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Systematic risk ranking of microbiological hazards in infant foods

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ABSTRACT

Ensuring food safety, particularly for vulnerable groups, like infants and young children, requires identifying and prioritizing potential hazards in food chains. We previously developed a web-based decision support system (DSS) to identify specific microbiological hazards (MHs) in infant and toddler foods through a structured five-step process. This study takes the framework further by introducing systematic risk ranking (RR) steps to rank MH risks with seven criteria: process survival, recontamination, growth opportunity, meal preparation, hazard-food association evidence, food consumption habits of infants and toddlers in the EU, and MH severity. Each criterion is given a semi-quantitative or quantitative score or risk value, contributing to the final MH risk calculation via three aggregation methods: semi-quantitative risk scoring, semi-quantitative risk value, and outranking multi-criteria decision analysis (MCDA). To validate the criteria and ranking approaches, we conducted a case study to rank MH risks in infant formula, compared the results of the three risk ranking methods, and additionally evaluated the ranking results against expert opinions to ensure their accuracy. The results showed strong agreement among the three methods, consistently ranking *Salmonella* non-Typhi and *Cronobacter* spp. and Shiga-toxin-producing *Escherichia coli* as the top MH risks in infant formulae, with minor deviations. When MHs were ranked after an initial hazard identification step, all three methods produced nearly identical MH rankings, reinforcing the reliability of the ranking steps and the selected criteria. Notably, the risk value and MCDA methods provided more informative MH rankings compared to the risk scoring method. The risk value and risk scoring methods were implemented into an online tool, called the MIcrobiological hazards risk RAnking decision support system (Mira-DSS), available at https://foodmicrobiologywur.shinyapps.io/MIcrobial_hazards_RAnking/. In conclusion, our framework enables the ranking of MH risks, facilitating intervention comparisons and resource allocations to mitigate MH risks in infant foods, with potential applicability to broader food categories.

1. Introduction

Microbiological hazards (MHs), such as pathogenic bacteria, viruses, or parasites can enter the food chain at various stages from production, processing, transportation, storage, and final meal preparation (WHO, 2015). They can originate either from natural environments, infected animals, human handlers, contaminated processing equipment/environment, or via the addition of potentially contaminated ingredients such as spices and herbs. Consumption of foods contaminated with MHs can lead to mild or even occasionally severe foodborne infections or poisoning in humans (ANSES, 2020; FDA, 2019).

Several well-known and notorious MHs include *Salmonella*, *Listeria monocytogenes*, pathogenic *Escherichia coli*, *Campylobacter, Clostridium botulinum, Bacillus cereus,* and Norovirus. However, these are not the only MHs that cause foodborne diseases in humans. There are more than 30 MHs reported in the United States as well as in the European Union, as summarized in Scallan et al. (2011) and Yeak et al. (2022, 2024).

In today's globalized society, MHs can swiftly traverse the food chain across borders (Garre et al., 2019). Their presence in food products still poses a substantial health risk to all consumers, but especially threatening vulnerable groups like infants and young children below the age of five as they accounted for one-third of all deaths from foodborne

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diseases (WHO, 2015) due to their less well-developed immune systems. The consequences of exposure for this group can result from mild discomfort to severe dehydration, systemic infections, and even death (WHO, 2015). Based on global estimates, young children (below the age of five) account for one-third of deaths from foodborne diseases (40 % of the total Disability-adjusted life year −DALYs), with a larger share of these statistics emanating from developing countries in Southeast Asia or Africa (Kirk et al., 2015; WHO, 2015). Notably, these numbers are lower for children below the age of five in Europe, accounting for ~ 27 % of DALY and 17 % of deaths. Albeit to a lesser extent, foodborne diseases still impact young children in Europe (Kirk et al., 2015; WHO, 2015). Therefore, for enhanced consumer safety, particularly for the vulnerable, it is of paramount importance to effectively control and mitigate MH risks within food supply chains. In this sense, the European Project SAFFI (Safe Foods for infants) focussed particularly on food safety for young children under the age of three (Engel et al., 2022; Yeak et al., 2022).

Mitigation of MHs risk in food chains requires a multifaceted approach, such as the implementation of good manufacturing and hygiene practices, the establishment of hazard analysis critical control points (HACCP), and the adherence to safe cooking and storage procedures. Integration of complementary methods, such as predictive microbiology and systematic approaches further enhances risk mitigation strategies (Allende et al., 2022). Moreover, conducting a thorough risk analysis or quantitative microbial risk assessment (QMRA) enriches the understanding of the potential hazards, and aids in devising more targeted and effective safety strategies (FDA, 2020; Majewski, 1992; Ronnie et al., 2012; Varzakas, 2016). Despite these strategies, the complete elimination of all MHs potentially present in a food product is impossible. To further support these processes of HACCP and QMRA, large data sources can be progressively used to help identify additional or new risks and evaluate if the relevant risks are sufficiently controlled. Integrating systematic approaches that harness such diverse databases into decision support systems (DSS) also enhances the effectiveness of risk management strategies.

Some examples of such systematic approaches are for instance Risk Ranger, a spreadsheet-based tool for food safety risk assessment (Ross and Sumner, 2002), the pathogen-produce pair attribution risk ranking tool (P3ARRT) for fresh produce (Anderson et al., 2011), a DSS to categorize MH risks in composite products (EFSA BIOHAZ Panel, 2012), the FDS-iRISK risk assessment system to evaluate and rank food hazards pairs (Chen et al., 2013), a model for ranking MHs in food of non-animal origin (FoNAO) (EFSA BIOHAZ Panel, 2013), multicriteria ranking of parasites (Devleesschauwer et al., 2017) and a systematic decision framework to rank MHs in scarce data setting (Crotta et al., 2022), and others are summarized by Bevilacqua et al. (2023). Additional approaches for the mitigation of chemical, microbiological, and physical risks are reviewed by Van der Fels-Klerx et al. (2018).

While existing systems for ranking MHs have proven useful, they primarily focus on individual food commodity groups (FoNAO /composite/ ready-to-eat foods) or only consider a few notorious MHs. This suggests a clear opportunity for expansion by including additional relevant MHs in different food categories. In our earlier work, we developed the Microbiological Hazards Identification (MiID) DSS to streamline the process of identifying MHs in foods for infants and young children through a structured five-step procedure (Yeak et al., 2024), found at https://foodmicrobiologywur.shinyapps.io/Microbial_hazards_ID/).

The objective of this study was to subsequently rank the identified MHs in foods intended for infants and young children using a quantitative data-driven approach. Eight risk ranking (RR) steps and seven criteria were defined and used to rank the MHs risks in infant foods, and results were compared between three risk aggregation methods. The risk ranking framework developed in this study is implemented into a web-based tool called Mira- **MI**crobiological hazards risk **Ra**nking, available at https://foodmicrobiologywur.shinyapps.io/MIcrobial_hazards_RAnking/.

2. Methods

2.1. Identification of microbiological hazards (MHs)

The 34 MHs reported to be the most relevant in infant food chains (Yeak et al., 2024) were included in this study. The identification of MHs using the MiID-DSS tool in selected food items adhered to the procedures as described in Yeak et al. (2024). Briefly, the hazard identification (HI) procedure involved five sequential steps: hazard-food pairing, process inactivation, recontamination, growth opportunity, and the selection of MH association level with a food item. However, the MiID-DSS output is qualitative and unranked. Therefore, we expanded the HI framework into an RR framework, which tailored the HI procedure to incorporate quantitative data, or semi-quantitative data when full quantitative data was unavailable, and included additional criteria for MHs ranking.

The RR procedure defined in this study works in tandem with the HI procedure implemented via the MiID-DSS (Yeak et al., 2024) to selectively rank only prioritized MHs out of the 34 most relevant MHs. However, if the HI procedure is not performed beforehand, the RR procedure includes all 34 MHs in the ranking.

2.2. Risk ranking (RR) framework

2.2.1. Risk ranking steps and criteria

The sequential steps within the HI procedure (Yeak et al., 2024) formed the basis for the RR framework. The HI-steps 1 to 4 aligned with RR-steps 1 to 4, covering hazard-food pairing, process inactivation (renamed to process survival in RR for examining residual risk post-processing), recontamination and growth opportunity. These steps remained the same for both frameworks, with HI being qualitative and RR semi-quantitative.

The RR framework expanded on the HI framework by introducing additional steps for quantitative risk ranking. Step 5 (meal preparation effect) assessed the extent of MH reduction by consumers at home, while step 6 (hazard-food association −HFA) examined MH prevalences in foods using four sources: 10 years outbreak prevalence data of an MH in the EU (6A) and USA (6B), food contamination prevalence data of an MH in given food products in the EU from 1980 to 2022 (6C) and in the USA from 2000 to 2022 (6D). These sources were qualitatively integrated with other sources to indicate MH presence in HI (i.e. hazard-food association) (Yeak et al., 2024) but utilized quantitatively in RR.

Furthermore, the RR framework introduced new quantitative measures in steps 7 and 8. Step 7 analyzed food consumption patterns among infants and toddlers within the EU, shedding light on potential MH exposure. Step 8 evaluated MH severity based on health impact, measured in DALY per case. These steps, along with steps 2–6, were then assigned either semi-quantitative or quantitative values for MH ranking, forming the RR criteria. To ensure consistency, steps 2 – 8 were labeled as criteria (C) 2–8 in the RR framework. Specifically, C2-C5 represents hazard-food characteristics (HFC), C6 denotes hazard-food association (HFA), C7 pertains to food consumption, and C8 signifies MH severity (Fig. 1).

2.2.2. Risk ranking knowledge rules

In addition to the defined criteria, RR knowledge rules were devised to guide the decision-making process for assigning appropriate semi-quantitative or quantitative values to each criterion within the respected decision tree. These rules were written based on the collected semi-quantitative or quantitative data in combination with food safety expert opinions. The explanation and implementation of the specific RR knowledge rules per criterion are elaborated stepwise in section 2.3. Adhering to these rules ensured a systematic and objective evaluation of the impact of different RR criteria, facilitating informed decision-making throughout the RR process. Moreover, the system can be further improved with additional knowledge rules when they become known in the future.

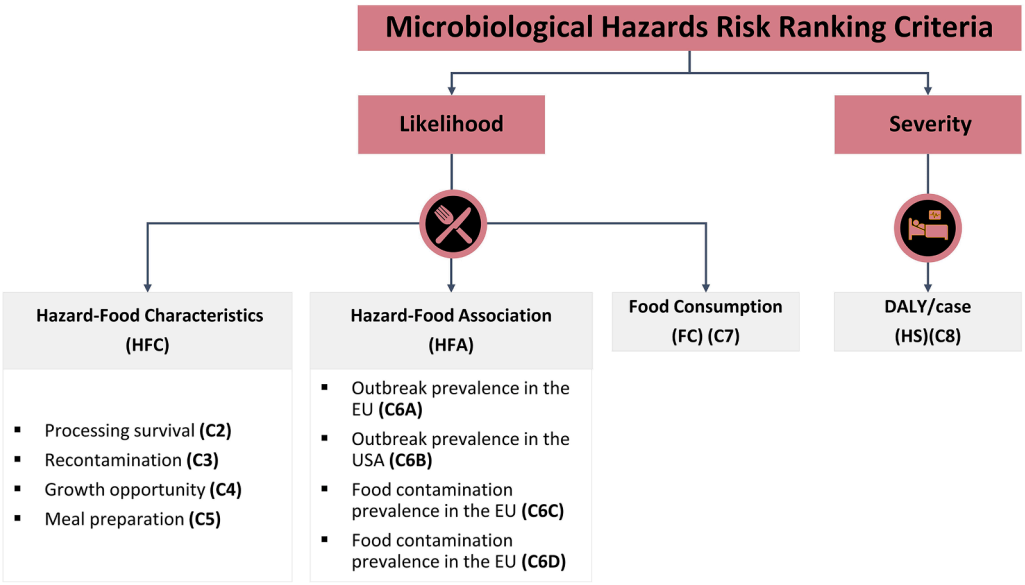

Fig. 1. Risk ranking criteria for microbiological hazards (MH). The risk of each MH was calculated based on the semi-quantitative data obtained for hazard-food characteristics (HFC), the quantitative prevalence (hazard-food association, HFA) and food consumption data (FC), and the quantitative severity data, expressed in Disability-Adjusted Life Years (DALY) per case.

2.2.3. *Risk ranking methods*

Using the RR criteria (Table 1) corresponding to the RR steps (see section 2.2.1) and knowledge rules (detailed in section 2.3), we employed three different risk-ranking methods to compare the risk-ranking outcomes in this study. These were **1)** semi-quantitative risk scoring; **2)** semi-quantitative risk value; and **3)** outranking multi-criteria decision analysis (MCDA) method. Both semi-quantitative risk scoring and risk values use equation (1) to calculate the total risk for all MHs while the MCDA outranking method used the preference ranking organization method for enrichment of evaluations (PROMETHEE) algorithm to aggregate total risk for each MH (see section 2.2.3.3). Step 1 is a yes/no criterion and not ranked, thus equation 1 does not have a C1 criterion.

Table 1
Risk ranking criteria and parameters.

Criterion	Group	Description	Parameter
C2	Hazard-Food Characteristic (HFC)	Food compositions and processing survival	Factory
C3[a]		Recontamination post-processing	
C4		Growth opportunity based on food composition, storage, distribution, and retail conditions	Distribution and Growth
C5		meal preparation by consumers at home	Consumer
C6[n]	Hazard-Food Association (HFA)	Outbreak C6A: Ten years of foodborne outbreak data in the EU C6B: Ten years of foodborne outbreak data in the USA Food contamination C6C: Food contamination and recall data in the EU from 1980 to 2022 C6D: Food contamination and recall data in the USA from 2000 to 2022	Prevalence
C7	Food consumption (FC)	Food consumption of infants and toddlers in the EU	Consumption
C8	Hazard Severity (HS)	DALY/case	Severity
Optional		Include hazard with no/low evidence	

[a] addition of risk values from all possible recontamination categories. [n] = 4. Refers to the total number of sources C6A-C6D used in this study. To maintain consistency, each criterion number corresponds to its respective RR step, as described in section 2.2.1.

$$\textbf{Total Risk} = (\mathbf{C2}+\mathbf{C3})^{*}\mathbf{C4}^{*}\mathbf{C5}^{*}(\mathbf{C6A}^{*}\mathbf{C6B}^{*}\mathbf{C6C}^{*}\mathbf{C6D})^{\frac{1}{n}}{}^{*}\mathbf{C7}^{*}\mathbf{C8} \quad (1)$$

All factors were multiplicative except C2 and C3 which followed the addition of risk values from all possible recontamination categories. n = 4 refers to the total number of four sources used in this study to quantify the prevalence of an MH. Details are listed in Table 1.

2.2.3.1. Semi-quantitative risk scoring. In the risk scoring method, each criterion (Table 1) was assigned a risk score based on different categories of the severity and likelihood of the occurrence of MHs in foods. Scores were assigned for each MH based on the scoring level and description in Table 2, and the total risk scores were calculated using Equation (1).

2.2.3.2. Semi-quantitative risk values. In the framework of the semi-quantitative risk values method, any available quantitative data was utilized. For criteria lacking such data, the method allowed for the estimation of semi-quantitative risk values. These estimates derived from available data and the collective knowledge of food safety experts, represented the most plausible probabilities. This method served as a preliminary step toward achieving a comprehensive quantitative ranking of all RR criteria. As more quantitative data becomes accessible in the future, these initial estimates can be refined or replaced to ensure ongoing relevance and accuracy. However, it is important to note that these values do not accurately represent the exact probability of encountering each particular MH. Their primary use is for making relative comparisons within this risk ranking model, rather than providing precise probabilistic predictions.

This approach is similar to the Risk Ranger tool (Ross and Sumner, 2002), but integrates a larger volume of quantitative data across similar criteria. Importantly, it also included additional epidemiological data to enhance its precision. The total risk in this approach was calculated using the same Equation (1) as the risk scoring method, utilizing

Table 2
Description of the risk scoring system for all risk ranking criteria.

Criterion	Score level	Score Description
C2-Process survival	1	very unlikely to survive after processing, inactivation of at least 12 log
	2	unlikely to survive after processing, inactivation of at least > 5 log
	3	inactivation of less than 5 log
	4	not inactivated, or minimal inactivation of < 2 log
C3- Recontamination	0	no risk of recontamination (closed bag processing)
	1	very low risk of recontamination (0.05 %)
	2	low risk of recontamination (0.5 %)
	3	medium risk of recontamination (5 %)
	4	high risk of recontamination (50 %)
C4- Growth opportunity	1	low risk- growth of hazards in foods is needed to cause illness, butthe food composition does not support growth, or food composition supports growth, but foods were stored in refrigeration OR freezing conditions, with no potential temperature abuse
	2	medium risk- growth of hazards in foods is needed to cause illness, food composition supports the growth and storage in refrigeration conditions but with potential temperature abuse
	3	high risk- growth of hazards in foods is not needed to cause illness, or hazard needs to grow to cause illness and the food composition support the growth
C5- Meal preparation	1	Cooking of > 70 °C in the whole product
	2	Cooking of < 70 °C in a proportion of the product
	3	Ready-to-eat foods
C6- Hazard food association	1	not reported
	2	very low prevalence < 1 %
	3	low prevalence 1 % − < 10 %
	4	medium prevalence 10 % − < 40 %
	5	high prevalence ≥ 40 %
C7- Food consumption	1	not reported
	2	< 1 % of infants and toddlers consume the selected food
	3	1 % − < 10 % of infants and toddlers consume the selected food
	4	10 % − < 40 % of infants and toddlers consume the selected food
	5	≥ 40 % of infants and toddlers consume the selected food
C8- Hazard severity	1	low impact hazard, with DALY/case < 0.05
	2	medium impact hazard, with DALY/case 0.05 − < 0.5
	3	severe impact hazard, with DALY/case 0.5 − < 5
	4	critical impact hazard, with DALY/case ≥ 5

identical RR criteria and parameters (see Table 1). The assignment of risk values to each criterion for every MH was based on a devised decision tree and RR knowledge rules, elaborated in detail in section 2.3.

2.2.3.3. Multi-Criteria decision analysis (PROMETHEE). As a comparison, the outranking MCDA PROMETHEE method was used to calculate the total risk for each identified MH using the above-mentioned RR criteria (Table 1). The PROMETHEE method was developed by Brans and Vincke (1985) and Brans et al. (1986), involves performing pairwise comparisons among all the alternatives (Membré, 2014). This method has recently been used in food safety (Eygue et al., 2020; FAO, 2017; Palmont et al., 2023). PROMETHEE ranks MHs using the Phi (ϕ) score, ranging from −1 to 1. A negative Phi score (ϕ -) indicates an MH was outperformed by others on one or more criteria, while a positive Phi score (ϕ +) means it outperformed others on one or more criteria. If an MH scores −1 or + 1, this indicates that it is systematically outclassed by all others or outperforms all others, respectively. The final score is the sum of ϕ + and ϕ -.

To perform the ranking of MHs based on their risk values (not risk scores), specific parameter settings per criterion, as justified in Table 3, were employed on each MH. This calculation was performed using the PROMETHEE package version 1.1 (Ishizaka et al., 2018) within R (version 4.2.3) (R Core Team, 2023). The indifference and preference thresholds were established to assess the significance of differences across criteria. For this analysis, the V-type preference function was selected, showcasing a linear relationship between the differences in hazard values and their impact on the criteria. Under this preference scheme, moderate hazard levels were deemed less preferable, meaning options that have moderate (neither high nor low) values for the relevant criteria were less preferred compared to those with values that are either very high or very low. The applied settings aimed to produce a ranking where the highest ϕ score indicated the most significant risk.

2.3. Implementation of risk ranking knowledge rules per ranking criterion Hazard-Food characteristics (HFC)- criteria 2–5

The likelihood of MHs occurrence in foods was estimated based on the efficacy of process inactivation i.e., the chance of MH survival after food processing (C2), the recontamination based on environmental factors and food handling (C3), the post-processing control based on the growth opportunity of MH in foods of different compositions (pH and water activity a_w), and the storage, distribution and retail conditions (C4) and lastly, the meal preparation effect (C5), i.e., inactivation of MHs during the home-cooking process.

2.3.1. Criterion 2: Processing survival

Processing survival refers to MH survival after food processing. Greater process efficacy means lower MH survival chances, and vice versa. This efficacy is influenced by food compositions listed in Table 4, which can either increase or decrease the risk for MH. In instances where a food item exhibits multiple relevant compositions from Table 4, the component that resulted in the highest risk value in C2 is taken. The food items included in this study are based on the FoodEx2 scheme as defined by EFSA (Supplementary Table S1).

In this study, the chance of MH survival was examined based on seven MH inactivation groups as described in Yeak et al. (2024). These are Hazard Groups 1–3 (vegetative bacteria, non-heat resistant viruses, and vegetative parasites), Hazard Group 4 (parasite cysts), Group 5 (heat-resistant viruses and heat-labile toxins), Group 6 (bacterial spores), and Group 7 (bacterial toxins). The MHs were grouped based on the time required to achieve one log reduction (*D*-value) under different temperatures (Supplementary Table S2A). The inactivation of these MH groups was derived based on the logD values and the thermal processing conditions as shown in Table 5 below (processing time and temperatures used were as described in Yeak et al. (2024), and the RR knowledge rules below. The standard procedures described for thermal processing are illustrated in Fig. 2. Semi-quantitative risk values representing the chances of survival of the seven MH groups were derived (see Table 5 and Supplementary Table S2) based on the logD values reported for MHs (Supplementary Table S2A), and the scientific literature mentioned below. These risk values represent the best estimated MH survival probability based on the thermal inactivation data and food safety expert knowledge of MH inactivation.

2.3.1.1. RR knowledge rule Process Survival 1: No treatment. No processing leads to no MH inactivation, and thus the chance of MH survival is high, with an estimated probability value of 1 (Fig. 2, Table 5).

2.3.1.2. RR knowledge rule Process Survival 2: pasteurization, boiling, and sterilization. Pasteurization: All vegetative bacteria, non-heat-resistant viruses, and vegetative parasites are inactivated by at least 6 log. Parasite cysts are slightly more heat resistant than vegetative parasites

Table 3
Parameters used to run PROMETHEE II on R Software.

Parameters	C2 + C3	C4	C5	C6	C7	C8	Justification
Indifference	0	0	0	0	0	0	The indifference threshold is zero as the criteria values are considered real numbers (without uncertainty).
Preference	$2.5 \cdot 10^{-5}$ [a]	1 [b]	1 [c]	0.056 [b]	0.47 [c]	8.47 [b]	The preference threshold reflects where a difference between 2 scores makes a real added value in the decision.
Type of preference	V-shape	V-shape	V-shape	V-shape	V-shape	V-shape	"V-shape" to generate a proportional preference.
Weight	1/6 [d]	1/6 [d]	1/6 [d]	1/6 [d]	1/6 [d]	1/6 [d]	We assume that the 7 criteria had the same weight on the final risk.

a: To establish the preference values, our first choice was to take the difference between the 75th and 25th percentiles of the values of hazards for the given criterion.
b: When the difference between the 75th and 25th percentiles was low (difference lower than 5% of the maximum values of the hazards for the given criterion), we choose the difference between the penultimate and the second percentiles.
c: When the criterion values were the same across all hazards, the constant value was used in the analysis.
d: In PROMETHEE, C2 + C3 is considered as one criterion as their combined effect provides a more comprehensive assessment of the risk posed by the hazard. As a result, the combined criterion is weighted as 1/6 of the total, rather than being treated separately as 1/7 each.

Table 4
Food composition that influences microbiological hazard inactivation or growth opportunity in foods.

Food composition	Influence on hazard inactivation efficiency	Influence on growth opportunities
High fat	Negative	
Low a_w (0.80 – 0.90)	Negative	
Dry product ($a_w < 0.5$)	Negative	
pH < 4.5		Negative
4.5 ≤ pH ≤4.8		Negative
pH ≥ 10		Negative
Neutral pH		None

(Franssen et al., 2019; Gérard et al., 2019; Mirza Alizadeh et al., 2018) and thus are estimated to be inactivated for at least 5 log. Heat-resistant viruses such as Hepatitis A, Hepatitis E, Rotavirus, and some genotypes of Norovirus are estimated to only have 3 log reduction under pasteurization conditions based on reported reduction values in literature (Butot et al., 2009; Bosch et al., 2018; Bozkurt et al., 2021; Miranda and Schaffner, 2018; Patwardhan et al., 2020; Roos, 2020;). Bacterial spores and heat-stable bacterial toxins are not inactivated by pasteurization (den Besten et al., 2018; Eijlander et al., 2019; Necidová et al., 2019; Tsutsuura and Murata, 2012; Wells-Bennik et al., 2016), thus the estimated probability of survival equals 1.

Boiling: Thermal treatment at 90 °C-100 °C for 2–5 min, or 90 °C for 10 min is sufficient to inactivate all MH groups for about 10 log except for bacterial spores and heat-stable bacterial toxins (Ceylan et al., 2021; EFSA Panel on Biological Hazards (Biohaz), 2015; van Asselt and Zwietering, 2006;), which may only be partially inactivated for about 3 log. Thus the estimated probability of MH survival ranges from 10^{-3} to 10^{-10} (Fig. 2, Table 5).

Sterilization: Thermal treatment at 100–121 °C for 20 min, or 121 °C for 3 min (spores inactivation) (Ceylan et al., 2021; FAO and Codex Alimentarius, 2007) or > 135 °C for 3–5 s inactivates all MH groups for at least 12 log and the estimated probability of MH survival ranges from 10^{-12} to 10^{-20} (Fig. 2, Table 5).

2.3.1.3. RR knowledge rule Process Survival 3: food composition effect. High-fat and dry foods decrease the inactivation efficacy of MH in thermal processing (Ceylan et al., 2021; Liu et al., 2022). In this study, about 2 log lower reduction was estimated based on food safety expert knowledge for the same processing condition in high-fat and dry foods (Fig. 2, Table 5).

2.3.2. Criterion 3: Recontamination

The recontamination of MHs after food processing can occur via environmental routes and/or food handling. The 34 MHs were categorized into 5 recontamination categories, which are MHs associated with wet environments, MHs associated with dry environments, MHs associated with dry herbs and spices, MHs associated with other dry ingredients and MHs associated with humans (Supplementary Table S3). The estimated semi-quantitative risk values were assigned based on the devised decision tree (Fig. 3), representing the best-estimated recontamination probability based on collective food safety expert opinions. The total recontamination risk is then derived by summing the risk values from all relevant recontamination categories.

2.3.2.1. RR knowledge rule Recontamination 1: processing in closed bags. Processing of foods in sealed environments or closed bags refers to zero risk of recontamination (Fig. 3). Nonetheless, the value 0 in this criterion merely implies that the recontamination risk (C3) is excluded from the total risk calculation (equation (1), and will not be used to multiply with risk values in other criteria.

Table 5
Survival probability of seven microbiological hazard groups post-processing.

	No treatment [a]	Thermal processing [b]			Thermal processing in high fat/dry foods [c]		
Hazard group	**No inactivation**	**Pasteurize**	**Boil**	**Sterilize**	**Pasteurize**	**Boil**	**Sterilize**
1. Vegetative bacteria	1	10^{-6}	10^{-10}	10^{-20}	10^{-4}	10^{-8}	10^{-18}
2. Non-heat-resistant viruses	1	10^{-6}	10^{-10}	10^{-20}	10^{-4}	10^{-8}	10^{-18}
3. Vegetative parasites	1	10^{-6}	10^{-10}	10^{-20}	10^{-4}	10^{-8}	10^{-18}
4. Parasite cysts	1	10^{-5}	10^{-10}	10^{-20}	10^{-3}	10^{-8}	10^{-18}
5. Heat-resistant viruses and heat-labile toxins	1	10^{-3}	10^{-10}	10^{-20}	10^{-1}	10^{-8}	10^{-18}
6. Bacterial spores	1	1	10^{-3}	10^{-12}	1	10^{-1}	10^{-10}
7. Heat-stable bacterial toxins	1	1	10^{-3}	10^{-12}	1	10^{-1}	10^{-10}

[a] No treatment thus high chance that microbiological hazard survive
[b] Thermal processing with low fat and/or liquid foods, low chance that microbiological hazards survive
[c] Thermal processing with high fat and/or dry foods, medium chance that microbiological hazards survive

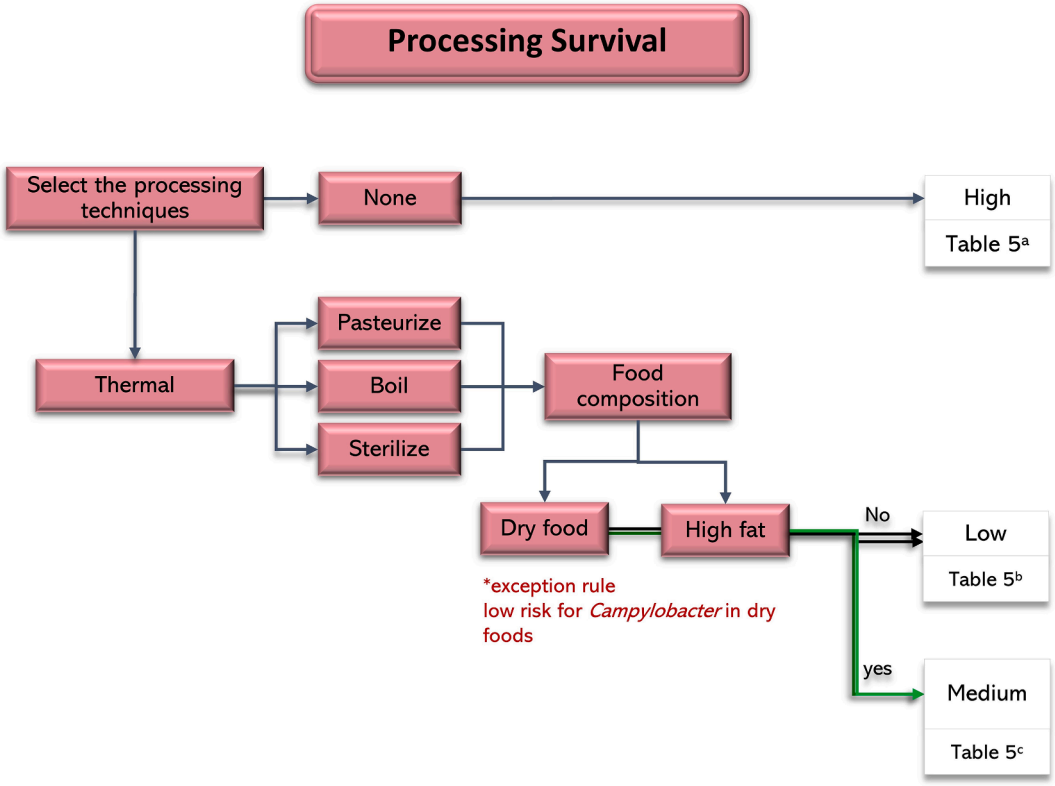

Fig. 2. Microbiological hazards survival based on selected processing techniques and food compositions. Green arrow- yes; black arrow- no. High[a], low[b], and medium[c] refer to the chance of microbiological hazard survival based on the different processing conditions listed in Table 5. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

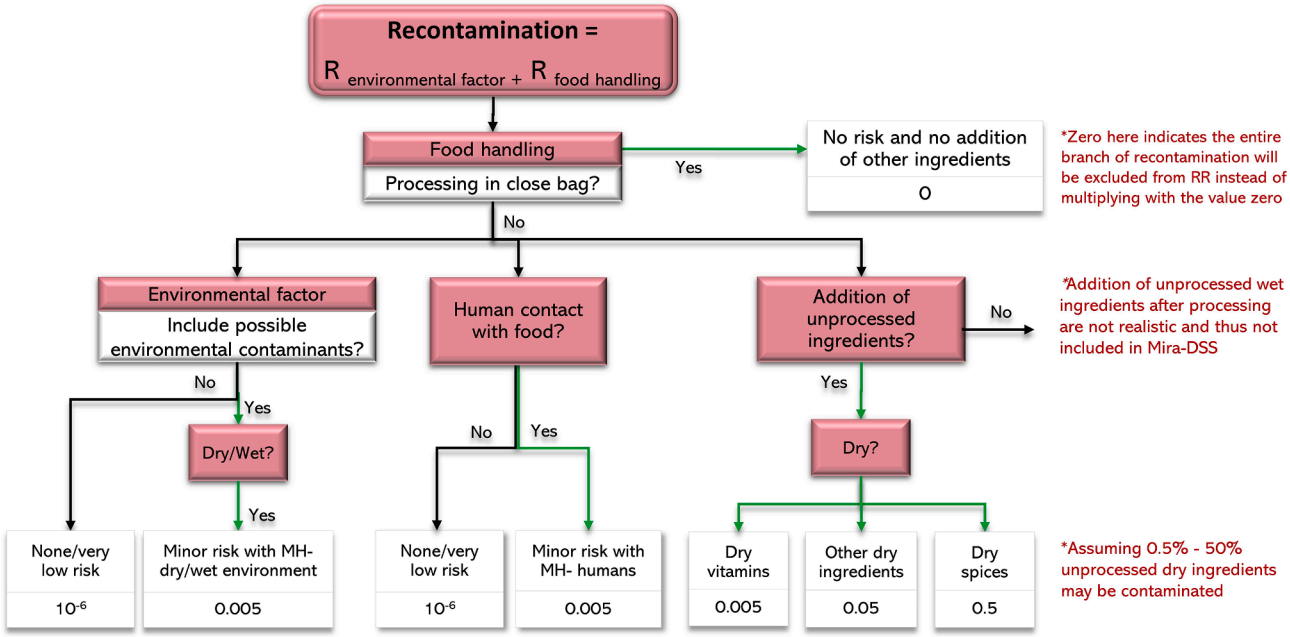

Fig. 3. Recontamination from processing environment, food handling during processing and addition of unprocessed ingredients. Green arrow- yes; black arrow- no. The addition of wet unprocessed ingredients in processed foods was not included as an option in the Mira-DSS. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

2.3.2.2. RR knowledge rule Recontamination 2: environmental and human contaminants. If environmental contaminants were deemed irrelevant, a small risk value of 10^{-6}, representing the estimated probability via expert knowledge was assigned for all MHs. If environmental contaminants were deemed relevant, an estimated risk value of 0.005 (representing the estimated probability) was assigned to MHs associated with either dry or wet processing environments (See Supplementary Table S3). This was based on the assumption that 0.5 % of food products

would be recontaminated by the respective environmental contaminants. Similarly, if there was human contact with foods, MHs with human association (*S. aureus,* Norovirus, and Hepatitis A) (ANSES, 2020; Bintsis, 2017), were estimated to have a risk value of 0.005 by food safety experts, assuming 0.5 % of food products could be recontaminated via human carriers.

2.3.2.3. RR knowledge rule Recontamination 3: addition of unprocessed dry or wet ingredients. The addition of different types of unprocessed dry ingredients poses different risks. Dry herbs and spices usually have high microbial contamination levels (FAO and WHO, 2022), likely due to minimal processing, and can come from various regions of the world. Other dry ingredients such as flour or powders are usually associated with contamination in raw agricultural products, such as *Salmonella* spp. and pathogenic *E. coli* (Ardent Mills, 2019; Eglezos, 2010; Forghani et al., 2019), but typically less contaminated than herbs and spices, whereas dry vitamins are relatively clean compared to the previous two (Tournas, 2009). Based on the literature and food expert knowledge, the risk values (estimated probability) for dry herbs and spices are estimated to be 0.5 (assuming 50 % of unprocessed herbs and spices were contaminated), 0.05 for general dry ingredients (assuming 5 % of unprocessed flours or powders were contaminated) and 0.005 for vitamins (assuming 0.5 % of unprocessed vitamins were contaminated) (Fig. 3, see Supplementary Table S3).

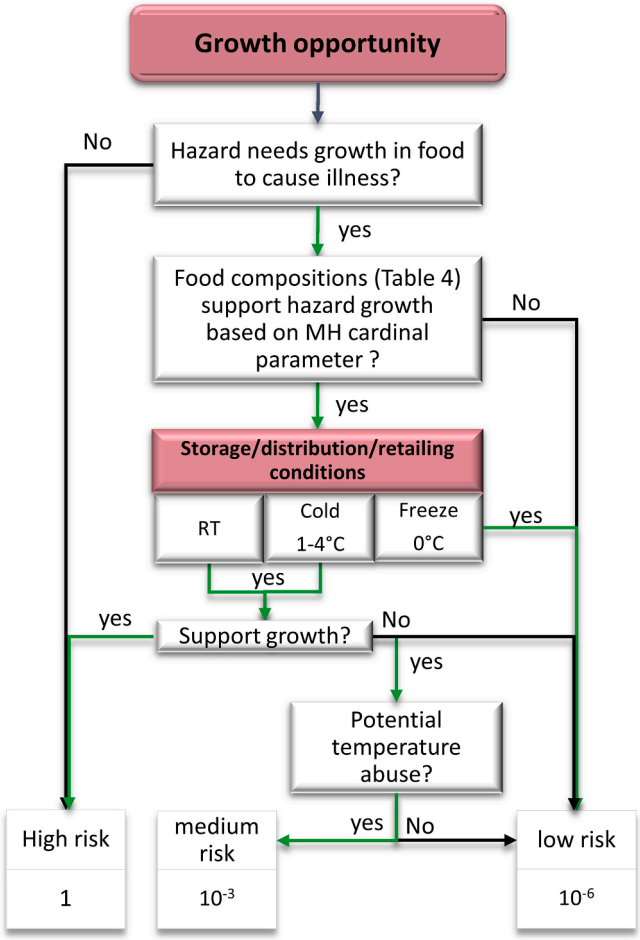

Fig. 4. Growth opportunity of microbiological hazards. Based on the growth opportunity, food composition and the storage, distribution and retailing conditions. RT indicates room temperature. Green arrow- yes; black arrow- no. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

2.3.3. Criterion 4: Growth opportunity

The growth opportunity of MHs in foods was analysed using a decision tree (Fig. 4), devised based on different scientific literature and written RR knowledge rules (references provided under specific RR rules below). Whether MHs could grow in a selected food item was based on the considerations of food composition factors, such as pH, water activity (a_w) (see Table 4), storage, distribution, and retail conditions, along with known cardinal parameter data for MHs (Supplementary Table S4A).

2.3.3.1. RR knowledge rule growth opportunity 1: High-risk microbiological hazards. Viruses, parasites and infectious bacteria *Brucella* spp., *Campylobacter* spp., *Mycobacterium bovis, Salmonella* spp., *Shigella* spp., and *Yersinia enterolitica* do not require growth in food to cause illness (Adams et al., 2015; FDA, 2019; Stella et al., 2013), and were assigned with the risk value of 1 (= estimated probability of 1) regardless of whether they would be able to grow or not in/on the product. *Cronobacter* spp. is also added as a high-risk MH as it causes severe illness for infants below the age of 6 months (Muytjens et al.,1983; Reij et al., 2009). For MHs that require growth in food (*Aeromonas caviae*, *Bacillus cereus, Clostridium botulinum, Clostridium pefringens, Listeria monocytogenes, Staphylococcus aureus*, and *Vibrio* spp. to cause illness (Adams et al., 2015; FDA, 2019; Stella et al., 2013) or to produce toxins, and which can grow in foods (based on selected compositions in the food composition column listed in Table 4 and cardinal parameter data (Supplementary Table S4A), and transported at room temperature have also a risk value of 1. (Fig. 4, see details in Supplementary Table S4).

2.3.3.2. RR knowledge rule growth opportunity 2: Low-risk microbiological hazards. MHs that require growth in food but cannot grow in foods (based on selected composition in Table 4), or MHs that can grow in foods but are transported under refrigeration or freezing conditions with no possibility of temperature abuse are considered to be in very well-controlled condition post-processing and thus possess low-risk (International Commission on Microbiological Specifications for Foods (ICMSF), 2005; Adams et al., 2015; ANSES, 2020, 2022) (see Supplementary Table S4A). A small risk value of 10^{-6} was estimated, assuming that an MH may be uncontrolled in a 1 per million chance (Fig. 4, see details in Supplementary Table S4).

2.3.3.3. RR knowledge rule growth opportunity 3: Medium-risk microbiological hazards. MHs that require growth in food to cause illness (Adams et al., 2015; FDA, 2019; Stella et al., 2013), and can grow in foods (based on selected composition in Table 4 and cardinal parameter data in Supplementary Table S4A), but are transported at low temperatures (1 °C – 4 °C) with the possibility of temperature abuse during transport, were estimated to have a medium risk value of 0.001 (Fig. 4, details in Supplementary Table S4). This estimation was based on the assumption from food safety experts that 0.1 % of these MHs may be uncontrolled in foods post-processing.

2.3.3.4. RR knowledge rule growth opportunity 4: Exception for MHs. *Vibrio* spp. includes *V. cholerae*, *V. parahaemolyticus*, and *V. vulnificus.* They have similar maximum growth temperatures at about 43 °C, but the minimum growth temperatures are 10 °C, 5 °C and 8 °C, respectively. *V. parahaemolyticus* is also an exception in which the recorded minimum pH that supports growth is 4.5, and the minimum a_w is 0.94 (Supplementary Table S4A). In this study, the most stringent cardinal values were used for *Vibrio* spp. (Supplementary Table S4).

2.3.4. Criterion 5: Meal preparation

The meal preparation by consumers at home determines whether the MHs in foods (if not fully inactivated via processing or came in as contaminants) would be further inactivated. If no meal preparation was involved i.e., ready-to-eat foods, no MHs were further inactivated, thus

Table 6
Inactivation of microbiological hazards during meal preparation.

Hazard group	Ready to eat	Cooking < 70 °C	Cooking > 70 °C
1. Vegetative bacteria	1	0.01	0.0001
2. Non-heat-resistant viruses	1	0.01	0.0001
3. Vegetative parasites	1	0.01	0.0001
4. Parasite cysts	1	0.1	0.001
5. Heat-resistant viruses and heat-labile toxins	1	1	0.01
6. Bacterial spores	1	1	1
7. heat-stable bacterial toxins	1	1	1

all MH groups retained a risk value of 1 (Table 6). If heating processing was done at home, such as cooking above 70 °C (e.g., for ready-to-heat foods), the risk values estimated for each MHs group followed the same logic as presented for C2. However, as this step is not as tightly controlled as food processing by industry, the inactivation effects were presumed to lead to a reduction of about 4 logs, which is lower than the reductions reported for C2 (Table 6). Cooking at > 70 °C mainly inactivates MH groups 1–3 with estimated risk values of 0.0001, while MH groups 4 and 5, which are more heat-resistant, have estimated risk values of 0.001, and 0.01, respectively (Table 6, details in Supplementary Table S5). Bacterial spores (group 6) and heat-stable bacterial toxins (group 7) were estimated with a risk value of 1 as they are likely not inactivated under the same conditions. Minimal heating processes at < 70° result in even lower MH reduction effects, and thus the estimated risk is higher and assumed to be at 10^{-2} to 1 (Table 6).

2.3.5. Criterion 6: Hazard-Food association

As stated in section 2.2, the branch of HFA (C6) incorporated different types of MH prevalence data in a given food product into the RR process. The term "prevalence" refers to how often an MH contaminated foods and caused foodborne outbreaks or food recalls. In this study, the outbreak and food contamination prevalence data were collected via four different sources (see Table 1) and were used to quantify the prevalence per MH in given food products.

2.3.5.1. Hazard-outbreak prevalence. Data spanning 10 years (2011–2021) on outbreaks caused by MHs in various food product categories in the European Union was gathered in **6A** using the One Health Zoonoses report issued by the European Food Safety Authority (EFSA) (European Food Safety Authority and European Centre for Disease Prevention and Control (EFSA and ECDC), 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2021, 2022a, 2022b). These data are also available at the EFSA foodborne outbreaks dashboard, https://www.efsa.europa.eu/en/microstrategy/FBO-dashboard. In addition to the data from the EU, outbreak information in the United States **(6B)** from 2008 to 2018 was also collected. This data was sourced from two platforms: a list of multistate foodborne outbreaks provided by the Centers for Disease Control and Prevention (CDC), which can be accessed at https://www.cdc.gov/foodsafety/outbreaks/lists/outbreaks-list.html. These data are also available at the National Outbreak Reporting System (NORS) dashboard, https://wwwn.cdc.gov/norsdashboard/ (Data collected in 2021). To determine the prevalence of an MH in a specific food product category, the total number of outbreaks caused by the specific MH in that category was divided by the total number of outbreaks caused by all MHs reported for the same category over the 10 years (Supplementary Table S6, S6A-S6D).

2.3.5.2. Hazard-food contamination prevalence. Food recall data due to MH contamination in the EU from 1980 to 2021 **(6C)** was collected from the Rapid Alert Food and Feed portal (RASFF) (RASSF portal, 2022, data collected up to March 2021) and the RASFF annual reports (RASFF, 2020, 2021). Food recall data due to MH contamination in the United States from 2007 to 2022 **(6D)** reported by the Food Industry Council were collected from the database available at https://www.foodindustrycounsel.com/recalls/. Similarly, to determine how frequently a specific MH contaminates a food category, the number of product recalls due to that MH was divided by the total recalls caused by all MHs in that food category (Supplementary Table S6, S6A-S6D).

The MH prevalence risk values were derived from all collected data (6A-6D) by taking the 4th root of the product of all evidence, as described in Equation (1) (where n = 4 is used in this study, explained in section 2.2.3). The calculated risk values represented the estimated likelihood that an MH was associated with the food products. The root was used to achieve an average value for the prevalence data, ensuring a balanced representation of the overall risk. For MHs without any reported evidence, a conservative risk value of 10^{-6} was applied to give the minimal risk estimation that there is a one per million chance of the unreported MH being associated with the respective food product.

2.3.6. Criterion 7: Food consumption of infants and toddlers

Food consumption data reflects the eating habits of infants and toddlers (0 to 3 years) in the EU. The frequency of their consumption of certain foods correlates with the risk of exposure to MHs associated with those foods. Therefore, incorporating this data helps to assess the potential risk posed by MHs in relation to the consumption habits of the target population.

The Comprehensive Food Consumption Database (accessed in February 2022) (https://www.efsa.europa.eu/en/microstrategy/food-consumption-survey) provided extensive data on food consumption throughout the EU. Data from 29 EU-wide surveys were analysed to obtain consumption data (in grams per day) for infants and toddlers based on the FoodEx2 hierarchy. The consumption frequency of each product by infants and toddlers was quantified by dividing the total number of infant and toddler consumers of a given food product by the total number of subjects in each survey. The average consumption was determined by the mean consumption figures obtained from all 29 surveys, and the average ratio was used as the risk value, serving to represent the estimated probability of infants and toddlers being exposed to MHs associated with the respective food products (Supplementary Table S7-S7A). However, it is crucial to recognize that these averages varied across the broader 0–3 year age range due to evolving dietary preferences and consumption patterns as children progress through developmental stages. For instance, ~ 20 % of infants aged 0–1 year consumed Infant formulae, and this percentage became ~ 7 % when accounted for infants and toddlers up to 3 years (Supplementary Table S7-S7A).

2.3.7. Criterion 8: Hazard severity

Risk, as defined by the Codex Alimentarius, evaluates the likelihood and severity of health impacts caused by food hazards (CAC, 2001). All previous aspects are related to the likelihood of the hazards resulting in negative impacts. One way to measure the severity of health impacts is through the Disability-Adjusted Life Year (DALY), a metric used to quantify the global health burden caused by diseases or injuries. It takes into account the number of years of healthy life lost due to premature death or disability caused by a particular hazard (WHO, 2015) and captures all dimensions of public health outcomes in one metric.

In this study, the hazard severity of all 34 MHs was assessed using DALY/case as a measure. The reported global DALYs of all 34 MHs for global foodborne diseases were used (WHO, 2015) (Supplementary Table S8), except for MHs that lacked data and were not included in the WHO report. These were *Cronobacter* spp., *Yersinia* spp., *Cyclospora cayetanensis*, *Aeromonas* spp., and viruses (Astrovirus, Rotavirus, Flavivirus, Hepatitis E, and Sapovirus). For these listed MHs in which DALY was not available, other literature sources were used to calculate or estimate the DALY/case as presented below.

Notably, the DALYs per case used in this study represented global figures, which differed from those specific to the EU region (from equal up to ~ 3 times higher globally than in the EU). However, the decision to

use global DALY data was intentional to ensure a more comprehensive and adaptable approach to hazard severity assessment as the adoption of global DALYs/case ratios would not impact the relative ranking of MHs within the study framework.

2.3.7.1. Calculation of DALY/case for unreported MHs by WHO. The estimated DALY for *Cronobacter* spp. in the Netherlands was reported to be 19–24 per year (Reij et al., 2009). An average number of 22 was taken. The number of cases per year used in the DALY estimation was 8, so the DALY/case was estimated to be ~ 2.75 for this organism. For *Yersinia* spp., the DALY and the number of foodborne cases from Denmark in 2017 were used (Monteiro Pires et al., 2020), and the calculated DALY/case was 0.452 (Supplementary Table S8A).

C. cayetanensis is an intestinal parasite that infects the human small intestine, causing symptoms like watery diarrhoea. It can last for weeks or months if left untreated (Almeria et al., 2019; Ortega and Sanchez, 2010), and the effect was estimated to be similar to illnesses caused by *Cryptosporidium* and *Giardia* spp. Hence, its disability weight, a measure of disease severity, was assumed to match that of *Cryptosporidium* or *Giardia* spp., which is 0.074 (WHO, 2015). Subsequently, the Years Lived with Disability (YLD) were calculated using the number of incident cases (548) reported in the United States (see section 2.3.5), multiplied by the disability weight (0.074) and the duration of disability (approximated to one month or 0.08 years), and YLD was found to be 3.2. The Years of Life Lost (YLL) is zero since there were no reported deaths caused by *C. cayetanensis*. Thus, the estimated DALY is ~ 3.2 and DALY/case is ~ 0.006 (Supplementary Table S8A).

Aeromonas spp. like *Aeromonas caviae* and *Aeromonas hydrophila* are opportunistic foodborne pathogens that are present in various foods and mainly associated with aquatic environments (Daskalov, 2006; Pal et al., 2020). It can cause serious infection in the vulnerable population, especially children, the elderly, and the immunocompromised. Symptoms included diarrhoea, nausea, and gastroenteritis (ANSES, 2020; Public Health Agency of Canada, 2012). To the best of our knowledge, there were no recorded fatalities associated with this MH, leading to an estimated YLL of zero. For YLD, seven confirmed cases were reported in the EU in 2017 (EFSA and ECDC, 2019) with no cases in other years. The disability weight for moderate diarrhoea agent (0.154) was taken (WHO, 2015), and the duration of disability was estimated to be 5 days, resulting in a YLD of 0.015. The DALY/case is ~ 0.002 (Supplementary Table S8A).

For viruses, data from the Netherlands in 2011 was used to estimate DALY/case (Mangen et al., 2015). The calculation of the DALY per case followed the same logic as aforementioned, and details for the calculation are presented in Supplementary Table S8 and S8A. The calculated DALY/case for Astrovirus, Rotavirus, and Sapovirus was 0.005, for Hepatitis E was 0.434, and for Flavivirus (usually associated with milk products (Hennechart-Collette et al., 2022)) was 0.002.

2.3.8. Optional filter based on additional evidence

As described in section 2.1, the RR approach in this study begins with an initial HI step using the MiID-DSS (Yeak et al., 2024) to rank prioritized MHs from a pool of 34. However, if this step is skipped, all 34 MHs were considered. In such cases, an optional filter can be applied based on additional evidence to exclude MHs with minimal association with the selected food products. The association evidence for MHs in food categories was obtained from various sources, including EU Commission regulations (Commission Regulation, 2005), outbreak statistics and food contamination incidents in the EU and USA (European Food Safety Authority and European Centre for Disease Prevention and Control (EFSA and ECDC), 2022b; RASSF portal, 2022; White et al., 2022) and literature describing relevant food reservoirs and/or vehicles for MHs (ANSES, 2020; Adams et al., 2015; FDA, 2019; Public Health Agency of Canada, 2012). Each hazard-food pair was evaluated based on the total number of counts, with 0 counts indicating no association, 1 to 2 counts considered low association, 3 counts indicating medium association, and 4 to 5 counts classified as high association strength. This data allows for the optional exclusion of MHs with minimal supporting evidence (0–2 association counts) from the final RR procedure (see Supplementary Table S9).

2.4. Microbiological hazards ranking (Mira) tool development

The RR criteria and procedures outlined in sections 2.1 to 2.3 were implemented into a user-friendly online prototype (The **Mi**crobiological Hazards **Ra**nking **D**ecision **S**upport **S**ystem) to facilitate the RR of MHs in various foods for infants and children up to the age of three. Two of the three RR methods mentioned in section 2.2.3 (the semi-quantitative risk scoring and risk value) were included in the Mira DSS and were constructed using the R language (R Core Team, 2023) in a Shiny-based standalone web application (accessible at https://foodmicrobiologywur.shinyapps.io/MIcrobial_hazards_RAnking/.) The codes for the Mira-DSS are stored in a GitHub repository https://github.com/albgarre/Mira_app for cloud-based hosting and access. The workflow of each ranking procedure in the DSS is shown in detail in the user manual, which is accessible via the online tool.

3. Results and discussion

Given that infants and toddlers under one year, when not breastfed, rely almost exclusively on powdered formulae as their sole nutritional source, we conducted a case study following the scenario presented in Table 7 to rank the microbiological hazard (MH) risks in infant formulae. The reported RR criteria and RR knowledge rules described in section 2 were used to rank all 34 MHs in infant formulae. The outcomes were compared among the three RR methods, namely risk scoring, semi-quantitative risk value, and outranking MCDA (see section 2.3.3). Furthermore, we analysed the ranking results with and without the inclusion of the HI step, done via the MiID- DSS (Yeak et al., 2024) as described in section 2.1.

3.1. Ranking of 34 microbiological hazards in infant formulae

In cases where no initial identification of MHs was performed in step 1, all 34 MHs were subjected to quantitative ranking in steps 2–8 using C2-C8 (see section 2.2.1). Despite using different RR aggregation methods, the ranking of all 34 MHs in infant formulae yielded consistent outcomes with minor variations. Across all three RR methods, the top five MHs posing the highest risks consistently included *Salmonella* non-Typhi, *Cronobacter* spp. and STEC (Table 8, detailed ranking results can be found in Supplementary Table S10-S12).

3.1.1. Risk scoring ranking

The risk scoring method used the scores corresponding to C2-C8 described in Table 2 to calculate the total risk score for all MHs with equation (1). The final risk scoring results (presented in Table 8A) revealed that *Cronobacter* spp. (864) obtained the highest rank,

Table 7
Case study scenario for infant formulae.

Product: Infant formulae	FoodEx2 code: A0EQMC- L3
Processing parameters	Thermal pasteurization (72 °C, 15–30 s)
Recontamination	Dry environment, addition of vitamins and trace elements
Growth opportunity	pH 6.5, a_w 0.2, transport at room temperature
Meal preparation	Ready to eat
HFA	Food Category: Milk and dairy products
Food consumption	0.073926 (an average of ~ 7.4 % of infant and todlers < age 3 consumed infant formulae in the EU)

Table 8
Final risk ranking results of all microbiological hazards in infant formulae using the risk scoring, risk value and multicriteria PROMETHEE risk aggregation methods. C2: processing survival; C3: recontamination; C4: growth opportunity; C5: meal preparation; C6: hazard-food association; C7: food consumption; C8: hazard severity (see details for each criterion in Table 1). Panel A: ranking results without the hazard identification step. Panel B: ranking results with the hazard identification step.

A: Ranking without the hazard identification step

Rank	Genus	C2	C3	C4	C5	C6	C7	C8	Risk score
1	*Cronobacter* spp.	2	2	3	4	2	3	3	864
2	***Salmonella* non-Typhi**	2	2	3	4	4	3	1	576
3	Hepatitis A	3	1	3	4	2	3	2	576
4	**STEC**	2	2	3	4	3	3	1	432
5	*Clostridium botulinum*	4	2	1	4	2	3	3	432
Rank	**Genus**	**C2**	**C3**	**C4**	**C5**	**C6**	**C7**	**C8**	**Risk value**
1	***Salmonella* non-Typhi**	10^{-6}	0.005	1	1	0.23	0.074	0.028	2.34×10^{-6}
2	**STEC**	10^{-6}	0.005	1	1	0.056	0.074	0.011	2.29×10^{-7}
3	***Cronobacter* spp.**	10^{-6}	0.005	1	1	1.63×10^{-4}	0.074	2.8	1.65×10^{-7}
4	non-STEC	10^{-6}	0.005	1	1	9.22×10^{-5}	0.074	0.046	1.55×10^{-9}
5	*Shigella*	10^{-6}	0.005	1	1	6.84×10^{-5}	0.074	0.024	6.13×10^{-10}
Rank	**Genus**	**C2**	**C3**	**C4**	**C5**	**C6**	**C7**	**C8**	**ϕ Phi score**
1	***Salmonella* non-Typhi**	10^{-6}	0.005	1	1	0.23	0.074	0.028	0.042
2	**STEC**	10^{-6}	0.005	1	1	0.056	0.074	0.011	0.040
3	*Fasciola* spp.	10^{-5}	10^{-6}	1	1	10^{-6}	0.074	8.5	0.025
4	Hepatitis E	10^{-3}	10^{-6}	1	1	10^{-6}	0.074	0.43	0.022
5	***Cronobacter* spp.**	10^{-6}	0.005	1	1	1.63×10^{-4}	0.074	2.8	0.021

B: Ranking with the hazard identification step

Rank	Genus	C2	C3	C4	C5	C6	C7	C8	Risk score
1	***Cronobacter* spp.**	2	2	3	4	2	3	3	864
2	***Salmonella* non-Typhi**	2	2	3	4	4	3	1	576
3	**STEC**	2	2	3	4	3	3	1	432
4	non-STEC	2	2	3	4	2	3	1	288
5	*Cryptosporidium* spp.	2	1	3	4	2	3	1	216
Rank	**Genus**	**C2**	**C3**	**C4**	**C5**	**C6**	**C7**	**C8**	**Risk value**
1	***Salmonella* non-Typhi**	10^{-6}	0.005	1	1	0.23	0.074	0.028	2.34×10^{-6}
2	**STEC**	10^{-6}	0.005	1	1	0.056	0.074	0.011	2.29×10^{-7}
3	***Cronobacter* spp.**	10^{-6}	0.005	1	1	1.63×10^{-4}	0.074	2.8	1.65×10^{-7}
4	non-STEC	10^{-6}	0.005	1	1	9.22×10^{-5}	0.074	0.046	1.55×10^{-9}
5	*Cryptosporidium* spp.	10^{-5}	10^{-6}	1	1	1.12×10^{-4}	0.074	0.035	3.15×10^{-12}
	Genus	**C2**	**C3**	**C4**	**C5**	**C6**	**C7**	**C8**	**ϕ Phi score**
Rank									
1	***Salmonella* non-Typhi**	10^{-6}	0.005	1	1	0.23	0.074	0.028	0.046
2	**STEC**	10^{-6}	0.005	1	1	0.056	0.074	0.011	0.044
3	***Cronobacter* spp.**	10^{-6}	0.005	1	1	1.63×10^{-4}	0.074	2.8	0.031
4	non-STEC	10^{-6}	0.005	1	1	9.22×10^{-5}	0.074	0.046	0.024
5	*Cryptosporidium* spp.	10^{-5}	10^{-6}	1	1	1.12×10^{-4}	0.074	0.035	0.013

followed by *Salmonella* non-Typhi (576), Hepatitis A (576), STEC (432), and *C. botulinum* (432). However, limitations in the scoring method are evident as multiple MHs obtained identical risk scores, making it hard to distinguish and prioritize them (Supplementary Table S10). For example, except for the top risk *Cronobacter* spp., *Salmonella* spp. and Hepatitis A were both ranked second, where eight MHs received a score of 432 (STEC, *C. botulinum* (both non-proteolytic and proteolytic), *Brucella* spp., *Mycobacterium tuberculosis* var. Bovis, *Yersinia enterolitica, Echinococcus multicularis* and *Fasciola* spp.), resulting in a shared third rank (only the first two are shown in Table 8A). *Echinococcus multicularis* (324) was thus ranked 12th, non-STEC and *L. monocytogenes, Shigella* spp. and Hepatitis E each scored 288, tying for the 13th position. The marginal differences in score magnitude led to similar rankings, failing to effectively differentiate them further.

3.1.2. Risk value ranking

The final ranking results achieved using the risk value method (see sections 2.2.3.2 and 2.3) were *Salmonella* non-Typhi (risk value of 2.3×10^{-6}), STEC (2.3×10^{-7}), *Cronobacter* spp. (1.7×10^{-7}), followed by non-STEC ($1.6x\ 10^{-9}$) and *Shigella* spp. ($6.1x\ 10^{-10}$). The risk values for both non-STEC and *Shigella* spp. were ~ 100 and 1000 folds lower than the top three MHs, respectively, indicating that the risks of these two MHs were much lower in infant formulae (see Table 8A). This quantitative insight provided by the risk value method offers a quantitative range of the relevance of each MH and highlights distinct "breakpoints" in the risk analysis. Nevertheless, MH without known association with infant formulae, like *Shigella* spp. appeared in the top 5 in the ranking, which could be attributed to its ability to cause illness without needing growth in foods (thus receiving high-risk values in C4 and C5). Moreover, the current representation of hazard prevalence in C6 is based on the food category (i.e., milk and dairy products) rather than specific food products (i.e., infant formulae) due to data scarcity for very specific information. This inherently introduced a degree of bias into the MH ranking given that the risk associated with the broader food category may not accurately reflect the risk of a specific food item. Despite this limitation, it is important to highlight that incorporating the prevalence data at the category level still factors an important risk dimension, and contributes to a more comprehensive and informed RR than the complete exclusion of such data. As more product-specific data becomes available in the future, the ranking methods can be further refined and the precision of the ranking will increase. The risk value method also displayed a larger scale of differentiation, in which none of the MH (see full ranking results in Supplementary Table S11) received the same risk value as observed above for the risk scoring method, allowing for more distinctive rankings between MHs in the same food product.

3.1.3. Multi-Criteria decision analysis (MCDA) PROMETHEE

MHs in infant formulae were also ranked using the MCDA

PROMETHEE method (see section 2.2.3.3). The results obtained ranked *Salmonella* non-Typi ($\phi = 0.042$), STEC ($\phi = 0.040$), *Fasciola* spp. ($\phi = 0.025$), Hepatitis E ($\phi = 0.022$), and *Cronobacter* spp. ($\phi = 0.021$) as the top five MHs (Table 8A). Similar to the results obtained via the risk value method, no MHs receive the same ϕ score (Supplementary Table S12). This alignment was logical as the dataset employed in PROMETHEE constituted risk values rather than scores. However, the MCDA ranking method differed from the risk value ranking; instead of multiplying criteria, it involved pairwise comparisons of risk values. This algorithmic difference led to variations in the rankings. Nevertheless, a similar issue arose where MHs like *Fasciola* spp. and Hepatitis E, with no known association with infant formulae, were ranked relatively high, likely due to the reasons explained above for both risk scoring and risk value methods.

Moreover, some MHs that ranked relatively low in the risk scoring and risk value methods appeared relatively high in the MCDA ranking. For instance, *B. cereus* and Rotavirus were ranked 24th and 26th in the risk scoring, and 22nd and 17th in the risk value method, respectively, but ascended to 14th and 7th, respectively, in the MCDA method under identical scenarios (Table 7). This discrepancy can be attributed to the outranking approach used in PROMETHEE, which compared all criteria in a pairwise manner. MHs that 'outrank' others on more criteria emerged as high risk in the ranking. The cumulative results of these pairwise comparisons were expressed in positive (outranking) and negative (counter-outranking) scores for each MH. For example, *B. cereus* was ranked relatively higher than other MHs in infant formulae because the presence of its spores was considered. *B. cereus* spores have a higher survival chance in C2, a higher recontamination possibility in C3, no inactivation in C5, and are often detected in contaminated foods (C6). Thus, despite its comparatively low severity (C8) and inability to grow in dry infant formulae (C4), it achieved a high rank in the list.

The MCDA approach offers flexibility and is highlighted by the ease of integrating additional criteria such as data quality or evidence weight, making it a robust tool for classifying food safety-related risks (FAO, 2017). Recently, the PROMETHEE method has been used to rank both microbiological and chemical hazards associated with emerging dietary practices (Eygue et al., 2020), ready-to-eat dishes sold in France (Poissant et al., 2023) and to rank chemical hazards in infant food (Palmont et al., 2023). Despite its advantages and the availability of an R package, its usage may pose a challenge for some users due to the requisite programming expertise. Additionally, it is important to recognize that while PROMETHEE is a potent decision-making tool, its effective implementation hinges on sound judgment and a comprehensive understanding of the data to select appropriate preference functions and weights for the criteria.

3.2. Limitation of ranking all 34 MHs

While all three RR methods ranked *Salmonella* non-Typhi, *Cronobacter* spp., and STEC as primary MHs associated with infant formulae, they displayed varying rankings due to method-specific factors. To mitigate this, an optional evidence filter was employed (explained in section 2.3.8) to exclude MHs with negligible associations. This filtering produced highly congruent top-10 rankings across all methods (Supplementary Table S10-S12), resolving ranking discrepancies resulting from method preferences. As a result, all three methods concurred on the top MHs*: Salmonella* non-Typhi*, Cronobacter* spp., STEC, non-STEC, and *Cryptosporidium* spp.

However, the most effective approach involves conducting an HI step initially and then ranking only the relevant MHs identified for a specific food product. Thus, in the following step, we first identified the most relevant MHs using the MiID DSS (section 2.1), and the subsequent ranking results were compared among the three RR methods to ensure a more precise and relevant ranking of MHs for the given context.

3.3. Risk ranking of MHs identified via MiID-tool in infant formulae

Under the same study scenario (Table 7), MHs in infant formulae were first identified using the MiID-DSS tool (https://foodmicrobiologywur.shinyapps.io/Microbial_hazards_ID/) (Yeak et al., 2024), and then ranked with the Mira-DSS (section 2.4).

The HI step effectively narrowed down the 34 most relevant MHs into five specific MHs in infant formulae. These were *Salmonella* non-Typhi, STEC, *Cronobacter* spp., non-STEC and *Cryptosporidium* spp. All MHs do not require growth in foods to cause illness and can survive in low-water activity products (FAO, 2022; Stella et al., 2013). The ranks of all five MHs were identical for the risk value method and the MCDA PROMETHEE method, with *Salmonella* non-Typhi identified as the top risk. In the risk-scoring method, the ranks were also the same with only one exception: *Cronobacter* spp. was ranked the top risk instead of *Salmonella* non-Typhi (see Table 8B).

This consistent rankings across all three RR methods demonstrated the robustness and reliability of the ranking process for the selected relevant MHs. It highlighted the agreement and consistency among the methods in ranking the top MHs posing risks to infant foods, especially when integrating the HI step done via the MiID-DSS. This integrated approach ensures a comprehensive and accurate evaluation of potential MHs in infant foods, enhancing the overall reliability of the Mira DSS.

4. Conclusion

This study presented the methodologies and criteria used to systematically rank MHs in infant foods. With an initial HI step, the rankings of MHs in infant formulae showed high comparability among all three RR methods (risk scoring, risk value, and MCDA-PROMETHEE). Although each RR method has its strengths and limitations, the consistency in ranking outcomes highlighted the robustness of the selected criteria, procedures, and decision trees in assessing top MH risks in infant foods. Based on the ranking comparisons discussed above, it became evident that the risk value method offered more insightful rankings and was simpler to apply. While the MCDA method was also informative, it was more complex and less transparent. The use of risk scoring method without the initial HI step was not ideal as it was impossible to rank the risks for MHs with identical scores.

Integration of the risk scoring and risk value methods into the Mira decision support tool enhances accessibility and usability. Its adaptable framework can be extended to a wide range of foods and accommodate more quantitative data as they become available in the future to ensure its ongoing relevance. Additionally, the Mira DSS has the potential to broaden its scope to encompass other age groups by updating the initial list of 34 MHs to include newly emerging hazards, if they arise.

The ranking framework developed in this study effectively prioritises MH risks and can assist risk managers in resource allocation, supporting decision-making within Quantitative Microbial Risk Assessment (QMRA) and Hazard Analysis Critical Control Points (HACCP) for both industry and authorities. It is designed to evolve with additional data integration, ensuring continual improvement in effectiveness and accuracy over time.

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CRediT authorship contribution statement

Kah Yen Claire Yeak: Writing – review & editing, Writing – original

draft, Validation, Software, Methodology, Data curation, Conceptualization. **Alberto Garre:** Writing – review & editing, Software. **Jeanne-Marie Membré:** Writing – review & editing, Methodology, Conceptualization. **Marcel H. Zwietering:** Writing – review & editing, Supervision, Resources, Methodology, Funding acquisition, Conceptualization. **Heidy M.W. den Besten:** Writing – review & editing, Supervision, Methodology, 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.

Data availability

Data supporting the findings of this study are available within the article, its supplementary materials and the reported Github page.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.foodres.2024.114788.

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