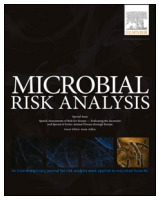
Microbial Risk Analysis 29 (2025) 100340

Contents lists available at ScienceDirect

Microbial Risk Analysis

journal homepage: www.elsevier.com/locate/mran



Microbial risk analysis from a food industry perspective – insights from an international survey

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ARTICLE INFO

Keywords:
Food safety
Microbiological hazards
Risk assessment
Risk communication
Risk management
Food business operator

ABSTRACT

Foodborne microbial hazards lead to substantial morbidity and mortality. To assure consumer protection, a need to move from hazard-based to risk-based food safety approaches is increasingly recognized. Food-business-operators play a crucial role by implementing risk management practices in their facilities. Still, there is very limited data on current approaches to ensure microbial food safety and the profiles and perceptions of professionals assessing, managing, and communicating risks in food industry. This study addresses food safety approaches and challenges in food industry aiming to provide data on microbial risk analysis according to Codex Alimentarius. A survey elicited responses from 108 food professionals involved in microbial risk assessment, risk management, or risk communication in the food industry. The findings highlight drivers and trends relevant to food safety and the food industries' internal decision-making processes. Most participants had risk-based food-safety management systems established. A microbial risk assessment according to Codex Alimentarius principles was conducted by 85 %. Professionals pinpointed areas that led to significant microbial incidents such as contaminated raw materials, poor hygiene, or emerging pathogens. Interestingly, one third of the participants believed that zero risk is possible, which contrasts with the scientific consensus that microbial food safety is not absolute as zero risk is not feasible. The results of this work provide insights into the implementation and understanding of microbial risk analysis from a food industrial perspective and could be leveraged to develop innovative microbial risk analysis frameworks that meet the challenges of future food systems.

1. Introduction

Annually, foodborne diseases are estimated to affect approximately 600 million people and claim the lives of 420,000 people, resulting in a global burden of 33 million disability-adjusted life years (Havelaar et al., 2015). Close collaboration between governmental bodies, food producers and consumers is crucial for strengthening food safety and food systems (WHO, 2022).

The food industry relies on the hazard analysis and critical control points (HACCP) approach for the systematic evaluation and control of foodborne hazards. Food-business operators usually use the HACCP approach in a qualitative and generic way, which limits its potential and does not allow for the quantification of the combined result of multi-point deviations from the individually set food safety standard (Chen et al., 2020). Hence, the relation of the operation of a HACCP system to measurable public health outcome is not feasible (Buchanan and

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https://doi.org/10.1016/j.mran.2024.100340
Received 1 October 2024; Received in revised form 7 December 2024; Accepted 27 December 2024
Available online 28 December 2024

Whiting, 1998). There are also still gaps in the implementation of food safety standards, particularly in the areas of HACCP and microbiological standards (Lee et al., 2023). To overcome the limitations of hazard-based food safety approaches, the necessity to move towards risk-based food safety management to assure consumer protection has been recognized (Barlow et al., 2015; Koutsoumanis and Aspridou, 2016). In an industrial context, the term "risk" could be used to a broader sense, covering food safety issues, but also food quality issues, as the quality could be altered by microbial spoilage (Membré and Boué, 2018). While a more quantitative application of the HACCP concept is also possible and enables a good connection with the upstream and downstream microbial risk assessment.

Microbial Risk Assessment (MRA) is a systematic approach to translate the potential presence of pathogens in the food production, processing, and preparation environments into statements of the likelihood and magnitude of a food safety risk defined in terms of adverse public health outcomes (Nauta, 2021). According to the Codex Alimentarius Commission, risk assessment is a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization (Codex Alimentarius Commission, 1999). In the mid-1990s, the World Trade Organization suggested for the first time a risk assessment basis for food safety. Soon thereafter, the Codex Alimentarius Commission defined risk assessment principles and practices for foodborne hazards and published respective guidance documents (Horton, 2001). The Risk Analysis Framework at the Codex Alimentariurs level consisting of three components – i.e. risk assessment, risk management, and risk communication – represents an internationally agreed-upon structure for assessing, managing, and communicating risks related to food safety. Its development and implementation by countries varies, reflecting differences in regulatory capacity, resources, and priorities (Lee et al., 2023). The process of risk analysis has been proven effective for reducing foodborne diseases through the design, development, implementation, evaluation, and communication of control measures to protect public health (Zwietering and Nauta, 2007). In the context of microbial food safety, it is used to develop an estimate of the risks to human health, to identify and implement appropriate measures to control the risks, and to communicate with stakeholders about the risks and measures applied (Nauta, 2021). In the European Commission, this Risk Analysis framework is legally embedded within Regulation (EC) 178/2002 (Anonymous, 2002). According to Membré and Boué (2018) the four steps of MRA are adaptable to the food processing context, but the risk-based food safety management concept has to be translated into practical guidelines for operational use. Food safety certification has emerged as a prominent and influential regulatory mechanism in this context (Zheng et al., 2023). Food safety standards protect consumers from foodborne illnesses, i.e. foodborne illnesses and food safety certifications are negatively correlated (Zheng et al., 2023) and help producers avoid the massive economic losses associated with food safety breaches Several food safety certification standards (e.g. ISO 22,000, FSSC 22,000, SQF, or Codex Alimentarius Guidelines) have increasingly mandated a risk-based approach grounded in comprehensive risk assessments in recent years (FSSC 22000, 2019). This paradigm shift emphasizes the identification, evaluation, and management of potential hazards throughout the food production and supply chain, ensuring that control measures are tailored to specific risks, even in the industrial setting and for defined purposes.

Microbial food safety risk analysis is growing more intricate due to new technologies, changing consumer preferences, globalization and increasing complexity of food trade, global warming, and shifts in population demographics. These factors demand a multifaceted new set of skills from industry professionals engaged in risk assessment, management, and communication in the food industry. Yet, the implementation status of risk-based approaches to food safety management in industry remains unclear. Our aim was to provide data on i) the current approaches applied in food industry to ensure microbial food safety and ii) the profiles and perceptions of professionals handling risk assessment, management, and communication in food industry with special emphasis on the challenges they perceive with regard to microbial risk analysis.

2. Materials and methods

2.1. Study population

A survey was conducted amongst professionals employed in food industry dealing in any capacity with foodborne microbial risk assessment, management, or communication. Participants were recruited via email invitation using a non-probabilistic, snowball sampling technique (Johnson, 2014). Personal invitations to food industry professionals were sent out in February 2023 to answer the survey and to disseminate it further. The exact number of individuals who received the survey invitation is unknown (no response rate calculation). The online survey platform SurveyMonkey^{R} was used to collect answers until May 2023. The survey was in English language. No personal identifiers were recorded in the survey and all responses were anonymous. Therefore, an ethical approval was not necessary.

2.2. Survey development for data collection

The survey consisted of 26 questions of which 21 were mandatory. A skip logic pattern was used depending on the answers provided. The answer types differed from question to question including multiple choice answers, ranking of given answers, and free commenting. The first section of the survey (5 questions) focused on company size (with the three categories 'small': <250 employees, 'medium': <250–1000 employees, and 'large' >1000 employees) and geographical footprint level (i.e. whether the company operates at intra-country regional, national, or international level), as well as certification status and continent. The second section (10 questions) focused on the respondents' understanding of food safety. The respondents ranked major drivers and trends as well as decision criteria relevant to food safety, gave insights on the internal relevance of food safety and their decision process regarding microbial hazards in food. Moreover, participants were asked about food safety management concepts put in place at the company. In the third section (11 questions), the knowledge of participants regarding risk analysis in general, and the conduct of risk assessment of microbial hazards in food with given challenges and limitations was addressed. A complete version of the survey is available as supplement (Appendix B), and online (SurveyPreview).

2.3. Data analysis and visualization

Data were exported from SurveyMonkey^{R}, compiled in Excel and subsequently processed for descriptive analysis using KNIME (https://knime.org) and SPSS Statistics (Vers. 29.0.0.0, IBM Corp.). To avoid sampling bias data analysis concentrated on descriptive statistics using frequency tables and cross tabulations. Inferential statistics were applied to ten questions (Q4-Q7, Q12, Q16, Q18, Q19, Q23, Q24) to analyze whether there was an association between the responses and the geographical footprint level and/or the size of the company. The inferential statistical analysis was conducted using R (Version 4.3.1). Data handling and visualization were performed using the tidyverse package of the software. The Kruskal-Wallis test, implemented in base R, was used to evaluate disparities in response patterns across company levels or sizes for Q6 and Q7. Dunn's post-hoc test was carried out using the dunn.test package to assess pairwise differences where the Kruskal-Wallis test showed significant results (p-value < 0.05). Fisher's Exact Test, utilized within base R, was applied to assess the independence between categorical variables across a variety of questions (Q4, Q5, Q12, Q16, Q18, Q19, Q23, and Q24). Specifically, the relationships within these questions in the context of company size and geographical

footprint level were examined as follows: I) to analyze the association of the geographical footprint level and the answer responses, the participating food business operators (FBOs) were separated into the three groups (a) regional, (b) national, and (c) international level; and II) to assess the association of the size of the company, i.e. the number of employees of the food business operator with the answer responses, participating companies were separated into 'small' (up to 250 employees), 'medium' (>250 - <1000 employees), and 'large' companies (>1000 employees). Additionally, the test was used to investigate the independence between company size and geographical footprint level directly, further exploring the nuances of these categorical variables' interactions. When significance was detected, the Pairwise Fisher's Exact Test was utilized to investigate the specific nature of associations between categorical pairs. The very few "I don't know" answers provided for the answers Q4 ($n = 4$), Q16 ($n = 1$), Q18 ($n = 4$), Q19 ($n = 2$), Q23 ($n = 2$), and Q24 ($n = 5$) were excluded from the statistical analysis. The sjPlot package was employed to generate tabular visualizations for both the data and the results of Fisher's tests.

3. Results and discussion

3.1. Respondents' key characteristics

Survey answers - either for all or parts of the questions (57 % overall completion rate) - were provided by 108 professionals employed in food industry, of which 65 chose to disclose their geographical locations: Europe (75 %), Africa (14 %), North America (8 %), and Asia (3 %). Therefore, the survey primarily provided insights into the European food industries' perspective. Most companies operate at international level (62 %), while 24 % and 9 % sell goods at national and regional level, respectively. This reflects the global food and agricultural trend of trade links, i.e. the number of trade flows between countries, which has increased from 11,000 in 1995 to more than 17,000 at the end of the second decade of the millennium (FAO, 2022a).

A good balance of respondents from small, medium, and large companies was achieved as one third (34 %) of the companies had fewer than 250 employees, 27 % employed between 250 and 1000 and 38 % employed more than 1000 people, respectively. These results allowed us to check for a possible association of the size of the company with the responses. It is reported that in medium and small food processing plants the likelihood of food safety incidents and subsequent foodborne illness outbreaks is much higher compared to large-sized food processing companies (Lee et al., 2021). It has previously been reported that smaller companies are less likely to implement food safety controls, including those that are mandatory, implying the costs of compliance are too high (Ollinger et al., 2004; Panisello et al., 1999). In contrary, the impact and magnitude of the impact of compromised food safety on firms were found to be influenced by firm-specific factors such as firm size and situational factors, e.g. media attention (Seo et al., 2013). In our study, companies with a greater number of employees were more likely to operate at an international level, whereas smaller companies tended to operate at regional or national levels (p-value = 0.0002, Fig. 1). Larger companies, particularly if belonging to a corporate, tend to trade their goods internationally and dominate the whole food supply chains (Clapp, 2022).

Almost 78 % of companies were certified in the field of food production, with 45 % certified according to more than one standard and 55 % certified under a single standard. The vast majority of companies participating in our survey were certified in the field of food production, mirroring the profusion of third-party certification schemes which have

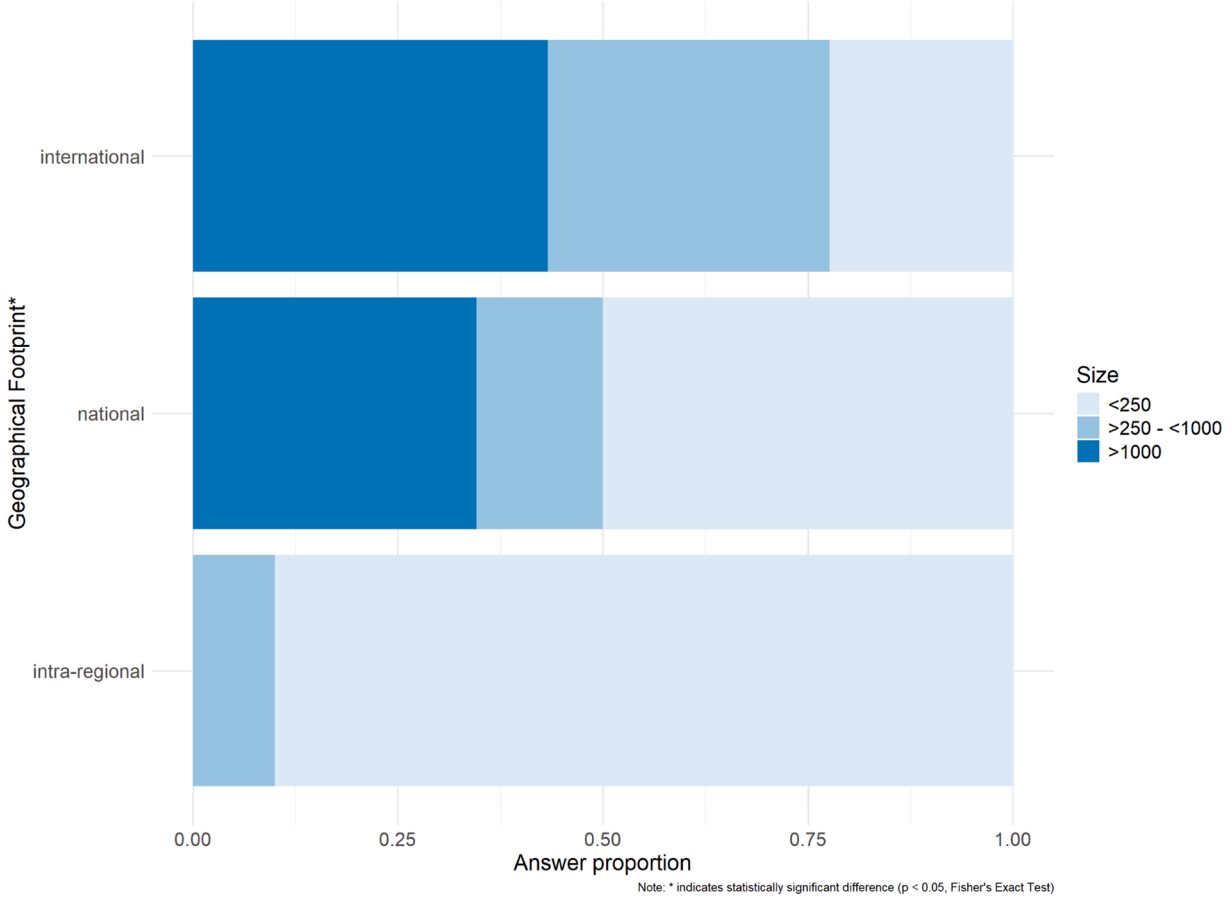

Fig. 1. Association between size (small = 37, medium = 28, large = 38) and geographical footprint level (intra-country region = 10, national = 26, international = 67) of the participating companies.

arisen in the last 20 years (Lee et al., 2021), including public-based (e.g. ISO 9001, HACCP and ISO 22,000) and industry-based schemes (e.g. GlobalGAP, SQF, BRC, IFS, FSSC 22,000). Public-based and industry-based certification schemes play distinct roles in ensuring food safety and quality, reflecting their origins, objectives, and levels of adoption. While public-based certification schemes aim to provide globally recognized frameworks for quality management systems, food safety practices, and regulatory compliance, industry-based certification schemes are often created by private organizations and tailored to the needs of particular industries or supply chains. In our survey, the International Food Standard (IFS Food) was most often (46 %) listed as certification standard by the respondents, followed by FSSC 22,000 (36 %), ISO 22,000 (33 %), and GMP+ (23 %), BRC Global Standard (14 %), Safe Quality Food (10 %), IFS Logistics (5 %) or others (Supplement, Figure S1). Food companies and agribusinesses have put considerable efforts into implementing and improving food safety management systems, since the Codex Alimentarius hygiene code of practice has become the worldwide reference (Kussaga et al., 2014). In our study, larger companies had significantly more often more than one food standard certification put in place compared to small companies (p-value: 0.025, Fig. 2). To trade internationally and have access to markets for high-value products, producers must be able to meet various national food regulations, a particular challenge for smaller producers (FAO and WTO, 2017). According to FAO/WTO the use of international food standards worldwide not only contributes to public health, but also helps reduce trade costs by making trade more transparent and efficient, allowing food to move more smoothly between markets (FAO and WTO, 2017). However, the implementation of these schemes is influenced by a variety of factors, including benefits such as improved product quality, enhanced consumer trust, market access, and compliance with regulatory requirements. These are often key motivators for food companies to adopt certification systems (Escanciano and Santos-Vijande, 2014; Macheka et al., 2013). At the same time, barriers such as high costs, complexity of requirements, limited technical knowledge, and resource constraints pose significant challenges, particularly for small and medium enterprises. These diverse factors have made it difficult for the food industry to consistently meet evolving expectations and challenges over time, especially in global supply chains where systems and standards vary widely (Lee et al., 2021). This analysis aligns with the study's objective of providing insights into industries' challenges with regard to currently applied approaches to ensure microbial food safety.

3.2. *Respondents' understanding of food safety and microbial risks*

Overall, respondents reported that the internal importance of microbial food safety in the individual food production context was scored very high (8.73 points out of 10). Respondents were further asked to rank decision criteria when dealing with a specific food safety issue, and most prioritized health risk, followed by food security issues, while environmental aspects were considered as least important. However, a potential bias needs to be considered due to self-reporting, the subject of the survey, and the role of the respondents in the company, e.g. as food safety manager. Inferential analysis of decision criteria revealed no significant associations between size and geographical footprint level of the companies.

About 30 % of the respondents further stated that zero risk was feasible, if all processes were optimized in the facility; in contrast, 70 % were of the opinion that microbial food safety is not absolute. Already in 1997 it was stated by Hathaway (1997) that when dealing with microbial hazards in foods the objective can only be to 'reduce microbial risks

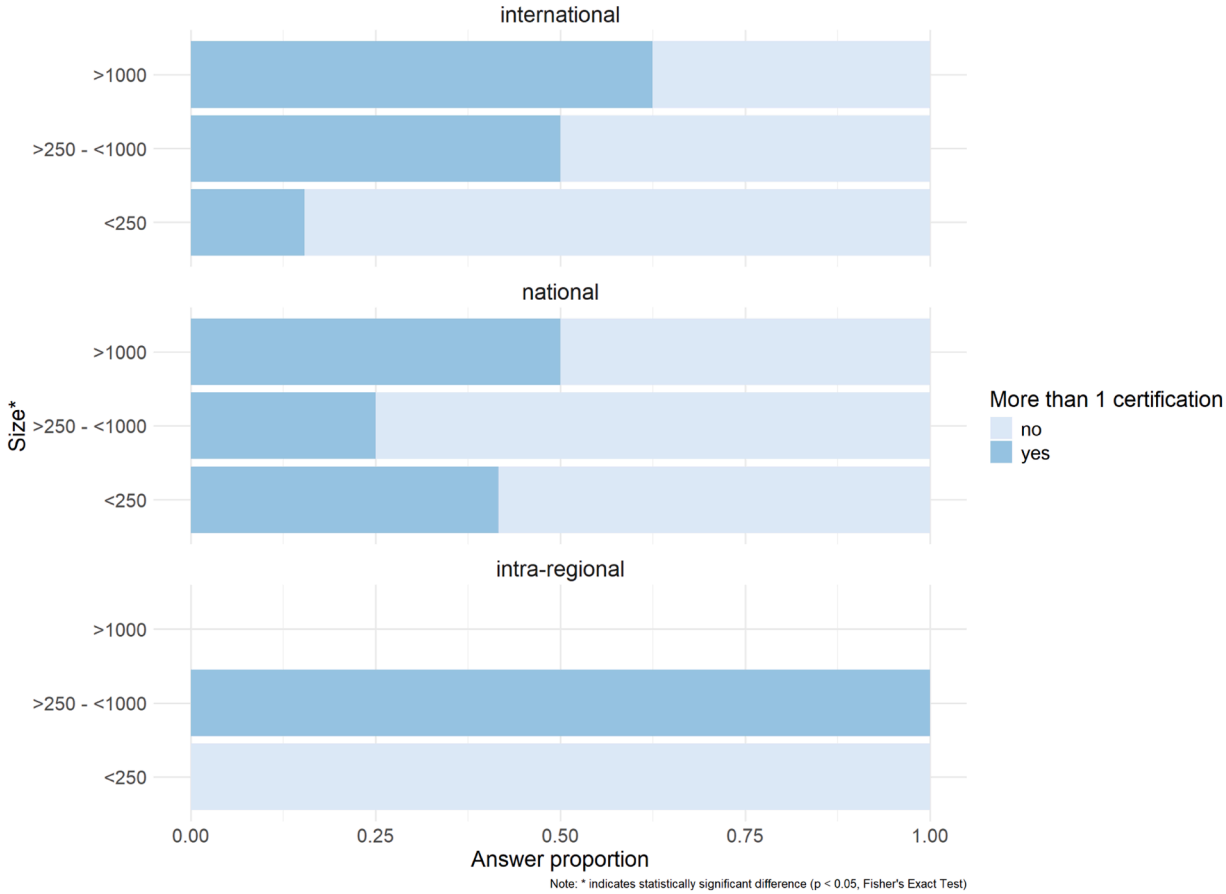

Fig. 2. Number of different food standards put in place in the participating companies (1 or >1) itemized for small (n = 28), medium (n = 25) and large (n = 30) companies.

to the minimum which is technologically feasible and practical'. Likewise, Mead et al. (2010) emphasized that there is no such thing as 'zero risk' if all steps in the food chain are considered. Since our results were surprising given the scientific consent that zero risk is not feasible for any kind of food and that a residual risk remains even in a fully compliant food safety system (Zwietering et al., 2021), we further analyzed if there was an association with the geographical location of the companies and the responses regarding the feasibility of zero food safety risk, but there was none (Figure S2). Likewise, no association with the size or geographical footprint of the participating company and the understanding of microbial food safety risks was identified. Possibly, the type of food industry the respondents were from may have influenced their answers. From a food safety perspective, a hazard is a potential source of harm, such as a microbiological, or physical agent that could compromise food safety. In contrast, risk refers to the likelihood and severity of harm occurring from exposure to that hazard. While a hazard exists as a possibility, risk quantifies its real-world impact and probability under specific conditions (Cioca et al., 2023). Distinction between the two terms 'hazard' and "risk' are a major issue in all risk communication efforts and both terms are perceived and used very differently in risk communication depending on the perspective of the stakeholders (Scheer et al., 2014). While there are selected contexts of extremely low risk such as sterilization in hermetically sealed cans (Zwietering et al., 2016) "zero risk" remains unattainable. However, the severity of the risk varies between products because it depends on a variety of factors. For instance, the probability of developing a foodborne disease after consuming a sterilised food product is extremely small, whereas the one associated with the consumption of half a dozen raw oysters is much bigger (Zwietering et al., 2021). Commercial sterility for instance is a process standard in food industry, where food is free from viable microorganisms capable of growing under normal storage conditions, with an accepted minimal risk of spoilage, typically quantified as 1 in 10,000 units. This ensures safety and shelf stability while balancing practical limitations in achieving absolute sterility (Diep et al., 2019). The understanding and assessing of this residual risks, i.e. the risk that remains even after a fully compliant food safety system, where the level of microorganisms in raw materials is within target levels, and processing and storage conditions conform to specifications, for different products is crucial for the different actors involved in food production to further fine tune food safety systems (Zwietering et al., 2021).

Participants were asked to rank major drivers and trends relevant to food safety in the near future in their company and 42 % of the respondents ranked the behavior of the consumer and food consumption patterns in first place, followed by (i) climate change, (ii) new food sources and food production systems, and (iii) sustainability; technological innovations and scientific advances, and urbanization and urban agriculture were considered as least important by the respondents. Inferential statistical analysis revealed several statistically significant differences: companies operating at regional, national, and international levels did not agree on the relevance of 'urbanization and urban agriculture' as a major driver and trend relevant to food safety in the near future (p-value: 0.02), with internationally operating companies considering this driver as less important compared to their nationally operating counterparts (p-value: 0.012, Fig. 3). Further, small companies rated 'technological innovations and scientific advances' as less critical compared to medium-sized companies (p-value: 0.008, Fig. 4). Overall, the different groups generally exhibited similar overall rankings and ranked the behavior (i.e. practices) of the consumer and food consumption patterns as most important. The shift of consumer behaviors is in response to a multitude of factors, such as climate change, a focus on

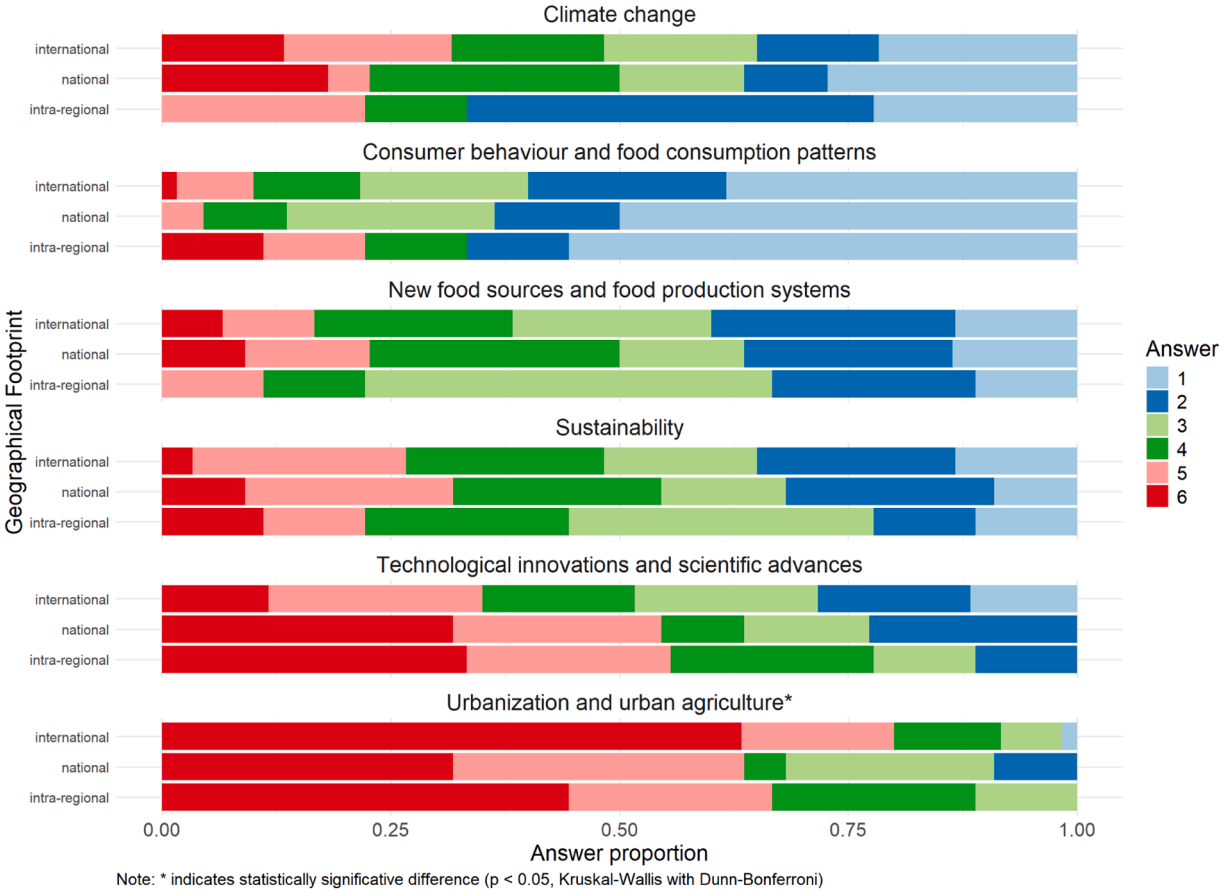

Fig. 3. Drivers and trends relevant to food safety in the near future itemized for the intra-country regional (n = 9), national (n = 22) and international (n = 60) geographical footprint level of participating companies (answer scores 1 = most important, 6 = least important).

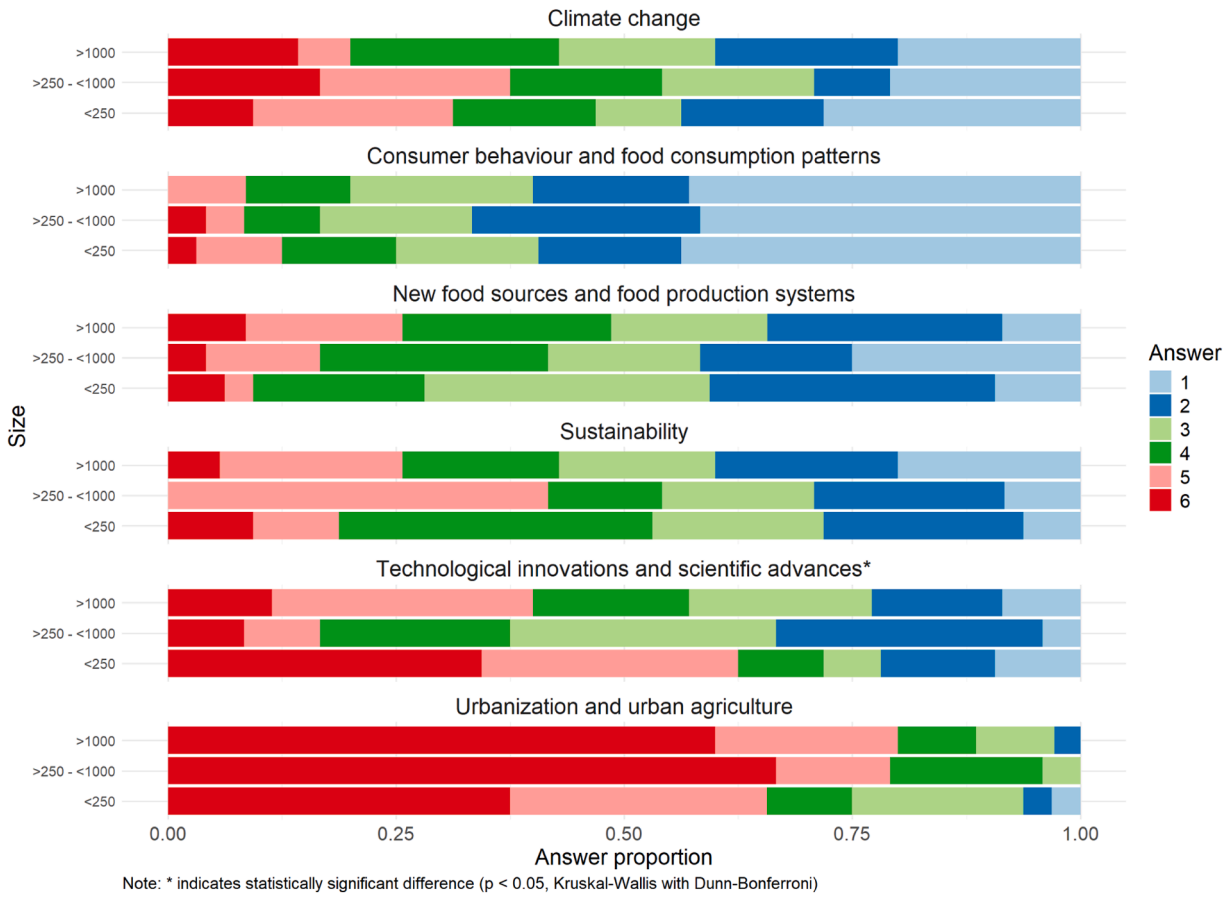

Fig. 4. Drivers and trends relevant to food safety in the near future itemized for small ($n = 32$), medium ($n = 24$) and large ($n = 35$) companies (answer scores 1 = most important, 6 = least important).

improving health, concerns about the impact of food production on environmental sustainability, rising incomes, among many others (FAO, 2022b). These shifts are driving changes in the food purchasing and consumption habits of consumers that can be accompanied by potential food safety risks, which in turn need to be evaluated to protect consumer health (FAO, 2022b). According to Charlebois and Summan (2015), many food preference trends may influence the likelihood of contracting foodborne illness. For instance, the growing demand for convenience products such as "chilled ready meals" might create favorable conditions for *Listeria monocytogenes* (Quested et al., 2010). *Listeria monocytogenes* is a bacterial pathogen for which microbial risk assessment is particularly valuable in an industrial setting, as it provides insights into where effective interventions can be implemented throughout the entire manufacturing process (Gonzales-Barron et al., 2024).

3.3. *Internal management practices applied to ensure microbial food safety*

The actions performed by the companies represented in our study to decide on the relevance of microbial hazards in food were manifold and included the initiation of microbiological investigations (85 %), and internal discussions (65 %), often following an internal decision tree (63 %). About 42 % read relevant literature and aim for external advice, and 12 respondents further commented that they take their decision based on the associated risk, partly also conducting a formal risk assessment (Supplement, Table S1). Almost all participants, (93 %) specified that the Quality Management is involved in the decision-making process to overcome significant events (i.e. food safety incidents) in their company, but the Production (59 %) and R&D (54 %) departments, as well as the Directory/Executive Office (51 %) also frequently take part in the decision process. Others include colleagues from Legal, laboratories, a defined food safety crisis team, corporate respondents, as well as the quality management of suppliers, or the Food Authorities. A food safety crisis team may particularly been established in larger firms, in order to take more effective actions to recover their tainted brand image, while small firms may not have sufficient resources to recover from crises (Seo et al., 2013). Furthermore, the participants were asked to provide insights into factors and/or circumstances that have most often led to significant results in their companies in the past, and named most commonly raw material contamination, poor hygiene, changes in the process/product, and the emergence of 'new' hazards. These "new" hazards might occur due to the increasing temperature trends around the globe affecting the geographic distribution and persistence (Kuhn et al., 2020; Lake, 2017), or organisms showing increasing rates of antimicrobial resistances (MacFadden et al., 2018; McGough et al., 2020).

The approaches followed during the internal decision processes of relevant hazards present in food were most often based on the HACCP system, which was established, either fully or in parts, in more than 95 % of the participating companies (Supplement, Figure S3). As most participants of our study originated from Europe where a HACCP system is a legal requirement (see Article 5 of Regulation (EC) No 852/2004 (Anonymous, 2004), this result is not surprising. HACCP is part of the food safety management system (FSMS) of any food business operator and should be seen as a practical tool to control the food production environment and process and ensure food safety (Anonymous, 2022). However, for low and middle income countries it has been reported that food business companies are slow in adopting FSMS particularly due to barriers such as lack of financial resources, size of organization, inadequate infrastructure and facilities, and lack of top management

commitment, despite the acknowledgment of improved product quality and safety when implementing an FSMS (Macheka et al., 2013). A total of 88 % of the companies also fully follow prerequisite programs such as Good Manufacturing Practice (GMP), Good Hygiene Practice (GHP), or Good Agricultural Practice (GAP), which are defined as preventive practices and conditions and procedures such as training and traceability, that establish the basic environmental and operating conditions that set the foundation for implementation of HACCP-based procedures in the company (Anonymous, 2022), and which are also legally required within the European Union (Anonymous, 2004). Even a full risk-based management system including food-safety objectives, performance objectives, critical limits and/or microbial criteria was established fully in 78 % and partly in 18 % of the participating companies according to the food industry professionals. Still, a high number of respondents call for clear guidance on possible approaches (68 %), definitions of acceptable levels set by the government (68 %), and the availability of suitable methodologies (66 %) when implementing and possibly applying such a system, which suggests that the high percentage of "fully" implemented FSMS (78 %) should be interpreted with caution. According to the respondents, other needs include cost-benefit analysis and training. Failure in implementing a Food Safety Management system in food industry leads, in most instances, to compromised food safety and subsequent foodborne illness outbreaks (Lee et al., 2021).

3.4. Respondents' expertise regarding risk analysis and their perception on given challenges and limitations

Food products are sourced from all over the world, transported over long distances, produced under different cultivation practices and climatic conditions, and are manufactured using various processing techniques, creating more possibilities for incidences related to food safety hazards (Kussaga et al., 2014). When dealing with microbial hazards in food industry this calls for more robust FSMS including the application of the food safety risk analysis framework according to Codex Alimentarius principles (FAO and WHO, 2021). 88 % of respondents have indicated, that they are familiar to the concept of Microbial risk analysis according to Codex Alimentarius. Respondents were further asked on their respective roles according to this concept of Codex Alimentarius, and according to the answer responses, out of all respondents, 67 % hold the role of a Risk Manager, while 54 % and 30 % of the participants act as Risk Assessor and Risk Communicator, respectively. More than one-third of respondents fulfill multiple roles, with 46 % taking on all three distinct roles and 27 % assuming the dual role of risk manager and risk assessor, which may present particular challenges in decision-making.

Participants were further asked about what they perceived to be the biggest challenges in communicating food safety risks. The expectation of zero risk was cited most frequently (51 %), followed by the integration of other factors than food safety, e.g. food security, plant health, societal factors etc. (45 %). Missing stakeholder engagement (42 %) and limited resources for participatory approaches or pro-active communication (42 %) were also frequently reported. These challenges were, as a trend, particularly emphasized by participants from large and internationally operating companies. A critical barrier identified is the disconnect between consumer perceptions of food safety risks and the actual risks associated with products or processes (Wall and Chen, 2018). Many consumers mistakenly believe in the possibility of zero-risk food, which is unrealistic. Communicating that food is not sterile and that a residual degree of risk must be managed by the end user remains a significant challenge. However, the active inclusion of consumers in risk communication strategies is often overlooked in the literature, despite its importance. Engaging consumers in dialogue, rather than treating them as passive recipients of information, is essential for bridging the gap between perception and reality. Participatory approaches, such as focus groups or citizen panels, can be employed to better understand consumer concerns and tailor communication strategies accordingly. Moreover, psychological, sociological, and cultural factors significantly influence consumer risk perceptions, as highlighted by Baba and Esfandiari (2023). Addressing these factors requires targeted communication efforts that not only inform but also empathize with consumer concerns, providing context and actionable steps for managing risks. Despite its critical role in effective risk communication, the active integration of consumers as stakeholders in food safety frameworks remains insufficiently discussed in existing research and practice. Further exploration and practical implementation of consumer-inclusive strategies are crucial to advancing food safety communication.

Modeling as applied in microbial risk assessments is an integral part of the scientific evidence used to guide the response of risk managers to address the food safety associated with these food systems (Filter et al., 2022). About 86 % of respondents have either fully or in parts conducted a microbial risk assessment according to Codex Alimentarius guidelines in their individual work context. Mainly responsible for microbial risk assessment in the participants' companies are individuals with the titles of Quality Management Officers (45 %), the Food Safety Advisors (26 %), and the Quality Safety Officer (22 %). This is particularly remarkable as companies were previously reported to perceive risk assessment as a complex procedure suitable only for academia or public agencies, with few practical implications (Bevilacqua et al., 2023). These findings from our study may be connected to the growing emphasis in recent years on adopting a risk-based approach rooted in comprehensive risk assessments, as required by food safety certification standards like ISO 22,000. Most data used for the microbial risk assessment in the individual company context are in-house data (80 %), but also published microbial risk assessments (62 %) and peer-reviewed papers (61 %). About half of the participants (51 %) seek advice from external respondents in the field when conducting their own microbial risk assessment. This nicely emphasizes the importance of exchange of knowledge and data between disciplines and that managing microbial food safety risks heavily relies on concerted efforts of multiple stakeholders including academia. Key to ensure reuse of knowledge available as data, models and tools are user-friendly and interoperable open-sourced risk assessment tools and model repositories with harmonized data formats and consistent rules for knowledge annotation such as those developed by the RAKIP (Risk Assessment Modelling and Knowledge Integration Platform) Initiative who developed the so- called Food Safety Knowledge Exchange (FSKX) format. This development was accompanied by the creation of open-source software and other infrastructural resources to enable efficient exchange of domain-specific data and models (e.g. FSK-Lab, online model repositories) facilitating the adoption of FSKX (Filter et al., 2022). The RAKIP Initiative will work towards the establishment of a truly interoperable, modular food microbiology knowledge ecosystem that can support all food sector stakeholders including FBOs.

Food business professionals were further asked to rank factors affecting the feasibility and outcome of any microbial risk assessment and resources were ranked at first place, followed by data limitations, and costs. Challenges participants were currently facing when dealing with a microbial hazard in food and its assessment (Supplement, Figure S4) were food-matrix specific (49 %), or due to biofilm production (39 %), emerging pathogens (38 %), or the toxicity (i.e. ability to produce toxins that can harm host organisms)/resistance of microorganisms (36 %). Inferential analysis of these challenges revealed a statistically significant difference associated with the geographical footprint of the company and 'biofilm production' (p-value Fisher's test: 0.01). The pairwise Fisher test (p-value: 0.02) suggests that international companies more frequently acknowledge 'biofilm production' as a significant challenge compared to national companies (Fig. 5). Also, a statistically significant association was found for 'food-matrix specific challenges' (p-value: 0.02). Specifically, small companies perceived these challenges as more significant compared to large companies (p-value: 0.01, Fig. 6). These differences may stem from the varying complexities and technologies employed in the specific food production

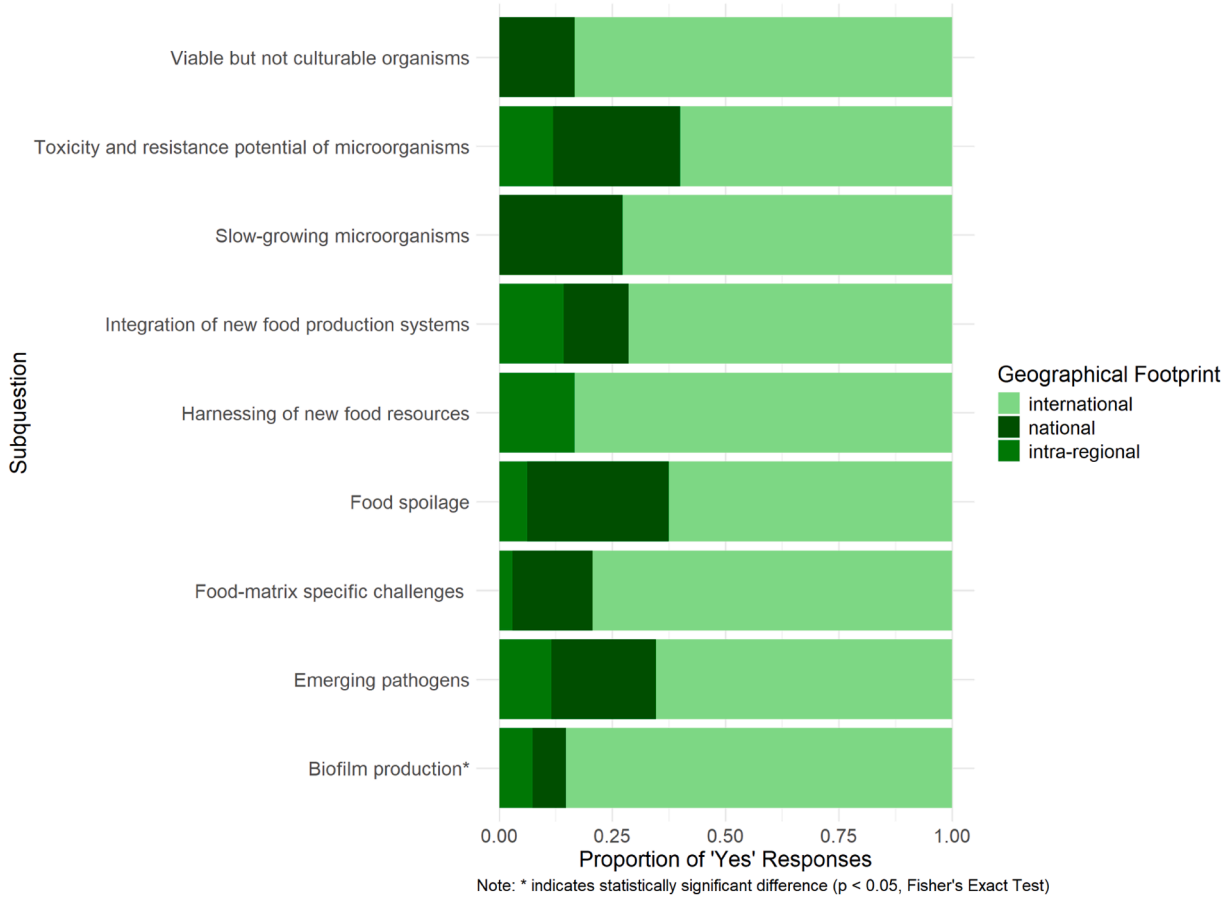

Fig. 5. Challenges of food-business companies when dealing with a microbial hazard in food and its assessment itemized for the intra-country regional ($n = 10$), national ($n = 26$) and international ($n = 67$) geographical footprint level of participating companies.

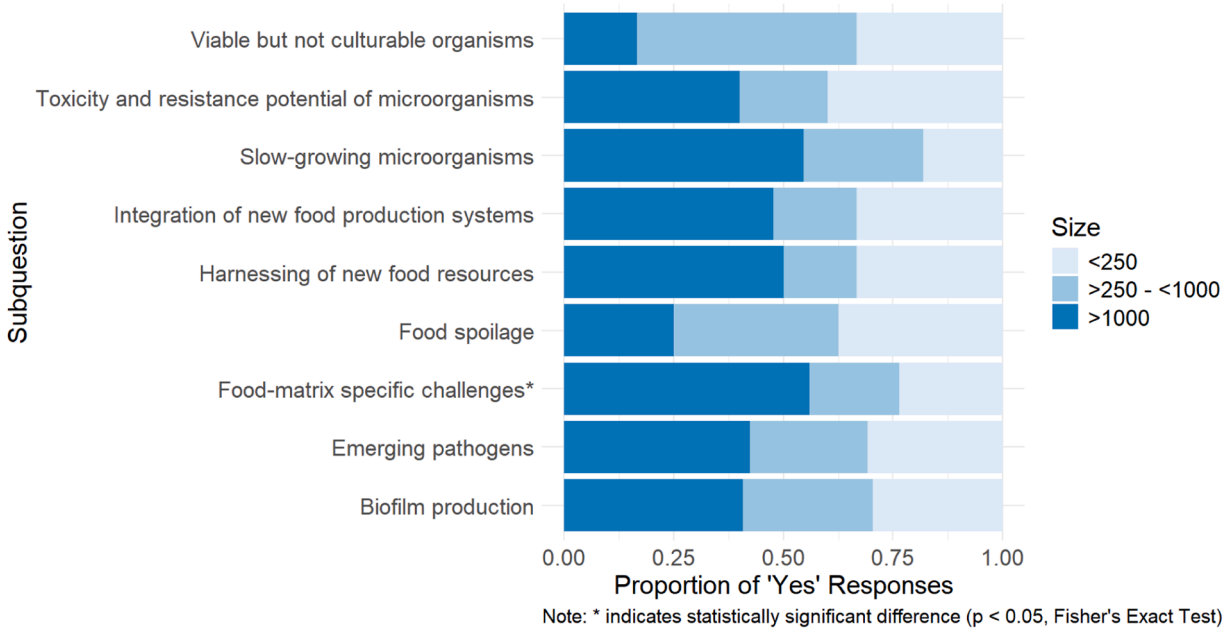

Fig. 6. Challenges of food-business companies when dealing with a microbial hazard in food and its assessment itemized for small ($n = 37$), medium ($n = 28$) and large ($n = 38$) companies.

processes within the participants' facilities. However, our data do not provide details on the types of food produced or processed in these facilities.

Participants were also facing a magnitude of different limitations when applying existing risk assessment approaches in their specific company context (see Supplement, Figure S5), such as interdisciplinary knowledge transfer gaps (48 %), microbe-specific challenges (e.g. adaptability, changeability, host interaction, amongst others), limitations in data access and scientific advice (30 %) and methodological challenges (28 %). Therefore, it is not surprising that a high number of food industry professionals described the need for training/capacity building, technological advances (microbiological analysis, risk analysis software etc.), more (in-house) data, more regulation and/or guidelines. Other reported needs include awareness/sensitization of the consumer as well as more knowledge exchange between the different parties involved to ensure food safety. One participant suggested a forum where food-business operators, government and respondents from academia exchange and build knowledge to work towards a common goal (Supplement, Table S2). These findings nicely emphasize the need to engage various stakeholders and addressing foodborne microbial risks in an integrated, participatory effort as exemplified by Zinsstag et al. (2023) leading to benefits that could not be achieved if the different sectors worked alone.

The food business professionals' finally provided insights into their expectations for microbial risk assessment approaches developed to meet the challenges of future food systems (Supplement, Table S3). The professionals call for an approach which is highly adaptable and flexible, easy-to use and not too complex and practicable in the facility. Still, microbial risk assessment approaches are inherently complex due to the multitude of factors that need to be integrated to allow for valid conclusions. Yet, the applicability of probabilistic modelling techniques allowing the inclusion in models of realistic inputs rather than worst-case values, is beneficial to decision makers when tackling safety or spoilage issues; hence, providing an added-value to industry operating under the risk-based food safety management framework (Membré and Boué, 2018).

Also, harmonization, data sharing and interdisciplinarity were emphasized by the food industries' professionals which is consistent with scientific evidence on this subject (Filter et al., 2022). Others expect future microbial risk assessment approaches to obtain faster results, achieve higher acceptance by the government, or enhance the awareness of consumers that a zero-food safety risk does not exist, calling for more innovative and creative communication strategies to engage with consumers using all available media channels in an open and transparent way as suggested by Wall and Chen (2018).

4. Conclusions

While the survey was not representative and in size relatively small, it provided valuable insights into the food industry's implementation and perspective on microbial risk analysis. It identifies drivers and trends relevant to food safety and internal decision-making processes. According to the respondents of this study, risk-based FSMS as well as various food standards certification schemes are established in the facilities of most participants. The majority of respondents declared to be well versed in microbial risk analysis and to have conducted a formal microbial risk assessment according to Codex Alimentarius. In spite of this, one third of the respondents falsely believed that zero microbial risk is attainable if processes were optimized. Overcoming the misconception of zero-risk requires a multi-faceted approach that combines education, communication, regulatory adjustments, and practical demonstrations of the principles of risk mitigation. By fostering a deeper understanding of risk concepts and encouraging a realistic perspective on food safety, more effective risk assessment, management, and communication practices that align with scientific and practical realities can be developed.

Main areas leading to significant microbial results in the production setting of the participating companies were contaminated raw materials, poor hygiene, changes in the process/product, or the emergence of new hazards. These findings will help to set priorities when addressing food safety risks.

As most responses were from companies based in the EU and operating internationally, there may be a potential bias towards practices and challenges that are more prevalent in European and globally active businesses. Conversely, the distribution of company sizes was balanced, with approximately one third of respondents representing small, medium, and large companies, respectively. This more equitable representation may provide a more accurate reflection of the industry in terms of company size.

Managing microbial food safety risks is highly complex as not only public health risk but also socio-economic dimensions such as economic impacts, consumer acceptance, social sensitivity and environmental impacts need to be considered and balanced in a timely way (Ali et al., 2022). Food business professionals face a magnitude of challenges when assessing and managing food safety risks. Food production is inherently complex, and measures aimed at enhancing food safety may inadvertently lead to increased food waste, higher environmental impact, and elevated food prices. Furthermore, the use of overly conservative safety margins and worst-case scenarios in risk assessments could amplify these effects, potentially compromising the nutritional value of food and negatively impacting food security. Balancing safety with these broader considerations is crucial to ensure sustainable and equitable outcomes. The valuation of food safety risks refers to the process of assessing and assigning value to various risks. This involves evaluating the potential impacts of different risks on consumers health, as well as considering the trade-offs associated with various risk management strategies. This process facilitates the estimation of costs related to different risks (Ehling-Schulz et al., 2024). The multifold challenges of future food systems can only be successfully addressed in a concerted effort involving stakeholders from industry, academia, government, non-governmental organizations (NGOs), and consumer organizations addressing the differing perspectives and perceptions of food safety risks. With the help of risk-based food safety management concepts grounded in holistic microbial risk analysis, such as the recently proposed risk negotiation framework (Ehling-Schulz et al., 2024), stakeholders are empowered to collaboratively address complex food safety challenges. Risk negotiation emphasizes a dialogue-centered approach, enabling parties to evaluate multiple risk dimensions, trade-offs, and priorities in a transparent and inclusive manner. FBOs, as key players in this process, could take an active role in balancing foodborne health risks with economic, environmental, and operational considerations. Our findings highlight limitations in the current practices of FBOs, such as fragmented communication, lack of integrated risk perspectives, and inadequate stakeholder engagement, all of which could be addressed by adopting the negotiation-based framework. This approach offers the potential to close these gaps by fostering shared responsibility, improving decision-making, and achieving more balanced and effective risk management solutions.

Funding statement

This work was funded by the SNSF (Swiss National Science Foundation, Sinergia grant number CVRSII5_209253).

Data availability

Data will be made available on request.

CRediT authorship contribution statement

Alexandra Fetsch: Writing – original draft, Visualization, Validation, Supervision, Methodology, Investigation, Formal analysis,

Conceptualization. **Nunzio Sarnino:** Writing – review & editing, Visualization, Validation, Formal analysis. **Konstantinos Koutsoumanis:** Writing – review & editing. **Maarten Nauta:** Writing – review & editing. **Martin Wiedmann:** Writing – review & editing. **Katharina D.C. Stärk:** Writing – review & editing. **Monika Ehling-Schulz:** Writing – review & editing. **Roger Stephan:** Writing – review & editing. **Sophia Johler:** Writing – review & editing, Supervision, Resources, Project administration, Funding acquisition, Conceptualization.

Declaration of competing 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.

Acknowledgements

The authors are particularly thankful for the valuable support of Claudia Fricker-Feer, Annett Winkler, and Matthias Filter during the development phase of the survey.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.mran.2024.100340.

Data availability

Data will be made available on request.

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