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Methods to perform risk-based inspections of food companies

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Abstract: Risk-based monitoring programs are increasingly applied for cost-effective monitoring of food safety. Such programs ideally consist of three steps: risk-ranking, risk-based inspections, and cost-effective monitoring. Various methods have been described to perform the first step of risk-based monitoring. However, once the risk-ranking has been completed, identifying the hazard-food combinations to monitor, the frequency of inspection needs to be established based on a prioritization of food business operators (FBOs). The aim of this paper is to provide an overview of methods available for risk-based inspections. Literature shows that FBO's food safety compliance can be assessed based on company size, historical monitoring data, and socio-economic factors influencing compliance behavior. Non-compliance can either be intentional or unintentional. The latter can be assessed by evaluating the food safety culture of a company. Various models—ranging from qualitative (e.g., focus groups) to quantitative (e.g., scoring)—can be used for this purpose. These models usually include an evaluation of the organizational structure (e.g., management control, communication, commitment), the technical food safety environment (e.g., hygienic design, zoning), and employee characteristics (e.g., knowledge, risk awareness). Intentional non-compliance can be assessed using food fraud vulnerability tools. These tools incorporate factors influencing the likelihood of food fraud at the company, that is, opportunity, motivation, and (lack of) control measures. The literature indicates that either self-assessment tools or risk matrices are applied. There is no global consensus on the methods to apply for risk-based inspections. Depending on time and budget available as well as preferred output, one of the presented methods may be applied for prioritizing FBOs.

KEYWORDS
compliance, food fraud, food safety, prioritization

1 | INTRODUCTION

Following the General Food Law (Regulation (EC) 178/2002), food business operators (FBOs) are responsible for the safety of the product they sell. Food safety management systems (FSMS), such as International Organization for Standardization (ISO) and Hazard Analysis and Critical Control Points (HACCP), have been applied globally to prevent and control the presence of food safety hazards (Gil et al., 2017). Despite precautionary measures, microbial and chemical hazards may still be present in the final food product. Monitoring programs are applied to verify the proper performance of the FSMS by checking for the presence of pathogens or chemical contaminants and to identify possible food safety issues. Food safety is, however, complex and a wide range of hazards may be present in the various food products. Since resources are limited, monitoring programs should be as effective as possible focusing on those hazards and food products with the highest risk (Focker & van der Fels-Klerx, 2020; Presi et al., 2008). Apart from budgetary reasons, risk-based monitoring is increasingly required in European Union (EU) legislation as for example indicated in Regulation (EU) 2017/625. Risk is, hereby, defined as a combination of the probability of an adverse health effect caused by the presence of a hazard in a food product, and the severity of that effect (CAC, 2015).

The establishment of a risk-based monitoring program consists of several steps: 1. Risk-ranking (what to monitor: which hazard-food combinations?); 2. risk-based inspections (where to monitor: which food companies?); and 3. cost-effective monitoring (how to monitor: how many samples and where in the food chain?) as indicated in Figure 1. In the first step of a risk-based monitoring program, the hazard-food combinations to be included in the monitoring are identified (van Asselt et al., 2012). Several methods are available to rank hazard-food combinations (EFSA Panel on Biological Hazards, 2012; Swedish National Food Agency et al., 2018; Van der Fels-Klerx et al., 2018). These methods vary from qualitative to quantitative methods. When benchmarks for probability of the hazard and its severity for human health are clear, a qualitative method is useful since it requires a limited amount of time and data to perform the ranking. Usually, expert elicitation is used to categorize the risk in ordinal categories such as high, medium, and low. In contrast, quantitative methods make use of numerical estimates of the probability and severity of food safety hazards. Examples of such methods are full risk assessments or the cost of illness approach (Van der Fels-Klerx et al., 2018). Quantitative methods are objective and transparent, but require a considerable amount of time and data. Furthermore, these methods are more complex since the outcome should represent the uncertainty in the calculations. This uncertainty may arise from the exposure or severity of hazards as well as in the steps in the food supply chain influencing food safety hazards (Swedish National Food Agency et al., 2018). Semi-quantitative ranking methods use an approach in between qualitative and quantitative methods. These methods are usually based on classes or scores that assess the probability and severity of a hazard (FAO, 2017). Risk Ranger is an example of a semi-quantitative tool to assess microbial hazards (Ross & Sumner, 2002). All methods available for risk-ranking have their pros and cons and depending on the purpose of the ranking and time and resources available, a method can be selected to perform a risk-ranking (Van der Fels-Klerx et al., 2018). Since many methods are available, van der Fels-Klerx et al. (2015) developed a decision tool that can aid risk managers in selecting the most appropriate risk-ranking method.

When FBOs are inspected, it generally has a positive effect on food safety (Mari et al., 2013). However, due to economic constraints, it is not feasible to inspect all FBOs. Therefore, once the hazard-food combinations have been identified, a risk-based inspection scheme should be drafted targeting those FBOs with the highest likelihood of non-compliance. Expert consultation may be used for this purpose as well as modeling techniques and/or historical analytical data and results from food safety inspections (van Asselt et al., 2012). This study aimed to provide an overview of currently available methods for risk-based inspections of food companies with a focus on Europe. Both food safety authorities (FSAs) and FBOs can use the output of this study to set up their risk-based monitoring programs.

2 | MATERIALS AND METHODS

2.1 | Literature review

A literature review was performed to identify methods that can be used to prioritize FBOs for food safety inspections. The following search strings were used in Scopus without restrictions toward time of the publication (the initial search was performed on September 24, 2019 and updated July 26, 2021):

(TITLE-ABS-KEY ("food safety" OR "food fraud*") AND TITLE-ABS-KEY (culture* OR climate* OR behavior* OR behavior* OR participation OR "risk awareness" OR "organization* characteristic*" OR "firm* characteristic*") AND TITLE-ABS-KEY (inspection* OR "official control*" OR "risk-based inspection*" OR "risk-based surveillance" OR "risk-based control*" OR compliance* OR "compliance risk*" OR "organizational risk*") AND NOT TITLE ("geographic* origin*" OR kitchen* OR consumer* OR retail*))

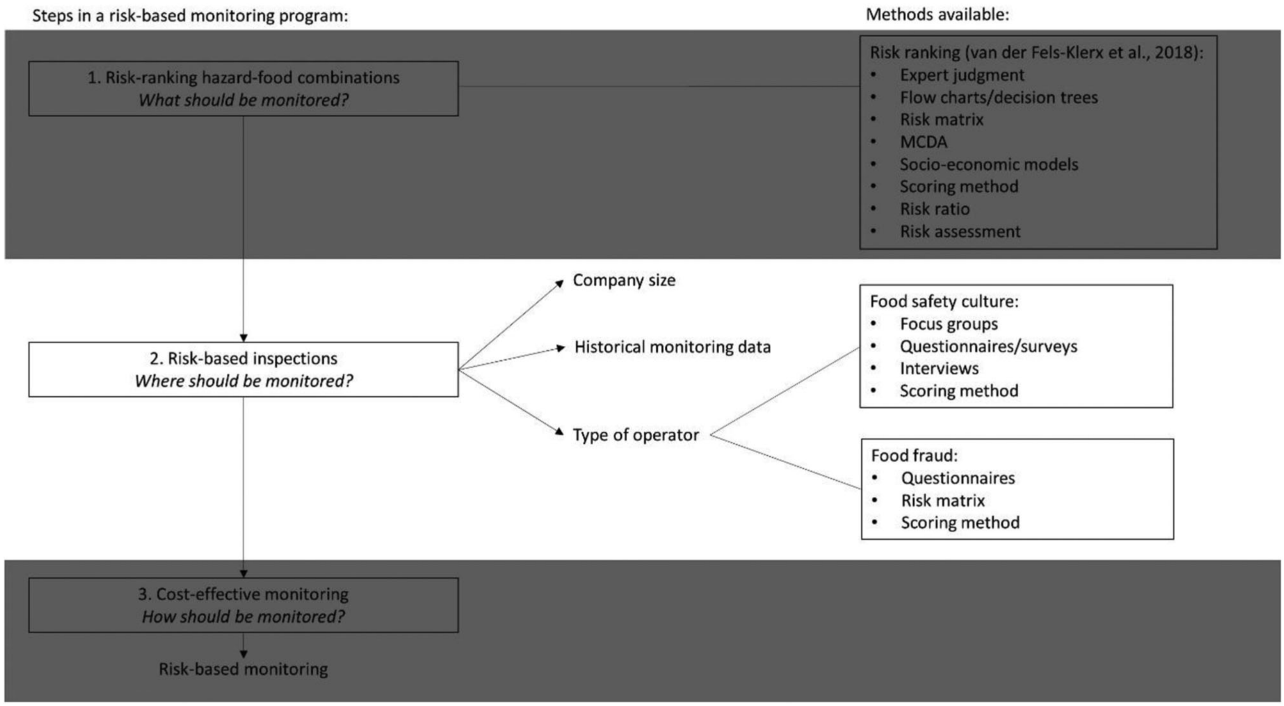

FIGURE 1 Steps in a risk-based-monitoring program with methods available for risk-based inspections (grey: out of scope for this paper)

Only papers published in English (full text) were included. The obtained hits were first screened for their relevance based on title, keywords, and abstract. In the next step, the full text was read, and relevant articles were included. Additionally, snowballing based on the selected relevant articles was used to obtain additional information.

Additional to the literature research, audit reports from the Food and Veterinary Office (FVO) were consulted to obtain information on risk-based inspections performed by EU Member States (MS) via the following website: https://ec.europa.eu/food/audits-analysis/country_profiles/index.cfm. For each Member State of EU-27 and the UK, the most recent audit report was selected (in September 2019). This gave an overview of methods that FSAs currently use to prioritize audits.

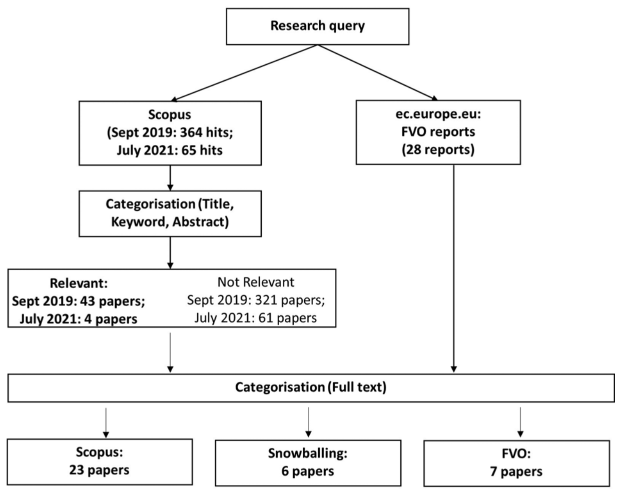

FIGURE 2 Approach and search results literature study

3 | RESULTS AND DISCUSSION

The literature screening resulted in a total of 429 papers that were evaluated based on title, keywords, and abstracts. This resulted in 47 papers that seemed relevant for the topic. Finally, 23 papers were included in this paper to describe methods for risk-based inspections. Snowballing resulted in an additional six relevant papers. Furthermore, the available 28 FVO reports were read in full of which seven contained relevant information that was included in this paper (see Figure 2).

Once hazard-food combinations are ranked, inspections should be prioritized as not all suppliers or FBOs can be visited to check for irregularities. In general, FBOs can be prioritized for inspection based on the type of food they produce and the human health risks related to this, which can be ranked using the risk-ranking methods indicated previously. Other elements to prioritize FBOs are the size of the business, past records of non-compliance (historical data), the type of activities, and the type of operator (BEUC, 2019). These factors are described in the sections below. The fact that food safety is not only influenced by the intrinsic product characteristics, but also by the behavior of the FBOs and food handlers has increasingly been recognized over the past decade (Arendt et al., 2015). Companies can intentionally or unintentionally be non-compliant to food safety regulations. These two elements are further elaborated upon in the section on food safety culture and food fraud, below.

3.1 | Effect of company size

Several studies indicated that small businesses have higher probabilities of non-compliance than larger firms. Smaller firms usually have a lower knowledge level with respect to food safety and a lower competence to maintain a network to obtain relevant information on food safety risks. Furthermore, they lack the capital to implement FSMS and to invest in training of staff. In general, small businesses, therefore, have more difficulties to adopt new legislation or to cope with conflicting rules (e.g., in different countries) than large businesses (Harrison et al., 2016; Herath et al., 2007; Mercado et al., 2018). Although larger firms are generally more complex, they usually implement food safety systems and participate in certification schemes. Indeed, Jacxsens et al. (2015) showed that certified FSMS were present in 83% of the micro and small FBOs, 94% of the medium-sized FBOs, and 100% of the large FBOs. FVO reports indicated that some EU FSAs take the size of the company into account in their inspection regime. For example, inspectors in Croatia and Denmark use the farm size as a selection criterion for inspection (European Commission, 2018, 2019b).

3.2 | Use of historical data

Results of statistical analysis on historical monitoring data, reflecting the analytical results of previous analyses of collected samples for food safety hazards, may be used in order to prioritize companies (Lee et al., 2009). Several European FSAs use historical data on non-compliances as input to their risk-based inspections. There are, however, large differences in the implementation of risk-based inspections across Europe. Borraz et al. (2021) showed that in France FBOs are primarily ranked based on the hazard, whereas in the Netherlands only non-compliances are incorporated in the risk-based approach. Germany and the UK include both the consequence of non-compliance and the probability of food safety violations in their assessment (Borraz et al., 2021). The UK FSA uses historical data as one of the main elements to determine inspection frequency. Companies with good results are subject to a lower inspection frequency than previously non-compliant companies (BEUC, 2019). FVO audits also showed that competent authorities (e.g., from Ireland, Portugal) frequently consider the FBO's compliance history when drafting the inspection plan (European Commission, 2019a, 2019d). The FBO's historical performance can be derived from results of earlier audits by the competent authority. Furthermore, the company's willingness to cooperate with inspectors is relevant and can be assessed by the extent to which companies appropriately follow up an audit and rectify their errors. In addition to inspection reports and follow-ups, information from the Rapid Alert System Food and Feed (RASFF) can be used (European Commission, 2019c). Some competent authorities (e.g., from Malta, Portugal, and UK) use a scoring system to combine the performances on several parameters (European Commission, 2017, 2019a, 2019e). For example, a company could score insufficient (1 point), satisfactory (2 points), or optimal (3 points) for each of 15 parameters, such as veterinary medicinal use, non-compliant results, or non-reactive to questionnaires from the authority. The sum of the scores on the 15 parameters provides an indication of the prioritization of individual companies for official control (European Commission, 2019a). Ramalho et al. (2015) indicated that FBOs who properly implemented an FSMS in the past had a higher intention to do the same in the future. Therefore, history of correct food safety behavior could indicate that this correct behavior will retain in the future (Ramalho et al., 2015). FSAs, generally have limited resources, and therefore, the frequency of inspections is usually lower than for private agencies. Therefore, in some countries, FSAs may also base their frequency of inspections on private compliance schemes. However, such meta-control (controlling the controllers) depends on a good cooperation between public and private agencies as well as transparent and consistent agreements on the implementation of such meta-control (Verbruggen & Havinga, 2015).

Outside Europe, FSAs also use historical data. The New Zealand FSA, for example, uses a framework for determining the number of product batches that should be inspected during the border control of imports based on test results. Initial control is strict and is reduced based on a good history of compliance (Govindaraju et al., 2010). Overall, historical data are a valuable source of information to prioritize FBOs and can thus be used as input to risk-based inspections.

3.3 | Compliance behavior

As indicated previously, FBOs can be classified based on company size and historical inspection results. However, socio-economic behavior also plays an important role in the FBO's food safety compliance (van Asselt et al., 2012). Most companies have an intrinsic motivation to comply with food safety regulations since incidences may negatively impact their image and can have financial consequences as the 2011 EHEC crisis in Germany showed (Karch et al., 2012). However, food fraud incidents show that not all companies have the same honesty principles, and this is not a new phenomenon as food fraud dates back to the ancient Greece and Rome (Shears, 2010). Cultural and behavioral factors such as corruption level and ethical business culture influence food compliance (Manning & Soon, 2019). The literature review revealed that there are methods available to assess a business' food safety culture as well as their food fraud vulnerability. Both aspects are elaborated upon in the following sections.

3.3.1 | Assessing food safety culture

Food handlers with strong internal motivation to satisfy consumers and prevent human food poisoning have a high tendency to show correct food safety behavior, which is independent of age and gender of the food handlers (Arendt et al., 2015). Beside consumers' satisfaction, social norms (the opinion of family and peers) are also valued by food handlers. The studies of Fietz et al. (2018) and Simpson and Rorie (2011) concluded that fear for reputational damage within an FBO's social network prevents food handlers and managers to perform incorrect food safety behavior (Fietz et al., 2018). Especially, the latter study showed that this peer pressure had a greater impact on managers than a sanction imposed by the authority (Simpson & Rorie, 2011). Fishbein and Ajzen (2010) extensively studied the influence of socio-psychological factors on human behavior. They indicated that people's behavioral intentions depend on their attitude (i.e., internal valuation of the aspects connected to a behavior), subjective norms (i.e., values the social environment attributes to a behavior), and their perceived behavioral control (which is the extent to which people believe they can perform the behavior). Each of these elements is influenced by people's background (e.g., personality, age, religion, knowledge).

With the help of the identified characteristics that influence the level of compliance, several methods have been developed to assess an FBO's food safety culture, which range from qualitative methods (such as the use of focus groups) to more quantitative methods (such as questionnaires using scales). The method chosen depends on the available time and resources, the needs for the study and the required ease of application (Griffith et al., 2010). Griffith et al. (2010) and Nyarugwe et al. (2018) used six and four characteristics, respectively, in their assessment of a food safety culture. The six characteristics in the first study are solely behavioral and managerial characteristics: management, leadership, communication, commitment, environment, and risk awareness. Nyarugwe et al. (2018) included both technological and behavioral and/or managerial factors to assess the food safety culture. These factors are: microbiological safety performance; actual food safety and hygiene behavior; (technical and organizational) enabling conditions; and employee characteristics. These four characteristics were assessed using 25 indicators that were scored between 1 and 3 enabling to classify FBOs into reactive, active, or proactive. The more proactive an FBO operates, the stronger the food safety culture of that FBO. The outcome was depicted as spiderwebs (Nyarugwe et al., 2018). In the assessment of Griffith et al. (2010), no scoring method was used, but the six elements were assessed individually based on predefined characteristics. De Boeck et al. (2015) developed a self-assessment tool based on the elements identified by Griffith et al. (2010). Through a survey among employees, an FBO can perform a self-assessment on the food safety climate within the business. The survey evaluates leadership, communication, commitment, resources, and awareness based on 28 indicators. A five-point Likert scale was used (totally disagree, disagree, neutral, agree, totally agree) to score the indicators. Remarkably, the indicators primarily concern management statements (e.g., "in my organization, the leaders set clear objectives concerning hygiene and food safety"). Although the tool has been developed as a self-assessment tool, the authors indicate it can be transformed into a tool applicable for public or private auditors and inspectors (De Boeck et al., 2015). Recently, the authors proposed a triangulation of methods combining their self-assessment tool with methods to assess the performance of the FSMS present (De Boeck et al., 2019). Like Nyarugwe et al. (2018), Jespersen et al. (2016) used a rubric to develop a food safety maturity model. The model allows to assess an FBO's maturity toward a food safety culture. Within this rubric, five capability areas were classified using five stages of maturity ranging from 1 (doubt) to 5 (internalize). The capability areas were described as follows: perceived value, people system, process thinking, technology enabled, and tools and infrastructure. An increased internalization of the capability areas indicates a more mature food safety culture (Jespersen et al., 2016). Manning (2020) proposed to expand Jespersen's classification from 5 to 7 stages of maturity ranging from 1: unaware and non-compliant with legal and moral requirements to 7: integrity based organizational climate that exceeds the legal and moral requirements. The model of Taylor and Rostron (2018) was built as a rubric based on a questionnaire with the purpose of assessing food safety culture. The model is called Culture Excellence Assessment and consists of four categories (people, process, purpose, and proactivity) with 20 dimensions. Like De Boeck et al. (2015), it is a self-assessment tool that FBOs can use to identify strengths and weaknesses with regards to the food safety culture as well as benchmarking against peer companies (Taylor & Budworth, 2018; Taylor & Rostron, 2018). The model has been adopted by the

British Retail Consortium (BRC) as a module called Food Safety Culture Excellence and is an addition to the annual food safety audit (https://www.brcgs.com). It provides an overall score for food safety culture based on scores for the underlying dimensions and shows an increase or decrease compared to the previous year. As such, the outcome of the tool can be used by corporate and governmental auditors and inspectors to prioritize companies based on their likelihood of compliance. Wright et al. (2012) developed a food safety culture diagnostic tool specifically aimed at inspectors, which was approved by the UK FSA. The tool comprises a survey with a total of 34 open questions. The outcome of the questionnaire, own observations, and documents available (e.g., documents on FSMS or food hygiene training) were used to classify companies in five categories: calculative non-compliers, doubting compliers, dependent compliers, proactive compliers, and leaders. The classification can be used to provide advice to the inspectors on improving the company's food safety culture (Wright et al., 2012). Nayak and Taylor (2018) evaluated the usefulness of the toolkit by interviewing inspectors. Although the tool is very detailed, it was not seen as practical as it is complex and time consuming. Furthermore, the outcome did not give additional information compared to the food hygiene rating scheme that also needs to be filled in. Apart from assessing FBO's compliance behavior based on questionnaires and observations, models can also be applied to simulate the level of compliance using the FBO's characteristics such as their risk averseness and their likelihood to be influenced by other FBOs (van Asselt et al., 2016).

3.4 | Assessing food fraud

The primary aim for intentional non-compliance is economic gain (Spink et al., 2019). Three elements have been identified that influence fraudulent behavior: opportunities, (internal) motivations, and control measures. Various factors are underlying these three key elements. For example, the complexity of a supply chain may provide an opportunity for food fraud. Furthermore, a lack of detection negatively influences the food fraud control measures (Moyer et al., 2017; van Ruth et al., 2018). Van Ruth et al. (2017) incorporated these various factors into a food fraud vulnerability assessment (FFVA) tool called SSAFE Food Fraud Tool that was made available as a freely downloadable app. The tool comprises 9 questions related to opportunities, 20 to motivations, and 21 to control measures. The outcome is a spider web showing the vulnerabilities for each of these factors (van Ruth et al., 2017). The SSAFE tool has been used to assess food fraud vulnerability of several supply chains, which showed that the tool is capable of comparing the vulnerability of these supply chains, and also the differences between actors in the supply chain (van Ruth et al., 2018). This allows to pinpoint inspection activities to the most vulnerable actors within the highest ranked vulnerability supply chains. Another approach is developed by the Committee of the Sponsoring Companies of the Treadway Commission (COSO) who established a corporate risk map, which essentially is a risk matrix plotting the likelihood and impact of food fraud for a certain company based on their risk averseness (Spink et al., 2016). The US Pharmacopeial Convention (USP) (2016) also used a risk matrix to plot the likelihood of food fraud versus the potential impact. The likelihood in this case is characterized by vulnerability contributing factors. For example, the contribution of the supply chain on food fraud depends on its organizational structure. When a firm is vertically integrated in a supply chain (e.g., the raw materials originate from company-owned farms), fraud vulnerability is lower than firms that source their ingredients in an open market. A recent study in China indicated that not only the complexity of the supply chain, but also the complexity of the product influences the possibilities for food fraud with more processed foods having a higher likelihood of food fraud (Li et al., 2020). The USP identified a total of nine contributing factors, that is, the supply chain, the audit strategy, the supplier relationship, the history of the supplier regulatory, quality or safety issues, susceptibility of QA methods and specs, the testing frequency, geopolitical considerations, fraud history, and economic anomalies. Once the likelihood has been categorized based on the contributing factors, the human health and economic impact are assessed. The outcome is depicted in a vulnerability characterization matrix (US Pharmacopeial Convention, 2016). Spink et al. (2016) used the risk matrix concept to draft the Food Fraud Initial Screening (FFIS) model in which expert elicitation is used to rank health hazard risks in an FFIS matrix. The matrix allows a categorization of (group of) products (*y*-axis) versus market and regions (*x*-axis) into very low to very high risk for food fraud. The outcome of the human health ranking is combined with the financial impact to achieve an overall corporate risk-ranking. Their screening method can be seen as an initial step prior to a more elaborate FFVA (Spink et al., 2016).

According to a small survey (n = 19) performed by Soon et al. (2019), food companies primarily use an in-house assessment tool for food fraud (37%), followed by the Campden Threat Assessment and Critical Control Point (TACCP) assessment (26%), other methods (such as product testing) (26%), and the SSAFE Food Fraud Tool (11%). Where HACCP is applied to identify and mitigate food safety hazards ensuring safe food products, vulnerability assessment critical control point (VACCP) aims at identifying and controlling vulnerabilities in the food supply chain with respect to food fraud and TACCP aims to protect food products from deliberate contamination with the intention to cause harm. The Campden TACCP assesses both food fraud and malicious attacks (Soon et al., 2019). The survey showed that there are many methods available for performing a food fraud vulnerability assessment and that not one method is preferred over the others.

4 | CONCLUSION

This study provides an overview of methods available for risk-based inspections as part of a risk-based monitoring program (see Figure 1). Once the hazard-food combinations have been prioritized, thereby identifying the type of FBOs to inspect, the frequency of inspection needs to be established. FBOs can be classified based on the company size, historical data, and likelihood of compliance. The current study shows that assessing historical data is a valuable tool to determine the frequency of inspection. Furthermore, the study also showed that there are various methods available to assess intentional and non-intentional compliance behavior. Models available for assessing an FBO's food safety culture range from qualitative to quantitative methods. General elements in these are: organizational structure (e.g., management control, communication, commitment), technical food safety environment (e.g., hygienic design, zoning), and employee characteristics (e.g., knowledge, risk awareness). The Food Safety Culture Excellence module is most advanced as it is available in the BRC global standards. Intentional non-compliance can be assessed using various food fraud vulnerability tools, which are either based on self-assessments such as in the SSAFE Food Fraud Tool or risk matrices plotting the likelihood and impact of food fraud such as in the FFFVA tool. Currently, there is no globally accepted process to perform such a vulnerability assessment, but factors influencing the likelihood of food fraud, that is opportunity, motivation, and (lack of) control measures should be incorporated in the assessment. Depending on available time and budget as well as preferences with respect to the output, one of the available methods to prioritize FBOs based on food safety culture and food fraud vulnerability can be chosen to assess a FBO's food safety compliance. In this respect, it is relevant to apply these methods as objectively as possible and document the choices made to allow for transparency in the prioritization.

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AUTHOR CONTRIBUTIONS

Dr. E. D. van Asselt was responsible for project administration, and guided the research by contriving the methodology and analyzing the data. Finally, she wrote the main text of this paper. Ms. Y. Hoffmans performed the literature review and provided the input used to write this paper. Furthermore, she added sections of the text and reviewed the document. Dr. E. F. Hoek–van den Hil was involved in drafting the methodology and contributing to as well as reviewing the text of this paper. Prof. H. J. van der Fels-Klerx supervised the research, contributed to the methodology, and reviewed the paper on scientific soundness.

CONFLICTS OF INTEREST

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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