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# Food safety surveillance through a risk based control programme: Approach employed by the Belgian Federal Agency for the Safety of the Food Chain

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# Food safety surveillance through a risk based control programme: Approach employed by the Belgian Federal Agency for the Safety of the Food Chain

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## SUMMARY

**The principal responsibility of the Belgian Federal Agency for the Safety of the Food Chain (FASFC) is to guarantee the safety along the food chain. In order to accomplish this responsibility, the FASFC has developed an integrated official control program to check compliance with various regulations. The original methodology developed and applied by FASFC is presented. This methodology is based on risk evaluation, statistical tools and current scientific knowledge.**

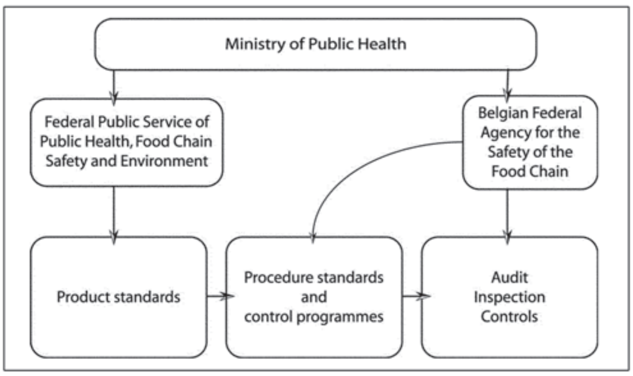
**Keywords:** *Animal welfare; Control programmes; Food chains; Food health and safety systems; Food hygiene; Food inspection; Food law; Food legislation; Food poisoning; Food production chain surveillance systems; Food safety; Foodborne diseases; Foods; Foodstuffs; HACCP; Hazard Analysis Critical Control Points; Product standards; Risk analysis.*

## 1. INTRODUCTION

### 1.1. Tasks of the Belgian Federal Agency for the Safety of the Food Chain

In Belgium, the safety of the food chain is the responsibility of the Ministry of Public Health. Within this ministry, tasks are divided over the Federal Public Service of Public Health, Food Chain Safety and Environment and the Federal Agency for the Safety of the Food Chain (FASFC). The former instance deals with the normative tasks. It takes charge of the establishment of product standards with respect to safety, standards for the control of animal and plant diseases and standards for animal welfare. FASFC is an autonomous entity responsible for risk evaluation, risk management and risk communication (Figure 1). The principal tasks of FASFC are: (1)control, analyses and expertise of food and feed and their primary compounds, (2)control of and expertise in the production, transformation, conservation, transport, trade, import and export of food and feed and their primary compounds, (3)granting approval and authorisation to perform certain activities in the food chain, (4)integration and elaboration of tracing and identification systems of foodstuffs and their primary compounds in the food chain including their control and (5)communication towards the different sectors involved and the consumers (15).

*Figure 1. The tasks of the Belgian federal agency for the safety of the food chain*




Food safety is a major concern for society as a whole and for public authorities and producers in particular.

The different food crises of the 1990s and, more in particular, the Belgian dioxin crisis of 1999 revealed the weak spots of the safety systems of that time and encouraged lawmakers to look for more effective means to protect consumers and to define the details of various action plans related to the safety of the food chain (1,20).

### 1.2. Trends worldwide

The Commission of the Codex Alimentarius continuously defines international standards, directives and recommendations aimed at limiting the risks related to food health and safety. The Codex Alimentarius developed risk analysis, integrated food chain approach and the HACCP system (Hazard Analysis Critical Control Points). This general approach was integrated into the legislation of the European Union and forms the legal basis of all food health and safety systems in the Member States.

### 1.3. Trends in the European Community

In 2000, the European Commission issued the White Paper on Food Safety, which establishes the Commission's political priorities with the objective to achieve the highest possible protection of consumers' health within the European Union (2). The establishment of an independent European Food Safety Authority (EFSA) and the improvement of legislation pertaining to the various aspects related to foodstuffs and official inspections are the pillars of this new food safety policy.

The food production chain surveillance system cannot be effective without full co-operation of every party involved. Therefore, the responsibility for producing safe foodstuffs and for the inspection of this primary production is shared between businesses, the national relevant authorities and the European Commission. By putting into daily practice the provisions pertaining to food safety, each producer plays an essential role in adequately protecting consumers' health. On the other hand, the pertinent authorities control the producers where the latter assume their primary responsibility for foodstuffs and manufacturing processes guaranteeing adequate traceability of their foodstuffs. Acting through the Food and Veterinary Office, the Commission implements an audit and inspection program in order to examine the effectiveness of control systems applied by national authorities.

Within this framework the European Union laid down the Food Law in 2002. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 is the legal basis describing the overall and integrated approach to safety throughout the food chain (7).

The general food law pursues the protection of human health and consumers' interests, applying high standards of animal health and welfare, plant health and environment. The general principles and rules of the food law are based on proven scientific knowledge and take into account all available evidence. For that reason the EFSA was established in 2000 to provide independent information on all issues related to these fields and to ensure adequate information on the risks to the public. Finally, the food law lays down emergency measures, which have to be taken when health is at risk.

The food law is complemented by a wide range of measures that aim at recasting and simplifying the existing regulations relating to hygiene (hygiene package).

General food hygiene rules are laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, complemented by Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (8,9). On the other hand, Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 lays down requirements for feed hygiene (12).

Since January 1$^{st}$, 2006, Regulation 882/2004/CE of the Parliament and the Council of 29 April 2004 is the European reference for the execution of the official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfares rules (10). This execution concerns the entire food chain on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. This Regulation lays down a Community framework for national control systems in order to improve the assessment quality at Community level and, hence, to increase the level of health and safety of food throughout the European Union. It stipulates that the exploitation of control systems will remain the responsibility of the individual Member States and, in this respect, that they shall establish and implement integrated multi-annual control plans in accordance with broad guidelines drawn up at Community level. Multi-annual control plans permit the monitoring of a broader range of sample matrices and hazards.

Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 lays down specific rules for the organization of official controls on products of animal origin intended for human consumption (11).

## 2. ORIGINALITY

According to article 3 of the abovementioned Regulation (EC) No 882/2004, the organization of the official controls must be based on risk analysis, especially with respect to their frequency and priority.

Within this context, this article describes the overall and objective analyses of risks related to emerging diseases in animal or plant productions or to the contamination of food and feed produced, processed or placed on the market in Belgium. It includes controls with sampling and controls without sampling (inspections).

## 3. OBJECTIVES

The objective of this article is to describe the methodology developed and applied by FASFC with respect to organization of official controls performed to check the compliance with regulations falling under its competence in general and food safety in particular. The main goal is to attain a coherent and integrated control program for the entire food chain. On the one hand, the applied methodology provides an additional value to the programme, while on the other hand it makes it possible to optimise the quality of information, which may subsequently be used in risk analyses.

## 4. PROGRAMMING OFFICIAL ANALYSES AT FASFC

FASFC has adopted an approach that allows an objective programming of official controls on the basis of risk evaluation. The approach based on the use of statistical tools for programming a control campaign took into account certain aspects such as relevance, objectives and methodology.

When establishing a control program that includes sampling, the FAFSC makes a distinction between several situations, which determine how the number of analyses must be defined:

a. The number of analyses is imposed by regulations.
b. The number of analyses is determined by risk analysis.
c. The number of analyses is linked to a monitoring.
d. The number of analyses is estimated beforehand.

### 4.1. Programming analyses when the number is imposed by regulations

In this first situation, when regulations impose or recommend a certain frequency or number of checks, the programming team describes the criteria defined by the regulations and indicates how these will be implemented in order to achieve the goals set.

For instance, the Commission recommendation of 14 December 2005 on inspection programs in the field of animal nutrition for the year 2006, submitted in accordance with Directive 95/53/EC of the Council stipulates that each Member State should perform 20 microscopic analyses per 100,000 tons of manufactured compound feedstuffs in order to detect the presence of processed animal protein (PAP) (3,5). So, for Belgium, where annual production amounts to some 6,000,000 tons, the number of samples on which a microscopic analyses must be performed, amounts to 1,200. Samples should be taken from raw materials (RM) and from compound feedstuffs (CF) according to a CF/RM ratio of 6/1 (to the extent that mainly CF are eaten by the animals). The following distribution and recommendations are applied for samples of compound feedstuffs:

- In order to control the production line of ruminant and non-ruminant feedstuffs: CF ruminants/CF non ruminants = 2/1.
- In order to maintain the necessary control pressure among feedstuff producers without omitting downstream checks and mainly to ascertain the absence of contamination during transport and storage: CF manufacturers/CF farmers = 4/1.
- Feedstuffs sampled at farms preferentially originate from manufacturers that are authorised to use PAP, since the risk of cross-contamination is *a priori* greater in these cases.
- Given the period at risk of contamination by feed, preference should be given to check feedstuffs intended for young cattle.
- As for non ruminant feed, preference should be given to feedstuffs that are not made of PAP and that are manufactured after a formula with PAP.
- Given the risk of cross-contamination, the following distribution has been adopted for raw materials samples: Fishmeal/other RM = 3/1.

The distribution of animal feed samples planned for the official control programme in Belgium in 2006 is presented in Table 1.

*Table 1. Distribution of animal feed samples planned for the official control program in accordance with Directive 95/53/EC of the Council (Belgium, year 2006)*

| Sample type | Sample | |
|---|---|---|
| | Number | Approximate ratio |
| CF/RM* | 1030/170 | 6/1 |
| Ruminant CF/non-ruminant CF | 690/340 | 2/1 |
| CF producers/CF owners | 830/200 | 4/1 |
| Fish meal/other RM | 125/45 | 3/1 |

**CF: Compound feedingstuffs; RM: Raw material.*

### 4.2. Programming analyses when the number is statistically defined: programming for the purpose of detecting contamination

The following statistical approach is adopted only for programming checks for the purpose of detecting, with a certain confidence level, the contaminations exceeding a predefined prevalence level. The confidence level and the predefined prevalence level depend on the risk posed by the hazard that must be controlled.

The implementation of the statistical approach includes the following steps, in this order:

1. ***Hazards*** that must be controlled in order to secure the food chain, health or guaranteed practices under the responsibility of the FASFC are identified. For this, the programming team uses all available information (e.g. previous findings, legal or scientific recommendations) in order to establish the list of hazards. The lists of undesirable substances or diseases provide a satisfactory basis. The list of hazards covers all parameters that are analyzed by the FASFC within the framework of its competences. Some of these parameters may not have any incidence on food safety (e.g. observance of guarantees and standards).
2. For each of the hazards identified, the ***groups of products, animals, plants***, ... that are likely to be contaminated, diseased ... and, hence, involve a risk for food safety, plant or animal health and production or animal welfare are analyzed. The group of products, animals, plants constitutes a population that is subject to a similar risk with respect to the hazard in question. The groups may be divided into subgroups. In that case, a risk analysis is carried out for the different groups and subgroups.
3. The importance of each ***population*** is estimated. The batches that constitute the population must be clearly defined, specifying particularly the units taken into account (individuals, tons, source...). Populations that are considered as being important (>10,000 batches) may be considered as infinite.
4. For each combination of a population and a parameter to be analysed, the ***confidence level*** and the ***prevalence level to be controlled*** are determined. The prevalence level to be controlled and the confidence level are determined according to the section 4.2.1. and the section 4.2.2.
5. The ***number of analyses to be carried out in the population*** is calculated.
6. The analyses are distributed between the ***sample matrices that constitute the population***.
7. The ***sites of sampling*** are chosen.

### 4.2.1. Determining the confidence level

To determine the ***confidence level*** to be attained at the control, three parameters are used:

- The degree of ***harmful*** effect of the hazard, the disease, the parameter related to toxicity, virulence or negative economic impact;
- The ***prevalence*** of the contamination or the disease within the population to be controlled;
- The ***contribution*** of the population to the overall food chain contamination, to the dissemination or the impact of the disease.

The first parameter, the degree of ***harmful effect*** of the hazard (e.g. a disease, a contaminant), is scored on a scale from 1 to 4 with:

***Score 1***
Not harmful or negligibly harmful (in particular for parameters which are not directly related to food safety, animal disease or plant disease).

***Score 2***
Probably harmful (especially for parameters that are indicators of the hygiene of foodstuffs; standard value applied in the absence of more specific indications).

***Score 3***
Seriously harmful (for toxic agents, infectious agents or agents which cause moderate symptoms of gastro-enteritis).

***Score 4***
Very harmful (notably for toxic food agents and agents provoking infections at a small infectious dose and/or with high mortality rates).

The score attributed to the degree of harmful effect is used to determine the prevalence level to be controlled and the confidence level, which have to be aimed for.

The list of hazards and harmful effects related to these hazards is submitted for the scientific advice of the Scientific Committee of the FASFC with the understanding that these scores:

- Are based upon the available scientific information.
- Take into account harmful effects both on public health and animal and plant production (e.g. economic impact).
- Intervene in establishing a program aimed at detecting the presence of the hazard.
- In the case of multi-residue analyses (combination of analyses) the score for the combination equals the maximum score for the analyses (hazards) of which it is composed.

The second parameter, the ***prevalence***, is used to indicate to what extent the hazard occurs and may harm the population (sample matrices). For diseases, this parameter is specifically used to estimate the seriousness of the hazard according to the probability of the introduction of the pathogen onto the national territory or/and of the risk of spreading from the primary outbreak(s) that have been identified.
The prevalence is the first component of population exposure and takes into account the frequency of exceeding a standard and, if necessary, the frequency of analytical detections (presence below a limit value).
It is an estimation of the prevalence that is scored on a scale from 1 to 4:
*Score 1*
Low analytical detection and standard not exceeded; very low prevalence.
*Score 2*
Standard is exceeded a few times or else regular analytical detections but no exceeding of standard; standard value in case of insufficient information (low probability of prevalence).
*Score 3*
Regular exceeding of standard or else frequent analytical detections and standard exceeded a few times (average probability of prevalence).
*Score 4*
Frequent analytical detections and exceeding of standard (high probability of prevalence).

Ideally, the estimation of the prevalence is performed over a three-year reference period (time covered by the multi-annual program).

The ***contribution*** is the second component of exposure. Starting from the principle that the overall exposure of an individual to a hazard results from many sources of contamination, the contribution represents the relative importance the population (sample matrices) account(s) for in the risk related to this hazard.
*Score 1*
Limited contribution because the population (sample matrices) is (are) insignificantly consumed and/or other populations (matrices) account for an important part of the overall exposure to the hazard under consideration.
*Score 2*
Average contribution, standard value when insufficient information.
*Score 3*
Substantial contribution because the population (sample matrices) is (are) significantly consumed and/or contribute(s) substantially to the overall exposure.
*Score 4*
Very substantial contribution because the population (sample matrices) is (are) very significantly consumed and/or is virtually the exclusive source of overall exposure.

The harmful effect associated with the two components of exposure, represented in the following formula:

***Harmful effect + (Prevalence x Contribution)***

is the risk that makes it possible to determine the confidence level, namely:
*90%:*
total score attaining 2 to 6 (e.g. low toxicity, limited contamination through foodstuffs under consideration).
*95%:*
Total score between 7 and 12 (e.g. average toxicity, average contamination through foodstuffs under consideration).
*99%:*
Total score between 13 and 20 (e.g. the foodstuff under consideration is a substantial source of contamination of the food chain by a (very) hazardous contaminant).

Originally, the formula was a sum of three components (harmful effect, prevalence and contribution). Given that the harmful effect intervenes both in the determination of the prevalence level to be controlled and the confidence level, it assumed too much weight compared to the two other factors. Therefore it was decided to restrict its influence by including the other factors as a product that represents the exposure.

### 4.2.2. Determining the prevalence level to be controlled

The ***prevalence level to be controlled*** (PLC) is defined as the contamination rate (infection rate) that has to be detected with a given confidence level. The absence of non-compliance suggests, with a certain confidence level, that the accepted prevalence is not exceeded.
Logically, the more harmful a hazard is, the lower its accepted prevalence and the sooner it has to be

detected.

The PLC is determined according to four hazard classes:

1: Not or slightly serious: PLC=10%
2: Probably serious: PLC=5%
3: Serious: PLC=2.5%
4: Very serious: PLC=1%

### 4.2.3. Calculating the number of batches to be tested

The calculation of the number of batches to be tested within a given population is based upon a normal approximation of a binomial distribution (14).

Tests of the population are subdivided among products, animals or plants that constitute the entire population and the sampling locations are designated.

This methodology is used, e.g., to define the number of tests, which have to be realised for the purpose of detecting dioxins, dioxin-like PCBs and marker PCBs in foodstuffs. The number of tests is then compared to the requirements of Directive 96/23/EC determining the minimum number of animals to be sampled annually according to the national surveillance plans (6).

The population considered in this approach consists of all meat obtained from animals that were exposed to environmental contamination by dioxins, dioxin-like PCBs and marker PCBs. In this case this population comprises the following animal species: cattle, pigs, poultry, horses, sheep, aquaculture fish, farmed game, wild game and rabbits.

Fishery products, milk and eggs are tested separately. It should be noted that a more stringent control for the presence of dioxins, dioxin-like PCBs and marker PCBs in feedstuffs has been installed in order to reduce the risk of accidental contamination through food.

The harmful effect of dioxins, dioxin-like PCBs and marker PCBs is based on the evaluation made by the International Agency for Research on Cancer (IARC) and recent scientific information. 2,3,7,8 TCDD dioxin has been categorized as carcinogenic for humans by the IARC (19,22). Hence, score 4 has been attributed to the "dioxin group". The IARC categorized dioxin-like PCBs as 'probably' carcinogenic for humans. Yet, according to recent scientific information they are considered as being as toxic as dioxins; hence a score 4 has been attributed. Marker PCBs were considered as probably carcinogenic for humans and attributed a score 3.

The prevalence was defined on the basis of the results of previous control programmes. As each year, 1 or 2 non-compliant cases (dioxins and/or PCBs) are detected (for all species without distinction), score 2 is attributed to these three hazards.

Dioxins and PCBs are highly persistent because of their high affinity for lipid-rich tissues (18). They accumulate in the tissues of exposed animals, mainly in fat. Dairy products, eggs, meats and fish are the main sources of exposure of humans. Only the 'meat' population is considered here and thus score 3 has been attributed.

For these three hazards, a 95% confidence level (CL 95%) was defined on the basis of these 3 criteria. The PLC, based upon the mark "harmful effect", equals 1% for dioxins and dioxin-like PCBs and 2.5% for marker PCBs.

The "meat" population is considered as an infinite population (> 10,000 carcasses).

The statistical calculation of the number of samples is based on the following modified Cannon and Roe formula (17,21):

$$n = [1-(1-\alpha)^{1/D}] * [N-(D-1)/2]$$

where:

n is the sample size required to have a probability $\alpha$ that at least one non-conform result is detected in the sample.

$\alpha$ is the confidence level.

N is the size of the sampling population.

D is the expected number of not conform results.

The previous statistical calculation yields the number of samples to be taken for the purpose of testing for dioxins and dioxin-like PCBs amounting to n =299 (CL 95% ; PLC 1%) and to n=119 (CL 95% ; PLC 2.5%) for marker PCBs.

This number of samples was then distributed among the various animal species. The majority of samples (90%) are taken from beef, pork and poultry meat, the categories with the highest consumption rates. The remaining samples (10%) are taken of the meat of animal species with lower consumption rates.

The samples to be submitted to an analysis of the three hazards were distributed as follows:

- Adult bovine animals: 40% of the samples. These animals live long and are exposed to a risk of accidental contamination through feedstuffs; they are susceptible to environmental contamination during grazing.

- Calves: 15% of the samples. Animals reared according to an intensive system, with no access to an open-air run, slaughtered before the age of 1 year.
- Pigs: 15% of the samples. Low risk of environmental contamination.
- Poultry: 20% of the samples. Low risk of environmental contamination. These animals have a short life and, therefore, bioaccumulation is limited. The samples are further distributed among the various categories of poultry, mainly on the basis of the production level: broilers (72%), culled chickens (18%), turkeys (8%) and other poultry (ducks and geese: 2%).
- Sheep: 3% of the samples. Animals that live long and show a risk of environmental contamination.
- Horses: 3% of the samples. Animals that live long and show a risk of environmental contamination.
- Aquaculture fish: 2.5% of the samples. These animals receive commercial feed with a high content of fish oil that may contain more substantial rates of dioxins and PCBs.
- Rabbits: 0.5% of the samples. Low consumption and a short life.
- Farmed game: 0.5% of the samples. Low consumption and a short life.
- Wild game: 0.5% of the samples. Low consumption.

Table II shows the number of samples to be taken in accordance with the statistical approach.

*Table 2. Number of samples to be taken in accordance with the statistical approach to detect dioxins, dioxin-like PCBs and marker PCBs according to the Directive 96/23/EC*

| Animal species | Dioxins | Dioxin-like PCBs | Marker PCBs |
|---|---|---|---|
| Cattle | 120 | 120 | 48 |
| Calves | 45 | 45 | 18 |
| Pigs | 45 | 45 | 18 |
| Broilers | 44 | 44 | 18 |
| Culled chickens | 11 | 11 | 5 |
| Turkeys | 5 | 5 | 2 |
| Other poultry | 1.2 | 1.2 | 0.5 |
| Sheep | 9 | 9 | 3.6 |
| Horses | 9 | 9 | 3.6 |
| Fish | 7.5 | 7.5 | 3 |
| Rabbits | 1.5 | 1.5 | 0.6 |
| Farmed game | 1.5 | 1.5 | 0.6 |
| Wild game | 1.5 | 1.5 | 0.6 |

To allow a statistical analysis of the results, a minimum number of 10 samples has however been withheld for each animal species (13).
In order to comply with the minimum number of animals required by Directive 96/23/EC, the number of samples of broilers has been increased to 60 for dioxin-like PCBs and to 30 for marker PCBs.
To facilitate the traceability of the origin of the contamination in the case of non-compliant results, the meat samples are taken from carcasses at the slaughterhouse. On the other hand, samples of fish are taken at the fish farms.

### 4.3. Programming analyses of which the number is statistically defined: programming for the purpose of estimating true prevalence within a population

The statistical approach described below is used only for programmes with the purpose of estimating true prevalence within a population, with a certain accuracy and confidence level. The number of samples to be tested essentially depends on the accuracy and confidence levels to be attained. Hence, the higher the required accuracy of the true prevalence at a given confidence level, the higher the number of samples required. For example, figure 2 shows the number of samples to be taken in function of the confidence level required and the expected prevalence in the case of testing for *Campylobacter* spp., knowing that the population size (cuts of poultry with skin) equals 238,000,000 carcasses and that a precision of 5% is required. This procedure of programming makes it possible, e.g., to verify the efficiency of risk management measures.

Applying the statistical approach successively involves the following steps:

1. Define the ***list of hazards*** of which the prevalence has to be estimated. The lists of undesirable or forbidden substances or diseases provide a useful basis. The list of hazards includes all parameters that are examined by the FASFC within its scope of competence. Some of these parameters may not have an incidence of food safety (e.g. the observance of guarantees and standards).
2. For each of the hazards identified, inventory the ***groups that constitute the population of products, animals, plants***, ... involved in the estimation. For this, the expert will use all useful information (e.g. previous findings, legal or scientific recommendations) to establish this

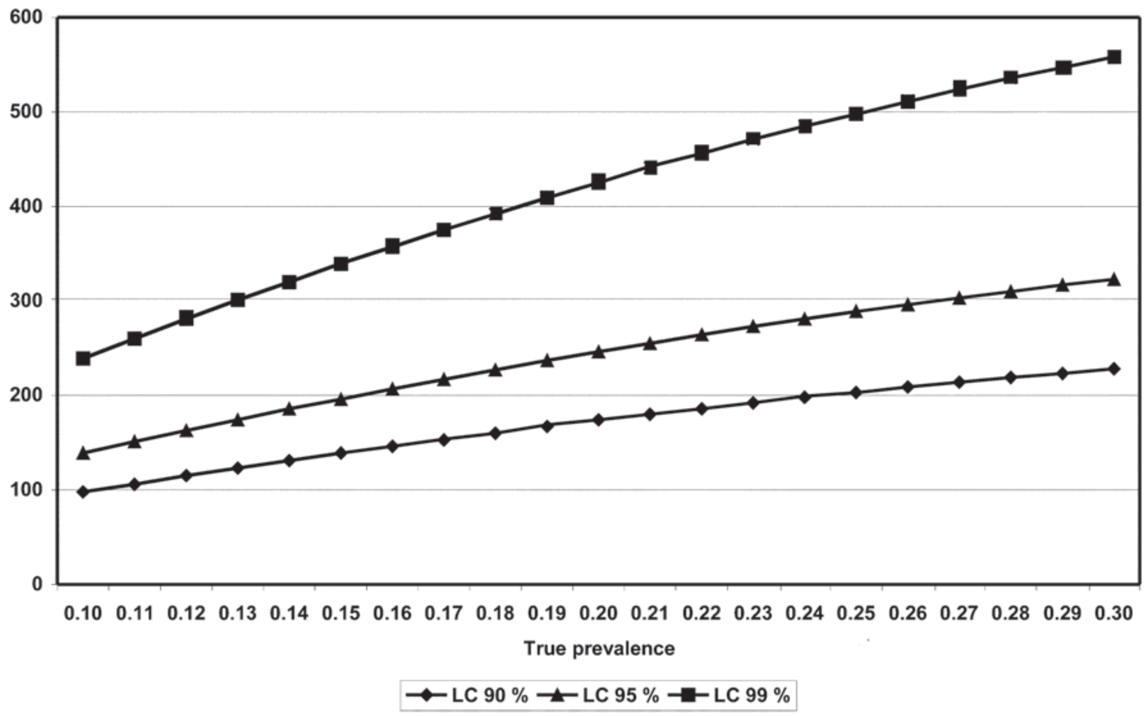
list. The groups may be divided into subgroups if such is deemed useful by the expert. In that case, a risk analysis is performed for the various groups and subgroups.

3. Estimate the importance of each ***population***. The batches making up the population must be clearly defined, specifying in particular the units chosen (individual, tons, herds...). Populations that are considered as important (>10,000 batches) may be considered as infinite.
4. Determine the estimated prevalence on the basis of experience; 50 % is retained as standard value when insufficient information is available (at this value the binomial variance is highest, guaranteeing a maximum sample size).
5. Define for each combination of population and parameter to be analysed the ***level of accuracy*** and the ***confidence level*** to be attained when estimating true prevalence.
6. Calculate the ***number of analyses to be performed on the population***.
7. Distribute analyses among the ***matrices that constitute the population***.
8. Choose the locations of sampling.

This methodology is used, e.g., to define the number of analyses for the purpose of estimating the true prevalence of *Salmonella* contamination of poultry meat.

On the basis of the analyses of previous years, the true prevalence of *Salmonella* contamination of poultry meat at the time of slaughtering is estimated at approximately 15% of the carcasses (16). Carrying out analyses in slaughterhouses during the successive annual campaigns makes it possible to establish the determination of the true prevalence of *Salmonella* contamination of poultry meat on the one hand, and to assess the efficiency of the preventive measures taken by farms to limit this infection on the other hand. The number of analyses performed during this study conditions the accuracy of the real prevalence estimation, while the mode of sampling has an effect on the representativeness of the study. Within this context, 196 analyses of poultry carcasses are required to estimate the true prevalence of *Salmonella* contamination with 95% confidence and 5% accuracy. Samples are taken all year round, at random, from batches of broilers and layers brought to the different slaughterhouses of the country.

*Figure 2. Required sample size in function of the true prevalence, the confidence interval (population size of 238,000,000 units and accuracy of five percent)*



### 4.4. Programming analyses when the number is defined arbitrarily

The approach described below is linked to the occurrence of a previous event (e.g. slaughtering, import) and aims at detecting a contamination. The number of analyses to be performed depends on the frequency of controls and the prevalence of the considered event.
This methodology is used, e.g., to define the number of samples that must be submitted to a test for detecting B1 aflatoxins in pistachio nuts according to the decision 2005/85/CE (4). In that case, the number of analyses actually carried out depends on the number of pistachio nuts lots imported into Belgium from Iran. Each lot is tested for B1 aflatoxins. This number is estimated from the annual imports database.

### 4.5. Adjusting the number of analyses

Although the programming of analyses is based in the first place on risk analysis, it may seem necessary to further examine some aspects, such as the question whether the number of analyses may be increased to take into account the various kinds of sensitivity (media, political, economic or consumers' issues). To allow for the existing constraints, this increase is limited to 20% of the initial level defined by the method. In some particular cases, the adjustment of the number of analysis may however be more substantial.
For instance, within the context of detecting substances with an anabolising effect (hormones), the number of targeted samples to be tested is defined by European legislation on the basis of the number of animals slaughtered during the previous years. Directive 96/23/EC defines the categories of substances that must be detected in products of the various animal species as well as the level and the frequency of sampling. For bovine animals, the minimum number of samples to be analysed for the purpose of detecting substances with an anabolising effect must amount to at least 0.4% of the animals slaughtered, i.e. some 2,300 analyses. Given the political sensitivity of the hormone issue in Belgium, nearly 4,500 products are tested per year.

## 5. PLANNING OFFICIAL INSPECTIONS AT FASFC

The approach described below is risk based and, similarly to the programme of checks with sampling, renders objective the method for defining the number of inspections to be planned.
The planning of inspections involves the following steps:

1. Divide the feed chain into a series of ***fields of activity*** presenting a particular risk profile.
2. Attribute a ***sensitivity level*** to each of the fields of activity thus identified.
3. Attribute basic, reduced and increased ***inspection frequencies*** to each of the fields of activity that have been identified.
4. Study the ***average profile*** of the operators for each of the identified fields of activity, based upon specific criteria.
5. Choose the ***annual inspection frequency*** to be applied on the basis of the average profile of the operators of the identified fields of activity.

### 5.1. Divide the food chain into fields of activity

The food chain is divided into various fields of activity based on similar risk profiles of the operators. They are treated in an identical way when planning the inspection activities.
As far as possible, this subdivision takes into account the structure of the Directorate General Control of FASFC and must allow categorisation of each type of operator according to his activities.

### 5.2. Attribution of a sensitivity level to each field of activity

To each field of activity is attributed one of the following sensitivity levels:
- Low sensitivity (LS).
- Medium sensitivity (MS).
- High sensitivity (HS).

The choice of the sensitivity level reflects the risk related to the activity of the operators working in the fields of activity concerned. It takes into account the experience acquired and the existence of specific regulations for risk management, if present.
The sensitivity level determines the ratio between the annual inspection frequency of a "good" and a "poor" operator within a certain field of activity

### 5.3. Attribution of inspection frequencies to each field of activity

Three categories of inspection frequencies should be taken into account:
- Reduced frequency (category 1).
- Basic frequency (category 2).
- Increased frequency (category 3).

To each field of activity a basic inspection frequency is attributed ($F_i$). This basic frequency corresponds to the number of inspections that should be carried out each year on an operator considered as representative of a field of activity of category 2.

Apart from primary productions, the reduced and the increased frequencies are calculated for each field of activity taking into account the basic frequency and the sensitivity level (Table 3).

For plant, animal or mixed primary productions, the reduced and the increased frequencies respectively amount to $F_i/4$ and $2F_i$, with $F_i$ being the basic frequency.

*Table 3. Calculation of inspection frequency, taking into account the sensitivity level of the field of activity*

| Inspection frequency | Category | HS | MS | LS |
|---|---|---|---|---|
| Reduced | 1 | $F_i/2$ | $2F_{ii}/3$ | $3F_{iii}/4$ |
| Basic | 2 | $F_i$ | $F_{ii}$ | $F_{iii}$ |
| Increased | 3 | $2F_i$ | $2F_{ii}$ | $3F_{iii}/2$ |

*LS: Low sensitivity. MS: Medium sensitivity.*
*HS: High sensitivity*

## 5.4. Defining the average profile of the operators for each of the fields of activity

The average profile of the operators of a particular field of activity is defined by the sum of the scores attributed to three following criteria:

- The presence of a validated self-checking system (SCS).
- The results of inspections during a certain reference period.
- The number of penalties incurred during the last two years.

The average marks for these three criteria are calculated according to the Table 4.

## 5.5. Choice of the inspection frequency to be applied in accordance with the average profile of the operators of the fields of activity that have been identified

The average profile of the operators of a certain field of activity determines the annual frequency that should be applied. By way of illustration: a field of activity counting 1,000 registered operators who may be distributed as shown in Table 5 according to the criteria.

When comparing the total score for the average profile of the operators of the field of activity derived from Table 5, i.e. 40.2, with Table 6, the inspection frequency must be the basic frequency.

Table 7 shows the breakdown of the food chain into fields of activity, as well as the values of the basic, reduced and increased frequencies that must be applied to these fields according to their average profile.

## 6. CONCLUSIONS

FASFC is responsible for the control of the food chain as a whole. To achieve this goal, FASFC has developed an original method to plan its samplings and inspections. It is based on a scientific and statistic approach. The application of statistical principles adds value to the control program and allows for the collection of a maximum amount of information for further risk assessment.

Regulation 882/2004 stipulates that the Member States should plan an integrated control programme to cover several years, allowing the strategic objectives laid down by the relevant authority to be achieved. One of the objectives of the strategic plan of FASFC is the realisation of a safe food chain through the limitation of possible consumer exposure and by reducing the incidence of crises. Food safety rests in the first place on preventive measures taken by the operators themselves, more in particular the number of verifications and controls. The operator thereby becomes responsible for the product delivered. FASFC assures the food safety by means of the official controls.

The integrated approach contributes to an increased food safety and quality along the food chain, to an increased animal welfare and to a higher sanitary level for animal and plant products.

Lastly, the establishment of this plan has also helped to further integrate the various fields of expertise within FASFC.

*Table 4. Calculation of the average profile of the operators of a field activity*

| Criteria | Percentage of operators complying with the criterion | Scores | Sum of scores |
|---|---|---|---|
| Validated self-checking system (SCS) | % of operators with a validated SCS | x 40 + | Sum of score for « SCS » |
| | % of operators without a validated SCS | x 0 = | |
| Results of inspections | % of operators in Class I[#] | x 20 + | Sum of score for « Inspections » |
| | % of operators in Class II | x 14 + | |
| | % of operators in Class III | x 8 + | |
| | % of operators in Class IV | x 0 = | |
| Penalties [$] | % of operators with 0 penalties | x 20 + | Sum of score for « Penalties » |
| | % of operators with $s_i$ warnings | $\frac{1}{n}\sum_{i=1}^{p} n_i(20-2s_i)^{*}$ + | |
| | % of operators with $s_i$ official infringement reports | $\frac{1}{n}\sum_{i=1}^{p} n_i(20-6s_i)^{**}$ + | |
| | % of operators with $s_i$ suspended or withdrawn approvals | $\frac{1}{n}\sum_{i=1}^{p} n_i(20-10s_i)^{***}$ | |
| Average profile of the operators of a field of activity = | | | Total of scores |

[#]*Inspection class: inspections are based on checklists (CL). At present, CL are based on 23 scopes. Each list is divided into chapters and sections whose relative importance is reflected by a weighting factor. Several CL may be used during a single inspection (e.g. CL auto-control, CL building and infrastructure, CL labelling). Similarly a weighting of different CL is employed when calculating the final score (e.g. CL auto-control receives a higher weighting than CL labelling). The classification in a certain inspection class depends on the final score, which this takes into account three levels of weighting (section, chapter, CL).*

[$]*A weighting of the penalties has been provided for: warning (-2 points), official infringement report (-6 points), suspension or withdrawal (-10 points).*

**n is the number of operators having incurred at least a warning; $S_i$ is the number of warnings; $n_i$ is the frequency of prevalence of value $S_i$.*

***n is the number of operators having incurred at least an official infringement report; $S_i$ is the number of official infringement reports; $n_i$ is the frequency of prevalence of value $S_i$.*

****n is the number of operators having incurred at least a suspension or a withdrawal; $S_i$ is the number of suspensions or withdrawals; $n_i$ s the frequency of prevalence of value $S_i$.*

*Table 5. Calculation of the average profile of the operators of a specific field of activity, according to the criteria (self-checking system, inspections, penalties, exports)*

| | | | | | Sub-total of scores | |
|---|---|---|---|---|---|---|
| | | | **SCS** [1] | | | |
| | *Yes* | | *No* | | | |
| Number | 200 | | 800 | | **8,0** | ***a*** |
| Percent | 20,0% | | 80,0% | | | |
| Points | 40 | | 0 | | | |
| Score [3] | 8 | | 0 | | | |
| | | | **Inspections** | | | |
| | Classe I [2] | Classe II | Classe III | Classe IV | | |
| Number | 250 | 450 | 250 | 50 | **13,3** | ***b*** |
| Percent | 25,0% | 45,0% | 25,0% | 5,0% | | |
| Points | 20 | 14 | 8 | 0 | | |
| Score [3] | 5 | 6,3 | 2 | 0 | | |
| | | | **Penalties** | | | |
| | *0 warnings* | *1 warning* | *2 warnings* | *3 warnings* | **19,0** | |
| Number | 600 | 300 | 75 | 25 | | |
| Percent | 60,0% | 30,0% | 7,5% | 2,5% | | |
| Points | 20 | 18 | 16 | 14 | | |
| Score [3] | 12 | 5,4 | 1,2 | 0,35 | | |
| | *0 infringement reports* | *1 infringement report* | *2 infringement reports* | *3 infringement reports* | | |
| Number | 700 | 250 | 50 | 0 | | |
| Percent | 70,0% | 25,0% | 5,0% | 0,0% | **17,9** | |
| Points | 20 | 14 | 8 | 2 | | |
| Score [3] | 14 | 3,5 | 0,4 | 0 | | |
| | ***No withdrawal*** | | ***Withdrawal*** | | | |
| Number | 990 | | 10 | | | |
| Percent | 99,0% | | 1,0% | | **19,9** | |
| Points | 20 | | 10 | | | |
| Score [3] | 19,8 | | 0,1 | | | |
| | | | | **Average mark of penalties** [4] | **18,9** | ***c*** |
| | | | | **Average profile of operators** [5] | **40,2** | |

[1]*Self-checking system.*

[2]*Inspection class: inspections are based on checklists (CL). At present, there are 23 CL. Every list is divided into chapters and sections whose relative importance is reflected by a weighting factor. Several CL may be used during a single inspection (e.g. CL auto-control, CL building and infrastructure, CL labelling). Similarly a weighting of different CL is employed when calculating the final score (e.g. CL auto-control receives a higher weighting than CL labelling). The classification in a certain inspection class depends on the final score, which this takes into account three levels of weighting (section, chapter, CL).*

[3]*Score: product of the percentage and the number of points.*

[4]*Average mark of penalties: is the sum of each score for warnings, infringements reports and withdrawal divided by three.*

[5]*Average profile of operators: is the sum of "a", "b" and "c".*

*Table 6. Determining the inspection of frequency in a field of activity of the basis on the average operator profile*

| Average profile of the operators of the field of activity — *SumTotal of scores* | *Category* | Annual frequency to be applied to the field of activity |
|---|---|---|
| 61 to 80 | 1 | Reduced Frequency |
| 39 to 60 | 2 | Basic Frequency |
| 0 to 38 | 3 | Increased Frequency |

*Table 7. Basic, reduced and increased frequencies applied in the fields of activity*

| Fields of activity | | Sensibility [1] | Basic frequency (Category 2) | Reduced frequency (Category 1) | Increased frequency (Category 3) |
|---|---|---|---|---|---|
| | | | Inspections (n/year) | | |
| Suppliers of agriculture | Feed (approved firms) | HS | 1,00 | 0,50 | 2,00 |
| | Feed (authorised firms) | MS | 0,50 | 0,33 | 1,00 |
| | Feed (registered firms) | LS | 0,33 | 0,25 | 0,50 |
| | Pesticides | LS | 0,33 | 0,25 | 0,50 |
| | Fertilisers | LS | 0,33 | 0,25 | 0,50 |
| Primary production | Plant primary production | MS | 0,25 | 0,06 | 0,50 |
| | Animal primary production | MS | 0,25 | 0,06 | 0,50 |
| | Centers of collect and storage (sperm, embryos) | LS | 1,00 | 0,50 | 2,00 |
| | Centers of gathering and staging points (live animals) | MS | 0,50 | 0,33 | 1,00 |
| | Centers of quarantine (live animals) | HS | 1,00 | 0,50 | 2,00 |
| | Transport and trade (live animals) | MS | 0,50 | 0,33 | 1,00 |
| Proccess | Cutting plans with specified risk materials (SRM) | HS | 18,00 | 9,00 | 36,00 |
| | Cutting plans without specified risk materials (SRM) | HS | 12,00 | 6,00 | 24,00 |
| | Meat preparations, minced beef | HS | 12,00 | 6,00 | 24,00 |
| | Fish preparations | HS | 12,00 | 6,00 | 24,00 |
| | Centers of dispatch and purification of live bivalve molluscs | HS | 0,50 | 0,33 | 1,00 |
| | Process (meat, fish, gelatin, …) | HS | 4,00 | 2,67 | 8,00 |
| | Process (milk products) | MS | 0,50 | 0,33 | 1,00 |
| | Process (egg products) | MS | 0,50 | 0,33 | 1,00 |
| | Process (oils and fats) | HS | 1,00 | 0,50 | 2,00 |
| | Process (particular food : Novel food, diet, ...) | HS | 1,00 | 0,50 | 2,00 |
| | Process (other produits) | MS | 0,50 | 0,33 | 1,00 |
| | Storage of meat | MS | 0,50 | 0,33 | 1,00 |
| | Storage of fish | MS | 0,50 | 0,33 | 1,00 |
| Distribution | Wholesalers | LS | 0,33 | 0,25 | 0,50 |
| | Collectivities | MS | 0,50 | 0,33 | 1,00 |
| | Butchers | HS | 1,00 | 0,50 | 2,00 |
| | Retailers other than butchers | LS | 0,33 | 0,25 | 0,50 |
| | Restaurants | MS | 0,50 | 0,33 | 1,00 |
| | Storages of food | LS | 0,33 | 0,25 | 0,50 |
| | Transport of food | LS | 0,33 | 0,25 | 0,50 |

*[1]LS: Low sensitivity. MS: Medium sensitivity. HS: High sensitivity*

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