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Quantitative risk assessment model to investigate the public health impact of varying *Listeria monocytogenes* allowable levels in different food commodities: A retrospective analysis

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ABSTRACT

Invasive listeriosis is a potentially fatal foodborne disease that according to this study may affect up to 32.9 % of the US population considered as increased risk and including people with underlying conditions and co-morbidities. *Listeria monocytogenes* has been scrutinized in research and surveillance programs worldwide in Ready-to-Eat (RTE) food commodities (RTE salads, deli meats, soft/semi-soft cheese, seafood) and frozen vegetables in the last 30 years with an estimated overall prevalence of 1.4–9.9 % worldwide (WD) and 0.5–3.8 % in the United States (US). Current *L. monocytogenes* control efforts have led to a prevalence reduction in the last 5 years of 4.9–62.9 % (WD) and 12.4–92.7 % (US). A quantitative risk assessment model was developed, estimating the probability of infection in the US susceptible population to be 10–10,000× higher than general population and the total number of estimated cases in the US was 1044 and 2089 cases by using the FAO/WHO and Pouillot dose-response models. Most cases were attributed to deli meats (>90 % of cases) followed by RTE salads (3.9–4.5 %), soft and semi-soft cheese and RTE seafood (0.5–1.0 %) and frozen vegetables (0.2–0.3 %). Cases attributed to the increased risk population corresponded to 96.6–98.0 % of the total cases with the highly susceptible population responsible for 46.9–80.1 % of the cases. Removing product lots with a concentration higher than 1 CFU/g reduced the prevalence of contamination by 15.7–88.3 % and number of cases by 55.9–100 %. Introducing lot-by-lot testing and defining allowable quantitative regulatory limits for low-risk RTE commodities may reduce the public health impact of *L. monocytogenes* and improve the availability of enumeration data.

1. Introduction

Invasive listeriosis is a rare but severe foodborne illness caused by *Listeria monocytogenes* that affects increased risk individuals such as elderly (>65 yrs.), pregnant women and neonates and 'highly susceptible' populations with underlying disease conditions or comorbidities (i.e., diabetes, cancer, and inflammatory diseases) (Falk et al., 2016; FAO/WHO, 2004; Goulet et al., 2012; Pohl et al., 2017, 2019). These subpopulations may account for 20–30 % of the total population but suffer the vast majority of the listeriosis cases (Falk et al., 2016; Goulet et al., 2001; Pérez-Rodríguez et al., 2017; Pouillot et al., 2015).

Overall incidence rates of invasive listeriosis worldwide were estimated by WHO in 2010 as 0.34 reported cases per 100,000 population (0.10–0.47 among different regions) (de Noordhout et al., 2014). In the United States (US), a rate of 0.28 cases per 100,000 population was estimated for 2020 and in the European Union (EU) a rate of 0.47 cases was estimated in 2018 (CDC, 2021; ECDC, 2020). While the incidence rates are low, case fatality rates (CFR) are high in the US and EU as last reported CFR were 15.9 and 15.6 %, respectively (EFSA and ECDC, 2019; Scallan et al., 2011). An increase in listeriosis incidence is

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expected due to demographic changes and health status factors such as the aging of the population, higher percentage of consumers with underlying disease conditions (e.g., suffering a disease such as type-2 diabetes or surviving a serious condition such as cancer or AIDS) and increased consumption of high-risk ready-to-eat (RTE) foodstuffs (EFSA BIOHAZ Panel, 2018; Pohl et al., 2017, 2019). Attempts to assess listeriosis incidence need to account for changes in the 'highly susceptible' population. However, these estimation efforts are compromised by the lack of granularity regarding the prevalence of underlying conditions in the population and changes in food consumption patterns among 'highly susceptible' persons.

L. monocytogenes has been the focus of several quantitative risk assessment models (QMRA) aimed at estimating the incidence of invasive listeriosis based on a single food commodity (FDA/Health Canada, 2015; FSIS, 2010; Pasonen et al., 2019; Zoellner et al., 2019) or several RTE commodities (EFSA BIOHAZ Panel, 2018, 2020; FAO/WHO, 2004; FSIS, 2003; Garrido et al., 2009; Pérez-Rodríguez et al., 2017; Pradhan et al., 2009). The evaluation of listeriosis incidence among highly susceptible populations in QMRA models due to the consumption of various food commodities is still very limited (Falk et al., 2016) but can be very valuable to guide future risk management efforts (Farber et al., 2021).

Risk mitigation measures evaluated to reduce the prevalence of *L. monocytogenes* contamination in foods have been focused on the use of growth inhibitors and anti-listerial formulations, modified atmosphere, heat treatment during processing (i.e., pasteurization or blanching), post-lethality treatments (i.e., high pressure processing or irradiation), improved sanitation, worker behavior, cheese aging, adequate refrigeration temperature and proper handling and cooking at home (Campagnollo et al., 2018; Endrikat et al., 2010; EFSA BIOHAZ Panel, 2020; FDA/Health Canada, 2015; Gallagher et al., 2016; Pasonen et al., 2019; Pradhan et al., 2009; Tirloni et al., 2018). The use of microbial regulatory limits and testing schemes such as environmental monitoring (particularly food contact surfaces) and final product testing are also potential risk mitigation strategies to reduce the overall *L. monocytogenes* prevalence. The approaches to control *L. monocytogenes* in ready-to-eat (RTE) foods differ worldwide and can be summarized as following a zero tolerance (absence in 25 g) or a maximum enumeration level of 100 CFU/g depending on if the food allows the growth of the pathogen (e.g., pH, water activity, frozen) (Farber et al., 2021). Importantly, the use of a generic zero tolerance regulatory limit for all RTE food commodities (that may or may not support the growth of *L. monocytogenes*) may have several unintended consequences; food waste may increase with more food recalls, the food industry may be discouraged from collecting direct food contact surface samples, and regulatory agencies may limit enumeration of end-product samples, thereby reducing the overall accuracy of the risk assessment models due to the lack of enumeration data (Archer, 2018; Chen et al., 2003; Farber et al., 2021). Such an approach also has the potential to distort the degree of attention and type of prevention efforts needed as food commodities pose a different risk level relative to this pathogen.

The impact of different quantitative microbiological criteria (i.e., 100 CFU/g) and sampling plans based on enumeration levels (CFU/g) (i.e., quantitative three-class sampling plans) for food commodities that do not support the growth of *L. monocytogenes* laid out by Farber et al. (2021) on reducing the risk of illness have been evaluated in previous studies (Chen et al., 2003; FAO/WHO, 2004; FSIS, 2003; Lambertini et al., 2019). However, changing the regulatory limits need to be accompanied by adequate sampling plans to allow industry to detect contaminated lots and comply with the new microbiological criteria. The main objectives of this study were: i) perform a retrospective analysis of the changes in prevalence and concentration levels of *L. monocytogenes* in various commodities (RTE salads, deli meats, soft and semi-soft cheese, RTE seafood and frozen vegetables) over the last 30 years; ii) estimate the net public health effect of removing lots with certain levels of contamination (1, 10 and 100 CFU/g) from the market. Most frozen vegetables are marketed with validated cooking instructions and are not considered RTE foods. However, frozen vegetables may also be consumed without following these instructions in their entirety, such as directly adding them to smoothies or salads. Due to these consumer behaviors, the U.S. Food and Drug Administration (FDA) in its draft guidance identifies specific frozen vegetables, such as peas, kale, carrots, and spinach, as more likely to be consumed without cooking (FDA, 2017, 2018; Kataoka et al., 2017; Zoellner et al., 2019). For this study, the exposure dose associated with frozen vegetables was assumed to be the level of contamination at the point of purchase with no reduction due to cooking or increase due to prolonged storage in a thawed state.

2. Methodology

2.1. Literature search

A literature review was carried out using PubMed, Web of Science and Google Scholar for studies published between 1990 and 2020 providing the prevalence and/or enumeration levels of *Listeria monocytogenes* in RTE salads (packaged salads with or without meat/seafood excluding raw commodities and herbs), deli meats (ready-to-eat poultry or meat product with or without heat treatment), soft and semi-soft cheeses (from pasteurized and unpasteurized milk), RTE seafood (hot/cold-smoked salmon, other smoked fish, salted, canned, dried, heat-treated and pickled seafood) and frozen vegetables (see Appendix A for a complete list of references). Other RTE food commodities such as sandwiches, refrigerated and frozen desserts, nuts, etc. were not included in the study. Data were retrieved from original experimental studies (excluding reviews, conference proceedings, book chapters and artificially inoculated studies) and US regulatory surveillance reports including USDA Food Safety Inspection Service (FSIS) and Food and Drug Administration (FDA). There was no restriction in the number of samples tested in the study and studies included those published in English and Spanish. The review published in 2019 by Churchill et al. (2019) was used as reference to collect prevalence and enumeration data on *L. monocytogenes* in RTE salads, soft cheeses and deli meats published studies and updated with new studies released between 2019 and 2020 (Appendix A). The studies conducted in the US were selected and analyzed to estimate the prevalence and enumeration levels for the US scenario. Prevalence of contamination data for the last five years (2015–2020) in the US was used to develop the quantitative risk assessment model (QMRA).

2.2. L. monocytogenes prevalence and enumeration data

Data obtained from published studies were used to estimate the *L. monocytogenes* prevalence in food products at retail level worldwide and in the US for each commodity by adding total number of *L. monocytogenes* positive samples (at least 1 CFU in 25 g) over the total number of samples analyzed per commodity in all studies combined. As the actual prevalence for each food category was assumed to be unknown, a beta distribution was built to represent uncertainty on this parameter based on the collected data (Table 1). The percentage of samples reported to be >100 CFU/g were also estimated for each commodity (Fig. 1). *L. monocytogenes* enumeration level data (log CFU/g) were obtained from published studies that reported the microbial levels found in the product or number of samples with a certain concentration range. A total of 5638 samples were reported to be enumerated among all commodities where 97.7 % were provided as a range of microbial levels or above/below a quantification threshold and 2.3 % were provided as a single microbial count (CFU/g). The enumeration data were incorporated in the quantitative model by using different approaches depending on the type of data published: i) single microbial count (CFU/g) was not further processed and was used as a single value assuming homogeneous concentration throughout the lot; ii) concentration within a microbial level range (i.e., 10–100 CFU/g) was modeled with a uniform distribution between the minimum and maximum

Table 1
Model inputs for the baseline enumeration model.

Inputs	Distribution/value	Reference
Prevalence	~Beta (n + 1, n-p + 1) *n*: total number of samples; *p*: positive samples for *L. monocytogenes*	Data collected in this study
Within lot concentration (log CFU/g)	Within lot variability was characterized by: Single value Range: ~Uniform (min., max.) # samples <100 CFU/g: ~Uniform (0.04, 99) # samples >100 CFU/g: ~Uniform (101, 10× reported microbial level)	Data collected in this study
L. monocytogenes concentration at retail (log CFU/g)	Normal ($\mu_{\text{all samples}}$, $\sigma_{\text{between lots}}$)	Data collected in this study
L. monocytogenes growth rates (GR) (log CFU/g/h)	RTE salad GR = (0.0144 × (T + 1.60))^2 (closed bag) GR = (0.016 × (T + 4.26))^2 (open bag) Deli meat Products with growth inhibitors (GI): 34.9 % Products without growth inhibitors (w/out GI): 65.1 % Turkey (GI) GR: ~Logistic (0.0975, 0.0253) Turkey (w/out GI) GR: ~Logistic (0.2755, 0.0723) Ham (GI) GR: ~Logistic (0.1065, 0.0282) Ham (w/out GI) GR: ~Logistic (0.1941, 0.0472) Beef (GI) GR: ~Logistic (0.1258, 0.0517) Beef (w/out GI) GR: ~Logistic (0.2722, 0.0646) Soft/semi-soft cheese FSIS GR1: ~Normal (0.0034, 0.0057) FSIS GR2: ~Normal (0.0037, 0.012) FSIS GR3: ~Normal (−5.42 × 10^{-4}, 0.0055) FSIS GR4: ~Normal (−0.002, 0.0013) $\sqrt{GR}$ = 0.0056 × (T + 11.375) $\sqrt{GR}$ = 0.0049 × (T + 5.1837) GR = (0.0090 × (T + 10.47))^2 RTE seafood FSIS GR: ~Normal (0.0062, 0.004)	Sant'Ana et al. (2012) Koseki and Isobe (2005b) Pradhan et al. (2009) cited in Gallagher et al. (2013); FSIS (2020) FSIS (2003) Tiwari et al. (2014) Uhlich et al. (2006) FSIS (2003)
L. monocytogenes lag phases (min, max) (h)	Turkey (GI): 57.36–572.88 Turkey (w/out GI): 11.04–133.20 Ham (GI): 146.64–830.88 Ham (w/out GI): 9.60–406.56 Beef (GI): 64.32, 547.44 Beef (w/out GI): 26.88, 313.44	Pradhan et al. (2009) cited in Gallagher et al. (2013)
L. monocytogenes growth during transport (log CFU/g)	Transport temperature (°C): ~Normal (16.8, 4.5, truncate (0, 30)) Transport time (h): ~Uniform (0.5, 1.0) Growth during transport (log CFU/g): Average growth rate at transport T*transport time	Tsironi et al. (2017)
L. monocytogenes growth during storage at home (log CFU/g)	Home storage temperature (°C): ~Laplace (4.06, 2.31, truncate (−5, 13)) RTE salad Use by date (UBD) (h): ~Betageneral (60.74, 80.71, 288.74) Purchase date (PD) (h): ~Triangular (0.1, UBD × 0.8 × 0.5, UBD × 0.8) Storage time at home (h): ~Exponential (UBD-(PD + transport time)/3, truncate (UBD × 1.25)) Growth during storage at home (log CFU/g): Average growth rate at home storage T*storage time Deli meat Storage time at home "sliced in store" (h): 0.47*Weibull (49.92, 199.92, truncate (408)) Storage time at home "pre-sliced by manufacturer" (h): 0.46*Weibull (30.96, 492, truncate (1608)) Storage time at home "pre-sliced by store" (h): ~Exponential (1.74, truncate (1512)) Growth during storage at home (log CFU/g): IF (storage time < lag phase, 0, (storage time-lag phase)*growth rate at home storage T*% slicing scenario Soft/semi-soft cheese Time remained unopened (h): ~Weibull (Normal (19.92, 2.088), Normal (120, 14.4))) Number of servings: ~Poisson (Normal (2.7, 1)) Time between servings (h): ~Exponential (Normal (79.2, 26.4)) Storage time from opened till last consumption (h): Number of servings*time between servings Growth during storage at home (log CFU/g): Average growth rate at home storage T*storage time RTE seafood Total storage time (h): ~Pert (12, Uniform (72, 120), Uniform (360, 720)) Growth during storage at home (log CFU/g): Average growth rate at home storage T*storage time	Pouillot et al. (2010) Nauta et al. (2003) Pouillot et al. (2010); FSIS (2003) FDA/Health Canada (2015) FSIS (2003)
Maximum Population Densities (MPD) (log CFU/h)	RTE salad: ~Normal ((0.04*home storage T + 12.43, EXP (−0.17)), truncate (4, 9)) Deli meat: ~Normal ((0.17*home storage T + 5.69, EXP (−0.12)), truncate (4, 9)) Soft/semi-soft cheese: ~Normal ((0.17*home storage T + 4.35, EXP (−0.12)), truncate (4, 9)) RTE seafood: ~Normal (((0.10*home storage T + 4.60), EXP (−0.12)), truncate (4, 9))	Koseki and Isobe (2005a) Pérez-Rodríguez et al. (2017)
L. monocytogenes concentration at home (CFU/g)	IF((concentration at retail + growth during transport + growth at home) > MPD, MPD, (concentration at retail + growth during transport + growth at home)) ~Poisson (10^ concentration at home)	Estimated in this study
Consumption estimates	Portion size (g): ~Normal (mean, SD) for each population	CDC (2018)

(*continued on next page*)

Table 1 (*continued*)

Inputs	Distribution/value	Reference
	Annual consumption frequency (number of servings/person): Normal (mean, SD) for each population (Table 2)	
	Total annual number of servings per population: Annual consumption frequency*population size	
Contaminated servings and ingested dose	Contaminated servings: Number of servings*Prevalence	Estimated in this study
	Dose (CFU) = Portion size*concentration at home	
Dose-response models	Exponential model: $P_{inf} = 1 - (1 - r)^D$	
	r-Values FAO/WHO model: General population: 2.37×10^{-14}	FAO/WHO (2004)
	Susceptible population: 1.06×10^{-12}	
	r-Values Pouillot model:	Pouillot et al. (2015)
	Healthy adults: 7.90×10^{-12}	
	Older than 65 yrs.: 1.49×10^{-10}	
	Pregnant women: 2.01×10^{-09}	
	Highly susceptible: 2.24×10^{-09} as the average of all high susceptible subgroups (cancer, diabetes, HIV, transplant, organ failure)	
L. monocytogenes new prevalence and concentration at retail (threshold levels)	New prevalence by removing samples >1, 10 or 100 CFU/g	Estimated in this study
	New concentration by removing samples >1, 10 or 100 CFU/g	
Number of cases	Number of contaminated servings* $\int P_{inf}$	Estimated in this study
Number of reported cases	Number of cases/2.1 (underreporting factor)	Scallan et al. (2011)

concentration (CFU/g); iii) concentration lower than a certain microbial level (i.e., <100 CFU/g) was modeled assuming a uniform distribution ranging between 1 CFU in 25 g (0.04 CFU/g), as the minimum concentration, and the reported microbial level minus 1 CFU/g, representing the maximum concentration (i.e., 99 CFU/g); iv) concentration higher than a certain microbial level (i.e., >100 CFU/g) was modeled assuming a uniform distribution with a minimum concentration corresponding to the reported microbial level plus 1 CFU/g (i.e., 101 CFU/g) and a maximum concentration expressed as 10 times the reported microbial level (i.e., 1000 CFU/g). Between-lot variability was estimated by a log-normal distribution characterized by the mean of all lot concentration values representing the overall mean of *L. monocytogenes* concentration in that food commodity and standard deviation representing the variability of the mean concentration among lots (log CFU/g) (Lambertini et al., 2019). Appendix B shows the *L. monocytogenes* enumeration data collected from available studies.

2.3. Risk assessment model framework

A quantitative risk assessment model (QMRA) was developed using Microsoft Excel and @Risk 7.6 (Palisade Corp., NY) to estimate the public health outcomes (mean risk of illness, predicted number of listeriosis cases and number of reported cases) in the US population after the consumption of contaminated food commodities (Table 1). The modeling process was developed based on estimating the exposure levels to *L. monocytogenes* through the different food commodities and then using the estimates to input a dose-response model, in combination with consumption data, to produce public health outcomes. The exposure model described the fate of *L. monocytogenes* in the targeted food commodities from retail to home, considering as main factors the prevalence and concentration at retail point and the possible growth from purchase to consumption. For growth, predictive models were applied defining kinetic parameters for each food matrix and using as variables storage temperature, time and shelf-life, that were described on the basis of existing scientific literature and data. A more detailed explanation of the model is contained in the Appendix C. Prevalence data collected over the last 30 years (1990–2020) were compared with data obtained in the last 5 years (2015–2020) in the US. Due to data limitations, enumeration data for the whole study period (1990–2020) was used to populate the model. Models for the two time periods were run and compared by the impact on the public health metrics for each food category. The model considered prevalence as the only uncertainty input variable while for the other inputs, variability and uncertainty was not separated. Therefore, the model was two-dimensional, and estimates were reported by the mean and 95 % confidence interval (CI) values.

2.4. Exposure assessment

Microbial growth during transport was estimated from temperature and transport time data reported by Tsironi et al. (2017). US household

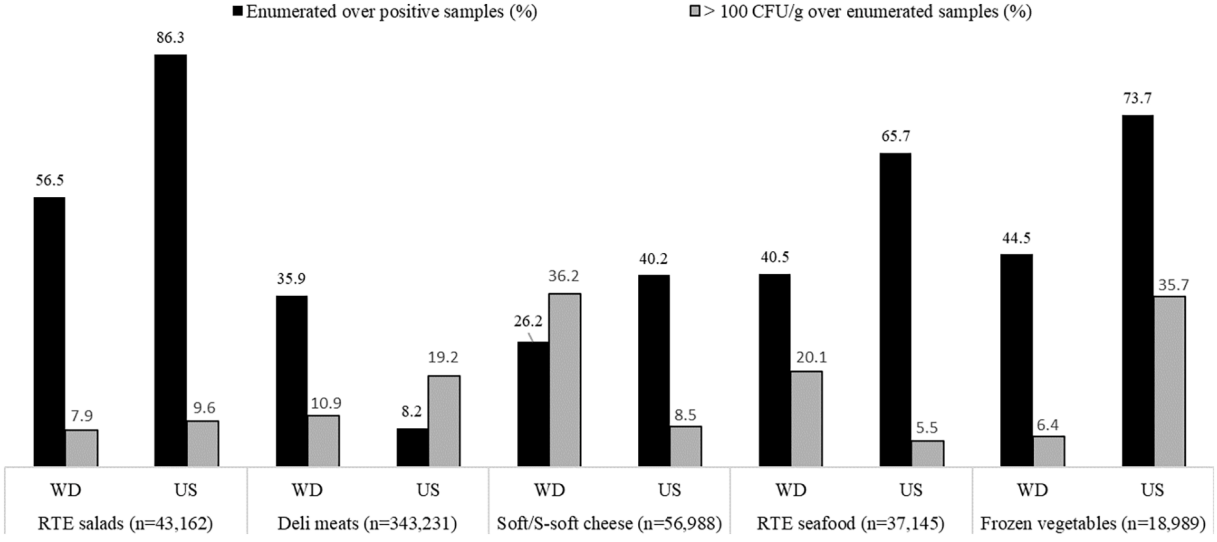

Fig. 1. Total number of samples analyzed, percentage of enumerated over the positive samples (%) and percentage of samples higher than 100 CFU/g over the total enumerated (%) and positive samples (%) for each commodity.

Table 2
Consumption patterns among population groups from NAHEMS dietary history (2015–2016) and foodnet.

Population group[a,b,c]	% over total population	RTE salads	Deli meats	Soft and semi-soft cheese	RTE seafood	Frozen vegetables
		Average individual eating occasions per year[d,e]				
Healthy adults (<65 yrs.)	67.1	105.1	87.8	23.2	26.3	29.6
Healthy adults (>65 yrs.)	12.2	134.0	79.5	27.0	22.2	28.9
Healthy pregnant women	0.9	88.3	62.5	18.4	37.0	21.1
Highly susceptible	19.7	103.3	86.3	22.8	25.8	29.1
Total increased risk	32.8	114.3	83.1	24.2	24.8	28.8

[a] The proportion of healthy population (<65 yrs., >65 yrs. and pregnant women) was estimated by calculating the proportion of the specific population over total population (329 million) from (Roberts et al., 2018; United States Census Bureau, 2018; U.S. Centers for Disease Control and Prevention/National Center for Health Statistics/National Vital Statistics System, 2019). The proportion of healthy elderly and pregnant women was calculated by subtracting the proportion that presented any of the comorbidities listed in the highly susceptible population.

[b] The proportion of highly susceptible population was estimated by calculating the number of cancers, HIV, organ transplant, diabetes, heart disease and inflammatory disease cases in the US from data sources (Department of Health and Human Services, 2019; CDC/Center for Chronic Disease Prevention and Health Promotion, 2019; CDC/National Diabetes Statistics Report, 2020; CDC/Cancer Data and Statistics, 2020; Dahlhamer et al., 2016; Helmick et al., 2008; Lawrence et al., 2008; NIH/National Institute of Diabetes and Digestive and Kidney Diseases, 2016; United Network for Organ Sharing (UNOS), 2018). The highly susceptible included the proportion of the population that presented any of the comorbidities listed for the general population (<65 yrs.), elderly and pregnant women.

[c] The proportion of increased risk was estimated by adding the proportion of healthy elderly, healthy pregnant women and highly susceptible.

[d] The number of individual food portions consumed per year for that RTE commodity in the highly susceptible population was estimated from (Coa et al., 2014) with self-reported dietary patterns in cancer patients where 21.6 % reported a 25 % increase in appetite, 48.5 % reported the same consumption pattern and 30.4 % reported a 25 % decrease.

[e] The number of individual food portions consumed per year for that RTE commodity in the increased risk population was estimated by the proportion of each population (>65 yrs. pregnant and highly susceptible).

refrigerator temperatures were modeled using data reported by Pouillot et al. (2010) and FDA/Health Canada (2015). Due to the lack of specific data, household storage time for RTE salads were calculated with the 'use by date' (UBD) considering purchasing behavior may be determined by the remaining shelf-life. Domestic storage time variation was then estimated by using the mathematical approach proposed by Nauta et al. (2003):

$$\text{Storage time} \sim Exponential\left(\frac{UBD - PD - Tt}{3}\right) \quad (1)$$

where UBD is the use by date time (h), PD is the purchase date (h), and Tt is the transport time (h). It was assumed that 5 % of domestic storage time values were over the recommended UBD.

Household storage times for RTE deli meats were based on estimates reported by Pouillot et al. (2010) for products "sliced in store" (47.3 %), "pre-sliced by manufacturer" (45.9 %) and "pre-sliced by store" (6.8 %). Due to the extended storage times for deli meat products, a correlation matrix between storage temperature and time was built (negative correlation −0.25) to avoid long time and high storage temperature combinations, which are expected not to contribute to risk as, under those conditions, the product would be probably spoiled making it unacceptable for consumption (Pérez-Rodríguez et al., 2007). Household storage time data for soft cheeses was obtained from FDA/Health Canada (2015) by adding the estimated time unopened (h) and the time remained opened till last consumption (h). Domestic storage time for RTE seafood was obtained from FDA/FSIS (2003).

L. monocytogenes growth rates in RTE salads were obtained from CB Premium software by using the data reported in Koseki and Isobe (2005a) for an opened bag and Sant'Ana et al. (2012) for an unopened bag. Growth rates for beef, turkey, and pork deli meats with and without inhibitors were obtained from Pradhan et al. (2009) cited by Gallagher et al. (2013) and FSIS (2010). An analysis of FSIS sampling data on RTE meat and poultry products (2013−2020) revealed that 34.9 % of the US meat industry that is inspected by FSIS uses a post-lethality treatment and/or growth inhibitors and this was used to model the lag phase durations (h) and microbial growth during storage assuming the potential recontamination with *L. monocytogenes* during slicing (FSIS, 2020). Growth rates in RTE seafood were obtained from data reported in FDA/FSIS (2003) and in soft and semi-soft cheese by using additional data from CB premium references (Uhlich et al., 2006; Tiwari et al., 2014). Maximum population density (MPD) values at retail were restricted to 10^4–10^6 CFU/g (depending on the maximum concentration reported in research studies in the food commodity). MPD at home were calculated based on the refrigerator storage temperature and for RTE salads were obtained from Koseki and Isobe (2005a) while for the rest of the commodities was estimated by the mathematical equations derived by Pérez-Rodríguez et al. (2017). The calculated MPD was assumed to be representative for the pathogen in each food type. Then, the MPD estimates were combined with the respective standard deviation values derived from the study by Pérez-Rodríguez et al. (2017) to define normal distributions describing MPD variation for each food category. Total *L. monocytogenes* growth from retail to consumption was estimated by adding the growth during transport and growth during storage at home calculated by taking the average of the growth rate for both unopened and opened package scenarios (Table 1). No growth during shelf-life was assumed for the frozen vegetables category.

2.5. Dose-response relationship

The exponential dose-response model developed by FAO/WHO (2004) for general ($r_{50th} = 2.37 \times 10^{-14}$) and susceptible ($r_{50th} = 1.06 \times 10^{-12}$) population and the log-normal exponential model developed by Pouillot et al. (2015) for healthy adults ($r_{50th} = 7.82 \times 10^{-15}$), older than 65 yrs. ($r_{50th} = 1.47 \times 10^{-13}$), pregnant ($r_{50th} = 1.99 \times 10^{-12}$) and highly susceptible (calculated weighted average value for all susceptible subpopulations $r_{50th} = 6.49 \times 10^{-13}$) were used to estimate the probability of illness. A conservative approach was used regarding virulence variability assuming all *L. monocytogenes* strains were able to cause human illness following the decision taken by most regulatory agencies (EFSA, 2018). The number of cases was estimated by integrating mathematically the estimated probability of illness distribution and incorporating, in the calculations, the uncertainty on prevalence by using 2.5th and 97.5th percentiles from the prevalence distribution.

2.6. Population and consumption estimates

The percentage of increased risk population in the US (32.9 %) was obtained by adding the healthy >65 yrs., healthy pregnant and highly susceptible subpopulations. The percentage of highly susceptible population in the US (19.7 %) was obtained by adding the subpopulations with underlying conditions, namely cancer (1.76×10^6 persons, CDC/Division of Cancer Prevention and Control, 2020a,b), renal or liver

Table 3
Average *L. monocytogenes* prevalence and enumeration level estimated among all food categories conducted worldwide (WD) and in the US.

Food category	Scenario	Samples analyzed over all commodities (%)	Total number of samples and estimated prevalence (%)[a]	Total number of enumerated samples and mean concentration (log CFU/g)[b]
RTE salads	WD	8.6	43,162	668
			2.2 (2.1–2.4)[b]	0.0 (−2.4, 2.5)
	US	6.0	18,760	386
			1.6 (1.4–1.7)	−0.5 (−2.8, 1.6)
Deli meats	WD	68.7	343,231	1671
			1.4 (1.3–1.4)	1.4 (−0.5, 3.3)
	US	86.6	270,346	119
			0.5 (0.5–0.6)	0.3 (−3.0, 3.6)
Soft/semi-soft cheese	WD	11.4	56,988	306
			2.0 (1.9–2.2)	1.5 (−1.9, 4.8)
	US	4.7	14,781	47
			0.8 (0.7–0.9)	−0.2 (−4.1, 3.8)
RTE seafood	WD	7.4	37,145	1490
			9.9 (9.6–10.2)	1.6 (−0.9, 4.1)
	US	2.3	7056	179
			3.8 (3.4–4.3)	0.4 (−2.4, 3.3)
Frozen vegetables	WD	3.8	18,989	758
			8.9 (8.6–9.4)	0.7 (−1.0, 2.5)
	US	0.4	1186	14
			1.7 (1.0–2.5)	1.6 (−1.2, 3.8)

[a] Calculated prevalence (having at least 1 CFU in 25 g) from all published studies (1990–2020).
[b] Uncertainty around prevalence was estimated by the mean and 95 % CI and variability around concentration by mean and 2.5th and 97.5th values truncated at the highest concentration value observed among all studies published (10^4–10^6 CFU/g).

failure (5.16×10^6 persons, NIH/National Institute of Diabetes and Digestive and Kidney Diseases, 2016; CDC/National Center for Health Statistics, 2019), solid organ transplant (3.65×10^4 persons, United Network for Organ Sharing, 2018), inflammatory diseases (bowel inflammatory disease, rheumatoid arthritis, giant cell arteritis) (4.53×10^6 persons, Dahlhamer et al., 2016; Helmick et al., 2008; Lawrence et al., 2008), HIV/AIDS (1.10×10^6 persons, U.S. Department of Health & Human Services/HIV.gov), diabetes (3.42×10^7 persons, CDC, 2020a, b) and heart diseases (1.82×10^7 persons, National CDC/Center for Chronic Disease Prevention and Health Promotion). The percentage of healthy elderly population (>65 yrs., 12.2 %) was obtained from the report by Roberts et al. (2018) subtracting the population > 65 yrs. that belong to the highly susceptible. The percentage of healthy pregnant (0.9 %) was obtained from data reported by U.S. Centers for Disease Control and Prevention/National Center for Health Statistics/National Vital Statistics System (2019) subtracting the pregnant population that belong to the highly susceptible.

Number of servings (mean ± SD) and log-scale of portion sizes (mean ± SD) (log g) for the different subpopulations (healthy adults, >65 yrs. and pregnant) and food commodities were obtained from the NHANES dietary history 2015–2016 (CDC, 2018). The dietary histories provide numbers of servings and sizes of each serving for two nonconsecutive days. For the total, elderly, and pregnant populations, two-day food histories were used to estimate number of servings in two days as well as average serving size for each food commodity. Weighted averages were taken using the NHANES survey weights to assure representativeness to the general US population. Numbers of servings for the highly susceptible subpopulation were calculated using a dietary survey among cancer patients where 21.6 % of the patients reported to eat 25 % more, 48.5 % same and 30.4 % 25 % less frequency of eating in respect to a previous healthy condition (Coa et al., 2014). It was assumed that portion sizes were similar to the healthy adult population. Annual consumption totals were estimated by multiplying the mean and standard deviation of the two-day consumption totals by 182 (i.e., 365 days/2). Table 2 shows the dietary pattern estimates for all the populations considered in this study.

2.7. Model simulation settings

The model was simulated with 100,000 iterations using Latin Hypercube sampling technique implemented in the software @Risk 7.6 (Palisade Inc., USA). The number of iterations was optimized to achieve a suitable convergence level in the main distribution statistics (mean, SD, and 95th percentile), considering that an output converges when the variation rate in the associated statistics was lower than 1 %. In the model, each iteration was regarded to represent an individual contaminated serving, with the corresponding individual dose simulated from a Poisson process. A quality check was also performed in the model simulation results to identify the appearance of invalid results. Output estimates were characterized by the mean and 95 % confidence interval (CI) values.

2.8. Public health impact of removing highly contaminated lots

The US baseline scenario for each food commodity (2015–2020) was compared with the application of different quantitative microbiological criteria assuming each lot was tested and removed from the production chain if were above the criteria of 1, 10 and 100 CFU/g. For this, a 3-class mixed sampling plan (m = absence in 25 g and M = 0.1, 1.0 or 2.0 log CFU/g) was used as a testing scheme to estimate the number of samples to be analyzed (n) to detect a contaminated lot with 95 % confidence by using two stringency levels (c = 1 and c = 2) (ICMSF, 2020). As with any sampling plan, certain percentage of positive lots could go undetected even having a concentration higher than the threshold level (1, 10 and 100 CFU/g) namely 'false negative lots'. The percentage of undetected positive lots were also estimated for each sampling scheme and threshold level. It was also assumed that the samples analyzed from a lot (i.e., 3 samples) represented the pathogen concentration within the entire lot and if all the samples were below or within the allowable limits then the entire lot was deemed to be acceptable. The US baseline model and the different scenarios were run and compared by the impact on the public health metrics (reduction of the overall prevalence and mean number of illnesses). When assessing the effect of removing lots above a certain threshold level, it was assumed that the *L. monocytogenes* enumeration level reported represented all positive samples (since some positive samples were not enumerated in the original study).

Table 4
L. monocytogenes prevalence reduction during last five years (2015–2020) over total period (1990–2020).

Food category	Scenario	Samples analyzed over all commodities (%)	Total number of samples and estimated prevalence (%)[a]	Prevalence reduction (%)[b]
RTE salads	WD	7.1	10,694 (0.8)	62.9 (54.3, 70.4)
	US	4.6	4865 (0.6)	57.9 (41.5, 71.4)
Deli meats	WD	66.7	100,102 (0.9)	40.8 (35.4, 45.9)
	US	85.5	90,785 (0.2)	45.7 (39.8, 51.7)
Soft/semi-soft cheese	WD	7.9	11,852 (1.9)	6.9 (−7.0, 19.7)
	US	6.2	6563 (0.3)	55.7 (32.5, 72.8)
RTE seafood	WD	8.8	13,159 (9.4)	4.9 (−0.9, 10.6)
	US	2.7	2838 (0.3)	92.7 (86.6, 96.8)
Frozen vegetables	WD	9.1	13,627 (5.1)	43.8 (38.9, 48.5)
	US	1.0	1066 (1.4)	12.4 (−57.8, 58.2)

[a] Calculated prevalence (having at least 1 CFU in 25 g) from studies published in the last 5 years (2015–2020).
[b] Prevalence reduction after 100,000 iterations (mean and 95CI) (1-prevalence (2015/2020)/prevalence (1990–2020)) over the value estimated for 30 years. Negative values indicate an increase in the prevalence during last 5 years.

3. Results and discussion

3.1. Retrospective analysis: overall prevalence and microbial load among food commodities (1990–2020) and (2015–2020) periods

The total number of samples evaluated in this study worldwide (WD) to estimate the prevalence of *L. monocytogenes* in food commodities over the last 30 years (1990–2020) was around a half-million samples (62.5 % collected in the US). RTE deli meats was the most sampled category representing 67 and 87 % of the total number of samples analyzed for *L. monocytogenes* for the WD and US scenarios, respectively, followed by soft and semi-soft cheeses (WD scenario) and deli salads (US scenario) (Table 3). These data reflect the food categories that have received the greatest regulatory and research sampling effort for the last 30 years. Soft and semi-soft cheese and RTE seafood categories were sampled more than double and triple worldwide than in the US scenario, respectively, probably due to a higher consumption in other parts of the world (i.e., European Union). In contrast, frozen vegetables was the least sampled category as these products do not support microbial growth and are not considered RTE through their on-package cooking instructions.

Overall *L. monocytogenes* prevalence ranged from 1.4–9.9 % worldwide (WD) and 0.5–3.8 % (US) depending on commodity (Table 3). Prevalence rates were significantly lower in the US (1.3–5.2×) than those reported worldwide. RTE seafood was the commodity with the highest prevalence in both WD and US scenarios. EU prevalence estimates reported by EFSA, for RTE food categories (RTE seafood, RTE deli meats and soft and semi-soft cheeses) whose values correspond to 0.5–10.3 % in 2008–2015 and 0.8–2.7 % in 2016–2018 period were in accordance with the levels estimated in this study, where the EFSA reports also identified RTE seafood as the category with the highest prevalence (EFSA, 2018; EFSA and ECDC, 2019).

L. monocytogenes enumeration data were limited and commodity-dependent, with enumeration rates from total positive samples ranging from 26.2–56.5 % (WD) and 8.2–86.3 % (US) (Fig. 1). As pointed out by Farber et al. (2021) the "zero-tolerance" regulatory approach may discourage direct food contact surfaces and final product testing, reducing the prevalence and enumeration data available. This may lead to under- or overpredicting risk if sample size is not representative of the overall food production. This is relevant for RTE deli meats in the US and soft/semi-soft cheese worldwide where only 8.2 and 26.2 % of all positive samples were enumerated, respectively, reducing the overall accuracy level of the risk assessment model. The percentage of enumerated samples higher than 100 CFU/g were similar for both scenarios and varied between 6.4–36.2 % (WD) and 5.5–35.7 % (US) (Fig. 1). The commodities with the highest percentage of samples exceeding 100 CFU/g were soft/semisoft cheese and RTE seafood for the worldwide scenario and frozen vegetables and RTE deli meats for the US scenario. Comparing both geographical scenarios, the percentage of high-count samples was higher in the US versus worldwide for RTE salads, deli meats and frozen vegetables and lower in the rest of commodities. Martinez-Rios and Dalgaard (2018) estimated an overall *L. monocytogenes* prevalence of 1.9 % in soft and semi-soft cheeses (from pasteurized and un-pasteurized milk) in the EU with an estimated 0.3 % of the total samples analyzed exceeding the compliance level of 100 CFU/g during the 2005–2015 period. Non-compliance rates estimated by EFSA ranged from 1.7, 0.4 and 0.06 % of the tested samples for RTE seafood, RTE deli meats and soft/semi-soft cheeses, respectively (EFSA, 2013, 2018).

Mean *L. monocytogenes* concentration ranged from 0.2 to 1.6 log CFU/g (WD) and −0.5 to 1.6 log CFU/g (US) (Table 3). The mean concentration found in positive samples was lower in the US scenario for all the commodities except in the case of frozen vegetables where

Table 5
Overall annual listeriosis incidence in the US by using the FAO/WHO and Pouillot dose-response models (2015–2020).

	FAO/WHO model				Pouillot model			
	Mean probability of infection[a]	Number of cases[b]	% over total cases	% reduction last 5 yrs.	Mean probability of infection[a]	Number of cases[b]	% over total cases	% reduction last 5 yrs.
RTE salads	P_{inf} hlth: 1.2×10^{-8} P_{inf} sus: 5.9×10^{-7}	84 (19–197)	4.0	60.8	P_{inf} hlth: 4.1×10^{-9} P_{inf} sus: 1.8×10^{-6}	33 (2–102)	3.2	61.4
Deli meats	P_{inf} hlth: 1.7×10^{-6} P_{inf} sus: 6.5×10^{-5}	1974 (508–4250)	94.5	64.9	P_{inf} hlth: 5.5×10^{-7} P_{inf} sus: 2.5×10^{-4}	998 (63–2781)	95.6	64.8
Soft and semi-soft cheese	P_{inf} hlth: 1.3×10^{-8} P_{inf} sus: 7.4×10^{-7}	11 (2–30)	0.5	64.6	P_{inf} hlth: 4.2×10^{-9} P_{inf} sus: 8.4×10^{-6}	3 (0–10)	0.3	53.7
RTE seafood	P_{inf} hlth: 3.5×10^{-8} P_{inf} sus: 1.3×10^{-6}	15 (3–47)	0.7	92.0	P_{inf} hlth: 1.1×10^{-8} P_{inf} sus: 2.9×10^{-6}	7 (0–30)	0.7	92.2
Frozen vegetables	P_{inf} hlth: 1.1×10^{-9} P_{inf} sus: 6.5×10^{-8}	5 (1–13)	0.2	17.9	P_{inf} hlth: 3.7×10^{-10} P_{inf} sus: 1.1×10^{-7}	2 (0–6)	0.2	17.6
Total		2089	100	–	–	1044	100	–

[a] P_{inf} susceptible is the sum of the probabilities of infection of older than 65 yrs., pregnant women, and highly susceptible subpopulations.
[b] Mean and 95 % CI after 100,000 iterations.

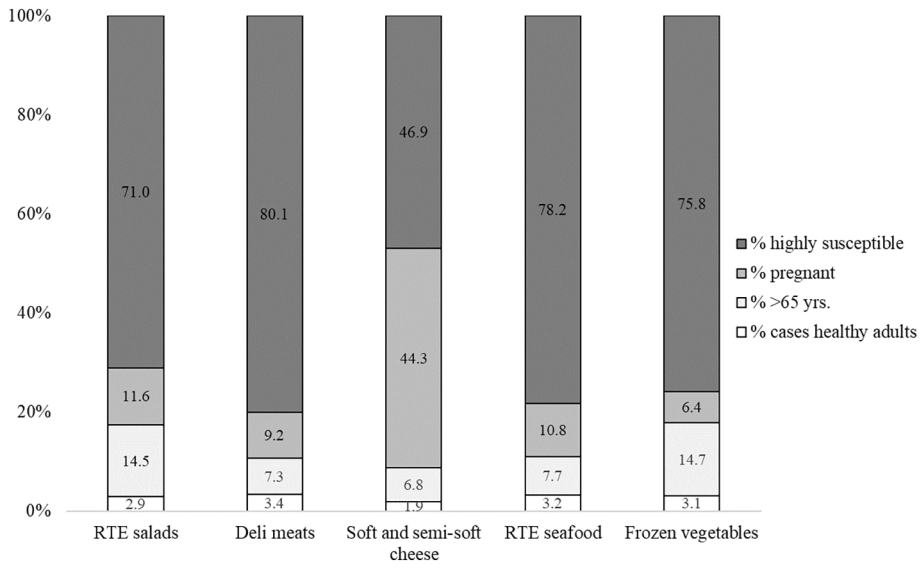

Fig. 2. Proportion of cases attributed to highly susceptible, pregnant, and elderly populations for each food commodity by using the Pouillot dose-response model (2015–2020).

concentration was higher, however it is important to note this was based on a very small set of unpublished data. Differences in prevalence and enumeration levels observed between US and WD scenarios may be due to a variety of factors including contamination level in raw materials, cleaning and disinfection protocols, environmental programs targeting *Listeria* spp. in surfaces and equipment and final product testing efforts (Magdovitz et al., 2020).

Previous industry and regulatory efforts targeting *L. monocytogenes* have led to a dramatic decrease in the prevalence of contamination during the last five years (Table 4). Reduction in prevalence rates ranged from 4.9–62.9 % (WD) and 12.4–92.7 % (US). Comparing EU prevalence rates between 2008–2015 and 2016–2018 periods there has been also a reduction in prevalence (32.4 % reduction in RTE deli meats, 58.9 % reduction in RTE seafood and 17.0 % reduction in soft and semi-soft cheese) (EFSA, 2017; EFSA and ECDC, 2019).

3.2. QMRA: probability of infection and number of listeriosis cases among food commodities and population groups in the US

The QMRA model estimated the mean probability of infection and number of listeriosis cases predicted per year in the US among the different food commodities and population groups by using data from the 2015–2020 period (Table 1). Table 5 shows the outputs of the model by using the FAO/WHO and Pouillot dose-response models. Probability of infection in the susceptible population was 10–100× higher than the general population by using the FAO/WHO model and 10–10,000× higher by using the Pouillot model. Despite these differences, estimated number of annual cases was within the same range for both dose-response models, showing similar percentages for the contribution of each food category on the total number of listeriosis cases (Table 5). Overall, mean number of cases predicted were 1044 and 2089 according to Pouillot and FAO/WHO model, respectively. This represents a decrease of 17.6–92.2 % in the estimated number of cases attributed to the total period (1990–2020) (Table 5). This is in agreement with the reported reduction in the incidence of listeriosis in the US observing a decline of 36 % for the period 2015–2019 compared to 1996–2000 (CDC, 2021). However, listeriosis incidence (cases per 100,000 population) has not decreased during the last 5 years according to CDC (0.24 in 2014 and 0.26 in 2018) and ECDC (0.46 in 2014 and 0.47 in 2018) (EFSA and ECDC, 2019). This fact has been discussed by other authors arguing that the increasing proportion of elderly and high-risk populations (i.e., cancer and AIDS survivors) in recent years may be responsible for the steady listeriosis incidence rate (EFSA, 2018; Pohl et al., 2017).

Several attempts have been made to estimate the annual incidence of listeriosis in the US. Scallan et al. (2011) predicted 1455 listeriosis cases (521–3018, 95 % CI) per year from data ranging from 2000 to 2008, Pohl et al. (2017) predicted 946 listeriosis cases (724–1279, 95 % CI) for 2020 in the US whereas Pérez-Rodríguez et al. (2017) predicted 2318 annual cases in the EU from animal-based products with 1400 cases attributed to deli meats (60.5 %), 19 cases to soft and semi-soft cheese (0.8 %) and 735 cases to RTE seafood (31.7 %). These predictions are similar to those reported in our study (Table 5). Reported listeriosis incidence in the US according to the surveillance system, is in the range of 577–675 (2010–2014) (CDC, 2015). If the effect of underreported cases is considered in the model by using the under-diagnosis factor derived by Scallan et al. (2011), the predicted number of reported cases was equal to 578 and 997 according to Pouillot and FAO/WHO model, respectively, which is within the range reported by CDC. Most cases were attributed to deli meats (>90 % of cases) followed by RTE salads (3.2 and 4.0 % according to Pouillot and FAO/WHO model), soft and semi-soft cheese and RTE seafood (0.3–0.5 and 0.7 %) and frozen vegetables, with the lowest contribution (0.2 %). Annual listeriosis cases attributed to deli meats by FSIS (2010) and Pradhan et al. (2009) (~1100 annual cases) are similar to those attributed in this study by using the Pouillot model but higher with the FAO/WHO model. Frozen vegetables were the commodity with the lowest public health risk with 2–5 cases predicted per year by using both dose-response models. A study by EFSA BIOHAZ (2020) also predicted similar listeriosis incidence in the EU with an estimated listeriosis incidence in frozen vegetables ranging from 0.04 to 1.6 cases per 100,000 population per year. The Interagency Food Safety Analytics Collaboration (IFSAC) (IFSAC, 2020) attributed 75 % of *L. monocytogenes* outbreak cases (1998–2018) to dairy and fruits food categories, 11.6 % to vegetable row crops, 4.9 % to meat and 2.0 % to fish. The differences on food attribution to listeriosis cases could be related to differences that may arise from using cases attributed to outbreaks and sporadic cases (as outbreaks tend to reflect specific amplifying events rather than the underlying distribution of *L. monocytogenes* across a commodity), and the limited data available related to contamination levels in several categories of food commodities at the point of food service or consumption.

Cases attributed to the increased risk (elderly > 65 yrs. and pregnant women) and 'highly susceptible' populations by the Pouillot dose-response model corresponded to 96.6–98.0 % of the total cases. Fig. 2

Table 6
Performance of a 3-class mixed plan for different concentration threshold values (1, 10 and 100 CFU/g) using *L. monocytogenes* lot concentration in the last 5 years in the US.

Food category	Lot concentration (log CFU/g)[a]	m (absence in 25 g)	M (log CFU/g)	% of positive undetected lots	% of lots above threshold level	n	
						P_{reject} = 95 %, c = 1[b]	P_{reject} = 95 %, c = 2[b]
RTE salads	−0.5 ± 1.2	−1.4 log CFU/g	0.1	1.6	30.9	4	5
			1.0	2.1	10.6	4	5
			2.0	2.4	1.9	4	5
Deli meats	0.3 ± 1.7		0.1	2.1	54.7	4	4
			1.0	3.2	34.0	4	4
			2.0	4.2	15.9	4	4
Soft/semi-soft cheese	−0.2 ± 2.0		0.1	2.2	44.0	4	5
			1.0	3.1	27.4	4	5
			2.0	3.9	13.6	4	6
RTE seafood	0.4 ± 1.4		0.1	0.8	58.5	3	3
			1.0	1.3	33.4	3	4
			2.0	1.8	12.6	3	4
Frozen vegetables	1.6 ± 1.3		0.1	0.2	87.6	2	3
			1.0	0.6	67.7	2	3
			2.0	1.2	37.9	2	3

[a] Mean and standard deviation of all enumerated samples after 100,000 iterations.
[b] Number of samples to be analyzed to detect a positive lot with 95 % confidence with one or two samples between m and M.

shows that the 'highly susceptible' population are responsible for 15.7–88.3 % of the cases among the different food commodities. Invasive listeriosis incidence among pregnant women and elderly varied between 6.4–44.3 and 6.8–14.7 %, respectively where soft and semi-soft cheese represented the category with the highest proportion of cases attributed to pregnant women and RTE salads and frozen vegetables to elderly due to the estimated higher consumption (frequency and portion size). Previous risk assessment and listeriosis incidence studies have estimated 80–95 % of the total listeriosis cases attributed to the increased risk population (Falk et al., 2016; Goulet et al., 2001, 2012; Pérez-Rodríguez et al., 2017; Pouillot et al., 2015). Studies by Goulet et al. (2001, 2012) estimated 61 % (1997) and 43 % (2001–2008) of the invasive listeriosis cases attributed to the highly susceptible population in France, Pouillot et al. (2015) attributed 53.4 % of the cases to the highly susceptible population in the US and Falk et al. (2016) attributed 93.2 % of the cases to the highly susceptible population in Canada where they estimated the vulnerable population as high as 39 % of the total population. Our estimates regarding the overall vulnerable population size in the US (32.9 %, including 19.7 % of the highly susceptible) and listeriosis incidence among highly susceptible population (46.9–80.1 %) are among those reported in the studies. However, previous estimates of the vulnerable population size (20 %) by FAO/WHO (2004) seem to be outdated. Several reasons may be argued to the estimated increase of the highly susceptible population such as improving cancer and AIDS survival rates, increased cardiovascular disease and diabetes incidence rates and the aging of the population. There are also reasons to believe that the highly susceptible population will continue to grow in the coming years due to advancements in cancer treatments and the increase in obesity rates. It seems clear that future population-based strategies aiming at reducing listeriosis incidence should be targeted to the highly susceptible population through advisory campaigns to avoid the exposure to potential 'high-risk' foods. Unfortunately, very little is known about the extent of the dietary changes when suffering a disease or having an underlying condition and is one of the main limitations of current risk assessment models.

3.3. Effect of removing highly contaminated lots on reducing overall prevalence and listeriosis cases

One of the risk management strategies that has been proposed that could lead to a decrease in the number of listeriosis cases is to include a quantitative microbiological criterion (i.e., <100 CFU/g) and a sampling scheme to test every lot and remove the highly contaminated lots from the market (Chen et al., 2003; European Commission (EC), 2005; Farber et al., 2021; FAO/WHO, 2004; FSIS, 2003; Pohl et al., 2017). This could be allowed by changing the final product microbiological criteria from a two-class plan (absence in 25 g or 'zero-tolerance') to a quantitative plan (either a two-class or three-class as explained by Farber et al. (2021) for food commodities that do not allow the growth of *L. monocytogenes* where positive samples are allowed below a threshold level or within a lower and upper bound level. A 3-class mixed plan was used as the testing scheme to detect lots with a concentration higher than the microbiological criteria proposed in this study (0.1, 1.0 and 2.0 log CFU/g) by using the *L. monocytogenes* lot concentrations estimated for different commodities (Table 6). The percentage of lots higher than 0.1 log CFU/g threshold level ranged from 30.9 to 87.6 % whereas 10.6–67.7 % were higher than 1.0 log CFU/g and 1.9–37.9 were higher than 2.0 log CFU/g. The number of samples to be analyzed to detect a contaminated lot with 95 % confidence with m (absence in 25 g) and M (0.1,1.0 or 2.0 log CFU/g) was between 2 and 4 samples when c = 1 (only one sample allowed to be between m and M) and 3 to 5 samples when c = 2 (Table 6). As with any sampling plan, certain positive lots could go undetected. The percentage of positive undetected lots namely 'false negative lots' ranged from 0.23 to 4.25 % depending on the testing scheme and threshold level (Table 6). These lots could contain a higher concentration than the threshold level and reach the market. The percentage of positive undetected lots could be decreased by applying a more stringent sampling plan thus increasing the probability of rejection from 95 to 99 %. Increasing the probability of rejection to 99 % would increase the number of samples to analyze to between 3 to 7samples reducing the positive undetected lots to 0.2–0.78 %. It is also acknowledged that microbial contamination in a lot can be heterogeneous, and parts of the lot can have concentration levels lower or higher than a certain threshold level. It was assumed in this study that the samples analyzed from a lot (i.e., 5 samples) represented the pathogen concentration within the entire lot and if all the samples were below or within the allowable limits then the entire lot was deemed to be acceptable. One of the benefits of a three-class sampling plan is that it would likely identify low levels of contamination that are likely to occur more frequently and result in the facility being alerted and prompting appropriate corrective actions, while also picking up high levels of contamination that are likely to occur less frequently and prevent these lots from entering commerce. Furthermore, the presence of a microbial limit provides processors the ability to implement more stringent environmental monitoring plans such as robust food contact surface testing. Further research is needed to estimate the variability of *L. monocytogenes*

Table 7
Effect of different threshold levels on the reduction of prevalence and cases in the US (2015–2020).

Removing samples > threshold[a]	RTE salads		Deli meats		Soft & semi-soft cheese		RTE seafood		Frozen vegetables	
	Prev. reduction (%)	Cases reduction (%)[b]	Prev. reduction (%)	Cases reduction (%)[b]	Prev. reduction (%)	Cases reduction (%)[b]	Prev. reduction (%)	Cases reduction (%)[b]	Prev. reduction (%)	Cases reduction (%)[a]
>1 CFU/g	15.7	67.3	39.1	61.1	33.4	66.2	40.7	86.9	88.3	100.0
>10 CFU/g	11.8	61.8	22.6	44.1	16.9	61.2	34.2	76.2	46.7	99.6
>100 CFU/g	9.3	59.1	19.1	35.1	8.4	35.8	4.5	31.8	33.3	96.6

[a] Enumeration levels used for the whole study period (1990–2020).
[b] Maximum reduction value obtained from FAO/WHO and Pouillot dose-response models.

concentration within lots of different RTE commodities to be able to incorporate it in future QMRA models and sampling schemes.

To study the public health effect of removing lots above the threshold levels on the overall prevalence and mean number of listeriosis cases, estimates from the US baseline risk assessment model (Table 5) were compared with the threshold risk assessment model (Table 7). Results showed that removing lots above a certain level decreased the overall prevalence and number of cases. Removing lots higher than 1 CFU/g yielded a prevalence reduction of 15.7–88.3 % whereas removing samples higher than 100 CFU/g produced a reduction in prevalence of 4.5–33.3 %.

Removing samples higher than 1 CFU/g also yielded a decrease in the number of cases by 61.1–100 % whereas using a 100 CFU/g limit the reduction varied between 31.8 and 96.6 %. Frozen vegetables were the commodity with the highest reduction whereas deli meats were the commodity with the lowest reduction. A higher consumption of deli meats as observed in Table 2 along with longer shelf-life periods (ranging from 17 to 67 days) (Pouillot et al., 2010) where extensive growth may occur from very low concentrations may undermine the net effect of removing contaminated lots. *L. monocytogenes* concentration level has been identified by previous risk assessment studies as one of the most important variables affecting the mean risk of illness (FDA/Health Canada, 2015; Zoellner et al., 2019). Other risk assessment studies have also reported a significant decrease in the number of listeriosis cases by adjusting the maximum concentration level allowable in a sample. A study by Chen et al. (2003) reported a reduction in the number of listeriosis cases of 99.5 and 89 % when maximum concentration was set at 100 and 10,000 CFU/g, respectively. FAO/WHO (2004) also highlighted the influence of mean concentration level on number of cases where an increase from 1 to 1000 CFU/serving increased the mean risk of illness by 1000-fold arguing that a less stringent microbiological limit (i.e., from absence to allowable limit) for low-risk food commodities could improve public health metrics by encouraging industry to implement robust environmental monitoring programs and a risk-based product-testing regimen such as the one proposed in this study. These steps can serve as an early warning indicator of potential breakdowns in *Listeria* management and prompt corrective actions in production systems (Farber et al., 2021). Furthermore, this novel risk management strategy may also have unintended beneficial consequences in the approach industry controls *L. monocytogenes* by adopting such wider monitoring and testing efforts and detecting and removing highly contaminated lots and improving the availability of enumeration data that can improve the accuracy of future risk assessment models. As opposite, an increased lot-by-lot testing effort by industry could add additional production costs and decrease the food available in the market especially for the most stringent conditions (>1 CFU/g) where between 30.9 and 87.6 % of the positive lots (0.5–1.5 % of the total number of lots) depending on the commodity (Table 6) would not meet the threshold criteria. Further cost-benefit analysis balancing public health protection and the availability of affordable food would be desirable.

The availability of *L. monocytogenes* prevalence and enumeration data on foods reflects current regulatory testing priorities and limitations. Although the incidence of listeriosis in the US is at historically low levels, rates of illness have not decreased in recent years, despite increased regulatory testing and associated recalls. Increasing product testing by industry with removal of contaminated lots with specified threshold levels of contamination for low-risk food commodities (not supporting pathogen growth) should provide net public health benefits by reducing the risk of exposure for highly susceptible populations. The public health benefit of various threshold levels may depend on the nature and level of risk associated with the food such as the type of food item and formulation (intrinsic properties), storage conditions (extrinsic properties), potential growth of *L. monocytogenes* during shelf-life, consumer behaviors, etc. In particular, special care is needed for highly susceptible people in long-term care and acute health care and hospital settings as invasive listeriosis seriously affects these subpopulations (Falk et al., 2016). Low-risk RTE and not-ready-to-eat foods contaminated with low levels of *L. monocytogenes* may pose risks as they have the potential to support growth when stored or handled improperly (e.g., thawing or slacking frozen vegetables), or served without adequate preparation to ensure safe consumption by highly susceptible people as seen in previous *L. monocytogenes* outbreaks (Buchanan et al., 2018). Industry should clearly label NRTE foods destined for such populations with validated on-package cooking instructions and employees should be trained to follow the recommended preparation steps accurately prior to serving highly susceptible people in these settings. This study provides guidance to national authorities as they formulate effective risk management strategies that account for differences in risk levels to optimize the use of threshold values in implementing preventive controls for *L. monocytogenes*.

CRediT authorship contribution statement

Fernando Sampedro: Conceptualization, Methodology, Validation, Formal analysis, Writing – original draft, Writing – review & editing, Visualization. **Fernando Pérez-Rodríguez:** Methodology, Validation, Formal analysis, Writing – review & editing. **Joseph L. Servadio:** Methodology, Formal analysis, Writing – review & editing. **Sanjay Gummalla:** Conceptualization, Resources, Writing – review & editing, Funding acquisition. **Craig W. Hedberg:** Conceptualization, Writing – review & editing, Supervision, Project administration.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Craig Hedberg reports financial support was provided by Frozen Food Foundation. Fernando Sampedro reports financial support was provided by Frozen Food Foundation. Craig Hedberg reports financial support was provided by Seafood Industry Research Fund. Fernando Sampedro reports financial support was provided by Seafood Industry Research Fund. Sanjay Gummalla reports a relationship with American Frozen Food Institute that includes: employment.

Data availability

Data will be made available on request.

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Appendix A. Supplementary data

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