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Review

Principles and approaches applied for foodborne microbial risk assessment: a scoping review of concepts, limitations and future directions

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ABSTRACT

Microbiological risk assessment (MRA) is a cornerstone of food safety governance, enabling sound science to set food safety standards, guidelines, and recommendations, that aim to ensure consumer protection and facilitate international trade. This scoping review summarizes recent developments, limitations, and future directions in foodborne MRA, based on literature published between 2013 and 2023. From 5909 records retrieved via four databases, 244 publications were screened, and 44 met the inclusion criteria. These publications focused on concepts and methods for assessing microbiological hazards in food, such as current challenges and limitations, or suggested new elements to be incorporated into risk assessment. Most studies referred to the Codex Alimentarius framework and addressed bacterial hazards in general food contexts. Stakeholder attention was mainly centered on government and industry, whereas consumer and societal perspectives were rarely represented. Additionally, challenges, such as data limitations, microbial adaptability, and food-matrix specificity, were recurrently highlighted. Several studies suggested updating the existing frameworks due to methodological limitations, lack of interdisciplinary integration, and gaps in stakeholder knowledge. In line with this, a shift toward the incorporation of OMICs data, harmonized methods, and — less frequently — artificial intelligence, was observed as potential tools to improve model accuracy, albeit with acknowledged risks of added complexity and uncertainty. This review highlights the importance of using and, where appropriate, adaptively extending the existing MRA framework to integrate emerging technologies and broader stakeholder perspectives. Such adaptation may support better navigation of complex food-system risks, provided that the scientific integrity and clear separation of risk assessment from risk management and communication are maintained.

1. Introduction

Safe, nutritious, and healthy food is a fundamental human right, and ensuring food safety represents an essential component of public health protection (Ayala and Meier, 2017; WHO, 2022). However, the risk of foodborne infections and intoxications remains a global challenge. Pathogenic bacteria and other microorganisms present in food are responsible for more than 200 diseases, that range from diarrhea to cancers. These foodborne diseases are a significant impediment to socio-economic development worldwide (Havelaar et al., 2015). According to the World Health Organization (WHO), it is estimated that unsafe food causes annually 600 million cases of foodborne diseases, 420,000 deaths, and 33 million years of healthy lives worldwide (Havelaar et al., 2015; WHO, 2022) in 2010 as reference year. The global burden of foodborne disease is not only a major public health concern, but has far-reaching implications for food security, sustainable development, market access, tourism, agriculture, and overall economic prosperity (Koigi, 2022). Therefore, ensuring access to safe and nutritious food, eradicating hunger while fostering a sustainable and resilient circular bioeconomy, and protecting ecosystems are key to sustaining life and promoting good health (Froidmont-Görtz et al., 2020; UN, 2015).

Foodborne diseases are largely preventable; however, achieving this requires coordinated action among governments, producers, and

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consumers to ensure food safety and sustain robust food systems (WHO, 2022). Advanced laboratory techniques, targeted surveillance, and rapid outbreak recognition have improved our ability to identify, track and control foodborne diseases (FAO and WHO, 2021; Gomes et al., 2025; Nauta, 2021; Rantsiou et al., 2018; Schadron et al., 2024). However, high adaptability of foodborne pathogens alongside novel molecular and microbiological technologies - OMICs, Artificial Intelligence, changing consumer preferences, complex global food trade, global warming, and demographic shifts - add layers of complexity to food safety risks' management. Risk analysis, comprises risk assessment, management, and communication, and provides a framework that has been widely applied to reduce foodborne diseases through the design, implementation, and communication of control measures (Zwietering and Nauta, 2007). In the context of microbial food safety, risk analysis provides estimates of the risks to human health and safety, identifies and implements appropriate measures to control the risks, and communicates with stakeholders about the applied measures (Nauta, 2021). In the European Commission, this Risk Analysis framework is legally embedded within Regulation (EC) 178/2002, which clearly states that food safety should be based on scientific principles (EC, 2002), while the Codex Alimentarius principles (FAO and WHO, 2014; FAO and WHO, 2021) remain the international reference for this framework.

Microbial risk assessment (MRA) is the science-based risk analysis component, providing a transparent, systematic evaluation of relevant scientific data to guide risk management decisions (Caffrey et al., 2019). The information generated from conducting a MRA can assist governments in setting national policies, criteria or providing public health advice, while supporting the industry in designing safer products for consumers (Bassett et al., 2012). The World Trade Organization agreements have recognized formal risk assessment as a mean of evaluating the safety of commodities in international trade, establishing consistent standards and guidelines, and resolving nontariff trade issues (Horton, 2001). In turn, the Codex Alimentarius Commission has defined risk assessment principles and practices for foodborne hazards (FAO, 2014). And recently, the Food and Agriculture Organization of the United Nations (FAO) and the WHO have published technical guidance on the conduct of microbial risk assessment in food (FAO and WHO, 2021). The transformation of agrosystems, the sustainability imperative (UN, 2015), significant technological advances, and the intertwined challenges of food safety and food security are generating new issues for the MRA. Yet, no study has systematically mapped the recent literature on MRA and these emerging developments.

This scoping review aimed to systematically map on current concepts and methods used for the risk assessment of microbiological hazards in food. We summarized approaches currently applied for foodborne MRA and described both its scope and the targeted audience, as well as challenges and limitations of the individual concepts as described in the literature. We also aimed to systematically identify innovative new elements that have been proposed to help adapt current MRA frameworks to meet the challenges of future food systems. Finally, beyond mapping existing methodologies, this review critically reflects on conceptual gaps and feasibility constraints, aiming to clarify how foodborne MRA can evolve to remain fit for purpose within complex food systems.

2. Material and methods

2.1. Scope and review questions

The Arksey & O'Malley framework (Arksey and O'Malley, 2005), and the JBI methodological guidance for evidence synthesis (Aromataris et al., 2024) were employed to guide this study.

The study applied a One Health-based approach to food safety risk analysis, integrating data and perspectives from veterinary, environmental, and public health domains. This approach guided the structure of our analytical framework and the formation of the expert team. The scope of this scoping review was to identify and describe the current literature relating to the concepts and methods used for risk assessment of microbiological hazards in food. The "Microbiological Risk Assessment (MRA) Guidance for Food" document, published by FAO (2021), was used as a framework to assess whether the methodology of each identified article aligned with risk assessment based on the Codex Alimentarius Commission principles for Risk Analysis. The review aimed to map the range of methodologies and approaches applied, identify challenges and knowledge gaps, and summarize future trends. We note that unlike a systematic review, which seeks to answer a narrowly defined research question with quality appraisal of studies, a scoping review is designed to explore breadth, identify concepts, and highlight gaps in knowledge. Thus, this study cannot determine definitively whether MRA is "fit for purpose" but rather provides a critical overview of evidence and directions for future development. The primary scoping review question was formulated using the Population, Concept and Context (PCC) framework (Peters et al. (2020), being Population (P): not applicable; Concept (C): microbial risk assessment principle/approach; and Context (C): food, food production chain. Accordingly, the main question was: *What is the status quo of the principles and approaches used for risk assessment of foodborne microbiological hazards?*

i. Additionally, three secondary questions were explored: What methods are currently applied for assessing microbial hazards in food, and in what context or matrix and stakeholder groups are they considered?
ii. What are current challenges of the individual methods and concepts applied for assessing microbial risks in food and what reasons and limitations are described in the literature?
iii. What are emerging trends and novel solutions for the assessment of foodborne microbial hazards and what elements are being suggested for updated or newly developed MRA approaches?

Elements of risk management or communication (e.g., stakeholder engagement, regulatory frameworks) extend beyond "pure" risk assessment but were jointly reviewed as these are integral or closely connected to MRA frameworks in the literature. Furthermore, we distinguish "multidisciplinary" from "interdisciplinary" research: the former refers to parallel disciplinary contributions without methodological integration, whereas the latter implies the combination of data, models, or concepts across disciplines into a unified approach (National Academy of Sciences, 2005).

This study's protocol was developed *a priori* and registered at Open Science Framework (Fetsch and Johler, 2023).

2.2. Identification of relevant studies

A comprehensive literature search of the four electronic bibliographic databases PubMed, SCOPUS, EMBASE, and Web of Science Core Collection was conducted for relevant articles; the search was executed on April 21st, 2023. The search strategy was developed using the PRESS (Peer Review of Electronic Search Strategies) as described in McGowan et al. (2016) and in consultation with a subject Librarian at the University of Zurich. Relevant studies included in the scoping review were identified by using three different sets of keyword combinations (Supplementary Table 1).

A filter was applied displaying only studies published within the last 10 years, covering the publication years 2013-2023. The Boolean terms AND/OR and medical subject heading (Mesh) terms were included in our search. We also scanned the reference lists of all relevant studies. In addition, a grey literature search for unpublished and difficult to locate studies, as well as publications and guidance documents from relevant regulatory authorities was conducted. All types of publications including peer-reviewed published articles/reviews, articles in conference proceedings, editorials, websites, and chapters in textbooks were considered relevant.

The search was thoroughly documented, including the search date, database, number of retrieved articles, and other relevant search records. In Supplementary Table 2, a full-search strategy employed in the PubMed database for this scoping review study is illustrated.

2.3. Eligibility criteria and selection of studies

Studies that report evidence on concepts/methods used for risk assessment of microbiological hazards in food and published in English within the last 10 years from the execution of the search (April 21st, 2023), i.e. covering studies with a publication date from 2013 to 2023, were included. The screening for potentially eligible studies was done in three phases. In phase 1, a comprehensive literature search across the selected electronic databases was conducted. All eligible articles were imported to an EndNote20 library created for the review and then further imported into a literature review software (DistillerSR, ©2025 DistillerSR Inc.). In phase 2, two persons independently screened the title and abstracts of the retrieved articles to identify if the publication met the predefined eligibility criteria. Any disagreements were discussed until a consensus was reached. The same procedure was followed in the third phase, when the full-text articles were screened. Articles found in the reference list of included articles and grey literature were screened using the same 3-phase approach. Following the PRISMA-ScR guidelines as described by Tricco et al. (2018) a flow diagram was used to report the search and screening results.

2.4. Data extraction and charting

The two different data extraction forms were designed using DistillerSR and consisted of the following: one person extracted basic characteristics (form 1) of the retrieved records such as author(s) and publication details, type and region of the study, and a summary of the studies' objectives and findings. Subsequently, two investigators systematically collected data from the retrieved records on the core questions of the Scoping Review (form 2) such as the risk assessment approach or method, the context, and the elements described, its consistency with Codex Alimentarius principles, the stakeholders(s) addressed, current challenges when assessing foodborne microbial hazards, rationale and future needs for updating existing risk assessment approaches, as well as suggested new elements for foodborne microbial risk assessment. The data extraction form was kept updated throughout the process until all relevant information had been extracted from the included articles. Conflicts on extracted data were addressed through discussion between the investigators until a consensus was reached. This data extraction and charting approach followed the recommendations described by Pollock et al. (2023).

2.5. Analysis of the evidence and presentation of the results

The PRISMA-ScR checklist (Tricco et al., 2018) was used to report the results of this Scoping Review (Supplementary Table 3). Relevant data from eligible studies were extracted using pre-tested forms and analyzed descriptively in Microsoft Excel® (Version 16.95.1), focusing on frequencies and themes. Percentages were rounded to whole numbers for clarity, and figures/tables simplified to avoid over-precision. All figures were created using Microsoft Excel® (Version 16.95.1) except for Fig. 5 (sunburst diagram), which was generated using Python (v3.11) libraries such as pandas and Plotly Express.

2.6. Methodological quality appraisal

The methodological quality or risk of bias of the included articles was not assessed in consistency with the guidance of scoping reviews (Page et al., 2021).

3. Results

3.1. Screening and eligibility results

In Fig. 1, the number of articles at each stage of the analysis is shown as a PRISMA flow diagram. Of the 5909 identified records, 44 articles (0.7%) were included for data extraction and results synthesis.

3.2. Publication attributes of included records

The characteristics of the 44 included records are summarized in Table 1, with the temporal distribution presented in Fig. 2. 2018 was the year with the most publications, largely due to a special issue in the *International Journal of Food Microbiology (IJFM)*. Overall, the included literature is unevenly distributed across publication type and geographic setting. As shown in Table 1, most records were published as peer-reviewed journal articles, with only a small number of reports or book chapters. Author affiliations were concentrated in Europe and North America, with limited representation from other regions (Fig. 3), indicating that the mapped discourse largely reflects high-income research and regulatory contexts. While first author affiliation provides a useful overview of geographic distribution, it may not fully capture the international and multi-country collaborations in some publications. Together, the included studies were published across 24 different sources, though the majority contributed only a single article (Fig. 4).

3.3. General characteristics of the included studies: context/matrix, methods for assessing microbial hazards in food, and stakeholder groups

The thematic scope of the included records is summarized in Table 2. Nearly all records explicitly addressed microbial risk assessment (MRA) explicitly. When mapped against the four core components of the Codex Alimentarius MRA framework - hazard identification, hazard characterization (including dose response assessment), exposure assessment, and risk characterization (FAO and WHO, 2021) most records addressed all components, whereas a smaller number focused on one or several individual steps, or incorporated complementary elements derived from chemical risk assessment, predictive microbiology or food safety management approaches. Government and risk assessors, industry and academia were the most frequently targeted stakeholder groups, while only a small proportion explicitly considered consumers or other societal stakeholders This dominance of governmental and industrial perspectives and the relative absence of consumer or societal actors is also highlighted in Fig. 5, illustrating how current MRA applications remain concentrated within institutional and expert domains rather than reflecting a fully interdisciplinary or participatory framework.

Most records addressed foodborne pathogens in general (Table 2). Foodborne antimicrobial resistance, spoilage organisms, and microbial toxins were less frequently covered, and no studies focused specifically on foodborne viruses. When non-bacterial hazards were considered, they were more often handled at a general level rather than through hazard-specific methodological development. "Food" in general was the most common context, followed by "food of animal origin. Codex Alimentarius MRA principles (FAO and WHO, 2021) were predominantly referenced while fewer studies addressed risk-benefit analysis or multi-criteria decision analysis (Table 2).

Fig. 5 visualizes the relationship of the contexts, methodological approaches, and stakeholder groups addressed in the included studies. The inner ring (context) shows that most studies addressed "food in general" followed by "food of animal-origin", while the middle ring (approach) reveals a dominant reliance on the Codex MRA framework and minor uptake of methods like risk-benefit and multi-criteria decision analysis. The outer ring (stakeholders) highlights how each methodological approaches are chosen by stakeholders. Governmental authorities, industry and academia were the most frequently targeted stakeholder groups, while consumers and other societal actors were less

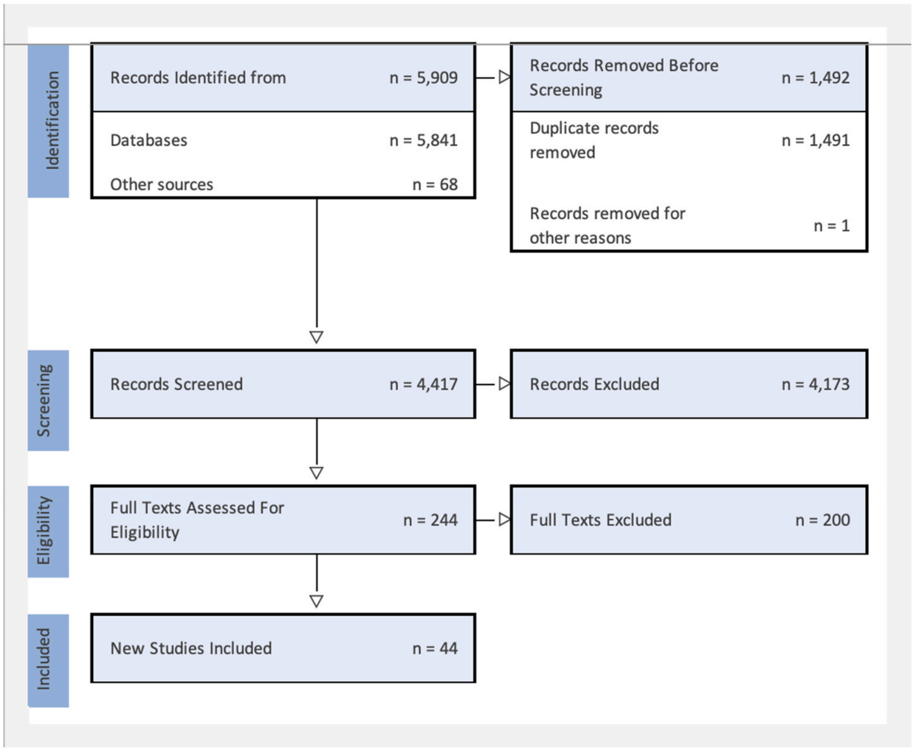

Fig. 1. The PRISMA (Preferred Reporting Items for Systematic reviews and Meta-analyses) flow diagram illustrates the flow of information through the different phases of our scoping review, specifically focusing on the search and selection of the studies.

frequently addressed. Records classified as risk–benefit analyses more frequently referenced multiple stakeholder groups compared with records focusing exclusively on microbial risk assessment. In these records, governmental, industry, and public health stakeholders were more often jointly represented. In contrast, records applying multi-criteria decision analysis (MCDA) approaches did not consistently demonstrate a similarly balanced stakeholder representation. MCDA-based records were most often oriented toward governmental or expert-driven decision contexts, with stakeholder involvement typically described at the level of decision support rather than explicit multi-stakeholder engagement (Fig. 5).

Taken together, the included literature is dominated by conceptual and methodological development, is concentrated in a small number of regions and institutional contexts and is supported primarily by a limited set of evidence streams. This pattern highlights the segment of the literature captured by this scoping review: records focused on how microbial risk assessment is structured and integrated, rather than on hazard-specific or context-dependent empirical applications.

3.4. Current challenges of microbiological assessment of foodborne hazards

Of the 44 records, 14 (32%) addressed current challenges with the methods and concepts applied for assessing microbial risks in food, while 30 (68%) did not (data not shown). The reported challenges are diverse. Frequently mentioned issues included: (i) data limitations (19 studies, 43%), (ii) food matrix–specific challenges (6 studies, 14%), and (iii) microorganism adaptability and variability (5 studies, 11%). Emerging pathogens, viable but non-culturable organisms, biofilm formation, new food production systems, and spoilage-related risks were less frequently mentioned. A summary of the main challenges and rationales with illustrative examples and their MRA implications is provided in Table 3.

Beyond these methodological constraints, several authors discussed broader systemic factors influencing the effectiveness of microbial risk assessment. Nauta (2021) addressed the global and complex good trade marketplace, global warming, and shifts in population demographics as current challenges. Similarly, Augustin et al. (2017) highlighted globalization as a challenge. Together, these studies illustrate that the limitations of current approaches are not only technical but also structural.

3.5. Rationale for the need to update currently available approaches and concepts used to assess microbiological hazards in food

Out of 44 records, 31 discussed reasons for updating MRA with methodological limitations being the most frequent rationale (25 studies, 57%). Further common reasons were limited data access and scientific advice (11/44, 25%) as well as interdisciplinary knowledge transfer gaps (10/44, 23%). Several studies noted microbe-specific challenges, such as lack of predictive power for microbial variability. One study highlighted that shelf-life predictions are not yet adequately considered in the currently available MRA approaches, although these could be useful to provide early warnings (Popov et al., 2013).

3.6. New elements and other suggestions for microbiological risk assessment

In total, 25 of 44 records discussed potential new elements for MRA.

OMICs integration was the most frequently proposed (15/44, 34%), followed by harmonized methods (10/44, 23%) and AI/machine learning (4/44 9%). Ross (2014) emphasized the need for transparency of the assessment process in terms of the data, knowledge used, assumptions made, resources or other limitations on the conduct of the risk assessment, and where uncertainty exists.

4. Discussion

This scoping review identified 5909 records related to MRA across four databases. After screening 244 publications, 44 met the inclusion criteria for detailed analysis. In total, over 99% of the identified

Table 1
Publication characteristics of 44 studies included in this review.

No	First author	Year of publication	Country first author affiliation	Source/Publisher	Source type	Study type	Study region	Key reference[a)]
1	Barlow, S.M.	2015	United Kingdom	Trends in Food Science & Technology	Review	Original research	Europe	no
2	Cocolin, L.	2018	Italy	International Journal of Food Microbiology	Peer-reviewed	Original research	Global	no
3	den Besten, H.M.W.	2018	The Netherlands	International Journal of Food Microbiology	Peer-reviewed	Original research	Global	no
4	Cubero González, S.	2019	Spain	International Journal of Food Microbiology	Peer-reviewed	Original research	Global	no
5	LeJeune, J.T.	2021	Italy	Foods	Peer-reviewed	Original research	Global	no
6	Lindqvist, R.	2019	Sweden	Critical Reviews in Food Science and Nutrition	Review	Original research	Global	no
7	Membré, J.M.	2021	France	Current Opinion in Food Science	Review	Original research	Europe	yes
8	Membré. J.M.	2016	France	Current Opinion in Food Science	Review	Original research	Global	yes
9	Nauta, M.J.	2018	Denmark	Trends in Food Science & Technology	Review	Original research	Global	yes
10	Pires, S.M.	2019	Denmark	Food Research International	Review	Original research	Europe/Global	no
11	Ramos, G.L.P.A.	2021	Brazil	Trends in Food Science & Technology	Review	Original research	Global	no
12	Taylor, D.D.	2022	United States of America	Journal of Food Protection	Peer-reviewed	Original research	Europe/North America	no
13	Van der Fels-Klerx, H.J.	2018	The Netherlands	Critical Reviews in Food Science and Nutrition	Review	Original research	Global	no
14	Anonymous	2014	Unknown	Food and Agricultural Organization of the United Nations	Grey literature[b)]	Guidance document	Global	no
15	Nauta, M.	2021	Denmark	Elsevier	Book chapter		Global	yes
16	Joshi, A.	2022	India	Food Research International	Review	Original research	Global	yes
17	EFSA Panel - Koutsomanis, K.	2019	Unknown	EFSA Journal	Grey literature	Report	Europe	yes
18	Rantsiou, K.	2018	Italy	International Journal of Food Microbiology	Peer-reviewed	Original research	Global	no
19	Haddad, N.	2018	France	International Journal of Food Microbiology	Peer-reviewed	Original research	Global	no
20	Koutsoumanis, K.P.	2016	Greece	Current Opinion in Food Science	Review	Original research	Global	no
21	Membré. J.-M.	2018	France	Food Research International	Peer-reviewed	Original research	Global	yes
22	Anonymous - FAO/WHO	2021	Unknown	Food and Agricultural Organization of the United Nations	Grey literature	Guidance document	Global	yes
23	Collineau, L.	2019	Canada	Frontiers in Microbiology	Review	Original research	Global	yes
24	Hathaway, S.C.	2013	New Zealand	Revue scientifique et technique	Peer-reviewed	Original research	Global	no
25	Pielaat, A.	2015	The Netherlands	International Journal of Food Microbiology	Peer-reviewed	Original research	Global	no
26	Ng, S.	2022	New Zealand	Journal of Food Science	Review	Original research	North America/Asia/Oceania	no
27	Guillier, L.	2022	France	Current Opinion in Food Science	Review	Original research	Global	yes
28	Boué, G.	2022	France	Frontiers in Nutrition	Peer-reviewed	Original research	Global	no
29	Surareungcha, S.	2022	Thailand	Horticultuarae	Peer-reviewed	Original research	Global	no
30	Verhagen, H.	2021	United Kingdom	Food Research International	Peer-reviewed	Original research	Europe/Global	no
31	Makita, K.	2021	Japan	Revue scientifique et technique (International Office of Epizootics)	Peer-reviewed	Original research	Global	no
32	Wu, F	2020	United States of America	Risk Analysis	Peer-reviewed	Original research	North America/Global	no
33	Pradhan, A.K.	2019	United States of America	ASM Press	Book chapter		Global	no
34	Augustin, J.C.	2016	France	Wiley	Book chapter		Global	no
35	Soman, R.	2016	India	Food Control	Peer-reviewed	Original research	Global	no

(continued on next page)

Table 1 (*continued*)

No	First author	Year of publication	Country first author affiliation	Source/Publisher	Source type	Study type	Study region	Key reference[a]
36	Membré, J.-M.	2016	France	Elsevier	Book chapter		Europe	no
37	Motarjemi, Y.	2014	Switzerland	Elsevier	Book chapter		Global	yes
38	Charlebois, S.	2014	Canada	Journal of Food Safety	Peer-reviewed	Original research	North America	yes
39	Ross, T.	2014	Australia	Elsevier	Book chapter		Global	no
40	Masood, F.	2014	India	Springer	Book chapter		Global	no
41	Caswall, J.A.	2013	United States of America	Elsevier	Book chapter		Global	yes
42	Popov, V.	2013	United Kingdom	WIT Press	Book chapter		Global	no
43	Martinovic, A. Martinovic and Nisic, 2019	2019	Montenegro	Novel strategies and tools for microbial risk assessment of foods of animal origin	Grey literature	Conference paper	Europe	no
44	Fegan N.	2018	Australia	Meat Science	Review	Original research	Global	no

[a] A record was classified as key reference if more than one of the specific (secondary) questions of the scoping review were addressed (see chapter 2.1).
[b] A record was categorized as grey literature if published outside of books and journals, including webpages, government documents, theses, online handbooks and manuals, and much more.

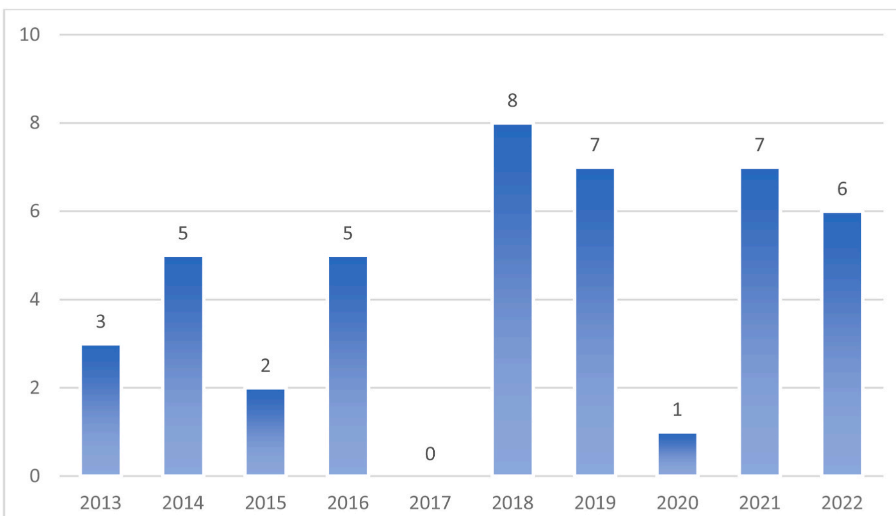

Fig. 2. Timeline illustrating the chronological order of published records included in the study (yrs 2013-2023).

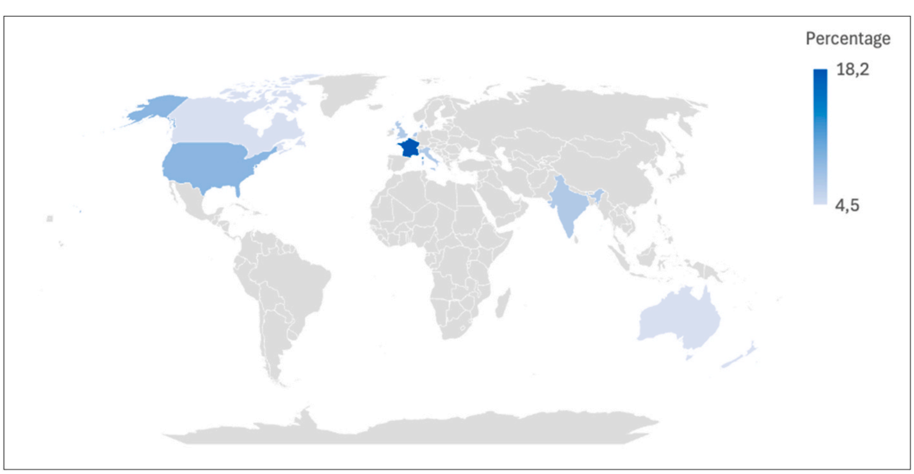

Fig. 3. Visual presentation of the geographic distribution of studies included in the research, mapping the countries of affiliation for the first authors.

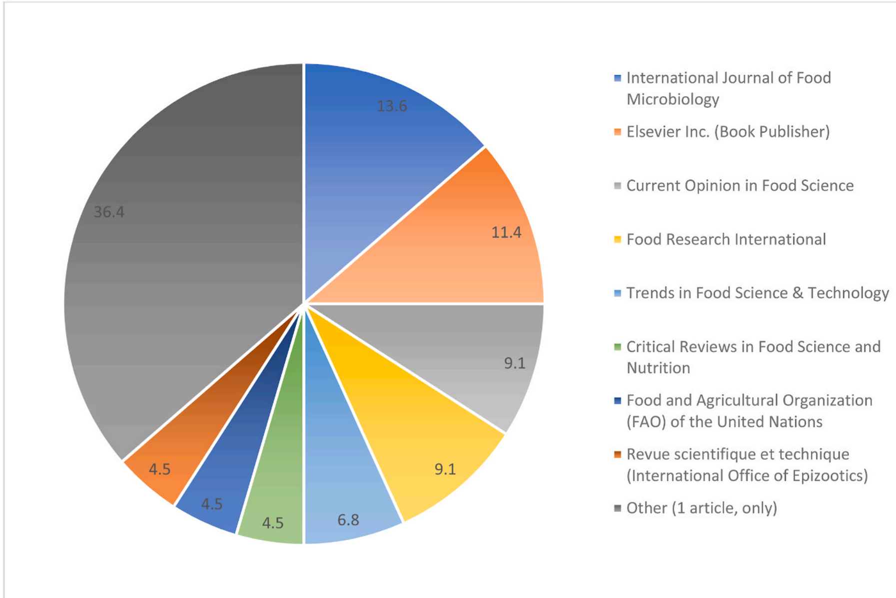

Fig. 4. Distribution of included records by publishing source. This figure visualizes the proportion of research records sourced from different publishing platforms, in percentages.

publications were excluded, as most publications were case-specific applications and therefore did not meet our inclusion criteria. This highlights that, although foodborne MRA is widely applied and highly relevant for addressing real-world questions, relatively few studies examine its conceptual and methodological foundations in depth.

Most records included in this study were published in scientific journals focusing on food-related topics. The variety of publishing sources and the global distribution of the first publishing author's affiliations express the general interest in the topic, also supported by the high number of records tackling the topic from a global perspective. Most of the included articles (71%) were peer-reviewed and appeared in journals ranked within the top quartile of their respective fields, reflecting a strong scientific foundation and high impact to the citation metrics.

Foodborne pathogens, antimicrobial resistance, and foodborne spoilage organisms were the main topics addressed in most of the records. None of the included references explicitly centered on foodborne viruses despite their prominent role in viral foodborne outbreaks over the past 20 years in the US (Olaimat et al., 2024), and in the EU (EFSA and ECDC, 2025). Although records dealing with viral hazard assessments do exist (*e.g.*. for norovirus or hepatitis A (Trząskowska et al., 2022; Yoo et al., 2023)), these studies were likely excluded from the selected records because they did not meet the eligibility criteria, being primarily applied studies. The full MRA principles of Codex Alimentarius (FAO and WHO, 2021) were most frequently addressed in a theoretical context, underscoring their high relevance and broad applicability as a foundational framework for risk assessment. In contrast, approaches such as risk-benefit analysis and multi-criteria decision analysis (MCDA) are employed either individually or in combination to concurrently assess multiple risks and benefits associated with specific food commodities supporting decision making in the broader field of food safety risk management (Ruzante et al., 2017). The comparatively low number of studies incorporating these newer approaches may therefore reflect the ongoing adaptation of these methodologies within the field. Nevertheless, reliance on the Codex should not obscure regional adaptations. For example, the EU integrates MRA into legally binding frameworks under Regulation (EC) 178/2002, while the US and China use distinct approaches to regulation. Our analysis indicates convergence around Codex principles, but also divergence in practice depending on regulatory traditions and resources. A substantial number of records addressed non-microbiological hazards, including those of chemical or nutritional origin, in addition to those of microbiological origin (Barlow et al., 2015; Boue et al., 2022; Lindqvist et al., 2020; Masood et al., 2014; Motarjemi, 2016; Nauta et al., 2018; Ng et al., 2022; Soman and Raman, 2016; Surareungchai et al., 2021; Van der Fels-Klerx et al., 2018; Verhagen et al., 2021; Wu and Rodricks, 2020). However, only one of the records considered the idea of evaluating the potential and required developments for a common framework to rank the risk of chemical and microbiological hazards.

A clear imbalance was also reflected between the targeted stakeholders, with almost all records targeting industry and government, while consumers were rarely considered. Given the technical and science-based nature of MRA, this distribution is not unexpected. Consumer and broader stakeholder perspectives are more typically integrated within risk management and risk communication processes, where they may inform scenario selection or decision-making, while the assessment itself remains a structured and evidence-based activity. Still, ensuring microbiological food safety is a multifaceted challenge that requires coordinated actions from all stakeholders (Charlebois and Summan, 2015). Our analysis suggests that while industry and regulators remain the dominant actors, academia contributes through methodological innovation. In industry, MRA is applied proactively during product development, process/formulation design and/or shelf-life determination, as well as retroactively in cases of incidents to estimate the impact on consumer safety or product quality when problems occur with marketed products (Membré, 2016). According to Membré (2016), the manufacturer is less interested in estimating the number of illnesses than in estimating the level of microorganisms on the food product or at the consumer's plate. In this context, the term ‘microbiological exposure assessment’ may better capture the intended meaning than the general designation MRA. This functional split helps explain why consumer perspectives are rarely addressed within MRA-focused studies, despite their relevance for legitimacy and trust in food-safety governance. Integrating consumer-derived information more actively into MRA-relevant steps could be achieved, for example, using consumer behavior data in exposure assessment. Consumer input may also inform scenario definition at the risk management stage, with resulting scenarios subsequently assessed within the risk assessment framework. Message-testing and preference elicitation to support risk communication, and evaluation of risk comprehension and behavioral responses

Table 2
General characteristics of 44 studies included in this review.

Characteristic	Count of each outcome[a)]
Theme/area of application	
Foodborne pathogens general	39
Foodborne bacteria	5
Foodborne parasites	1
Foodborne microbial toxins	5
Foodborne antimicrobial resistance	8
Foodborne spoilage organisms	8
Other	17
Context/Matrix	
Food general	35
Food of animal origin	9
Food of non-animal origin	2
Other	2
Risk assessment approach	
MRA principles of Codex Alimentarius	31
Risk-benefit analysis	5
Multi-criteria decision analysis	3
Other	19
Type of study approach	
Theoretical	40
Executive	6
MRA component(s) considered (based on the Principles of Codex Alimentarius)	
Hazard identification	3
Hazard characterization	1
Exposure assessment	1
Dose response	1
Risk characterization	0
Full MRA approach	33
Other	10
Targeted stakeholder(s)[b)]	
Industry	38
Government (including Risk Assessors)	39
Academia	25
Consumer	4
Other	3
Systematic illustration of the approach provided	
Yes	23
No	21

[a)] Each study can report multiple outcomes from multiple themes/areas of application, context/matrix, risk assessment approach, type of study approach, MRA elements considered, stakeholders targeted, therefore; the total counts will exceed the total number of included studies.
[b)] The targeted stakeholders groups were categorized in the context of this study as follows: (1) Government/regulatory authorities (Public bodies responsible for food safety regulation and risk assessment); (2) Industry (Food business operators applying MRA in production and safety management; (3) Academia (Research institutions developing and evaluating MRA methods); (4) Consumers (End users considered regarding exposure, handling, or risk perception); and (5) Other societal stakeholders (Non-regulatory public-health or civil-society actors.).

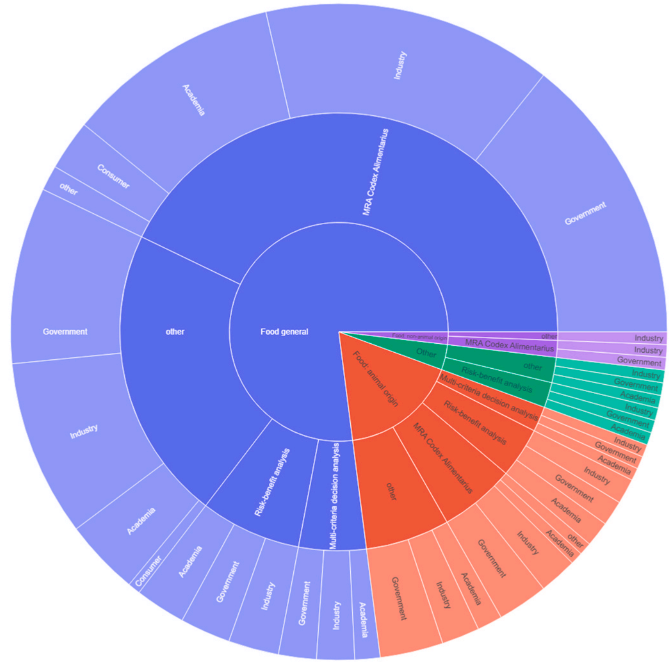

Fig. 5. Hierarchical sunburst diagram showing relationships among the *context* (innermost ring), *risk assessment approach* (middle ring), and *stakeholder group*[a)] (outer ring) addressed in the included studies. Arc width represents relative frequency. Wider inner arcs and narrow outer arcs indicate concentration of studies on a few methodological frameworks with limited stakeholder diversity. Interactive versions of the same figures are available from: to be added if the publishers allows reference to data repository. a) for the categorization of the 5 different stakeholder groups (1) Government/regulatory authorities; (2) Industry; (3), Academia; (4) Consumers; and (5) Other - see legend of Table 2 of this study.

may additionally be used in the broader context of risk analysis.

This scoping review aimed to identify challenges and rationales for updating MRA. The reviewed literature highlighted several obstacles that limit the practical implementation and continuous improvement of MRA, with the most frequently reported being limited data availability (Olaimat et al., 2024; Popov et al., 2013), heterogeneity of food matrices (Surareungchai et al., 2021), biological variability and adaptability of microorganisms (Cubero González et al., 2019; den Besten et al., 2018; Membré and Guillou, 2016; Membré et al., 2021; Motarjemi, 2016), and the need for better integration of knowledge across disciplines (Augustin et al., 2017; Pielaat et al., 2015). As illustrated in Table 3, these constraints translate into tangible methodological difficulties—such as incomplete dose–response information ((Haddad et al., 2018) inconsistent predictive models for matrix-specific processes (Surareungchai et al., 2021), validation needs for biological predictions (Cocolin et al., 2018) or limited transferability of genomic data into quantitative exposure assessments (Pielaat et al., 2015). These limitations are not newly emerging but recurrent themes that continue to challenge the

Table 3
Examples of challenges and rationales for updating MRA frameworks.

Category	Example from included studies	Implication for MRA
Data-related challenges	Lack of data availability, and adequate integration (Cocolin et al., 2018); uncertainty and variability impacting dose-response relationship (Haddad et al., 2018)	Hampers complete QMRA; requires alternative approaches and tools
Food matrix specificity	Survival of *Listeria monocytogenes* in ready-to-eat salads (Surareungchai et al., 2021)	Matrix properties strongly influence risk estimates
Microbe-specific challenges	Biofilm formation and resistance traits (Cocolin et al., 2018)	Increases difficulty of hazard characterization
Interdisciplinary gaps	Linking genomic predictions to phenotypic outcomes (Pielaat et al., 2015)	Requires integration of molecular biology with epidemiology
Software/ methodological gaps	Limited applicability of predictive tools (Cubero González et al., 2019)	Restricts uptake by regulators and industry

reproducibility and transparency of MRA (FAO and WHO, 2021; Nauta, 2021).

Adding to that are the constantly changing conditions (Augustin et al., 2017; Wu and Rodricks, 2020) as well as the risks' dynamic (Charlebois and Summan, 2015). Uncertainty and the way it is communicated was also a focus of the included records (Charlebois and Summan, 2015; Collineau et al., 2019; FAO and WHO, 2021; Membré and Guillou, 2016; Membré et al., 2021; Pradhan et al., 2019; Ross, 2014). Membré and Guillou (2016) highlighted the challenge of balancing the complexity of a MRA where variability and uncertainty along the farm-to-fork continuum are integrated, and its use by risk managers together with their need for discrete decisions. While conceptually belonging to risk management rather than risk assessment, these aspects were considered in this review because the included studies identified them as key contextual factors strongly influencing the quality and practical uptake of risk-assessment outputs.

Overall, the evidence suggests that the main barriers to advancing MRA are less technological than structural. They concern data infrastructure, methodological interoperability, and institutional readiness to adopt interdisciplinary collaboration (Augustin et al., 2017; FAO and WHO, 2021; Pielaat et al., 2015). Some authors also addressed the need for harmonization in surveillance and monitoring among countries, establishing a competent team (Makita, 2021), as well as better communication and coordination between expertise areas and organizations (Hathaway, 2013; Makita, 2021).

Over the years, the field of food safety and risk assessment has seen advances in the detection, characterization, and control of pathogens. Hence, machine learning, deep learning, and natural language-processing algorithms help in the efficient analysis of complex data and may be applied to these datasets for food safety prediction (Benefo et al., 2022). Several reviewed publications proposed the integration of new analytical tools and data sources — particularly OMICs, harmonized methodologies, and AI-based modelling — as potential extensions of existing MRA frameworks (Cocolin et al., 2018; den Besten et al., 2018; Guillier and Sanaa, 2022; Haddad et al., 2018; Koutsoumanis and Aspridou, 2016). Particularly, the holistic characterization of microorganisms in food through OMICs data was considered beneficial for improving model accuracy, reducing uncertainty, bridging QMRA to epidemiological data, and potentially paving the way towards precision food safety (Guillier and Sanaa, 2022). While the concept of precision food safety holds promises for tailoring interventions to specific hazards, the continuous evolution and genomic plasticity of bacterial populations challenge the notion of strictly defining pathogenic strains. We therefore argue, that precision food safety should be understood as a dynamic, adaptive framework that integrates real-time genomic and epidemiological data to continuously update risk characterizations and maintain responsiveness to emerging variants. Koutsoumanis and Aspridou (2016) as well as Haddad et al. (2018) further argued that the integration of OMICs in microbial risk assessment may lead to more targeted risk management, allowing to prioritize hazards more accurately. According to Pielaat et al. (2015) and Nauta (2021) OMICs-based techniques can provide refined identification, characterization, and source attribution of pathogens, linking genomic signatures to hazard traits. However, the translation of sequence or expression data into quantitative risk parameters remains uncertain and context dependent. OMICs are therefore best regarded as complementary to conventional approaches rather than as a replacement (FAO and WHO, 2021). Also, Collineau et al. (2019), claimed that the integration of OMICs data into MRA will likely introduce new sources of uncertainty, particularly regarding the thresholds of relatedness and the extent of correlation between genotypic and phenotypic profiles. The integration of OMICs data into risk assessment and decision-making processes (Rantsiou et al., 2018), the translation of genotype-level multidimensional information into single dimension associated with the measure of risk (Joshi et al., 2022; Membré and Guillou, 2016), as well as the prediction of genotypes to phenotypes (Koutsoumanis and Aspridou, 2016) are also challenging. Undoubtedly, specific protocols for OMICs applicability need to be developed to learn how to translate molecular events into practical applications (den Besten et al., 2018) and to develop risk assessment modelling approaches specifically fitted to the use of OMICs data (Koutsoumanis and Aspridou, 2016). The successful implementation of OMICs at the industrial scale is largely constrained by existing limitations, including the accuracy and reproducibility of protocols, the performance of bioinformatic tools, and data heterogeneity (Joshi et al., 2022). Further, expenses related to initial investment and running costs, human resources, laboratory and bioinformatics infrastructure are drawbacks of successful OMICs integration into MRA (Rantsiou et al., 2018). Apart from the OMICs data, only a few further elements or tool combinations were suggested in the included records. Makita (2021) hypothesized that microbial risk assessment may include in the future a combination of QMRA, mathematical modelling, genome sequencing, quantitative and qualitative socioeconomics, and even AI. Benson et al. (2014) argued that machine learning algorithms can be trained on datasets to develop predictive models that may be used to infer the evolutionary relationships among organisms. AI and machine-learning approaches may surely support pattern recognition and predictive analysis. Nevertheless, we emphasize that particular attention must be paid to the trustworthiness of these outcomes, alongside ensuring transparency throughout the training process. It is important to recognize that predictive models represent an integral, component of QMRA. In the near term, the most practical contribution of AI and machine-learning approaches is likely to lie in assisting data management, uncertainty analysis, and scenario exploration within established MRA structures rather than substituting expert judgement. Further application advancements may be achievable through the implementation of automatized techniques from the retrieval augmented generation (RAG) domain (Savvateev et al., 2024), which allow for data input specifications, or through post analysis features such as those described for our LLM-based Risk Negotiation model (Fetsch et al., 2025).

Methodological harmonization was frequently suggested to enhance consistency and comparability between assessments (Augustin et al., 2017; FAO and WHO, 2021). Fegan and Jenson (2018) suggested integrating a cost-benefit model into the risk assessment framework, enabling the estimation of the benefits of reducing the disease burden for different risk management strategies. The authors further emphasized the need to develop quality control systems for information collection and analysis to enable relevant comparisons (Fegan and Jenson, 2018). While harmonized methodologies and shared terminologies facilitate joint evaluations, excessive standardization may constrain flexibility and limit adaptation to local food systems.

Taken together, the integration of OMICs alongside harmonization efforts, and AI should be approached cautiously and pragmatically, ensuring that methodological innovation enhances and not obscures the transparency and reproducibility of MRA.

Beyond technological progress, the feasibility of implementing new or extended MRA approaches depends largely on organizational, cultural, and resource-related factors (FAO and WHO, 2021; Nauta, 2021; Zwietering and Nauta, 2007). Several authors observed that food-safety authorities and industry actors operate within a precautionary culture — often described as a “better-safe-than-sorry” approach — which promotes reliability and compliance but may also hinder methodological innovation (Augustin et al., 2017; Pielaat et al., 2015; Motarjemi, 2016). Studies such as Popov et al. (2013) and Motarjemi (2016) further noted that the effectiveness of MRA depends not only on scientific advances but also on managerial commitment and institutional prioritization of risk-assessment outcomes. When MRA results are poorly communicated or not integrated into decision processes, their practical value diminishes despite technical rigor. The transition toward more data-intensive, interdisciplinary frameworks requires capacity building at multiple levels: training assessors in quantitative methods, establishing data-sharing infrastructures, and fostering dialogue between scientists, regulators, and industry (FAO and WHO, 2021; Nauta, 2021). Donaghy et al. (2021) highlighted that integrating “Big Data” and AI-assisted analytics in food-safety risk management will only be successful if supported by transparent algorithms and clear documentation of assumptions. The reviewed studies also emphasized that analytical complexity must remain proportionate to the purpose of the assessment. Highly sophisticated, multi-OMICs or AI-based models may not necessarily provide more reliable results when data quality is uncertain or when timely, transparent decisions are required (Nauta, 2021; FAO and

WHO, 2021; Donaghy et al., 2021). Accordingly, incremental and well-documented integration of innovative tools into existing, validated frameworks — supported by targeted training, resource allocation, and cross-sector collaboration — appears to be the most feasible and sustainable strategy for advancing MRA (Augustin et al., 2017; Popov et al., 2013; Motarjemi, 2016; FAO and WHO, 2021). Because food safety is influenced by social, economic, and environmental factors, these dimensions are relevant at the interface between risk assessment and risk management. Changes in such factors may affect pathogen prevalence or exposure pathways (Charlebois and Summan, 2015). However, the scientific scope of microbiological risk assessment itself remains the structured, evidence-based evaluation of health risks. Stakeholder engagement, public involvement, and the balancing of broader societal objectives are primarily situated within risk management and communication processes. Decision-support tools such as multi-criteria decision analysis (MCDA) therefore complement, but do not constitute, MRA methods, as they support the evaluation of management options rather than the assessment of microbiological risk itself (Ruzante et al., 2017).

MRA aims to estimate the risk and the effect of factors on this risk then to be used in risk management to design approaches to prevent foodborne illnesses and promote human health (Benefo et al., 2022). As emphasized by Van der Fels-Klerx et al. (2018), there is no single best method for assessing the risks of foodborne hazards; the choice of method depends on the specific question, available data, resources and the needs of the risk manager. Close and structured communication between risk managers and risk assessors is therefore essential (Van der Fels-Klerx et al., 2018), a principle long embedded in the Codex Alimentarius risk analysis framework (FAO and WHO, 2006; Charlebois and Summan, 2015). However, the scientific scope of microbiological risk assessment itself remains the structured, evidence-based evaluation of health risks. Stakeholder engagement, public involvement, and the balancing of broader societal objectives are primarily situated within risk management and communication processed. A key element in this process is the effective integration of stakeholders into the whole process of risk analysis, ensuring multidisciplinary interaction, international collaboration, and efforts among all parties involved (Barlow et al., 2015; Caswell, 2013; Membré et al., 2021).

Broader stakeholder engagement becomes particularly relevant at the level of risk management and communication, where values, perceptions, and societal trade-offs must be considered. Such inclusive approaches also address the social dimensions of food safety governance and align with One Health and food-systems perspectives, fostering participatory and interdisciplinary collaboration (Van Paepeghem et al., 2024). In this context, risk–benefit analyses and decision-support tools such as multi-criteria decision analysis (MCDA) do not constitute MRA methods per se. Rather, they operate at the interface between risk assessment and risk management, translating quantified risks — and, where available, quantified benefits — into decision-relevant comparisons. Unless risks and benefits are expressed in commensurable units (e.g., DALYs), their balancing cannot be considered a purely technical assessment exercise but requires normative judgment. MCDA, therefore, complements QMRA by structuring management alternatives across multiple dimensions — health, economic, social, and environmental (Ruzante et al., 2017) — without replacing or redefining the core scientific assessment. In this way, stakeholder involvement enhances transparency and legitimacy in decision-making, while the methodological integrity of MRA as an evidence-based activity remains preserved.

The public should also be involved in the decision-making process (Membré et al., 2021). Rantsiou et al. (2018) emphasized the importance of bringing together the food industry, and both the food safety and public health authorities to achieve a common understanding and a coordinated approach. The key challenge remains in how the diverse interests and perspectives of stakeholders can be adequately acknowledged. A promising theoretical framework for addressing risks from a One Health perspective through the integration of negotiation was recently proposed by Ehling-Schulz et al. (2024). In this negotiation-centered approach, supported by AI technologies, stakeholders from multiple sectors collaborate to reach balanced solutions by considering different risk dimensions and trade-offs (Ehling-Schulz et al., 2024). In the context of food safety, Ehling-Schulz et al. (2024) suggest that transforming the traditional Codex Alimentarius-based framework (FAO, 2006) into a negotiation-based model could help balance food safety, food security and sustainability. Such a transformation would support broader strategic objectives (WHO, 2022), including the United Nations' 2030 Agenda for Sustainable Development Goals (UN, 2015). Building on this concept, Fetsch et al. (2025) recently proposed an AI-assisted negotiation framework that operationalizes such a negotiation-centered approach by integrating large language models (LLMs) and autonomous AI agents into risk analysis workflows. This framework addresses the limitations of conventional, siloed risk analysis by enabling stakeholders to simulate negotiation dynamics, explore trade-offs, and co-develop balanced solutions even under time and information constraints. Yet, the practical implementation of this "holistic" risk analysis approach requires a detailed operationalization concept, testing and refinement in real-world settings.

While all these developments illustrate the potential of next-generation QMRA, their implementation will require team-based efforts combining expertise from OMICs sciences, AI, as well as social and behavioral sciences. In practice, the feasibility of such integrated approaches depends on available resources, institutional flexibility, and willingness to move beyond disciplinary 'box-thinking'. Hence, incremental adaptation rather than wholesale transformation appears the most feasible path forward, balancing methodological sophistication with practical applicability.

By adopting a scoping review approach, we aimed to map the landscape of available evidence and critically assess its scope, rather than address narrowly defined question. This contrasts with systematic reviews, which evaluate evidence quality to test specific hypotheses (Munn et al., 2018). Accordingly, our insights are best interpreted as shedding light on key directions for methodological innovation and feasibility considerations.

5. Conclusions

This scoping review mapped current approaches and principles currently used for food microbial risk assessment, highlighting persistent challenges, limitations, and potential directions for future development.

Our evidence synthesis elaborated on the potential for integrating big data (such as OMICs data) into microbial risk assessment. One way to achieve this might be through the consideration of machine learning algorithms/AI–based solutions; however, this does require transparency, ideally evolving through a human-in-a-loop approach to combine human creativity and contextual insight with AI's analytical power to enhance innovation and decision-making. Yet, human–AI collaboration does not always outperform humans or AI alone, as challenges like communication gaps, trust, ethics, and coordination can limit its effectiveness (Vaccaro et al., 2024). Moreover, human decision making remains crucial given that AI often identifies correlations rather than causations.

Interdisciplinary, cooperative risk assessment processes should be designed to explicitly include – where appropriate - mechanisms for stakeholder engagement from the earliest stages, such as multi-sectoral workshops, participatory modeling sessions, or deliberative mapping exercises. Recent work further suggests that structured negotiation models can operationalize such integration by enabling iterative, evidence-based dialogue between technical experts, policymakers, and societal actors (Ehling-Schulz et al., 2024; Fetsch et al., 2025). Embedding negotiation-oriented frameworks within MRA could strengthen transparency, trust, and the translation of scientific evidence into adaptive food-safety governance.

CRediT authorship contribution statement

A. Fetsch: Writing – original draft, Visualization, Validation, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **I. Esteban Cuesta:** Writing – original draft, Investigation, Data curation. **M. Alinaghi:** Writing – review & editing, Methodology, Conceptualization. **M. Ehling-Schulz:** Writing – review & editing, Methodology, Conceptualization. **S. Johler:** Writing – review & editing, Supervision, Resources, Project administration, Methodology, Investigation, Funding acquisition, Data curation, Conceptualization.

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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.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.fm.2026.105081.

Data availability

Data will be made available on request.

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