.0001
Possible slicing a)	2.655	1.141	6.181	0.024	2.879	1.225	6.766	0.015	2.119	0.906	4.955	0.083

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Possible slicing is “No Sliced”

Sensitivity Analysis

Table 323: Odds ratio of Logistic Regression (Firth Approach) of single- factor (Possible slicing) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.008	0.004	0.018	<.0001	0.008	0.004	0.018	<.0001	0.009	0.004	0.020	<.0001
Possible slicing a)	2.478	1.086	5.656	0.031	2.673	1.148	6.223	0.023	1.983	0.869	4.524	0.104

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Possible slicing is “No Sliced”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Packaging type***(c)

GEE Analysis

Table 324: Odds ratio of GEE (Ind) Analysis of single- factor (Packaging type(c)) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.019	0.014	0.025	<.0001	0.019	0.014	0.026	<.0001	0.017	0.012	0.023	<.0001
Packaging type(c)	Modified atmosphere	0.661	0.303	1.440	0.297	0.679	0.309	1.490	0.334	0.695	0.311	1.553	0.375

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Packaging Type(c) is “All other packaging types”

Sensitivity Analysis

Table 325: Odds ratio of Logistic Regression (Firth Approach) of single- factor (Packaging type(c)) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.019	0.014	0.025	<.0001	0.019	0.014	0.026	<.0001	0.017	0.013	0.023	<.0001
Packaging type(c)	Modified atmosphere	0.699	0.321	1.523	0.368	0.723	0.325	1.606	0.426	0.740	0.330	1.659	0.464

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Packaging Type(c) is “All other packaging types”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Storage temperature at laboratory up to the end of shelf-life***

GEE Analysis

Table 326: Odds ratio of GEE (Ind) Analysis of single- factor (storage temperature at laboratory up to the end of shelf-life) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.023	0.008	0.067	<.0001	0.022	0.008	0.060	<.0001	0.023	0.008	0.062	<.0001
Temperature at laboratory	0.933	0.724	1.203	0.595	0.956	0.751	1.217	0.715	0.919	0.725	1.165	0.485

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Sensitivity Analysis

Table 327: Odds ratio of Logistic Regression (Firth Approach) of single- factor (storage temperature at laboratory up to the end of shelf-life) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.023	0.009	0.059	<.0001	0.021	0.008	0.054	<.0001	0.022	0.009	0.059	<.0001
Temperature at laboratory	0.939	0.755	1.168	0.572	0.962	0.774	1.196	0.730	0.926	0.741	1.158	0.500

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Remaining shelf-life***

GEE Analysis

Table 328: Odds ratio of GEE (Ind) Analysis of single- factor (remaining shelf-life) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.017	0.013	0.024	<.0001	0.018	0.013	0.025	<.0001	0.016	0.011	0.022	<.0001
Remaining Shelf-life	1.000	0.996	1.003	0.814	1.000	0.996	1.003	0.840	1.001	0.996	1.006	0.706

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Sensitivity Analysis

Table 329: Odds ratio of Logistic Regression (Firth Approach) of single- factor (remaining shelf-life) analysis for proportion of enumeration above 100 cfu/g at end of shelf-life in packaged (not frozen) hot or cold smoked or gravad fish for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.017	0.013	0.023	<.0001	0.018	0.013	0.024	<.0001	0.015	0.011	0.021	<.0001
Remaining Shelf-life	1.001	0.995	1.008	0.703	1.001	0.995	1.008	0.701	1.003	0.995	1.010	0.453

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

D.5. Single-factor model of prevalence for packaged heat-treated meat products at the end of shelf-life

- ***Type(c) of retail outlet***

GEE Analysis

Table 330: Odds ratio of GEE (Ind) Analysis of single risk factor (Type(c) of retail outlet) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.02	0.02	0.03	<.0001	0.02	0.02	0.03	<.0001	0.02	0.02	0.03	<.0001
Type(c) of retail outlet a)	All other types of retail outlet	1.57	0.39	6.31	0.53	2.07	0.49	8.72	0.32	1.90	0.46	7.95	0.38

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type(c) of retail outlet is "Supermarket or small shop"

Sensitivity Analysis

Sensitivity analysis using Firth approach was fitted from GEE final model. The results are in the following table:

Table 331: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Type(c) of retail outlet) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept	0.02	0.02	0.03	<.0001	0.02	0.02	0.03	<.0001	0.02	0.02	0.03	<.0001

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Type(c) of retail outlet a)	All other types of retail outlet	1.93	0.53	7.04	0.32	2.63	0.65	10.68	0.18	2.34	0.63	8.64	0.20

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type(c) of retail outlet is "Supermarket or small shop"

- ***Sampling season***

GEE Analysis

Table 332: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (Sampling season) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	0.69	0.88	3	1.39	0.71	3	1.53	0.68

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 333: Odds ratio of GEE (Ind) Analysis of single risk factor (Sampling season) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.02	0.01	0.04	<.0001	0.02	0.01	0.04	<.0001	0.03	0.01	0.05	<.0001
Sampling season a)	autumn	0.91	0.44	1.86	0.79	0.80	0.38	1.68	0.55	0.70	0.32	1.56	0.38
Sampling season	Spring	1.19	0.57	2.50	0.64	1.19	0.54	2.58	0.67	1.05	0.46	2.39	0.91
Sampling season	summer	1.00	0.48	2.06	1.00	1.06	0.51	2.24	0.87	0.95	0.43	2.11	0.90

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is "winter"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sensitivity Analysis

Sensitivity analysis using Firth approach was fitted from GEE final model. The results are in the following table:

Table 334: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single risk factor (Sampling season) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	0.74	0.86	3	1.47	0.69	3	1.82	0.61

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 335: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Sampling season) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.02	0.01	0.04	<.0001	0.02	0.01	0.04	<.0001	0.03	0.02	0.04	<.0001
Sampling season [a)]	autumn	0.90	0.46	1.76	0.76	0.79	0.40	1.56	0.51	0.70	0.37	1.33	0.28
Sampling season	spring	1.18	0.60	2.32	0.62	1.18	0.61	2.30	0.62	1.05	0.56	1.95	0.89
Sampling season	summer	0.99	0.51	1.95	0.98	1.06	0.56	2.01	0.87	0.95	0.52	1.74	0.86

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Sampling season is "winter"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Animal Species[(c)] of the origin of the meat product***

GEE Analysis

Table 336: Odds ratio of GEE (Ind) Analysis of single risk factor (animal species) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.02	0.01	0.04	<.0001	0.02	0.01	0.04	<.0001	0.03	0.01	0.05	<.0001
Animal species[(c) a)]	Other species	0.99	0.52	1.88	0.98	0.89	0.47	1.70	0.73	0.87	0.44	1.70	0.68

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Animal species[(c)] is "Avian species"

Sensitivity Analysis

Table 337: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (animal species) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.02	0.01	0.04	<.0001	0.02	0.01	0.04	<.0001	0.03	0.02	0.04	<.0001
Animal species[(c) a)]	Other species	0.96	0.51	1.81	0.89	0.87	0.48	1.58	0.64	0.85	0.48	1.49	0.57

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Animal species[(c)] is "Avian species"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Type of the meat product***

GEE Analysis

Table 338: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (type of meat product) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type of the meat product	2	8.44	0.01	2	8.06	0.02	2	8.24	0.02

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 339: Odds ratio of GEE (Ind) Analysis of single risk factor (type of meat product) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.02	0.01	0.03	<.0001	0.02	0.02	0.03	<.0001	0.02	0.02	0.03	<.0001
Type of the meat product [a)]	Paté	2.70	1.34	5.42	0.01	2.39	1.15	4.97	0.02	2.13	0.99	4.60	0.05
Type of the meat product	Sausage	0.95	0.51	1.76	0.87	0.70	0.36	1.34	0.28	0.60	0.32	1.14	0.12

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

a) : The reference category for Type of the meat product is "Cold, cooked meat product"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sensitivity Analysis

Table 340: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single risk factor (type of meat product) analysis for prevalence of meat product for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type of the meat product	2	9.14	0.01	2	8.32	0.02	2	7.92	0.02

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 341: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (type of meat product) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.02	0.01	0.03	<.0001	0.02	0.02	0.03	<.0001	0.02	0.02	0.03	<.0001
Type of the meat product [a)]	Paté	2.80	1.41	5.54	0.00	2.48	1.25	4.93	0.01	2.22	1.13	4.35	0.02
Type of the meat product	Sausage	0.97	0.54	1.76	0.93	0.73	0.36	1.49	0.39	0.63	0.31	1.28	0.20

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type of the meat product is “Cold, cooked meat product”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Packaging Place for meat***

GEE Analysis

Table 342: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (packaging place) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Packaging place for meat	2	1.32	0.52	2	0.50	0.78	2	0.22	0.90

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 343: Odds ratio of GEE (Ind) Analysis of single risk factor (packaging place) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.02	0.02	0.03	<.0001	0.02	0.02	0.03	<.0001	0.02	0.02	0.03	<.0001
Packaging place for meat	Packaged at retail	2.46	0.32	18.89	0.39	2.08	0.27	16.29	0.49	0.91	0.12	7.12	0.92
Packaging place for meat	Unknown	1.59	0.50	5.08	0.44	0.94	0.28	3.14	0.91	1.34	0.38	4.70	0.65

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Packaging Placeis “Packaged by the producer”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sensitivity Analysis

Table 344: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single risk factor (packaging place) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Packaging place for meat	2	3.18	0.20	2	1.66	0.44	2	0.94	0.62

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 345: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (packaging place) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.02	0.02	0.03	<.0001	0.02	0.02	0.03	<.0001	0.02	0.02	0.03	<.0001
Packaging place for meat	Packaged at retail	3.57	0.64	19.82	0.15	2.95	0.57	15.32	0.20	1.84	0.22	15.13	0.57
Packaging place for meat	Unknown	1.83	0.61	5.49	0.28	1.09	0.36	3.28	0.88	1.50	0.55	4.07	0.42

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Packaging Placeis “Packaged by the producer”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Possible slicing***

GEE Analysis

Table 346: Odds ratio of GEE (Ind) Analysis of single risk factor (Possible slicing) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.02	0.01	0.03	<.0001	0.01	0.01	0.03	<.0001	0.01	0.01	0.03	<.0001
Possible slicing [a)]	1.41	0.67	2.97	0.37	1.81	0.82	3.99	0.14	2.14	0.94	4.84	0.07

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Possible slicing is “No Sliced”

Sensitivity Analysis

Table 347: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Possible slicing) analysis for prevalence of samples contaminated by *Listeria monocytogene* in packaged heat-treated meat products for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.02	0.01	0.03	<.0001	0.01	0.01	0.03	<.0001	0.01	0.01	0.03	<.0001
Possible slicing [a)]	1.33	0.65	2.75	0.43	1.71	0.81	3.58	0.16	1.99	0.89	4.45	0.09

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Possible slicing is “No Sliced”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Packaging Type***[(c)]

GEE Analysis

Table 348: Odds ratio of GEE (Ind) Analysis of single risk factor (Packaging type[(c)]) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.03	0.02	0.04	<.0001	0.03	0.02	0.04	<.0001	0.03	0.02	0.04	<.0001
Packaging type[(c) a)]	Modified atmosphere	0.64	0.40	1.03	0.06	0.72	0.44	1.18	0.19	0.70	0.41	1.19	0.19

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category Packaging Type[(c)] is “All other packaging types”

Sensitivity Analysis

Table 349: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Packaging type[(c)]) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.03	0.02	0.04	<.0001	0.03	0.02	0.04	<.0001	0.03	0.02	0.04	<.0001
Packaging type[(c) a)]	Modified atmosphere	0.64	0.40	1.02	0.06	0.72	0.45	1.14	0.16	0.70	0.45	1.09	0.11

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category Packaging Type[(c)] is “All other packaging types”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Storage temperature at laboratory up to the end of shelf-life***

GEE Analysis

Table 350: Odds ratio of GEE (Ind) Analysis of single risk factor (storage temperature at laboratory) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.03	0.01	0.06	<.0001	0.02	0.01	0.05	<.0001	0.02	0.01	0.06	<.0001
Temperature at laboratory	0.95	0.79	1.14	0.60	1.01	0.83	1.22	0.95	1.00	0.80	1.24	0.98

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Sensitivity Analysis

Table 351: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (storage temperature at laboratory) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.03	0.01	0.06	<.0001	0.02	0.01	0.04	<.0001	0.02	0.01	0.05	<.0001
Temperature at laboratory	0.96	0.81	1.13	0.60	1.01	0.86	1.20	0.89	1.00	0.86	1.16	0.97

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Remaining shelf-life***

GEE Analysis

Table 352: Odds ratio of GEE (Ind) Analysis of single-factor model (remaining shelf-life) for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.020	0.015	0.026	<.0001	0.020	0.015	0.027	<.0001	0.022	0.016	0.029	<.0001
Remaining Shelf-life	1.003	0.996	1.009	0.416	1.002	0.997	1.008	0.425	1.004	0.997	1.010	0.252

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Sensitivity Analysis

Table 353: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (remaining shelf-life) analysis for prevalence of samples contaminated by *Listeria monocytogenes* in packaged heat-treated meat products for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.019	0.014	0.026	<.0001	0.020	0.015	0.026	<.0001	0.021	0.016	0.028	<.0001
Remaining Shelf-life	1.004	0.996	1.013	0.282	1.004	0.997	1.011	0.295	1.005	0.997	1.014	0.213

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

D.6. Single-factor model of proportion of samples with counts exceeding the level of 100 cfu/g for packaged heat-treated meat products at the end of shelf-life

- ***Sampling season***

GEE Analysis

Table 354: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (Sampling season) analysis for proportion enumeration above 100 cfu/g in packaged heat-treated meat products for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	1.34	0.72	3	1.09	0.78	3	0.71	0.87

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 355: Odds ratio of GEE (Ind) Analysis of single risk factor (Sampling season) analysis of proportion enumeration above 100 cfu/g in packaged heat-treated meat products all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001	0.01	0.00	0.03	<.0001
Sampling season a)	autumn	0.57	0.14	2.37	0.44	0.54	0.13	2.28	0.40	0.54	0.11	2.73	0.46
Sampling season	spring	0.37	0.07	2.12	0.27	0.44	0.08	2.52	0.36	0.52	0.08	3.37	0.49
Sampling season	summer	0.63	0.15	2.61	0.52	0.65	0.16	2.68	0.55	0.70	0.15	3.30	0.65

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category Sampling season is “winter”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sensitivity Analysis

Sensitivity analysis using Firth approach was fitted from GEE final model. The results are in the following table:

Table 356: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single risk factor (Sampling season) analysis for proportion enumeration above 100 cfu/g in packaged heat-treated meat products in all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Sampling season	3	1.48	0.69	3	1.43	0.70	3	1.34	0.72

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 357: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Sampling season) analysis with interaction of "EC 2073/2005 NSG" indicator for Proportion of samples with count exceeding the level of 100 cfu/g in packaged heat-treated meat products in all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001	0.01	0.00	0.02	<.0001
Sampling season a)	autumn	0.58	0.17	2.04	0.40	0.56	0.17	1.84	0.34	0.56	0.18	1.76	0.32
Sampling season	spring	0.42	0.09	1.90	0.26	0.49	0.12	1.96	0.32	0.55	0.16	1.94	0.36
Sampling season	summer	0.64	0.18	2.25	0.49	0.66	0.21	2.13	0.49	0.71	0.24	2.14	0.55

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category Sampling season is "winter"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Animal species[(c)] of the origin of the meat product***

GEE Analysis

Table 358: Odds ratio of GEE (Ind) Analysis of single risk factor (Animal species of the origin of the meat product) analysis of Proportion enumeration above 100 cfu/g of meat product for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.01	0.00	0.02	<.0001	0.01	0.00	0.03	<.0001	0.01	0.01	0.03	<.0001
Animal species[(c) a)]	Other species	0.36	0.13	0.97	0.04	0.38	0.14	1.04	0.06	0.29	0.11	0.82	0.02

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Animal species[(c)] is "Avian species"

Sensitivity Analysis

Table 359: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Animal species[(c)] of the origin of the meat product) analysis Proportion enumeration above 100 cfu/g in packaged heat-treated meat products for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.01	0.00	0.02	<.0001	0.01	0.01	0.02	<.0001	0.01	0.01	0.03	<.0001
Animal species[(c) a)]	Other species	0.34	0.12	0.96	0.04	0.36	0.14	0.96	0.04	0.29	0.12	0.70	0.01

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Animal species[(c)] is "Avian species"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Type of the meat product***

GEE Analysis

Table 360: Wald Statistics For Type 3 GEE (Ind) Analysis of single risk factor (Type of the meat product) analysis for Proportion enumeration above 100 cfu/g in packaged heat-treated meat products for all participating countries*.

Source	GEE (Ind)			GEE (Ind) - weighted sample planned			GEE (Ind) - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type of the meat product	2	2.79	0.25	2	4.51	0.10	2	4.36	0.11

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 361: Odds ratio of GEE (Ind) Analysis of single risk factor (Type of the meat product) analysis of Proportion enumeration above 100 cfu/g in packaged heat-treated meat products for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.00	0.00	0.01	<.0001	0.01	0.00	0.01	<.0001	0.01	0.00	0.01	<.0001
Type of the meat product [a)]	Paté	2.10	0.45	9.72	0.34	2.15	0.46	9.99	0.33	2.28	0.47	10.96	0.31
Type of the meat product	Sausage	0.27	0.03	2.12	0.21	0.16	0.02	1.25	0.08	0.17	0.02	1.38	0.10

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type of the meat product is “Cold, cooked meat product”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

Sensitivity Analysis

Table 362: Wald Statistics For Logistic Regression (Firth Approach) Analysis of single risk factor (Type of the meat product) analysis for Proportion enumeration above 100 cfu/g in packaged heat-treated meat products for all participating countries*.

Source	Firth			Firth - weighted sample planned			Firth - weighted population		
	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value	DF	Chi-Square	P-Value
Type of the meat product	2	3.37	0.19	2	3.71	0.16	2	4.45	0.11

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Table 363: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Type of the meat product) analysis Proportion enumeration above 100 cfu/g of meat product for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
			LL	UL			LL	UL			LL	UL	
Intercept		0.00	0.00	0.01	<.0001	0.01	0.00	0.01	<.0001	0.01	0.00	0.01	<.0001
Type of the meat product [a)]	Paté	2.52	0.64	9.89	0.19	2.52	0.70	9.01	0.16	2.59	0.79	8.52	0.12
Type of the meat product	Sausage	0.39	0.07	2.13	0.28	0.31	0.04	2.30	0.25	0.30	0.04	2.01	0.21

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Type of the meat product is “Cold, cooked meat product”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Possible slicing***

GEE Analysis

Table 364: Odds ratio of GEE (Ind) Analysis of single risk factor (Possible slicing) analysis of Proportion enumeration above 100 cfu/g in packaged heat-treated meat products for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.00	0.00	0.01	<.0001	0.00	0.00	0.01	<.0001	0.00	0.00	0.02	<.0001
Possible slicing [a)]	2.45	0.32	19.04	0.39	2.76	0.35	21.58	0.33	2.69	0.34	21.28	0.35

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Possible slicing is “Non-sliced”

Sensitivity Analysis

Table 365: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Possible slicing) analysis Proportion enumeration above 100 cfu/g in packaged heat-treated meat products for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.00	0.00	0.01	<.0001	0.00	0.00	0.01	<.0001	0.00	0.00	0.01	<.0001
Possible slicing [a)]	1.69	0.31	9.14	0.54	2.01	0.41	9.79	0.39	1.95	0.40	9.45	0.41

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Possible slicing is “Non-sliced”

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Packaging Type*(c)**

GEE Analysis

Table 366: Odds ratio of GEE (Ind) Analysis of single risk factor (Packaging type(c)) analysis of Proportion enumeration above 100 cfu/g in packaged heat-treated meat products for all participating countries*.

Source		GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.01	0.00	0.01	<.0001	0.01	0.00	0.01	<.0001	0.01	0.00	0.02	<.0001
Packaging type(c) a)	Modified atmosphere	0.67	0.23	1.97	0.46	0.75	0.25	2.24	0.61	0.65	0.20	2.12	0.48

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Packaging Type(c) is "All other packaging types"

Sensitivity Analysis

Table 367: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (Packaging type(c)) analysis Proportion enumeration above 100 cfu/g in packaged heat-treated meat products for all participating countries*.

Source		Firth				Firth - weighted sample planned				Firth - weighted population			
		OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value	OR	CL LL	CL UL	P-Value
Intercept		0.01	0.00	0.01	<.0001	0.01	0.00	0.01	<.0001	0.01	0.00	0.01	<.0001
Packaging type(c) a)	Modified atmosphere	0.67	0.25	1.80	0.43	0.75	0.30	1.89	0.54	0.66	0.28	1.57	0.35

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.
a) : The reference category for Packaging Type(c) is "All other packaging types"

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Storage temperature at laboratory up to the end of shelf-life***

GEE Analysis

Table 368: Odds ratio of GEE (Ind) Analysis of single risk factor (storage temperature at laboratory) analysis of Proportion enumeration above 100 cfu/g in packaged heat-treated meat products for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.02	0.00	0.11	<.0001	0.01	0.00	0.09	<.0001	0.01	0.00	0.10	0.00
Temperature at laboratory	0.74	0.46	1.18	0.21	0.82	0.50	1.37	0.46	0.89	0.51	1.56	0.70

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Sensitivity Analysis

Table 369: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (storage temperature at laboratory) analysis Proportion enumeration above 100 cfu/g of meat product for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.01	0.00	0.08	<.0001	0.01	0.00	0.05	<.0001	0.01	0.00	0.04	<.0001
Temperature at laboratory	0.76	0.51	1.13	0.17	0.85	0.58	1.24	0.39	0.92	0.67	1.26	0.59

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

- ***Remaining shelf-life***

GEE Analysis

Table 370: Odds ratio of GEE (Ind) Analysis of single risk factor (remaining shelf-life) analysis of Proportion enumeration above 100 cfu/g in packaged heat-treated meat products for all participating countries*.

Source	GEE (Ind)				GEE (Ind) - weighted sample planned				GEE (Ind) - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.003	0.002	0.006	<.0001	0.004	0.002	0.007	<.0001	0.004	0.002	0.008	<.0001
Remaining Shelf-life	1.009	1.004	1.014	0.000	1.008	1.003	1.013	0.002	1.010	1.004	1.015	0.001

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

Sensitivity Analysis

Table 371: Odds ratio of Logistic Regression (Firth Approach) of single risk factor (remaining shelf-life) analysis Proportion enumeration above 100 cfu/g in packaged heat-treated meat products for all participating countries*.

Source	Firth				Firth - weighted sample planned				Firth - weighted population			
	OR	CL		P-Value	OR	CL		P-Value	OR	CL		P-Value
		LL	UL			LL	UL			LL	UL	
Intercept	0.003	0.002	0.006	<.0001	0.004	0.002	0.007	<.0001	0.004	0.003	0.007	<.0001
Remaining Shelf-life	1.011	1.003	1.019	0.008	1.010	1.002	1.017	0.010	1.011	1.003	1.020	0.011

* : Portugal did not participate in the baseline survey and one non-MS, Norway, participated and is included in this analysis.

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.

ABBREVIATIONS

a_w	water activity
LAC	lactate
ln	natural logarithm
$\log_{10}$	logarithm with base 10
N_{ESL}	concentration of *L. monocytogenes* at date of testing at the end of shelf-life
N_{S}	concentration of *L. monocytogenes* at date of testing on the arrival at the laboratory
NIT	nitrite
P	phenol
t	time
T	temperature
RTE	ready-to-eat

The present document has been produced and adopted by the bodies identified above as author(s). This task has been carried out exclusively by the author(s) in the context of a contract between the European Food Safety Authority and the author(s), awarded following a tender procedure. The present document is published complying with the transparency principle to which the Authority is subject. It may not be considered as an output adopted by the Authority. The European food Safety Authority reserves its rights, view and position as regards the issues addressed and the conclusions reached in the present document, without prejudice to the rights of the authors.