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Designing a risk-based monitoring plan for pathogens in food: A review

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A B S T R A C T

Governmental food safety monitoring is moving towards risk-based monitoring. Three steps are needed to design an optimal risk-based monitoring plan for pathogens. First pathogen-product combinations need to be ranked, according to their probability of contamination of the sampled product, consequences to human health, or the combination of one or more of these aspects. Second, food business operators (FBO) that will be sampled need to be selected. FBOs can be selected based on historical data but also on socio-economic factors. These include both internal factors, such as the company size, the perception of the likelihood and the consequence of producing unsafe food, the social pressure, as well as external factors, such as the legislation in place, or the budget available. Third, for the selected pathogen-product combinations and FBOs, an optimal sampling strategy needs to be determined. The optimal number of lots to be sampled and the optimal number of samples per lot depend on the prevalence of the pathogen, the distribution of the pathogen between and within lots, and the available resources. Furthermore, the sampling strategy in terms of where and how the samples need to be collected from the lot is relevant to define. To the best of our knowledge, the three steps to design an optimal risk-based monitoring plan for microbiological hazards, as proposed in this study, have not yet been considered together. This study thus provides a basis to further optimize the risk-based monitoring process.

1. Introduction

In Europe, a set of regulations and recommendations to ensure food safety has been introduced, including a variety of strategies, from food safety management strategies, e.g. General Food Law (EU, 2002), setting maximum limits for the presence of food safety hazards in feed and food products, to laying down procedures for official food safety control. The Official Controls Regulation (EU) 2017/625 states that official controls must be performed in a risk-based manner, that minimizes the burden on businesses. Official controls should be efficient across the country and across the entire agri-food chain. Each member state should set up and regularly update a multi-annual national control plan (MANCP) containing the structure and organization of official controls (EU, 2017). Therefore, over the past decade, official, food safety monitoring has been moving towards risk-based monitoring. The idea of risk-based monitoring is to use most of the available resources for control of the presence of high risk hazards and/or high risk food products, and use less of the available resources for the low risk hazards and/or food products so as to detect more contaminated lots with the same resources (van Asselt, Noordam, Pikkemaat, & Dorgelo, 2018; van der Fels-Klerx et al., 2018; van der Fels-Klerx et al., 2015). A lot is here defined as "a set of sales units of a foodstuff produced, manufactured or packaged under identical conditions" (Council Directive 89/396). For example, Lee, Herrman, and Dai (2016) showed that risk-based sampling plans for animal feed provide a more effective risk management, where effectiveness is defined as the probability of detection per sample collected. Furthermore, a comparison between risk-based and random sampling approaches for *Listeria monocytogenes* and *Salmonella* spp. in ready-to-eat meat and poultry products in the US showed that risk-based monitoring is able to detect more positive samples than random monitoring. Monitoring results for several years (2005–2017) and for a large number of establishments (more than 60,000) were evaluated showing that percentages of establishments with at least one *Salmonella*-positive sample was 0.5% and 1.1% for random and risk-based, respectively. The same results were observed for *L. monocytogenes*: percentages of establishments with at least one *L. monocytogenes*-positive sample were 3.9% and 10.0%, respectively for random and risk-based monitoring (Mamber et al., 2020).

With setting up risk-based monitoring plans, three levels can be distinguished: First of all, food safety hazards, if applicable, in combination with food products (hazard-product combinations), need to be ranked. Second, out of all Food Business Operators (FBO) that produce the products identified at the first step, the FBOs to inspect and the frequency of inspection need to be identified. Third, samples from these FBOs need to be collected and analyzed in a cost-effective manner (van Asselt et al. 2012, 2021). All three steps of setting up a risk based monitoring plan are depicted in Fig. 1. To date, studies and reviews have focused on a single step, out of those three steps. van der Fels-Klerx et al. (2018) critically reviewed available methods for risk ranking, for both chemical and microbiological hazards, Devleesschauwer (2017)

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reviewed risk ranking methods for pathogens, and the EFSA Panel on Biological Hazards (2015) reviewed available user-friendly tools for risk ranking of microbiological hazards. van Asselt et al. (2021) reviewed available methods to select FBOs in a risk-based manner. Finally, Focker, van Der Fels-Klerx, and Oude Lansink (2018) reviewed methods available for cost-effective monitoring for both chemical and microbiological hazards. In contrast to these previous reviews, this paper presents the state-of-the-art regarding the methods available for risk-based monitoring for microbiological hazards in food, covering all three steps described above, to provide a basis for risk-managers to derive a concrete risk based monitoring plan, depending on the aim of the monitoring, the data, time, and budget available. It includes available risk ranking methods for microbiological hazards and tools to prioritize hazards, available models to select and prioritize FBOs, available models to design and/or optimize monitoring schemes for specific pathogen-product combinations, and available models linking risk ranking and sampling. The paper ends with conclusions on how these steps could be integrated to design a risk-based monitoring scheme for microbiological hazards in food and feed. The focus of this review is on official monitoring, by means of sampling and microbiological testing, to verify the compliance of the FBOs, in Europe. However, the methodologies discussed could be applicable elsewhere as well.

2. Risk ranking

2.1. Overview of methods

In order to help decision makers to establish priorities for control, prevention and surveillance of pathogens, the different pathogens, if applicable in combination with food products in which they occur, need to be ranked depending on their risk to human health. The literature review by van der Fels-Klerx et al. (2018) identified the following categories of methods used to rank microbiological hazards: risk assessment (RA) (72x), disease burden methods (25x), expert judgement methods (14x), flow charts or decision trees (7x), risk ratio methods (6x), stated preference (6x), scoring method (5x), multi criteria decision analysis (MCDA) (4x), and risk matrices (4x).

Methods for risk ranking should ideally be quantitative, should be transparent about the assumptions, uncertainties and limitations, and should be easily updated when new data become available (Mangen et al., 2010). The Scientific Panel on biological hazards (BIOHAZ) of the European Food Safety Authority (EFSA) (2015) concluded that quantitative stochastic models are most reliable for risk ranking, and that decision trees should be used only to demonstrate how decisions are taken with respect to classifying pathogen/product combinations into broad categories. However, as stated by van der Fels-Klerx et al. (2018), in case of lack of data, or resources, decision trees might be the best alternative to fully quantitative modelling techniques. By determining on what basis the ranking should be performed, for example, based on the number of illnesses expected, or on the burden of disease, or on a combination of different factors, possibly including socio-economic factors, the risk manager will be able to determine what approach to take. Three approaches: RA, burden of disease, and MCDA are discussed in more details in the next sections.

2.2. Risk assessment (RA)

The principle for performing a RA is common for all hazards, and guidelines for RA, written by the Codex Alimentarius Committee, are available (CAC, 1999). The same four basic steps, i.e. hazard identification, hazard characterization, exposure assessment and risk characterization are followed, in all RA studies. RA is commonly a bottom-up approach, based on the occurrence of hazards in foods and on the observed food consumption patterns. Top-down approaches, based on epidemiological data on the occurrence of illnesses in the population are less frequently applied. Quantitative microbiological risk assessment (QMRA) - assessing the pathogenic contamination of foods at the time of consumption and the number of people getting ill - is a commonly used method for prioritising microbiological hazards. However, a (QM)RA focuses on only one hazard at the time. The results of different RAs, such as the prevalence, the probability of illness or the number of illnesses expected in the population, can then be used for risk ranking. (QM)RA is a quantitative technique and, therefore, a preferred method for risk ranking, as stated in the previous paragraph. However, even though RA

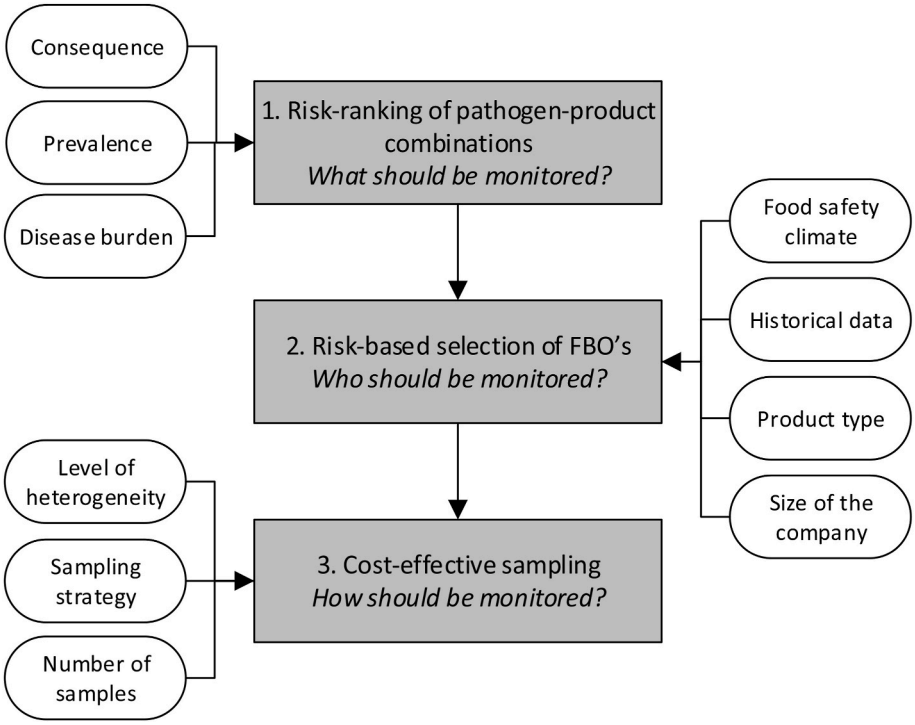

Fig. 1. The 3 steps of risk-based monitoring and the factors influencing the optimal budget allocation at each step. Adapted from: van Asselt et al. (2021).

is quantitative, several assumptions are included in the models used and these assumptions might not be the same between different RA's, limiting the comparability of RA's. In addition, the exact outputs of a RA depend on the data used and the risk management question at hand. Therefore, the results of different RA's might not always be comparable and useful to rank food safety hazards. Furthermore, to be able to prioritize hazards, a QMRA of all relevant hazards in all relevant food products is needed, but these might not be available for all hazards (Lindqvist, Langerholc, Ranta, Hirvonen, & Sand, 2020; van der Fels-Klerx et al., 2018).

2.3. Disease burden

Various studies have identified Disability Adjusted Life Years (DALY), Quality Adjusted Life Years (QALY) and Cost-of-Illness (CoI) methods as suitable methods to identify the microbiological hazards causing the highest risks to public health (Devleesschauwer et al., 2017; Lindqvist et al., 2020; Mangen et al., 2010; van der Fels-Klerx et al., 2018). In contrast to chemical hazards, there is a close relationship between exposure to microbiological pathogens via food consumption and the resulting levels of illness and death in the exposed human population. Therefore, burden of disease methods to quantify the impacts of microbiological hazards on human health are used more often for pathogens than for chemical hazards (van der Fels-Klerx et al., 2018; van der Fels-Klerx, van Asselt, Raley, Poulsen, & Frewer, 2015). DALYs are the sum of years lost due to premature mortality (YLL) and the years lived with a disability (YLD); one DALY being equal to one year of healthy life lost. QALYs are the quantity and quality of life generated by an intervention, one QALY being one (extra) year of life in perfect health. The CoI are costs of a foodborne disease in a given timeframe, including direct health care costs such as costs of treatment, and indirect health costs, such as loss of productivity due to illness. This method requires many data and is, therefore, not frequently used. Furthermore, CoI does not include a valuation in monetary units of the pain and suffering of patients. A ranking based on DALYs or on CoI might thus not lead to the same results. A study performed in the Netherlands showed, for example, that norovirus led to the highest total CoI in 2011, whereas *Campylobacter* spp. led to the highest DALYs in 2011 (Mangen et al., 2015).

Disease burdens in terms of DALYs and CoI of multiple pathogens (*Salmonella* spp., *Campylobacter* spp., *Escherichia coli* O157:H7, *L. monocytogenes*, *Staphylococcus aureus*, and *Clostridium perfringens*, *Yersinia*, *Toxoplasma gondii* and norovirus) have been quantified throughout the years and for several countries, such as the US, Australia, New Zeeland and several European countries (Batz, Hoffmann, & Morris, 2012; Buzby, Roberts, Lin, & MacDonalds, 1996; Kemmeren, Mangen, van Duynhoven, & Havelaar, 2006; Lake, Cressey, Campbell, & Oakley, 2010; Mangen et al., 2015; Monteiro Pires, Jakobsen, Ellis-Iversen, Pessoa, & Ethelberg, 2020; van Kreijl, Knaap, & van Raaij, 2006), as well as per larger regions and even globally (Devleesschauwer et al., 2015; Hald et al., 2016; Havelaar et al., 2015; Li et al., 2019). In most developed countries a limited list of known pathogens are responsible for 90% of the disease burden, expressed in DALYs, in the population. Therefore, besides the identification of pathogens, the identification of pathogen-product combinations is crucial. To do so, a quantitative risk ranking method combining risk assessment and disease burden should be used when enough data are available. As stated in the previous section, a major drawback to the use of fully quantitative risk ranking models is the extensive need for data. With changes in the supply chain or new products brought on the market, available data might not be sufficient. In case available data are not sufficient to derive a fully quantitative RA or disease burden study, semi-quantitative or even qualitative methods need to be used, for example Multi-Criteria Decision Analysis (MCDA), discussed in the next section. The use of a qualitative methods remains a better option than not using a transparent method at all to derive a risk-based monitoring plan.

2.4. Multi-Criteria Decision Analysis

MCDA gives the possibility of using as much quantitative data as available and fill the knowledge or data gaps with qualitative data, for example, obtained by expert elicitation. A study using MCDA to prioritize pathogens has been performed by the Norwegian Scientific Committee for Food and Environment (VMK). Twenty pathogens were selected for risk ranking. Expert elicitation was used to qualitatively score each pathogen on six criteria related to the incidence and the severity of illness: number of foodborne illnesses, acute morbidity severity, chronic morbidity severity, fraction of chronic illnesses, case fatality ratio, and probability for increased human burden of disease. After weighting the criteria, the overall pathogen scores were estimated. After ranking the pathogens based on these overall scores, the main food vehicles were identified for each of the selected pathogen (VMK, 2021). The French Agency for Food, Environment and Occupational Health & Safety (ANSES) ranked 35 microbial hazards including bacteria, viruses and parasites, as well as relevant pathogen-product combinations. The criteria used were the number of illnesses due to the pathogen and the pathogen-product combination, and the severity expressed in YLL and YLD. The criteria were quantitatively determined. After weighting the criteria, the ranking of pathogen-product combinations was estimated (ANSES, 2020).

Besides integrating RA outputs and disease burden, MCDA can be used to integrate additional criteria, such as socio-psychological aspects, that play an important role for the ranking of food safety hazards for official control (Kemmeren et al., 2006). The public risk perception to certain pathogens can be taken into account, for example, the risk perception for *Salmonella* spp. in infant food is very high (You, Lim, Shim, & Ju, 2018). This aspect is not included in a RA or disease burden methods. Ruzante et al. (2010) developed a framework to prioritize foodborne microbiological hazards considering public health, market impact, consumer risk acceptance and perception, and social sensitivity. MCDA was used to aggregate the different aspects. The method was applied to six relevant pathogen/product combinations in Canada, including: *Campylobacter* spp. in chicken, *Salmonella* spp. in chicken and spinach, *E. coli* O157 in spinach and beef, and *L. monocytogenes* in ready-to-eat meats. In this study, the examples of three different stakeholders were investigated, having different opinions on the importance of the criteria considered.

The weights given to the various aspects considered in the MCDA might, however, influence the ranking. Therefore, the aim of the monitoring plan needs to be identified beforehand e.g. the reduction of the number of illnesses, the reduction of disease burden, or maximizing the probability to detect contaminated lots in order to assign the weights to e.g. the number of illnesses the DALYs, or the prevalence of a pathogen in a product. Is should also be identified on beforehand which stakeholder groups are asked to set the weights. Finally, a sensitivity analyses should be done, indicating the impacts of the weights on the final ranking.

2.5. Risk ranking tools

RA and disease burden methods are mostly quantitative and quite objective, even though some assumptions are made in the models. However, they are complex as they require quantitative data and previous knowledge regarding the method and can, therefore, be applied by risk assessment experts only. Hence, risk ranking tools have been developed to be used by food safety authorities, industries, and other interested parties, having some knowledge on risk assessment, allowing for the input of personalised data to built-in models. The BIOHAZ Panel of EFSA reviewed eight risk ranking tools for biological hazards in food, summarized in Table 1, and assessed them using two case studies (EFSA Panel on Biological Hazards, 2015). In addition to helping the risk assessor by providing built-in models, most tools presented combined RA and disease burden approaches. US-FDA P^3ARRT, EFoNAO-RRT and

Table 1
Overview of available user-friendly tools for risk ranking of food pathogens based on multiple criteria such as the number of illnesses or the disease burden (based on: EFSA BIOHAZ, 2015).

	Specification	Main inputs	Outputs
US-FDA P^{3}ARRT Food and Drugs Administration (FDA), US Anderson et al. (2011)	Semi-quantitative	- Number of illnesses, hospitalizations, deaths - Infectious dose - Contaminated fraction - Consumption - Effect of storage	Ranking based on 9 input criteria: $\sum_{i=1}^{9} score_i * weight_i$
EFSA's Food of non-animal origin risk ranking model (EFoNAO-RRT) EFSA BIOHAZ Da Silva Felício et al. (2015)	Semi-quantitative, builds on US-FDA P^{3}ARRT	- Number of outbreaks, illnesses - DALY - Infectious dose - Contaminated fraction - Consumption - Effect of storage	Ranking based on 7 input criteria $\sum_{i=1}^{7} score_i * weight_i$
Risk Ranger Australian Food Safety Centre Ross and Sumner (2002)	Semi-quantitative (Qualitative inputs)	- Hazard severity - Consumption - Contaminated fraction - Infectious dose - Effect of processing, storage, cooking	- Number of illnesses - Probability of illness - Ranking
microHibro University of Cordoba, Spain González et al. (2019)	Quantitative	- Contaminated fraction - Effect of processing, storage, cooking - Infectious dose	- Number of illnesses - Probability of illness - Ranking
Swift quantitative microbiological risk assessment (sQMRA) Dutch National Institute for Public Health and the Environment (RIVM) (Chardon & Evers, 2017; Evers & Chardon, 2010)	Quantitative	- Contaminated fraction - Microbial growth - Effect of storage, cooking - Infectious dose - Consumption	- Number of illnesses - Probability of illness - DALY - CoI - Ranking
FDA-iRISK Food and Drugs Administration (FDA), US Chen et al. (2013)	Quantitative	- Contaminated fraction - Effect of storage, cooking - Infectious dose - Consumption	- Number of illnesses - Probability of illness - DALY - Ranking
Burden of Communicable Diseases in Europe (BCoDE) European Centre for Disease Prevention and Control (ECDC) (Colzani et al., 2017)	Quantitative	The number of cases as predicted by the sQMRA model can be used as input in the BCoDE model.	- DALY - YLD - YLL - Ranking

Abbreviations: CoI: Cost of illness, DALY: Disability adjusted life years, YLD: Years lives with disability, YLL: Years of life lost.

Risk Ranger use semi-quantitative tools based on several RA outputs (Anderson, Jaykus, Beaulieu, & Dennis, 2011; Ross & Sumner, 2002). MicroHibro is a fully quantitative tool based on RA (González et al., 2019). The tools sQMRA and FDA-iRISK are quantitative and are based on both RA and the burden of disease approach (Chardon & Evers, 2017; Chen et al., 2013; Evers & Chardon, 2010). BCoDE ("the Burden of communicable diseases in Europe") is a quantitative tool based on the burden of disease (Colzani et al., 2017). The BIOHAZ Panel concluded that the BCoDE tool, developed by the European Centre for Disease Prevention and Control (ECDC), can be used in combination with the outputs from FDA-iRISK tool to support transparent risk ranking. BCoDE provides meaningful outputs such as DALYs' per 100,000 population as well as per case (EFSA Panel on Biological Hazards, 2015). The drawback of this tool is that it does not take into account transmission pathways (e.g. airborne, direct contact, ingestion). Since it is not known if the diseases modelled are foodborne, to use this tool in the context of food safety, the tool needs to be used in combination with a bottom-up risk-ranking tool specific to food pathogens. FDA-iRISK is such a bottom-up tool, modelling the steps in the food supply chain, from farm to fork, to estimate, amongst others, the probability of illness per serving, the total number of illnesses in the population, and the number of DALYs. This predicted number of illnesses, with data regarding the gender and age distribution of the population, can then be used as input to the BCoDE tool which estimates the number of DALYs, both per case and per 100,000 population (EFSA Panel on Biological Hazards, 2015). The majority of the presented tools integrate both outputs of RA (e.g. probability of illness, number of illnesses) and disease burden. The relative importance of these aspects can be adapted, using the Multi-Criteria Decision Analysis (MCDA) approach.

3. Selection of FBOs

After having identified the most relevant pathogen-product combinations (step 1), the frequency of inspection for each FBO, need to be identified (step 2). A process to identify and prioritize FBOs for inspection has recently been proposed by van Asselt et al. (2021). FBOs can be ranked based on the company size, historical monitoring data and socio-economic factors, influencing compliance behavior. Smaller companies, in general, have a higher probability of non-compliance than larger companies. This is probably due to less specialized personnel available at smaller companies. Furthermore, a history of compliance frequently leads to appropriate food safety behavior that will be retained in the future. Socio-economic factors such as age, level of education, risk awareness, or the food safety culture, all influence the compliance level of an FBO as well (van Asselt et al., 2021).

The "food safety culture" has been used in several models, from qualitative models to quantitative models, as a factor influencing the likelihood of a FBO to produce safe food. The food safety culture is determined by external and internal factors. External factors are not related to the FBO itself and are, for example, national values and legislation, private standards, and public and private enforcement practices. Internal factors are factors related to the FBO, such as its organizational structure (high variability in workforce, procedures, training, management control), technological conditions (equipment hygienic design, sanitation program, protective clothing), employee characteristics (attitude, risk perception), and formal food safety programs such as Hazard Analysis Critical Control Points (HACCP) systems (design, implementation, verification, modification, improvement) (Luning et al., 2011; Nyarugwe et al., 2019).

Another approach to determine the likelihood of an FBO to produce safe food is using the Theory of Planned Behavior (TPB). Based on the TPB (Ajzen, 1991), the three aspects (named "constructs" in TPB) of attitude, subjective norms, and perceived behavioral control, define the intention of an FBO to produce safe food. It should be noted here, that the intention to produce safe food, is a proxy for the real behavior. Attitude provides insights into the positive (or negative) attitude towards producing safe food, for example, the perception of the likelihood and the consequence of producing unsafe food. Subjective norms refer to the perception that others (e.g. colleagues, managers, consumers) desire the production of safe food, in other words: the social pressure. The perceived behavioral control refers to the factors outsides one's control that influence safe food handling practices, for example, barriers due to procedures, or the available budget. Phillip et al. (2010) demonstrated that these three constructs of the TPB accounted for approximately half

of the variance in intentions of food handlers to perform safe food handling practices, with subjective norms having the greatest influence.

4. Sampling and analysis

The third step in designing a risk-based monitoring plan for food safety is allocating the optimal number of samples to the selected pathogen-product combinations, and collecting these samples in an optimal way. A high number of studies have focused on sample size estimations, whereas only a few studies focused on the optimal way of collecting these samples: the "sampling strategy". This section is limited to methods previously applied to foodborne pathogens. According to Lee et al. (2016) in order to accurately represent the population, a sampling plan should consider the sample size, the sampling points, the frequency of sampling, and the distribution of sample components. Sampling and analysis at each FBO requires a specific budget that should depend, amongst others, the volume of the products produced, the prevalence of the pathogen, and the costs of the analysis, to achieve a required level of certainty to detect potential contaminations. This section first provides examples of studies dealing with sampling strategies, then methods to estimate the sample size based on statistics, followed by simulation models used to estimate the performance of sampling plans. It ends with examples of models including the availability of limited resources in the design of a sampling plan (i.e. cost-effective sampling).

4.1. Sampling strategies

Pathogens are mostly heterogeneously distributed throughout a food lot. Therefore, in addition to the number the samples, the sampling strategy plays an important role. Two major strategies are random sampling and systematic sampling. With random sampling, each sample collected from the lot is independent from the previously samples collected; thus, each sample collected has the same probability to hit the contaminated fraction of the lot. When estimating the number of lots of a specific product to sample, the contaminated fraction refers to the expected proportion of contaminated lots whereas when estimating the number of samples to collect from one lot, the contaminated fraction refers to the portion of the lot expected to be contaminated, related to the distribution of the pathogen within a lot. The more heterogenous a pathogen is distributed, the smaller the contamination fraction. When applying systematic sampling, samples are collected at fixed intervals (e.g. one sample every 100 kg). The probability that the collected sample hits the contaminated fraction depends on the sampling interval, and the size of the contaminated fraction. For homogeneously distributed pathogens, the contamination fraction will be large and could even be equal to the size of the lot, whereas for heterogeneously distributed pathogens, the contamination fraction will be small. The larger the sampling interval, and the smaller the size of the contaminated fraction, the lower the probability that the collected sample hits the contaminated fraction (Jongenburger, Reij, Boer, Gorris, & Zwietering, 2011). Jongenburger et al. (2011) compared the probability to detect a local microbial contamination within a food lot, using random and systematic sampling strategies. Systematic sampling led to a probability of detection that was either equal or higher as compared to random sampling, depending on the contaminated fraction of the lot and the number of samples collected. In case of systematic sampling, the probability of detection reached its maximum when the sampling interval was equal to the size of the contaminated fraction. For example, in case of a lot of 1, 000 kg with a contaminated fraction of 10 kg, if a sample is drawn every 10 kg, one sample will hit the contaminated fraction. This means that the sampling strategy can be optimized based on the size of the lot (e.g. daily production) and an estimate of the size of the contaminated fraction, which can be based on previous data or expert knowledge. Xu and Buchanan (2019) compared several sampling strategies to detect pathogenic bacteria on leafy greens: the authors used simulation modelling to compare random, stratified and Z-pattern sampling plans and validated the modelling outcomes with a practical experiment. With stratified sampling, random samples are collected from each stratum, a homogeneous area in the field. The number of samples per stratum is proportional to the stratum's size. With a Z-pattern sampling plan, samples from the field are collected from the sides of the field and the diagonal line, forming a Z-pattern. Xu and Buchanan (2019) concluded that the mean detection rates of all three sampling plans were comparable but the uncertainty associated with each sampling plan was different: the variability of the Z-pattern sampling plan was much larger than the variability associated with the two other sampling plans, especially when the number of contaminated sites or the number of samples analyzed were small. Furthermore, a Z-pattern could be used when a field is sampled, but in case of a food lot, this approach might not be relevant.

4.2. Sample size calculations based on statistics

Results of statistical sample size calculations, which can be used to determine the number of lots of a specific product to sample or the number of samples to collect from a lot, mainly depend on the size of the contaminated fraction – and the desired precision of the sampling plan. . Furthermore, the population size, which can be the number of FBOs, the number of lots, or the size of a lot can be incorporated into the sample size calculation as well.

One of the formulas proposed to estimate the number of samples required to reject a contaminated lot with a probability of 95% ($\alpha = 0.05$), and with cf the contaminated fraction (%) based on historical data (van Schothorst, Zwietering, Ross, Buchanan, & Cole, 2009) is as follows:

$$n = \frac{\log(\alpha)}{\log(1-cf)} \sim \frac{3}{cf} \quad (1)$$

Using this formula, 29 samples would be needed in case 10% of the population (FBOs or lots) is contaminated, and 299 samples would be needed in case only 1% of the population is contaminated.

The following formula, based on the binomial distribution proposed by Dohoo, Martin, and Stryhn (2010), was used to calculate the number n of milk tanks to be tested in order to estimate the proportion of the milk tanks with an increased Total Bacterial Count (TBC) for each farm, with N the total number of milk tanks shipped and tested in a given time interval (the population size), and cf the contaminated fraction expressed as the probability of an increased TBC (Pantoja, Rosa, Reinemann, & Ruegg, 2012):

$$n = \left(1-\alpha^{1/N^{*}cf}\right) * \left(N - \frac{N^{*}cf-1}{2}\right) \quad (2)$$

Using this formula, with a population size (N) of 1000, 28.4 samples, rounded upwards, 29 samples, would be needed with a contaminated fraction of 10%, and 258 samples would be needed with a contaminated fraction of 1%.

Another example is the formula used by Lee et al. (2016), based on the binomial distribution, to estimate the sample size required for a pathogen, e.g. *Salmonella* testing in a feed lot:

$$n = \frac{Z_{\frac{\alpha}{2}}^{2}\, cf(1-cf)N}{(N-1)e^{2} + Z_{\frac{\alpha}{2}}^{2} cf(1-cf)} \quad (3)$$

with N the population size (number of a specific type of feed product produced), e the acceptable error, and $Z_{\alpha/2}$, the 97.5th percentile of the normal distribution with mean $\overline{n}$ p and standard deviation $\sqrt{\overline{n}p(1-p)}$, $\overline{n}$ being the average sample size during the past three years, and cf the contaminated fraction of the lot. Using this formula, again with a population size of 1000 and an acceptable error of 5%, the average samples size during the past three years of 30 or 300, based on the outcome of the rough estimate of 3/cf, the required sample size to estimate the contamination fraction would be 182, and 25, for contaminations

fractions of 10% and 1%, respectively. The estimated samples required are different to the results obtained with previous formulas. This is due to the aim of this formula. This formula was used to determine estimates of the confidence interval and the sample size to estimate the contained fraction for amongst others *Salmonella* in a specific feed product. The estimations were then used to assign a number of samples to specific FBOs based on their compliance history (Lee et al., 2016). Therefore, less samples were required to be collected at FBO's with a high compliance history, in other words with a low contained fraction, than at FBO's with a low compliance history. The three formulas presented here are summarized in Table 2.

The total variance of a sampling plan is the sum of the variance between sampled lots, the variance within lots, and the variance due to analytical measurement, with the variance between lots being the largest source of variance, often more than 50% (Jarvis, Hedges, & Corry, 2012). The probability to detect a contamination, therefore, strongly depends on the size of the contaminated fraction. As stated earlier, this is defined either as the number of contaminated lots to be expected, either as the portion of the lot expected to be contaminated, e.g. 10% of the lot is expected to be contaminated. When the size of the contaminated fraction is small, in case of a rare pathogen or highly heterogeneously distributed pathogen, the probability to detect a contamination will be low, because the spot where the sample is taken will not necessarily contain the contaminated fraction of the lot. Finally, the analytical procedure such as the preparation of the sample used and performance of the analytical test (i.e. sensitivity and specificity) that is used for the analyses of the pathogen affects the performance of a sampling plan (Colvin, Peterson, Kent, & Schreck, 2015; Zwietering & den Besten, 2016).

Aspects included in the above presented formulas are the size of the population, the size of the contaminated fraction, and the acceptable error. However, other aspects can be relevant to determine sample sizes for detection of pathogens in food lots, such as the performance of the analytical tests or expected variations in the size of the contaminated fraction due to seasonality, new technologies, or a preliminary risk evaluation of an FBO. Furthermore, the formulas described above assume a homogeneous distribution of the pathogen within the contaminated fraction, which might not be the case and might lead to an increased number of samples required to achieve the acceptable error. More advanced formulas or models for sample size calculations are needed to capture the above mentioned additional aspects, such as the distribution of pathogens within a lot, or the performance of the analytical test, as well as to add uncertainty and variability to the input variables. Simulation models found in the literature capture some of these aspects and are further discussed in the next section.

4.3. Simulation models

Simulation models are able to integrate multiple aspects that may affect the performance of a sampling plan, such as the prevalence of pathogens both between and within lots, the distribution of pathogens within a lot, and the performance of analytical methods. Such models may be applied to sampling at individual sampling point at different stages of the supply chain. Adding stochasticity to the input parameters will integrate the variability and uncertainty when estimating the performance of sampling plans, such as the variability in pathogen prevalence, due to amongst other, seasonality since seasonal patterns such as peaks of *Salmonella* spp. or *E. coli* O157:H7 have been observed in summer (Perez-Rodriguez, Gonzalez-Garcia, Valero, Hernandez, & Rodriguez-Lazaro, 2014; Williams, Ebel, & Cao, 2013). Risk managers can either choose to focus of average results, either take into account the uncertainty of the results. In case the average results of two scenarios are equivalent, the spread of the results can help the decision maker to make a more informed decision.

Perez-Rodriguez et al. (2014) studied the impact of the prevalence of *L. monocytogenes*, *Salmonella* spp., and enteric pathogenic viruses on the performance of (two-class) sampling plans in lettuce products. A stochastic model, based on a Bayesian network approach, was used to determine the probability to reject a lot with varying sample size. Input parameters considered included the distribution of the between-lot prevalence and the distribution of the within-lot prevalence. As expected, when the number of samples increased, the probability of detecting the contamination and rejecting a contaminated lot increased. (Perez-Rodriguez et al., 2014).

The International Commission on Microbiological Specifications for Foods (ICMSF) developed an (openly available) spreadsheet to estimate the performance of a sampling plan depending on the number of samples collected, the size of the samples collected, the mean concentration of the pathogen within the lot, the distribution of the pathogen within the lot, and the performance of the analytical test in terms of sensitivity and specificity. These inputs, including their uncertainty and variability if required and known, lead to the probability of hitting the contaminated fraction and the probability to accept the lot based on the sample(s) collected. Estimations are available for several sampling plans, such as the 2-class sampling plans (e.g. presence/absence of a pathogen) and the 3-class sampling plans (one or more samples are allowed to contain levels of pathogens below a certain limit) (ICMSF, 2020).

Other simulation models were used to assess the effectiveness of management options against specific pathogens in specific products, such as additional cleaning, setting maximum limits, but also increased monitoring. Zoellner, Jennings, Wiedmann, and Ivanek (2019) developed a customizable simulation tool to develop a sampling scheme to trace *Listeria* spp. on equipment and environmental surfaces in a cold-smoked salmon facility. Lambertini, Ruzante, Chew, Apodaca, and Kowalcyk (2019) presented a simulation model to explore the public health impact of prevalence- and concentration-based microbiological criteria for *Salmonella* spp. in raw chicken parts. One specific sampling plan was considered in this model for end-product monitoring, but the model can be extended to explore different sampling plans (Lambertini et al., 2019). In contrast to the above mentioned model, the following

Table 2
Three examples of formulas that can be used to estimate the number of samples required.

Formula	Inputs	Aim	Reference
$n = \frac{\log(\alpha)}{\log(1-cf)} \sim \frac{3}{cf}$	cf: An estimate of the contaminated fraction (%) α: the probability of rejection	To reject a lot with a certain probability	van Schothorst et al., 2009
$n = \left(1-\alpha^{1/N^{*}cf}\right)^{*}\left(N - \frac{N^{*}cf-1}{2}\right)$	cf: An estimate of the contaminated fraction (%) α: the probability of rejection *N*: the population size	To estimate the contaminated fraction	Dohoo et al. (2010) Pantoja et al. (2012)
$n = \frac{\frac{Z_{\alpha}^{2}\, cf(1-cf)N}{2}}{(N-1)e^{2} + \frac{Z_{\alpha}^{2}\, cf(1-cf)}{2}}$	cf: An estimate of the contaminated fraction (%) *e*: the acceptable error *N*: the population size $Z_{\alpha/2}$ the 97.5th percentile of a normal distribution with mean $\bar{n}$ and standard deviation $\bar{n}p(1-p)$ with $\bar{n}$ being the average sample size during the past three years	To estimate the contaminated fraction	Lee at el. 2016

models are not targeted to the monitoring of the end products only, and do include monitoring as one of the management options. Tenenhaus-Aziza, Daudin, Maffre, and Sanaa (2014) proposed a risk-based approach to optimize the management of *L. monocytogenes* in soft cheese made from pasteurized milk. A quantitative risk assessment, incorporating the impact of management options and sampling plans, was used to allocate potential intervention strategies to different food processing steps. The model used what-if scenarios to estimate the effects of different management options, including sampling schemes. McNamara, Miller, Liu, and Barber (2007) presented a farm-to-fork stochastic simulation model to determine which food safety interventions, including monitoring, were most efficient, and applied their model to *Salmonella* spp. in the pork production and consumption system in the US. Another example is the study of Nauta, Sanaa, and Havelaar (2012) in which the risk reduction of setting microbiological criteria for *Campylobacter* in broiler meat in 25 European countries was estimated. Probabilistic modelling was used to evaluate the effect of potential microbiological criteria.

4.4. Cost-effective sampling and analysis

Traditionally, sample size calculations depend on the prevalence and the desired precision of detecting a contamination, often using a probability of 95%. However, in many food facilities the number of samples is not based on calculations but rather on the available resources (Zoellner, Ceres, Ghezzi-Kopel, Wiedmann, & Ivanek, 2018). Resource constraints are not considered in the approaches discussed so far. Models rarely consider the costs of sampling and analysis. Only a few simulation models compare or optimize both the effectiveness and the costs of different sampling plans for pathogens in food products.

Benschop, Spencer, Alban, Stevenson, and French (2010) created a Bayesian model to predict which farms were most at risk of *Salmonella* spp. using Danish data from the national control program. Various monitoring schemes based on this risk classification were designed and then compared to each other using the costs and sensitivity of the sampling schemes. Another example is a simulation model developed by Baptista, Halasa, Alban, and Nielsen (2011) to assess the effectiveness and costs of several surveillance and control scenarios for *Salmonella* spp. in pigs at farm level and pork products at slaughterhouse level. In both these approaches, effectiveness and costs of the sampling schemes were compared, however, they were not integrated.

Instead of comparing the effectiveness and the costs of several options, Powell (2014) proposed an optimization model to optimize a two stage sampling process where m lots are selected for testing, then a number of n samples is drawn from each of the m lots using a fixed budget available for sampling and analysis. The model maximizes the number of contaminated lots that are rejected. A deterministic model under fixed prevalence was proposed, which maximized the following equation:

$$L_R = \frac{C_T}{C_l + nC_n}\left(1 - (1 - cf)^n\right) \tag{4}$$

with L_R the number of nonconforming lots, C_T the budget available for sampling, C_l the costs per lot, C_n the cost per sample, and cf the contaminated fraction. The optimal number of samples is, therefore, a function of the prevalence, the costs per lot and the costs per sample. Furthermore, a stochastic version of the model, modelling a variable prevalence, was proposed, using a Monte Carlo simulation to optimize the number of samples (Powell, 2014).

Cost-effectiveness ratios, simulation models, or optimization models can all three be used to improve the cost-effectiveness of sampling plans. Ratios and simulation models are able to compare the effectiveness and costs of a pre-set list of sampling schemes, whereas optimization models are able to optimize existing sampling schemes.

5. Combining risk-ranking and sampling

Risk ranking leads to a prioritization of pathogen-product combinations for governmental or industrial monitoring. These rankings can then be used to optimize the allocation of the budget available for monitoring, as formulated by McNamara et al. *(2007)*: "for a given budget of resources invested in food safety prevention, where can society obtain the greatest return in terms of QALYs saved or cost-of-illness averted?".

A first attempt to link risk ranking and sampling was done by Lahou, Jacxsens, Van Landeghem, and Uyttendaele (2014; 2015). The authors established a sampling plan for microbiological hazards based on risk categorisation of raw materials and meals served to consumers in food service operations. Microbiological risks were categorised, based on the epidemiological association of the food products with outbreaks, the prevalence of pathogens on the food products and the potential of the pathogens to grow and survive during storage and processing. Only pathogens classified as high risk were considered for the proposed sampling plan. However, the costs of sampling and analysis were not considered in this study. Furthermore, since only the hazards ranked as high risk were considered in the sampling plan, no direct link between risk-ranking and sampling was made since the samples were not distributed according to their risk category.

Another study considering both risk-ranking and sampling is the study of Pielaat, Chardon, Wijnands, and Evers (2018). These authors developed a method to apply risk-based monitoring for several pathogens, combining risk-ranking based on disease burden, in this case expressed in DALYs, and optimization of the sample size per pathogen-product combination, as based on cost-effectiveness. The sampling capacity is distributed proportionally to the contribution of hazards to the disease burden estimated in DALYs. Input variables are the prevalence of the pathogens, consumption data of food products containing the hazard, the disease burden caused by the hazard, and the sampling and analysis costs for the specific hazard (using the prevalence of the hazard to estimate the number of samples needed). The aim is to catch a maximum number of DALYs (thus, the highest reduction of disease burden in the population) with a minimum budget. Therefore, the criterion *cr* dividing the sampling and analysis costs by the DALYs attributed to the hazard is minimized:

$$cr = \frac{n * C_n}{DALY} \tag{5}$$

With n, the number of samples needed for each product based on baseline prevalence at retail, C_n the costs per sample including material and labour costs, and $DALY$ the disease burden for a pathogen/product combination deterministically estimated. This methodology was applied to several microbiological hazards in a range of food products: *Campylobacter* spp. in pork and poultry, *Salmonella* spp. in pork, *Toxoplasma* in pork, and Shiga-toxin producing *Escherichia coli* (STEC) O157 in beef, veal and mutton/lamb, using Dutch data (Pielaat et al., 2018). Results show that pathogen-product combinations with a low prevalence require much more samples than combinations with a high prevalence, as shown in section 4.2. The allocation of the budget per pathogen-product combination is a function of the contamination level of products and the prevalence of contaminated products.

6. Discussion

Due to conflict between national food legislation and requirements in other countries, the Joint Food and Agriculture Organization of the United Nations and the World Health Organization (FAO/WHO) established the food standards program in 1962. In the same year, the ICMSF was established. The ICMSF presents a structured approach for managing food safety, including sampling and microbiological testing (ICMSF, 2018). FBO's mitigate food safety risks using, for example, HACCP systems. The ICMSF stresses that HACCP systems provide a

greater assurance of safety than microbiological testing for specific pathogens (ICMSF, 2018). However, this review focusses on the monitoring performed by the food safety authorities, instead of the industry. The focus of this review was the control of end products placed on the markets, by means of sampling and microbiological testing, to verify the compliance of the FBOs in Europe. This review brings together three steps needed to set up governmental risk-based monitoring plans: the ranking of hazard-food product combinations, the identification of FBO's to inspect, and the estimation of the number of samples to collect at each selected FBO.

In most countries, disease burden studies are already available, and these can be used to select the pathogens causing high disease burden to the population. Furthermore, in order to facilitate the monitoring process, indicator microorganisms or hygiene indicators can be used to verify the adequacy of control processes when a correlation exists between the presence of this indicator microorganism and the pathogen of concern (Buchanan & Schaffner, 2015).

The identification of high risk products, the identification of FBOs, the sampling strategy, and the design of the optimal, cost-effectiveness sample size are remaining key steps to arrive at a risk-based monitoring plan. To date, research focused on one of these steps needed to design a risk-based monitoring plan, such as risk-ranking of product-pathogen combinations, the selection of FBOs, or sampling strategy. Furthermore, only a limited number of studies compared or optimized monitoring plans based on both effectiveness and costs. Adding to the limited number of these models, they are specific to the chosen pathogen-product combination.

The outcomes of each of the three steps described: risk ranking, the selection of FBOs, and the design of cost-effective sampling, heavily rely on the availability of input data. Ranking of pathogen-product combinations depends, for example, on the number of illnesses observed, or economic aspects, for which quantitative data are frequently lacking or inaccessible. Therefore, while developing new models and tools, available data need to be identified a priori, limitations of these data need to be identified as well as possible ways of improving or enriching these data in the future. A promising European initiative is the risk assessment modelling & knowledge integration platform (RAKIP) initiative by three European institutions specialized in food safety risk assessment (ANSES, France; BfR, Germany; and DTU Food, Denmark). This initiative aims to create a platform for open information exchange of models and data used for food safety risk assessment. The portal and the resources can be used by researchers, risk assessors, or risk manager. The results target amongst others national and international risk assessment institutions or FBOs (FoodRisk-Labs, 2021; Haberbeck et al., 2018; Plaza-Rodríguez et al., 2018).

The selection of FBOs depends on data available regarding the organizational structure of the company and/or on employee characteristics, and/or on their HACCP program in place, which might again not be available or inaccessible. Furthermore, the optimal sample size depends, amongst others, on the estimates of the prevalence of pathogens between and within the lots. These estimates should ideally be based on random monitoring, but such data are often not available. Since the Official Controls Regulation (EU) 2017/625 states that official controls must be performed in a risk-based manner, that minimizes the burden on businesses (EU, 2017), a large percentage of the available resources for monitoring should be spent on risk-based monitoring. However, part of the resources should also be spent on random monitoring for a wide variety of microbiological hazards in a wide variety of products. The aim of this random monitoring is to identify trends or unexpected deviations in the prevalence of food safety hazards in food products that had not been classified as high risk, or new food products, and to survey the emergence of new hazards. Comparison between risk-based monitoring and random monitoring should be continuously done, in order to find discrepancies or to validate the risk-based monitoring plans.

The probability to detect a contaminated lot strongly depends on the number of contaminated lots and the distribution of the pathogen within the lot. Between lot testing is the traditional approach used to ensure risk mitigation strategies are functioning as intended. Very small contamination fractions make it highly unlikely to detect the contamination with a limited number of samples (van Schothorst et al., 2009; Zwietering, Garre, Wiedmann, & Buchanan, 2021). Therefore, many samples, and thus a significant budget, are needed to increase the probability to detect pathogens with a low prevalence. With small contamination fractions, the risk per food product serving could be almost zero, however, in case of highly consumed products, the human health risk for the total population (e.g. expressed via the disease burden) can still be significant. With pathogens locally present in the batch, within lot testing becomes an important aspect as, similar to a low contamination fraction, the probability to detect the pathogen is highly unlikely with a low amount of samples collected from the lot (Zwietering et al., 2021).

In the rare studies that combined risk-ranking and sampling described above, the aim of the monitoring plan was to lower the disease burden as much as possible and, therefore, these studies included both the low and high-prevalent pathogens. However, another aim of a monitoring plan could be to actively survey so to detect as many positive samples as possible. When the effectiveness is defined as the probability of the sampling plan to detect contaminated lots, sampling efforts should be focused on the products and FBOs with the highest probability of contamination to increase the effectiveness of a monitoring scheme (Williams et al., 2013). As stated previously, increasing the number of samples collected for pathogens with a low prevalence might not be cost-effective. Therefore, when developing additional models for risk-based monitoring, the specific aim of the monitoring plan needs to be defined a priori: is the aim the reduction of disease burden, so directly protecting public health, or is the aim to detect as many contaminated food lots as possible, leading to more FBOs paying attention to food safety, and, indirectly also protecting public health?

Furthermore, food safety authorities should work more closely with the industry to improve the effectiveness of monitoring and lower the costs. They should facilitate and approve GHP and HACCP programs, including microbiological verification testing, of each FBO. For this purpose, they should continuously have access to the results of this testing (Buchanan & Schaffner, 2015).

7. Conclusion

To conclude, previous research focused mainly on one aspect related to risk-based official monitoring: on the ranking of product-pathogen combinations, on the selection of FBO's, or on the optimization of sampling strategies and sample sizes. Further research is recommended to develop a methodology to identify relevant pathogen-product combinations for risk ranking, to develop generic models and user-friendly calculation tools, combining risk ranking, the selection of FBOs and cost-effective sampling. Finally platforms where available data and models can be stored, shared, and linked are crucial to the further improvement of risk-based monitoring strategies.

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Declaration of competing interest

None.

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