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Balancing food safety and sustainability: trade-off risk assessments and predictive modeling

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Abstract

The importance of food safety to public health is reflected in its inclusion in the United Nations Sustainable Development Goals (SDGs)—SDG 2 (Zero Hunger), SDG 3 (Good Health and Well-being), and SDG 12 (Responsible Consumption and Production)—and the World Health Organization's food safety strategy. Its inclusion across multiple areas underscores how food safety is not an isolated objective but is closely tied to broader public health and sustainability goals. While the public often expects food to be "absolutely" safe, experts recognize that all foods carry a residual risk of causing foodborne illness and that zero risk is neither achievable nor desirable. Advances in diagnostics and surveillance systems (e.g., increases in test sensitivity and specificity) have increased the frequency of hazard detection in foods, including detection of hazards at levels that may pose minimal public health risks. However, efforts to manage these negligible risks can divert attention from more significant threats and may introduce unintended consequences that outweigh the intended benefits. To address this, holistic approaches and trade-off risk assessments are needed, accounting for the interrelationship between the health of humans, animals, and the environment (i.e., One Health) and evaluating both the costs and benefits of food safety measures, including direct expenses, externalities, social or legal constraints, and consumer preferences. Key tools enabling these risk assessments include Monte Carlo simulations and other modeling tools that are also being adopted for food safety applications, such as geographic information system models, agent-based models, and artificial intelligence (AI)-based predictive tools. These efforts can help define quantitative food safety goals that ensure appropriate, but not absolute, safety, so long as implemented controls are validated and verified. Technological advances, such as AI-enabled risk negotiation, offer new opportunities to integrate trade-offs in risk analysis and support more balanced, effective food safety strategies.

KEYWORDS

artificial intelligence, food safety, microbial, predictive modeling, public health, risk assessments, sustainability, trade-offs

Key points

- Zero risk of foodborne illness is neither achievable nor desirable; overly stringent food safety practices can lead to unintended consequences that outweigh their public health and societal benefits.
- Better trade-off risk assessments and associated predictive and decision-making tools must be developed to support food safety decision-making.
- Further development and implementation of risk negotiation approaches can help achieve societally acceptable sustainable food systems that produce sufficiently safe food.

Introduction

Food safety is a key determinant of public health (1). According to the most current estimates by the World Health Organization (WHO), microbial foodborne pathogens cause 600 million cases of illness annually (2). These illnesses result in 420,000 deaths (2)—a third (125,000 deaths/year) in children aged under 5 years (3)—and a loss of 33 million disability-adjusted life years (DALYs) (2). In 2019, the World Bank estimated that foodborne diseases cost US$110 billion/year in productivity loss and medical costs in low- and middle-income countries alone (4). The inclusion of food safety within the United Nations (UN) Sustainable Development Goals (SDGs) (5), which are a part of the 2030 Agenda for Sustainable Development, underscores not only its global importance to public health but also its close interconnection with sustainability. Accordingly, the WHO Global Strategy for Food Safety 2022–2030 aims to reduce the burden of foodborne illness (1), and the WHO is currently working with the World Bank to provide updated disease burden estimates (2).

Various food production and processing strategies, such as good agricultural practices, drying, pasteurization, sanitary equipment design, refrigeration and freezing throughout distribution, and strict microbiological limits for foods, can help reduce the presence of microbial foodborne pathogens and improve food safety. However, many of these approaches come with unintended consequences that can affect and limit their application, ranging from increased food insecurity to a variety of negative environmental impacts, including increased food waste. In addition, some technologies carry high costs (e.g., for equipment, power, and labor) or logistical challenges (e.g., access to skilled labor or necessary maintenance) that hamper their implementation in many parts of the world. Hence, for some food safety approaches, mandated use or overly stringent requirements (e.g., with regard to microbiological testing) could negatively impact food availability and sustainability.

The essentially ubiquitous trade-offs associated with strategies to improve microbial food safety represent an often underappreciated and unaddressed challenge. More specifically, while some groups and individuals may desire food that is "completely" safe, absolute safety, even regarding a specific challenge such as microbial food safety, is neither possible nor desirable (6). This problem has been acknowledged since at least 1993, when the Organisation for Economic Co-operation and Development defined safe food as "a reasonable certainty that no harm will result from intended uses under the anticipated conditions of consumption" (7). Consequently, food safety decisions at all levels (governments, companies, and individuals) must weigh various trade-offs to determine what constitutes "sufficiently safe" food or what food can be considered to show "reasonable certainty that no harm will result from intended use" (7). This approach of defining "sufficiently safe" food is also exemplified by concepts such as the "Appropriate Level of Protection" (ALOP) (8, 9), which involves defining acceptable levels of risk; this approach has been applied to set microbiological benchmarks for food safety (e.g., log reduction targets for foodborne pathogens). Another approach for defining acceptable levels of risk, particularly for food additives, includes setting a one-in-a-million risk level as "acceptable", with the United States Food and Drug Administration (FDA) declaring that lifetime risks lower than this one-in-a-million level should be considered *de minimis* under the so-called Delaney Amendment (10). However, the *de minimis* principle could be considered as an arbitrary threshold and thus may not be considered a satisfactory approach for distinguishing between negligible and non-negligible risk (10). Similarly, defining what is an "appropriate" level of protection can be challenging. Hence, approaches and tools for improving and facilitating food safety decisions must be further developed and applied to better reach consensus on what constitutes acceptable or tolerable risks (11), as well as negligible or non-negligible risks, for different foods across societies. Consistent with this, increasing the use of food chain information, scientific evidence, and risk assessment in making risk management decisions is a strategic pillar of the WHO Global Strategy for Food Safety (1).

This article details how global food systems are increasingly facing more, and sometimes competing, demands, such as (i) supporting public health protection by ensuring food safety while also (ii) striving for sustainability in food systems (including reduction of food waste). For example, discarding any food that tests positive for foodborne pathogens, without considering the likelihood of the food causing foodborne illness, may help safeguard public health but also contributes to food waste and associated consequences (e.g., greenhouse gas emissions). Thus, due to the "interconnectedness" of our food system (as illustrated by the One Health concept), there is a need to optimize, balance, and negotiate strategies that can improve the safety and sustainability of food systems to provide well-being and health to global populations while protecting constituents of food systems (e.g., farmers and food businesses) and the planet (e.g., animals, plants, and the environment). These challenges bring new urgency to the prioritization of risk-based decision-making—which has been previously been detailed by various agencies and groups (7, 12, 13) and will be discussed later in this manuscript—over hazard-based decision-making, which could be described as primarily focusing on pathogen detection and elimination. This focus on risk-based decision-making needs to overcome implementation barriers (e.g., challenges in defining acceptable food safety risk levels) and move beyond current approaches, including ALOP and "As Low as Reasonably Achievable" (ALARA) (14). Furthermore, explicit consideration of residual risk in policymaking will be essential to comprehensively drive implementation of risk-based food safety systems. The use of new approaches—e.g., artificial intelligence (AI) or new modeling tools—can help define acceptable levels of risk and consider residual risks while balancing competing interests in our complex food systems. While the focus of this article is on microbial food safety, many of the concepts detailed here, and particularly the need for trade-off risk assessments, also apply to chemical food safety risks, where some trade-off risk assessments have already been applied (e.g., 15).

Microbial food safety in the context of human health, One Health, and food system sustainability

Human health impacts of foodborne microbial pathogens

Pathogens commonly associated with foodborne illness cases include the bacteria *Salmonella*, certain *Escherichia coli* strains, *Listeria monocytogenes*, and *Campylobacter* (16), and viruses such as norovirus, hepatitis A virus, and hepatitis E virus (17). While many of these pathogens (e.g., norovirus) typically cause mild foodborne illnesses, characterized by vomiting and diarrhea, several pathogens can cause more severe illnesses. For example, *L. monocytogenes* typically causes severe invasive infections with symptoms including septicemia, encephalitis, and miscarriage; approximately 90% of listeriosis infections result in hospitalization, and 20% cause death. For other pathogens, specific strains may have a propensity to cause more serious infections. Enterohemorrhagic *E. coli* (EHEC), for example, are a subgroup of *E. coli* that can cause particularly severe symptoms, including kidney failure and hemolytic uremic syndrome (18). Other *E. coli* subtypes may either cause milder symptoms (e.g., diarrhea) or are not typically linked to foodborne disease at all (19). In addition, susceptibility to foodborne infections can differ substantially between population subsegments, with young, elderly, and immunocompromised individuals often carrying a higher risk.

Foodborne pathogens can also cause long-term sequelae with substantial public health impacts. For example, *Campylobacter* can trigger Guillain-Barré syndrome, a neurological autoimmune disorder whose symptoms include muscle weakness and sometimes paralysis; estimates of its occurrence range from 21.5–172 cases per 100,000 *Campylobacter* cases (20, 21). Other long-term sequelae of *Campylobacter, Salmonella, Shigella*, and *Yersinia* infections can include reactive arthritis (22–24). In addition to direct public health impacts, microbial foodborne illnesses have many other indirect impacts, including contributions to malnutrition and poor infant health (e.g., due to reduced nutrient absorption in individuals with re-occurring foodborne illness episodes) (25).

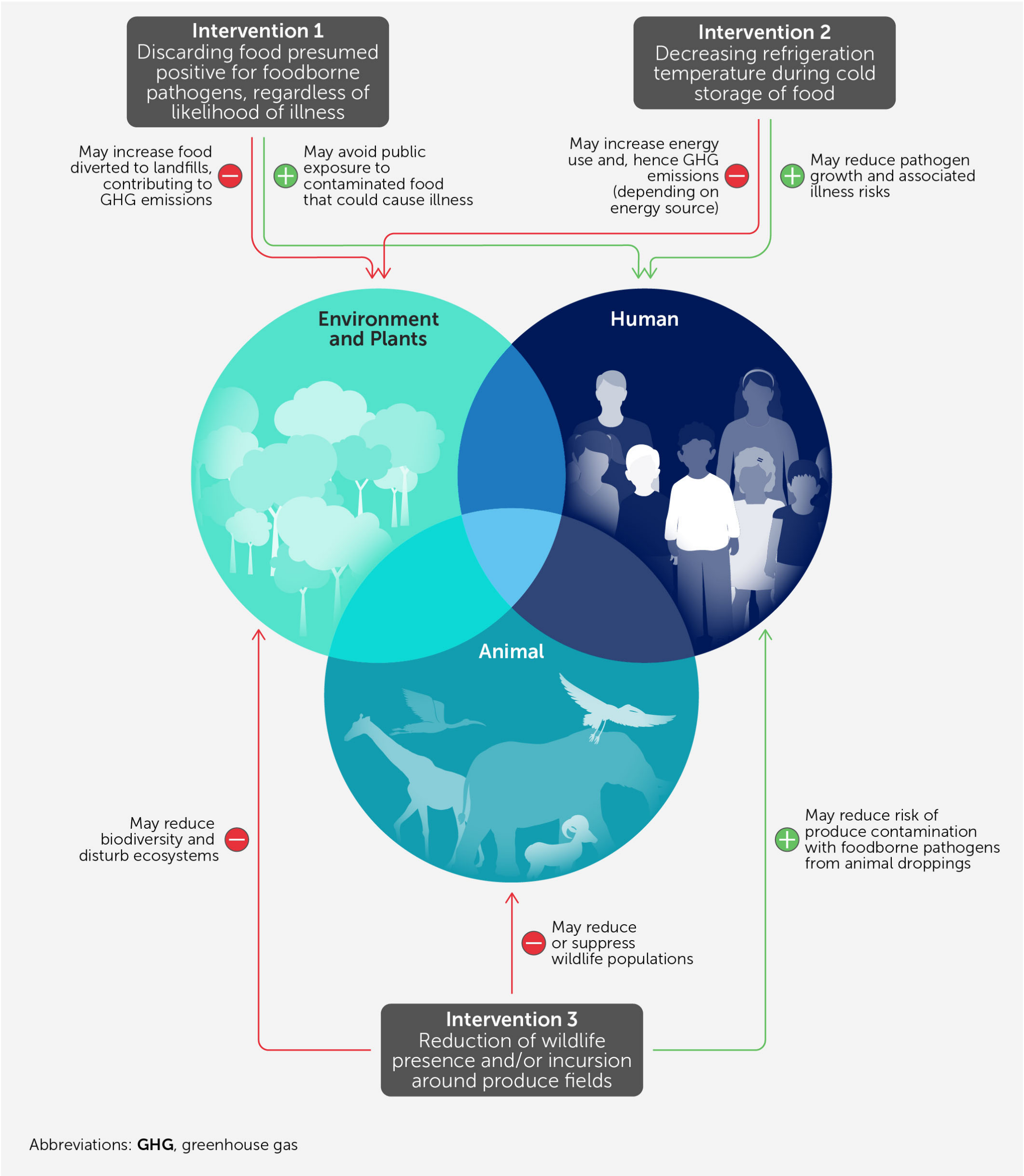
Microbial food safety and One Health

Many microbial food safety issues are closely linked to the microbial safety and quality of water and to animal health, as detailed in a number of reviews on One Health and food safety (e.g., 1, 26). For example, contaminated water can be an important source of pathogen contamination of different foods at different stages of the food chain, including primary production (e.g., if contaminated water is used for irrigation of produce), food processing, and consumer food preparation. Food animals infected with or carrying foodborne pathogens (e.g., *Salmonella*) not only represent an important "direct" source of foodborne pathogens (e.g., through contaminated meat, milk, or eggs) but also contribute more indirectly to transmission and dispersal. For example, runoff from animal facilities can introduce foodborne pathogens into water sources used for irrigation (27) as well as directly into pre-harvest environments, such as produce fields. Although less well documented, airborne dispersal of foodborne pathogens from livestock operations may also contribute to contamination of pre-harvest environments (28, 29). Wildlife, too, has been found to lead to the dispersal of foodborne pathogens through contamination of water or direct fecal deposition into pre-harvest environments (including in foodborne disease outbreaks linked to contaminated produce) (30, 31). As microbial food safety can be considered a One Health issue (1, 26), strategies designed to reduce food safety risks are likely to have wide-ranging impacts—both positive and negative (see Figure 1 and Table 1 for examples of food safety interventions and associated trade-offs).

Challenges for food system sustainability

Food safety is integral to UN SDG 2 (Zero Hunger), which aims to end hunger and achieve food security. This goal links to two further goals, SDG 3 (Good Health and Well-being) and SDG 12 (Responsible Consumption and Production), due to the need for safe and nutritious foods and the reduction of foodborne illness rates as well as the need for sustainable consumption and production patterns, which requires maintaining food safety while reducing food waste (5).

Major challenges for sustainable food systems include (i) ensuring access to safe, abundant, and nutritious food, (ii) minimizing damage to natural ecosystems, and (iii) assuring quality of life and prosperity for individuals and communities associated with food production, processing, and distribution (32). These major challenges must be addressed in the context of microbial food safety. Reducing public health impacts associated with microbial food safety is a significant challenge in its own, often classified as a "wicked problem" (33, 34), i.e., one that is challenging to address because of complex, contradictory, and changing requirements that are often difficult to recognize. "Wicked problems" have solutions that "are not true-or-false but better or worse" for which "the problem is never solved definitively" (33).



Abbreviations: **GHG**, greenhouse gas

FIGURE 1
Trade-offs involved with food safety interventions using a One Health framework, i.e., taking account of the interrelationships between the health of humans, animals, plants, and the environment. Food safety interventions may have a primary trade-off that may lead to subsequent trade-offs. For example, interventions 1 and 2 are expected to have benefits for human health, with trade-offs including potential negative implications for the environment and plants, which may also subsequently negatively affect human and animal health. Other interventions can clearly have multiple primary trade-offs; for example, Intervention 3 is expected to have benefits for human health with negative trade-offs for the health of animals as well as the environment and plants.

Some key challenges associated with ensuring food safety include (i) diversity of the food supply (ranging from canned products to fresh meat, seafood, and produce), (ii) diversity of food production around the globe (from highly sophisticated production facilities to informal, and often unregulated, food establishments), (iii) foodborne pathogen contamination that can occur throughout the food value chain, including in agricultural environments, during harvesting, or in processing plants, retail establishments, restaurants, homes, and during various transportation steps, and (iv) the vast magnitude of food that must be produced. To illustrate the last point, in 2022, approximately 26.7 billion chickens were raised globally (35), and the United States consumed approximately 6.2 billion pounds of tomatoes (36). It is also worth noting that food production must continue to increase as the human population grows; it is estimated that the global food demand will increase by over 35% during the first half of the 21st century (i.e., from 2005, 2007, or 2010 through to 2050) (37, 38), exacerbating the challenges in building and maintaining sustainable and safe food systems.

TABLE 1 Examples of possible negative impacts and unintended consequences (e.g., on sustainability and food availability) of different food safety strategies and interventions.

Food safety strategy/ interventions	Potential negative impacts/ unintended consequences	Details
Heat treatment (e.g., pasteurization), potentially with higher heats or extended times	Reduced nutritional content of foods, leading to reduced access to nutritious food and possibly increased risk of vitamin deficiencies	Heat treatment of fruit juices has been shown to reduce vitamin content (e.g., vitamin C) (39)
Chemical antimicrobials	Presence of chemical contaminants in foods that may impact human health, representing chemical food safety risks (e.g., increased risk of certain cancers)	Nitrites used to prevent the growth of *Clostridium botulinum* (40) in processed meat can lead to the formation of nitrosamines (41, 42). However, some research indicates that nitrates may positively impact cardiovascular health (43)
Chemical sanitation to reduce pathogens in food production (e.g., with peracetic acid)	Use of chemicals in food processing with possible negative impacts on worker welfare	Worker exposure to compounds (e.g., peracetic acid) that can be corrosive to eyes and skin (44)
Wildlife control and exclusion	Degradation of natural ecosystems and negative impacts on biodiversity	Excessive control of wildlife or removal of wildlife habitats to prevent pathogen introduction into pre-harvest environments may negatively impact biodiversity (45)
Overly conservative decisions to dispose of food products that (i) test positive for indicator organisms or (ii) were produced in food environments where index or indicator organisms were detected	Excessive food waste with associated negative environmental impacts and possibly reduced food availability	Detection of indicator organisms (e.g., coliforms), which have historically been used to characterize hygienic conditions, may be used inappropriately to classify a food as adulterated, leading to unnecessary product disposition and destruction (46)
"Environmentally unfriendly" packaging material (to reduce real or perceived food safety issues)	Excessive waste of materials used in food production and processing, leading to degradation of natural ecosystems (e.g., through increased microplastics pollution)	Consumer demand or other factors may lead to excessive use of packing materials to address perceived food safety risks that are minimal or unsupported. For example, despite limited evidence (47) that SARS-CoV-2 can be transmitted through consumption of contaminated food, a study (48) reported that 40% of surveyed consumers regarded COVID-19 concerns as very or extremely important in their decision to purchase food packaged in single-use plastics
Capital-intensive processing technologies and food safety strategies	Excessive food cost and resulting food security challenges if expensive microbial reduction processes are required	Use of high-pressure processing can enhance the safety of certain products but requires large investments into equipment, and hence, may increase food prices
Energy-intensive approaches that can decrease food safety risks (e.g., freezing or refrigeration)	Excessive energy use leading to increased emissions with associated negative environmental impacts	Guidance documents and regulations may require stringent practices that substantially increase energy consumption and business costs but provide minimal improvements in food safety over slightly less stringent practices. For example, slightly less cold frozen storage temperatures may substantially decrease costs and energy usage but are expected to have minimal food safety impacts
Excessive water usage to support pathogen control efforts (e.g., excessive cleaning and sanitation, frequent water changes in hydroponics)	Excessive water use, which can lead to water shortages and degradation of natural ecosystems	Water-intensive practices may be required by regulation or customer requirements to help create (sanitation) clean breaks (49). For example, construction of a commercial-scale brewery was halted after protests about exacerbation of water scarcity (50)
Excessive testing of foods with highly sensitive methods that detect pathogen levels unlikely to cause human disease	Negative publicity (e.g., recalls of produce) that drives consumers to less safe and/or healthy food options	A study that assessed meat recalls over 20 years found that successive recall events cumulatively influence market patterns over longer periods, suggesting that recall events can have long-term impacts on consumer trust in specific foods (51)

Hazard- and risk-based approaches to microbial food safety

In the literature, it is not uncommon to see the mention of hazard- and risk-based approaches to food safety. Hazard-based approaches have been defined as approaches where the detection of a pathogen (typically a pathogenic species), regardless of level or other factors that impact risk, is used as a basis for legislation and/or risk management action (52). Examples for this may be regulations that define any ready-to-eat (RTE) food that tests positive for *L. monocytogenes* as adulterated, regardless of levels or whether it would support growth of *Listeria*. Risk-based approaches, on the other hand, assess the probability of an adverse effect on an organism, including humans, given a certain exposure and scale risk mitigation strategies accordingly. The value of risk-based approaches to food safety is generally well recognized and broadly supported. For example, the WHO 2022–2030 Global Strategy for Food Safety recommends that "When setting and implementing regulatory requirements, the national food control systems should consider the whole food chain and take a risk-based approach" (1). However, a delineation between hazard- and risk-based approaches to microbial food safety is not straightforward. Since zero risk is unattainable, i.e., some residual risk always remains despite food safety interventions (see Figure 2 for an example illustrating residual risk), even so-called hazard-based approaches typically involve decisions about acceptable risk, often defined indirectly through sensitivity of detection methods, sample sizes, and sampling frequency. For instance, a food safety system requiring RTE food to test negative for *L. monocytogenes* in a single 25 g sample accepts a higher level of risk than one requiring five 25 g samples (125 g total). In practice, food safety systems and approaches are thus probably better viewed as “hazard-focused” or “risk-focused”, as nearly all systems incorporate some degree of risk-based decision-making.

Development and implementation of risk-focused food safety approaches often utilize quantitative microbial risk assessment (QMRA) (as detailed further below). However, other and simpler alternative approaches (e.g., risk profiling) can also be utilized (13); such alternative approaches to a full QMRA can be particularly important, as a frequently cited global challenge in implementing risk-based approaches is the availability of sufficient data and the capacity to collect and analyze it. However, some studies have also illustrated that meaningful QMRAs can be conducted with limited data, such as a recent QMRA of food safety interventions for *Campylobacter* spp. and *Salmonella* spp. along the chicken meat supply chain in Burkina Faso and Ethiopia (53).

Definition of an acceptable risk (or an acceptable risk reduction), particularly for risk-focused food safety approaches, is important for establishing action levels [e.g., <x colony-forming unit (CFU) of a given pathogen in a certain food product]. However, as the term “acceptable risk” implies that some level of foodborne illness is acceptable, other terms such as “tolerable risk” or “achievable risk” may be preferable, as outlined in a report on risk assessments for waterborne diseases (54). This report (54) also describes previous efforts to define acceptable microbial risks for water and thus may provide valuable learnings for food safety. Regarding food safety, previous attempts to help define acceptable risks included efforts to define ALOPs for different food safety hazards (e.g., *L. monocytogenes*), which could then be used to define specific food safety objectives (8, 9). However, the concept of ALOP and the associated nomenclature and definitions appear to have seen only limited global uptake since the World Trade Organization first described this concept in 1995 (55). To address the issue of defining limits for presence and levels of foodborne pathogens, the concept of ALARA is sometimes used (14); this approach, however, tends to focus more on technologically attainable risk reduction rather than societally acceptable risk levels and thus may be less valuable in the further development of risk-based food safety systems that consider societal costs, benefits, and trade-offs.

The choice of hazard- versus risk-focused food safety approaches can have important implications beyond the determination of regulatory limits for foodborne pathogens. For example, hazard-focused systems often emphasize end-product testing as a means of ensuring safety despite well-established evidence that it is largely ineffective at detecting contamination, especially when present at a low prevalence (56), though it remains useful as a verification tool. Risk-focused approaches, on the other hand, facilitate the setting of performance criteria (PC), which specify goals for the effectiveness of food safety interventions, ideally throughout production and processing (57, 58). For example, risk-focused approaches may determine that a 5-log reduction in a target organism (e.g., the most heat-resistant vegetative pathogen in raw milk) may be sufficient for one product, whereas a 4-log reduction may suffice for another (e.g., *Salmonella* in almonds) (59, 60). While decisions on appropriate PC rely on assumptions about pathogen distribution and initial contamination concentration in raw materials, which should be verified (see Figure 3), decisions on specific PC (and whether they are “fit for purpose”) should also take into account an acceptable risk (e.g., x human illness cases per year), a consideration used when proposing that a 4-log reduction may be appropriate for *Salmonella* in almonds.

In contrast, hazard-focused approaches may aim to eliminate pathogens in finished products and even in areas of food processing facilities that pose minimal risk to the product (this approach could manifest by regulators not accounting for sampling areas when reviewing industry environmental sampling data). This can misdirect resources: as a somewhat extreme example, food business operators may allocate similar resources to address pathogen contamination in a zone 4 site (far from food contact surfaces) as to contamination in a zone 2 site (near exposed food), despite the much higher risk posed by the latter (61). Similarly, a hazard-focused approach may give equal resources to control *L. monocytogenes* in products that do and do not support the growth of the organism, with the former representing a higher public health risk. These examples illustrate how a hazard-focused approach that demands equal attention be given to all hazards ignores the concept of opportunity cost, which Frank and Bernanke defined for an activity as “the value of the next best alternative that must be forgone to undertake the activity” (62). In our specific scenario, the opportunity cost is the cost of improving pathogen control in zone 4 by redirecting resources to control the pathogen in zone 2, resulting in greater benefits for public health and food safety. Although opportunity costs are rarely formally analyzed in food safety, they likely influence food business decisions (63). Consequently, a better understanding of these trade-offs could lead to more effective system design. Additionally, hazard-focused systems targeting zero detection may create other unintended consequences, such as less rigorous environmental sampling (e.g., sampling mostly clean surfaces), ultimately weakening validation and verification efforts.

Risk metrics

While risk-focused food safety approaches are frequently applied in public health decision-making, a somewhat “hidden” aspect of risk assessments is the variety of different metrics available to assess risk. These include different numerators, such as the number of foodborne illness cases, deaths, or quality-adjusted life years (QALYs), and different denominators, such as per serving, or per population per year (e.g., per million people per year) (see Figure 4 and Table 2 for further details on risk metrics, including QALYs). Crucially, the choice of risk metric may impact management decisions. For example, assessments using the number of foodborne illness cases

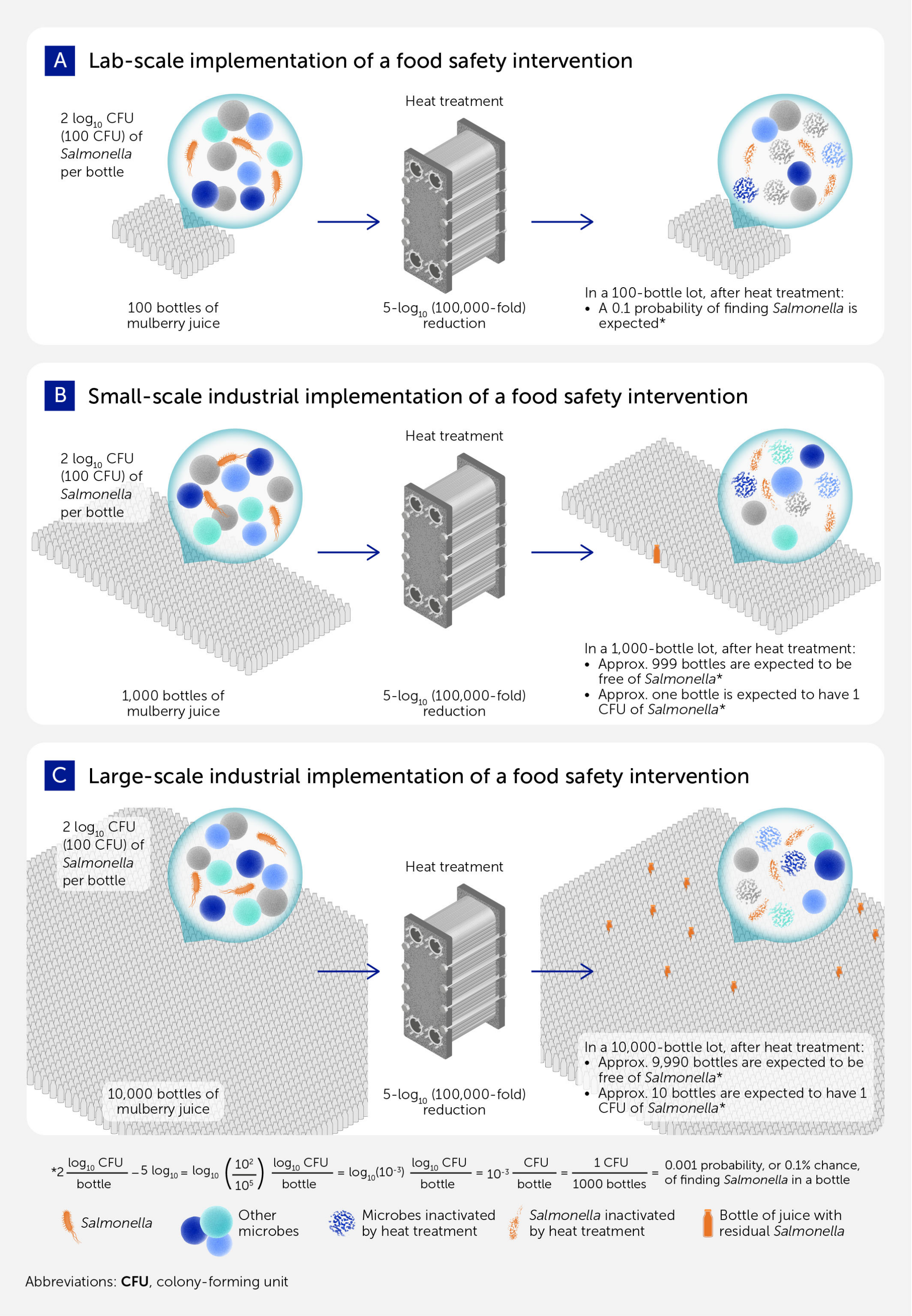
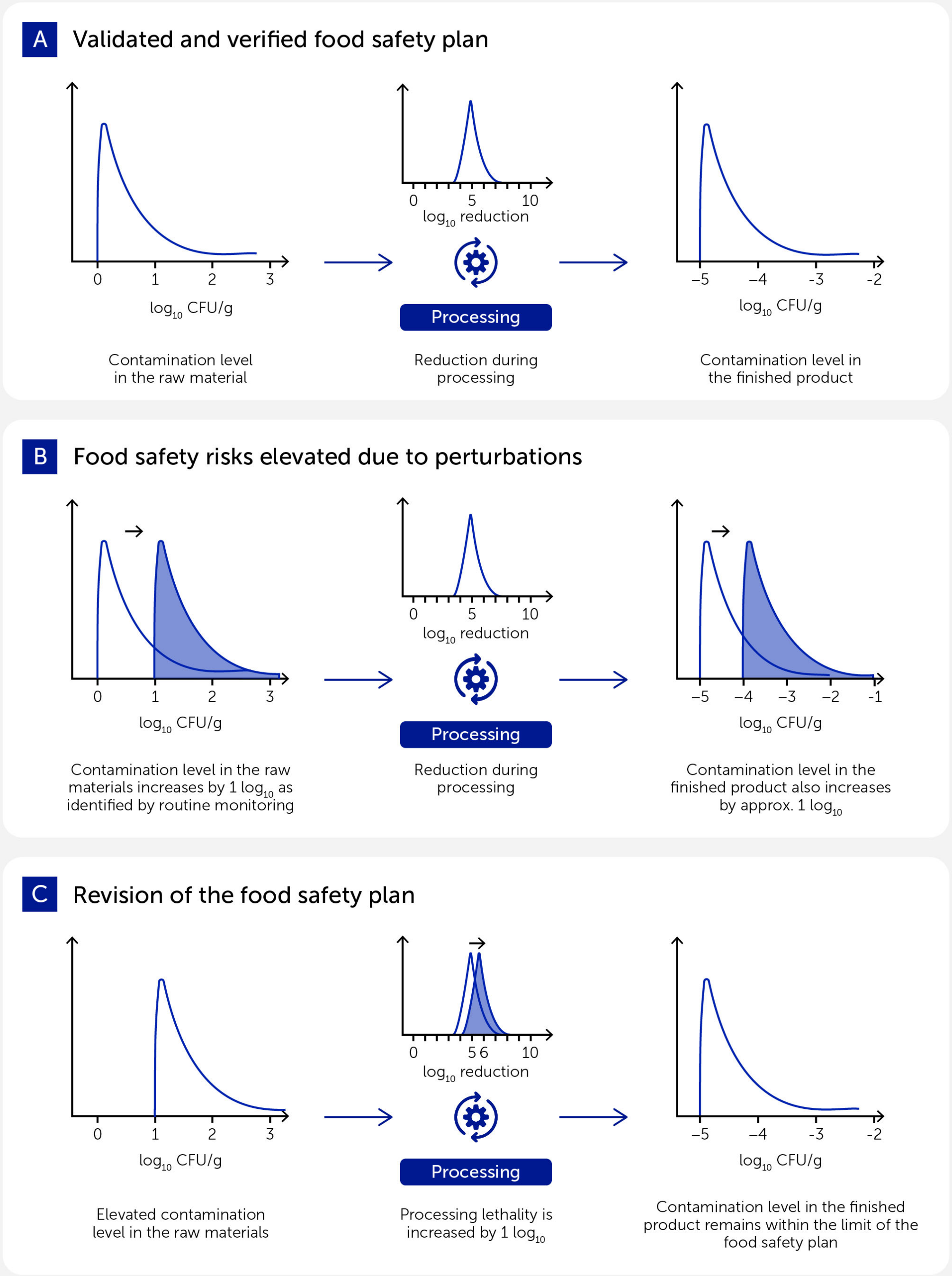


FIGURE 2
Illustration of residual risk in processed juice. Assuming all bottles of untreated juice are contaminated with 2 $\log_{10}$ colony-forming units (CFU)/bottle of *Salmonella* spp., a 5-$\log_{10}$ reduction would result in a theoretical *Salmonella* spp. concentration of −3 $\log_{10}$ CFU/bottle, or a 0.001 probability of a CFU of *Salmonella* spp. in a bottle (i.e., −3 $\log_{10}$ CFU/bottle = 10^{-3} CFU/bottle = 0.001 probability, or 0.1% chance, of a CFU/bottle). In **(A)** a 100-bottle lot, this would result in a 0.1 probability (0.001 × 100 bottles) of a bottle that is positive for *Salmonella* spp. In contrast, for lots of **(B)** 1,000 or **(C)** 10,000 bottles, there is an average risk that one (0.001 × 1,000 bottles) or 10 bottles (0.001 × 10,000 bottles), respectively, will be found positive for *Salmonella* spp. Realistically, in larger lots (e.g., 10,000 bottles), this residual risk will not be distributed uniformly across bottles (i.e., 1 CFU in 10 bottles) but may follow other patterns, such as a normal distribution (e.g., 3 CFU in one bottle, 2 CFU in two bottles, and 1 CFU in three bottles).



Abbreviation: **CFU**, colony-forming unit

FIGURE 3
Implementation of a validated and verified food safety plan for foods where heat treatment is a key food safety strategy. **(A)** Implementation of a validated and verified food safety plan, which can be designed to achieve a predetermined acceptable level of risk (e.g., x% risk of a product -positive test per year; <x human illness cases per year). **(B)** A routine monitoring program is a valuable part of a food safety plan, as it can detect perturbations that compromise the validity of the food safety plan (e.g., an elevated contamination rate in raw product), which can increase the risk of a product positive test. **(C)** The food safety plan can subsequently be modified, validated, and verified so that the risk returns to the predetermined amount, for example, by implementing a more lethal treatment. Alternative risk mitigation strategies may need to be implemented if a more lethal heat treatment is not feasible (e.g., due to excessive heat-related degradation of the sensory properties of a food) and, in some cases, the acceptable level of risk may need to be renegotiated (not shown in the figure). The graphs shown in each of the three panels depict the probability density functions for (i) the contamination level in the raw material, (ii) the $\log_{10}$ reduction that occurs during processing, and (iii) the contamination level in the finished product. With further modeling, the contamination level of the finished product can be used to assess the risk of foodborne illness, product positive tests, recalls, and outbreaks.

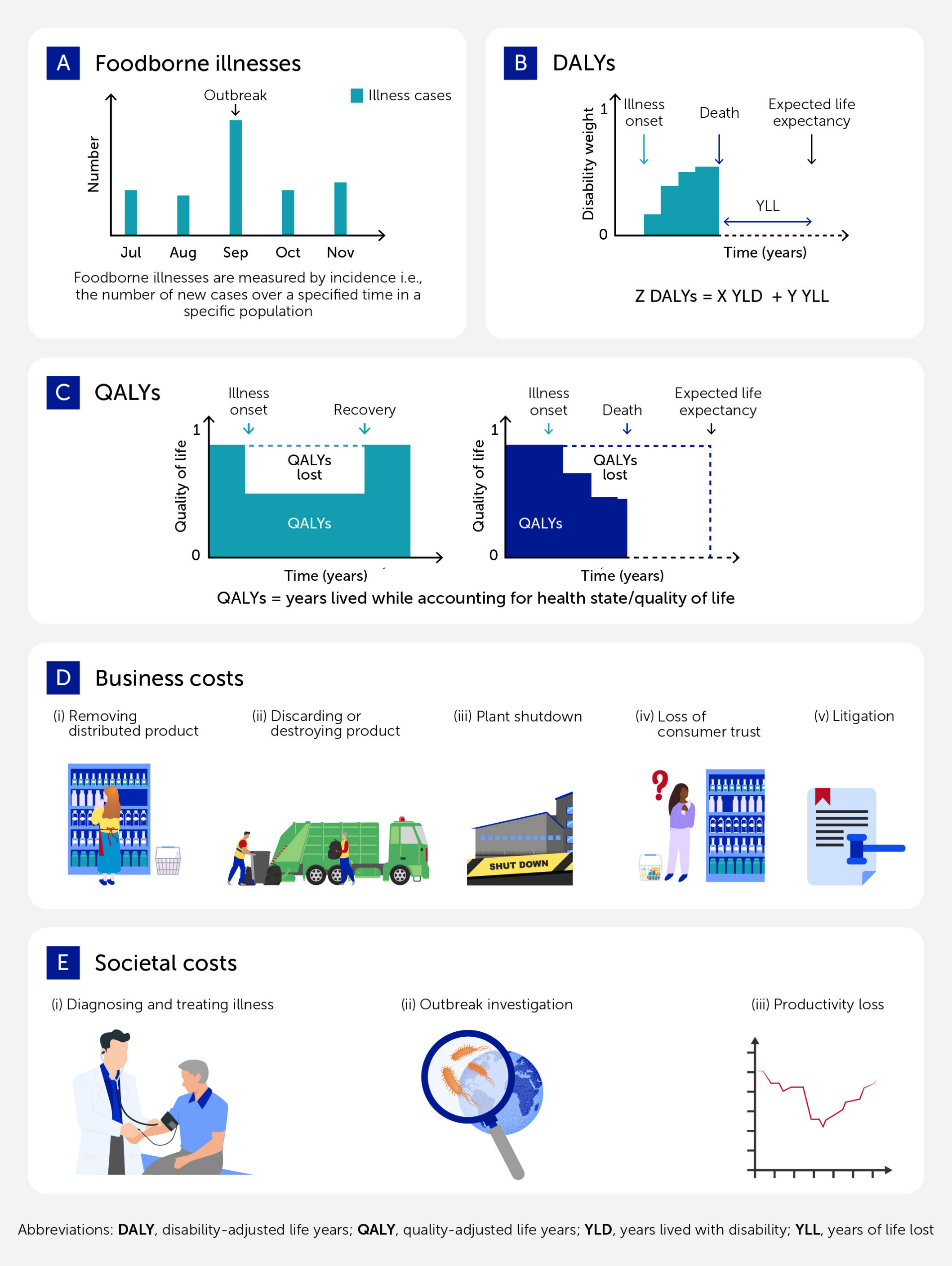


FIGURE 4
Illustration of public health and food business risk metrics. Risk metrics capture different aspects of public health and food business risk. **(A)** Foodborne illnesses are quantified by the incidence, or the number of new cases over a specified period of time in a specific population; an increased incidence of cases that are linked to a common etiological source indicates the occurrence of an outbreak. **(B)** Disability-adjusted life years (DALYs) represent a measure that accounts for years of life lost due to (i) disability (YLD) or (ii) premature mortality (YLL). **(C)** Quality-adjusted life years (QALYs) represent the years of life lived while accounting for the quality/health state of the lived years. **(D)** Examples of business costs associated with outbreaks and recalls include costs of (i) removing contaminated food from public distribution, (ii) destroying contaminated food, (iii) shutdowns of food plants (e.g., for sanitation and plant remediation due to regulatory action), (iv) loss of consumer trust, and (v) litigation (lawsuits) and other legal action. **(E)** Broader societal costs include the costs of diagnosing and treating illness, outbreak investigations, and productivity losses (e.g., due to illnesses that lead to individuals not being able to work). The depictions of DALYs and QALYs were based on (64) and (65), respectively.

TABLE 2 Examples of different food safety risk metrics used in public health and by food businesses.

Metrics	Description
Public health risk metrics: numerators[1]	
Foodborne illness cases and deaths	Number of foodborne illness cases or deaths caused by a given pathogen
Disability-adjusted life year (DALY)	DALYs are used to quantify the number of years that are lost due to disability and premature death caused by a hazard (e.g., foodborne pathogen). DALYs involve the use of disability weights to quantify the severity of a health outcome, with 0 representing full health and 1 representing death (66)
Quality-adjusted life year (QALY)	QALYs represent a measure that accounts for the years of life that are lived and the utility of those years, while accounting for the presence and severity of a health outcome due to a hazard (e.g., foodborne pathogen). QALYs involve the use of utility weights to calculate the utility loss associated with a health outcome, with 0 representing death and 1 representing full health (67). The utility weights in QALYs can be calculated using data on a patient's assessment of the impact on quality of life of different health states (67, 68)
Food business risk metrics: numerators	
Cost of recall	Factors considered when determining the cost of a recall (66, 69, 70) may differ substantially and include: • direct costs such as (i) product destruction, (ii) plant shut down, and (iii) restarting product lines or a facility after recall; • indirect costs such as (i) loss of consumer trust and (ii) loss in the valuation of a food business. The annualized cost of a recall could be estimated by accounting for: • prevalence of a contaminated product • likelihood of a positive product test • likelihood of a product being tested (e.g., by regulatory agencies)
Cost of outbreak	Past studies considering the cost of outbreaks focused on the cost to: • business (71, 72); • consumers (e.g., cost of illness) • society (e.g., due to loss of productivity or use of public resources in the regulatory response to the outbreak) (73) To assess the annualized cost of an outbreak, the likelihood of an outbreak needs to be quantified using an appropriate risk assessment that may define an outbreak as two (or more) reported disease cases that can be linked to a given product or facility (e.g., by whole genome sequencing)
Public health risk metrics: denominators	
Per serving	Number of foodborne illnesses or deaths expected across a certain number (e.g., 100,000) of servings, which can be calculated by accounting for the: • prevalence of contaminated servings • likelihood of illness due to exposure to a contaminated serving (74)
Per population per year	Number of foodborne illnesses or deaths expected in a population over a year, obtained by incorporating: • risk per serving (see above) • annual amount of consumption (e.g., servings) across a population (75)
Food business risk metrics: denominators	
Per number of products produced	The cost of recalls or outbreaks can be expressed per number of products produced or sold in a given year (for example, per number of servings or packages sold). This denominator would allow a food business to identify specific products or product lines that represent a higher risk
Per facility per year	The cost of recalls or outbreaks can be expressed per facility by accounting for products produced annually in a facility, as well as facility-specific factors that impact recall or outbreaks risks (e.g., the frequency and location of environmentally positive pathogen tests or the regulatory environment, which may affect the number of finished product tests performed by regulatory agencies; in some countries, virtually no finished product testing may be performed)

[1] While these public health risk metrics are typically used as numerators in food safety risk assessments, they can also be used as denominators. For example, cost-utility analyses use a ratio of the cost of an intervention as a numerator and QALYs as a denominator (68). Furthermore, a recent study calculated the cost-effectiveness ratio of interventions aimed at reducing the risk of foodborne illness due to *Salmonella* and *Campylobacter* by dividing the national annual intervention cost by a public health benefit metric based on DALYs (76).

in the United States may prioritize managing norovirus (estimated 5,461,731 cases and 149 deaths annually) (16) over *L. monocytogenes* (estimated 1,591 cases and 255 deaths annually), whereas assessments based on deaths would suggest the opposite; DALYs and QALYs represent one approach for unified risk metrics that take different dimensions of illness into account. Similarly, the choice of denominator can shape conclusions on food safety priorities. For example, based on "risk per serving", raw milk has a substantially higher risk of causing foodborne illness than pasteurized milk. However, pasteurized milk represents a larger "risk per population" (as compared to raw milk) due to its far greater consumption (6), suggesting that risk reduction efforts focusing on pasteurized products are justified even if raw milk represents a larger per serving risk. A published QMRA of *Salmonella* in almonds illustrates how risk metrics can guide food safety decisions. This analysis supported the use of a heat treatment process giving a 4-log reduction in this pathogen, which was estimated to result in fewer than one case of salmonellosis per year in the United States (59).

Importantly, risk-based decision-making at the food business level must often account for both public health risks and food business-level financial risks—sometimes out of necessity due to legal requirements such as the Sarbanes-Oxley Act in the United States (https://sarbanes-oxley-act.com/). Examples of food business-level risk metrics may include (i) recall risk and annualized recall cost, which factors in both the likelihood and financial impact of recalls, (ii) outbreak risk and associated annualized outbreak costs, considering the likelihood and financial impact of outbreaks, and (iii) costs of contamination events that do not lead to outbreaks or recalls, such as expenses related to product disposal, rework, or downgrading. The financial impacts of recalls and outbreaks should also account for the impacts of reputational damage.

As with public health metrics, different denominators may be used for business risk metrics, such as cost per unit produced or per facility. Since companies must prioritize addressing various types of risk, such as food safety, cybersecurity, or workplace safety, metrics that quantify the costs of different food safety risk management options can support more rational, data-driven decision-making. This applies both at the food business level and more broadly, for example when trade groups propose or mandate specific food safety practices. Financial risk metrics can also inform policy and regulatory decisions by identifying the most cost-effective risk management strategies. For instance, Ssemanda et al. (76) recently evaluated the cost–effectiveness of interventions to control *Campylobacter* and *Salmonella* in the chicken meat supply chain in Burkina Faso and Ethiopia, using intervention costs and avoided DALYs as key metrics (76). Similarly, another study evaluated the cost–benefit ratio of different *Campylobacter* interventions in poultry supply chains in Belgium (77).

Regulatory agency use of hazard- and risk-focused approaches

Regulatory agencies worldwide generally employ a combination of hazard- and risk-focused approaches to ensure food safety. Hazard-focused approaches are often favored for pathogens that cause severe illness, such as *L. monocytogenes*, and typically involve regulations that deem any detection of a pathogen in a finished product as evidence that a product is "unsafe" and, hence, adulterated. The current FDA policy on *L. monocytogenes* in RTE foods is widely regarded as an example of a hazard-focused approach (11). Under this policy, any FDA-regulated RTE product that tests positive for *L. monocytogenes*, regardless of concentration or whether the food supports pathogen growth, is considered adulterated. In contrast, some countries take a more risk-based approach to regulating *L. monocytogenes* in RTE foods. These approaches include setting different microbial limits depending on the food's characteristics. For example, Canada, Chile, and others have adopted a threshold of 100 CFU/g for foods that do not support *L. monocytogenes* growth, consistent with the Codex Alimentarius Commission guideline (78).

Regulatory agencies may also use hazard- or risk-focused approaches beyond standard-setting, such as for prioritizing inspections and other regulatory actions (11). Importantly, this allows regulatory agencies that operate under a hazard-focused standard (e.g., absence of *L. monocytogenes* in a 25 g RTE product sample) to implement a more risk-based system by focusing enforcement and testing on high-risk foods, such as RTE foods that support *L. monocytogenes* growth and have been linked to outbreaks. The United States Department of Agriculture (USDA) "*Listeria* Rule" (79, 80) provides an example of this approach. Under this rule, RTE deli meats, which have been implicated in several listeriosis outbreaks (81, 82), are classified into control alternatives based on (i) the capacity to control *L. monocytogenes* contamination and (ii) the product's ability to limit pathogen growth in the finished product. Alternative 1 products use both a post-lethality treatment to reduce or eliminate *L. monocytogenes* and an antimicrobial agent or process to inhibit its growth and are consequently considered to represent the lowest public health risk. In contrast, Alternative 3 products rely solely on sanitation practices to control contamination in the environment and product and are considered to represent the highest risk. Although all products are subject to the same legal standard for *L. monocytogenes* detection (i.e., absence in a 25 g sample is typically interpreted as "zero tolerance") (11), the USDA uses a risk-ranking algorithm that takes into account the control alternative, as well as production volume, type of product produced, and sampling history, to identify facilities for finished product testing (80). In addition, the USDA prescribes risk-based sampling frequencies for environmental *Listeria* sampling on food contact surfaces. For example, a 2022 Food Safety and Inspection Service directive indicates that there are no regulatory testing requirements for Alternative 1 products, while testing of food contact surfaces in the post-lethality environment, for *L. monocytogenes* or an indicator organism, is required for Alternative 3 establishments (83). These regulatory and enforcement strategies are supported by risk assessments that support significant public health benefits from reformulating RTE deli meats with growth inhibitors (84, 85).

Industry use of hazard- and risk-focused approaches

While regulatory agencies and international bodies, such as the Food and Agriculture Organization of the United Nations (FAO), frequently use QMRAs to guide food safety regulations and enforcement, food business operators (and particularly smaller food businesses) may often have limited access to such tools and resources. Food business operators with limited risk assessment expertise may also be prone to utilizing hazard-focused approaches and general food safety plans outlined in guidance documents (86). Consequently, they may use simple action limits, such as the absence of a hazard in samples assessed by end-product testing (with these limits often prescribed by regulatory agencies or buyers, e.g., retailers). Food businesses may also rely on qualitative (rather than quantitative) risk assessment approaches to manage food safety risk and develop and implement food safety systems. These assessments often lack standardized methods and may not formally support food safety decisions related to preventive controls or prerequisite programs. This is particularly evident in areas such as control of environmental hazards (e.g., *L. monocytogenes*), where decisions about sanitation frequency, maintenance protocols, and environmental monitoring are rarely grounded in formal qualitative or quantitative risk assessments and instead rely more heavily on classification of zones within food production facilities (e.g., as low or high hygiene and food contact or non-food contact surfaces) to define food safety measures including sampling frequency (87, 88).

While many companies implement fairly effective food safety systems using current practices, there are substantial opportunities to improve decision-making. Specifically, there is a need for (i) better and easier-to-use modeling and risk assessment tools suitable for industry and (ii) training and support for development and application of risk assessments; this is particularly important as regulators increasingly expect food safety systems to be "science- and risk-based". Building science-based systems will, however, require consensus on clear goals regarding foodborne illness risk, defined using either (i) absolute targets (e.g., a maximum allowable probability of illness per serving of a product), (ii) relative targets (e.g., a specific percentage reduction in illness risk for a product or pathogen), or (iii) business risk-focused targets using financial or operational risk metrics. Scientific methods, such as risk assessments, can then be used to identify and evaluate the best strategies for achieving these goals.

Risk assessment and predictive modeling for food safety and sustainability

Modeling tools and quantitative risk assessments play a key role in developing systems that assure a level of food safety appropriate for a society or business, which by necessity must balance multiple objectives, including food safety, public health, and the sustainability of food and agricultural systems. Over the past few decades, numerous studies have developed food safety risk assessments. These assessments are valuable for setting priorities and standards, including by regulatory agencies. For example, a 2003 USDA/FDA risk-ranking report (89) concluded that RTE deli meats posed the highest risk for listeriosis, supporting regulatory and enforcement efforts targeting these products in the United States. More targeted risk assessments and models evaluate the impact of specific regulatory practices and recommended control strategies for reducing foodborne illness. Increasingly, these tools are also being used to support risk management in specific industry sectors, such as the almond industry (59), and even at the level of individual companies and processing facilities (90).

Monte Carlo simulation-based quantitative microbial risk assessments

Monte Carlo simulation-based quantitative microbial risk assessments (MC-QMRAs) were first applied to microbial food safety questions in the early 1990s (91), although key components, such as dose–response modeling, trace back to the 1920s (92). Key applications include (i) risk ranking, (ii) evaluating the predicted impact of regulations, interventions, and control strategies, and (iii) identifying knowledge gaps to prioritize future research and resource allocation.

An MC-QMRA (see Figure 5 for details) consists of two components: (i) a QMRA, which typically estimates the likelihood of adverse health outcomes from exposure to a hazard (e.g., a foodborne pathogen) and (ii) a Monte Carlo simulation, which quantifies variability and uncertainty in the model outcomes. A typical QMRA includes four stages: hazard identification, exposure assessment, dose–response characterization, and risk characterization (Figure 5) (93). Although primarily used to assess public health risks, the stages of a QMRA can be adapted to assess other types of risk, such as business risk.

Within QMRAs, food value chain stages are typically represented using quantitative values or distributions that describe pathogen prevalence/concentration and/or process parameters (e.g., log reduction from heat treatment). Model inputs reflect either variability (natural heterogeneity within a system) and/or uncertainty (lack of knowledge or data) (94). For example, while both Lambertini et al. (75) and Farakos et al. (95) used distributions to represent the variability of *Salmonella* spp. concentration on pistachios, Farakos et al. (95) also represented uncertainty using this distribution by sampling its parameters (i.e., mean and standard deviation) using a Monte Carlo Markov chain.

Monte Carlo simulations work by iteratively sampling from the defined distributions to generate a range of possible outcomes. A single iteration yields one estimate of a risk metric (e.g., illness risk per 100,000 servings), while many iterations (e.g., 100,000) generate a distribution of the risk metric. This allows estimation of the mean, range, and confidence intervals of risk that can be compared to real-world data on foodborne illness prevalence (if such data are available for a given food–pathogen combination) to gauge the accuracy of the risk estimates. In a second-order MC-QMRA, variability and uncertainty are modeled separately, which helps identify both the likely magnitude of risk and the areas needing improved data (94).

In addition to their use for risk rankings, MC-QMRAs are commonly used to evaluate potential regulatory interventions. Examples include (i) modeling of *Salmonella* transmission through eggs, which informed United States regulations mandating refrigeration (96, 97), (ii) a joint FAO/WHO QMRA for *L. monocytogenes* (98), which found that public health risk did not differ substantially between acceptance limits of 0.04 and 100 CFU/g at the point of consumption, assuming certain contamination patterns, and (iii) a recent USDA QMRA that evaluated the impact of controlling *Salmonella* levels and targeting high-virulence serovars in raw chicken products (99).

Some MC-QMRAs were also specifically developed to support decision-making by industry, which often must manage microbial risks more stringently than required by regulation. For example, Zoellner et al. (90) modeled the risk of listeriosis from frozen vegetables, showing low median risk but high potential risk in worst-case scenarios involving improper cooking by vulnerable

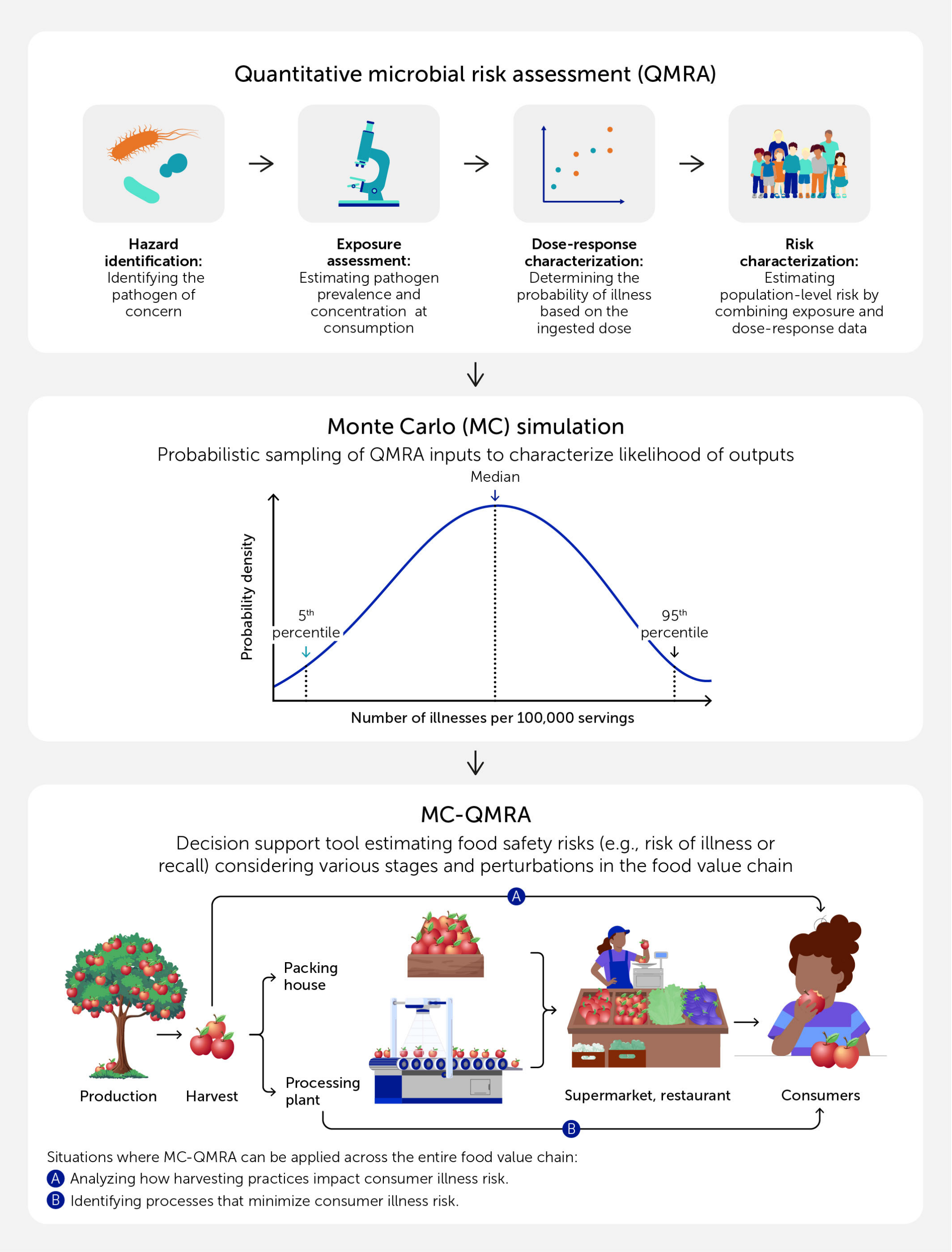


FIGURE 5
Conceptual framework for quantitative microbial risk assessment and Monte Carlo simulation and their integration for quantitative food safety risk assessments considering the various stages and perturbations in a food value chain. Integration of this framework into a more holistic approach to food safety decision-making is shown in Figure 6.

consumers—underscoring the importance of considering consumer behavior. Other MC-QMRAs have introduced alternative risk metrics, such as the probability of a positive product test (100, 101). Although published MC-QMRAs have yet to fully incorporate recall or outbreak costs as primary risk metrics, such metrics could provide valuable insights into business-level risks.

Other modeling tools used for microbial risk assessment and risk management

In addition to Monte Carlo simulations, other modeling tools are also being adopted for food safety applications, including geographic information system (GIS) models, agent-based models

(ABMs), and AI-based predictive tools. Mechanistic models grounded in molecular biology are also emerging to help predict microbial inactivation (102). Following external validation to assess predictive accuracy, the validated models can provide support for decision-making across the stages of the food value chain, including in complex and heterogenous environments (e.g., in agricultural fields with GIS models); these models also offer opportunities for conducting stakeholder-specific trade-off risk assessments.

GIS-based models

GIS-based models have diverse applications in food safety and can predict pathogen contamination risks based on spatial and environmental data. These models typically involve mapping locations of pathogen-positive sites and interpolating these data across geographical regions to identify high-risk areas and environmental drivers for pathogen contamination. Considered risk factors often vary spatially (e.g., proximity to pastures, roads, or water sources) and temporally (e.g., rainfall or temperature patterns). For example, some studies (103–105) used GIS models to predict pathogen contamination of soil or produce at the field level, accounting for variables such as proximity to land-use classes (e.g., pastures), soil properties, and weather. One study found that the likelihood of isolating *L. monocytogenes* from fields in the state of New York was influenced by the field's proximity to certain spatial features, such as roads and water (105).

GIS models can be used not only to determine food safety risk factors and help identify possible interventions to reduce risks but also to understand trade-offs involved in such interventions. For example, Karp et al. (106) reported that the prevalence of enterohemorrhagic *E. coli* in agricultural fields was associated with both proximity to grazing lands and removal of non-crop vegetation around fields. These findings illustrate that GIS models can be applied to conduct trade-off assessments, informing the implementation of various food safety-related measures relevant to produce, including (i) determining buffer zones between fields and grazing lands, which can involve balancing the loss in arable land with reductions in food safety risks and (ii) determining the impact of non-crop vegetation removal on both food safety risks and ecological disturbances.

Agent-based models

ABMs can be used to characterize the dynamics of pathogens in complex environments by considering events that can directly or indirectly influence pathogen introduction, persistence, die-off, or removal. While ABMs have been used to understand pathogen transmission in agricultural environments, for example, in grazing cattle (107), they have shown particular promise for assessing transmission and control of index organisms (e.g., *Listeria* spp.) and foodborne pathogens (e.g., *L. monocytogenes*) in processing facilities (108) and retail environments (109). For example, ABMs have been applied to simulate *Listeria* transmission in processing environments, revealing that pathogen persistence is higher in zone 4 areas such as loading docks—likely due to damaged surfaces and less frequent sanitation (110). ABMs have also been used to test intervention strategies. For example, Barnett-Neefs et al. (111) reported that risk-based sanitation, which is informed by facility-specific root cause analysis, can be effective for controlling Listeria in produce packing houses.

ABMs can also support decision-making by estimating costs and different trade-offs. For instance, increasing wet cleaning frequency may enhance sanitation but also increase the risk of pathogen spread due to water dispersion (112). ABMs are uniquely equipped to not only consider (i) how wet cleaning can impact pathogen dynamics, including die-off (due to exposure to sanitizers and disinfectants) and growth and/or dispersion (due to the presence of moisture) but also (ii) facility-specific challenges, such as evaluating pathogen dynamics in areas within a facility that are susceptible to pooling water.

AI-based models and predictive tools

AI tools, including machine learning models, are also increasingly being developed for food safety applications (113, 114), including risk assessments. For example, machine learning models have been developed to predict the presence of pathogens in agricultural water, utilizing various inputs such as weather, water quality, and microbial characteristics (115, 116). AI models also have the potential to enhance QMRAs and food safety decision-making more broadly. For example, machine learning models may (i) outperform traditional primary growth models by predicting novel growth phenotypes of bacteria (117), (ii) improve specificity of dose–response models by incorporating genomic data (118), and (iii) support scenario development for QMRAs by identifying emerging hazards, risks, and intervention strategies using natural language processing (119).

Neural networks have also been used to predict the growth/no-growth boundary of foodborne pathogens such as *Staphylococcus aureus* (120). While these tools can help refine predictions related to pathogen growth in MC-QMRAs, they can also be applied more directly to inform food safety decision-making (e.g., development of food safety plans), for example with improved decision-making on whether a given food supports pathogen growth (78).

Emerging tools for precision food safety

Advances in technologies such as genomics offer opportunities to improve risk assessments and develop precision food safety approaches—methods that are more targeted and data-driven than current practices, akin to precision medicine (121). For example, traditional food safety approaches often rely on broad taxonomic classifications (e.g., species or genus) to define hazards and regulatory targets. However, bacterial species or foodborne pathogens like *L. monocytogenes*, *Salmonella*, and *Cronobacter* include strains with substantial variation in virulence and other phenotypic traits. For certain pathogens for which virulence differences are well characterized—such as *E. coli*—regulations already target specific subtypes (i.e., *E. coli* O157 or broader groups of enterohemorrhagic strains, which include *E. coli* O157) (122). Genomic tools can further refine these approaches by identifying genetic markers—such as specific gene patterns or point mutations—

that correlate with virulence differences. For instance, studies on *L. monocytogenes* have identified point mutations causing premature stop codons in the virulence gene *inlA*, resulting in reduced invasiveness in human intestinal epithelial cells and reduced virulence in a guinea pig model (123–125). In addition, at least some of the *L. monocytogenes* strains that carry these mutations are frequently found in food isolates but are rare (and significantly under-represented) among human isolates, further supporting their reduced ability to cause human disease (126–129).

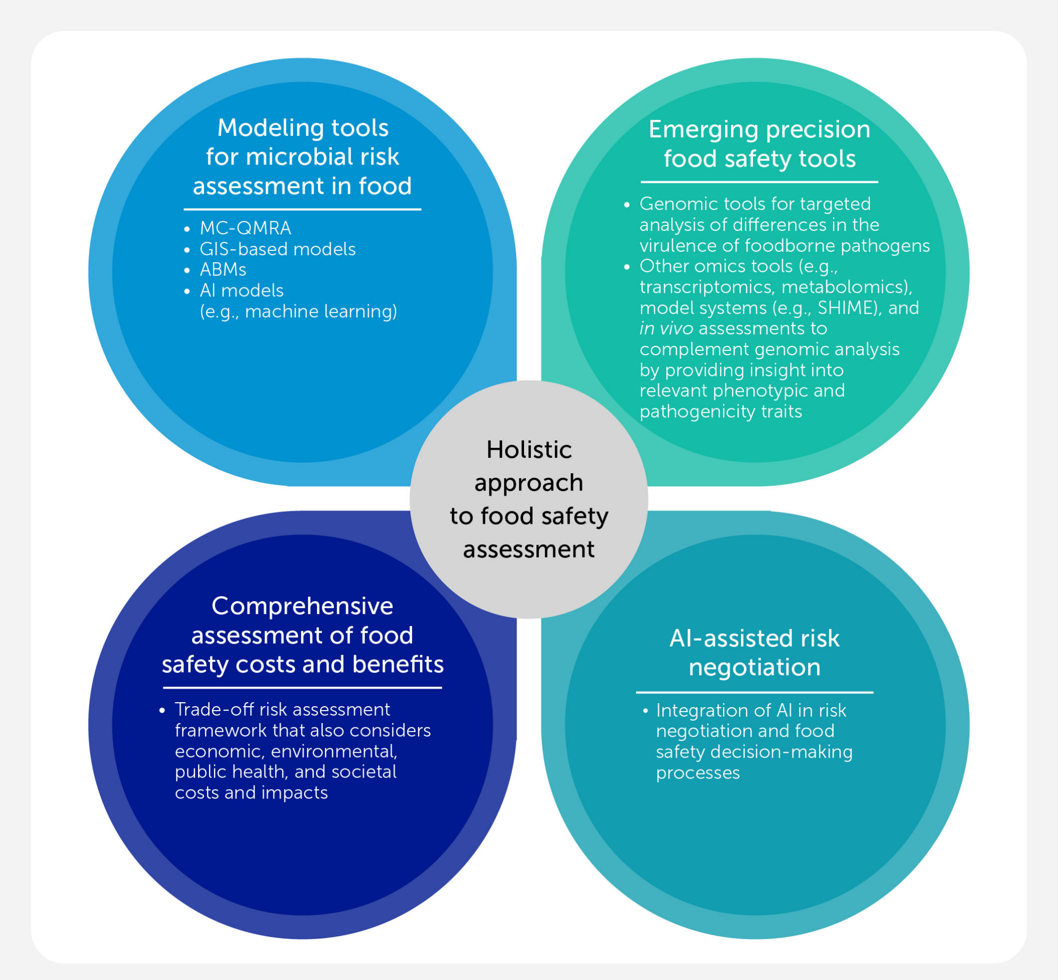
Food safety regulations rarely incorporate strain-level virulence differences. A recent WHO/FAO report acknowledged the potential benefits of such precision but also highlighted challenges, including risk communication and the cost of subtype-specific management (130). While virulence determinants in pathogens like *Salmonella* are less clearly defined, existing knowledge has been applied in risk assessments to evaluate the benefits of targeting high-risk strains. For example, a risk assessment on human salmonellosis cases from raw chicken parts found that public health risk is concentrated in finished products with high *Salmonella* levels and specifically, high levels of high-virulence serotypes; focusing control measures on high-virulence serotypes achieved public health benefits comparable to strategies targeting all *Salmonella* serotypes (131). Such targeted approaches could reduce food waste (by avoiding unnecessary rejection of low-risk products) and improve control strategies (e.g., by directing vaccination efforts or surveillance toward high-virulence serotypes). Hence, efforts should continue to focus on integration and use of genomic tools (132) in risk assessments to help with the development of more resource-efficient food safety systems, appreciating that some groups (e.g., some food business operators) may be more risk-averse than others and thus may select more conservative approaches to minimize business-related risk (e.g., due to litigation and legal action).

Trade-off risk assessments: current status and future developments

In the long term, a holistic approach to food safety (Figure 6) requires assessing both the benefits and costs of interventions—including the economic, environmental, societal, legal, and logistical considerations associated with different control strategies. Currently, most cost evaluations of food safety interventions occur after classical MC-QMRAs, which focus primarily on food safety outcomes. In some countries, regulatory impact assessments are required for high-cost regulations, but these are often qualitative and lack the methodological rigor (e.g., Monte Carlo simulations) of the initial MC-QMRA. Similarly, industry-led assessments typically consider costs only after the primary risk analysis, even though decisions on implementing food safety measures are often shaped as much by trade-offs as by the expected safety benefits.

Hence, there is a need for formal "trade-off risk assessments" that evaluate public health, environmental, social, and economic consequences of interventions within the risk assessment itself (see Appendix 1 for a list of terms that are relevant to trade-off risk assessments). Trade-off risk assessments represent one analytic approach that can be used to perform risk–benefit analyses (RBA), which can also be performed with more informal approaches. The term "multi-objective optimization" (a tool that can support "multiple-criteria decision-making") represents another, related concept that has been mentioned in efforts to optimize food systems while considering multiple factors and trade-offs (133). Trade-offs are already regularly evaluated in disaster management, often through less formal approaches. For example, as part of the emergency response to Hurricane Harvey in Texas in 2017 (134), the authorities in Houston issued stay-in-place orders to avoid evacuation-related casualties, which, drawing on prior experience, were expected to outweigh the benefits of evacuations (135). Researchers in other fields have proposed pairing risk assessments with life-cycle assessments (LCAs) to enable holistic and simultaneous analyses of local and global impacts of public health interventions (136–138). In one example, a hybrid QMRA-LCA that assessed two municipal water management plans in Sydney, Australia (137) found that one plan reduced foodborne illnesses (lower DALYs in QMRA) but increased energy use and climate-related health risks (higher DALYs in LCA), illustrating the importance of using complementary tools to fully capture trade-offs. Additional publications that provide further insight into integrating LCAs and risk assessments for microbial and/or chemical hazards include Harder et al. (139) and Kobayashi et al. (140).

In food safety, trade-off risk assessments have been used for chemical hazards. For example, the FDA's 2014 *Quantitative assessment of the net effects on fetal neurodevelopment from eating commercial fish* calculated the "net effects" of fish consumption by weighing the risks of methylmercury exposure against the benefits of nutrient intake during pregnancy using dual dose–response models (15). Considering the "net effects" of an action is representative of RBA, which allows trade-off decision-making that addresses whether consumption of a certain food (141) or change to a process (142) is warranted by simultaneously quantifying health-related benefits and consequences. Since RBA typically consider "localized" benefits and risks limited to the subset of a population that consumes a certain food, others have discussed the need to expand RBA to quantify regional and global health and environmental impacts (e.g., biodiversity loss) by incorporating LCA (143) or multi-criteria decision analysis (144); such approaches would also allow RBA to account for economic constraints and public preferences. Another example of a trade-off risk assessment is a study that used a risk–risk analysis approach to estimate DALYs from infant exposure to inorganic arsenic and aflatoxins in cereals, finding that shifting all infant cereal consumption to oats could substantially reduce health burdens (145). Despite these efforts, broader use of trade-off assessments is needed to quantify unintended negative impacts of food safety measures, including those affecting public health, sustainability, and society. For example, Kim et al. (131) recently assessed not only the benefits of stricter *Salmonella* product standards for raw poultry but also quantified associated food losses. Post-implementation studies have also suggested unintended consequences of food safety practices. For example, efforts to reduce pathogen contamination of produce through removing non-crop vegetation and replacing compost with other fertilizers were reported to possibly impact biodiversity, soil health, and carbon sequestration (45). Other examples of food safety sustainability dilemmas that could



Abbreviations: **ABM**, agent-based model; **AI**, artificial intelligence; **GIS**, geographic information system; **MC-QMRA**, Monte Carlo simulation-based quantitative microbial risk assessment

FIGURE 6
A holistic approach to food safety decision-making. Key aspects for holistic decision-making are (i) modeling tools for microbial risk assessment, (ii) emerging precision food safety tools [e.g. genomic and other omics tools, model systems (e.g., SHIME—Simulator of Human Intestinal Microbial Ecosystem), and *in vivo* experiments], (iii) comprehensive trade-off assessments considering costs and benefits, and (iv) artificial intelligence-assisted risk negotiation.

be addressed by trade-off risk assessments include balancing potential public health risks of water reuse with the environmental impacts of conserving water as well as balancing food safety risks associated with donation of left-over or expired foods with food security benefits (see Table 1 for additional examples). These scenarios underscore the value of trade-off risk assessments to quantitatively capture the full impact of food safety interventions at multiple scales including, for example, (i) individual-level health risks and benefits, (ii) local and regional sustainability impacts, and (iii) global environmental consequences (e.g., carbon emissions from recalls or product destruction). This will be particularly important as we try to address various impacts of climate change on food safety, which will include a need to balance food safety outcomes with sustainability impacts related to climate change (e.g., carbon emissions). See (146, 147) for further reading on the impacts of climate change on food systems and food safety.

Innovative approaches to socially acceptable food safety

As discussed, conventional risk assessment frameworks often fall short in addressing intersectoral trade-offs and the inherent complexity of achieving and defining appropriate levels of food safety in multi-sectoral food systems. A central challenge is the difficulty of comparing benefits and costs that are measured in different units, such as “illness cases avoided” versus “greenhouse gas emissions generated” or “implementation costs incurred”. Classical approaches attempt to harmonize these using common metrics, such as financial costs or DALYs. For example, one study assessed trade-offs between foodborne illness and the climate change impacts of two municipal water management plans, using DALYs as a shared metric (140).

However, using a single, shared metric for costs and benefits is often impractical and insufficient. In addition, risk perception by the general population also needs to be considered when trying to define acceptable food safety risks. To address this, Ehling-Schulz et al. (148) recently proposed an AI-assisted risk negotiation framework—a structured, multi-step process that includes (i) stakeholder roundtable formation, (ii) problem formulation, (iii) AI-supported risk assessment and valuation, (iv) risk negotiation, (v) communication and implementation, and (vi) outcome evaluation and risk renegotiation. AI tools, such as large language models and predictive analytics, can facilitate each step by reducing bias, enabling consensus-building, and fostering transparent, cross-sectoral engagement. This negotiation-based risk analysis has the potential to transform conventional, siloed risk assessments into participatory and more holistic processes that balance food safety and diverse trade-offs. However, this will require a fundamental shift away from a "zero-risk" paradigm toward a balanced risk negotiation model that acknowledges trade-offs between food safety, food security, sustainability, and economic feasibility. AI can assist in risk negotiation by analyzing large datasets, identifying trends, and simulating potential outcomes. Specifically, AI-powered multi-agent negotiation frameworks allow stakeholders such as policymakers, food producers, and consumer representatives to engage in structured decision-making processes that integrate a multitude of diverse perspectives.

By incorporating AI-assisted risk negotiation, food safety governance can become more adaptive, participatory, and transparent. This has the potential to improve risk communication and stakeholder trust as well as to enhance global food system resilience by fostering equitable and sustainable food safety solutions that accommodate societal needs. It is, however, important to consider that generative AI can be susceptible to fallacies including fabrication, and reasoning and mathematical errors (149). Thus, despite the advances made possible by generative AI, it is important that stakeholders maintain active oversight during the AI-assisted risk negotiation process to detect and rectify errors. Furthermore, a recent survey (150) found that approximately 39% of the US population aged 18 to 64 has used generative AI, suggesting the potential for more widespread uptake, which is essential to ensure that AI-assisted risk negotiation can benefit from, and provide benefits to, all participating stakeholders.

Future directions

While risk assessments have a long history of supporting food safety decision-making, most have focused on quantifying risks and evaluating risk reduction strategies, often without formally accounting for the associated costs or trade-offs or addressing factors considered more subjective, such as consumer risk perception (which may often reflect social and cultural factors, such as the importance of specific foods and food preparation practices for a given society). In contrast, fields such as emergency preparedness are moving toward impact forecasting (151), which involves considering both the likelihood and severity of hazards to facilitate trade-off decision-making; specific examples and discussion of trade-off decision-making in emergency preparedness include Dale at al. (152), Wild et al. (153), and Davidson et al. (154). Where feasible, using a single metric such as QALYs to quantify both benefits and unintended consequences can help rationalize trade-off decisions. Yet, even with unified risk metrics, society may assign different values to risks and costs incurred through different means. For example, in the field of health technology assessment, QALYs are used in cost–benefit analyses to help identify cost-effective healthcare interventions, but they can neglect societal preference for fairness by disregarding healthcare interventions for conditions that are not cost-effective to treat (e.g., rare, high-risk conditions with lower capacity for recovery) (155, 156). In the context of food safety, QALYs gained through food safety interventions may not be valued the same as those gained through reduced carbon emissions. Thus, we need further development of frameworks that support risk negotiation and allow societies to balance competing priorities and values (1).

While there are advantages to globally consistent food safety standards (e.g., for trade), trade-off decisions will likely have to consider whether a single food safety standard is socially acceptable in different regions with distinct societal expectations and needs. What is considered an acceptable risk or sustainable outcome in one context may not be in another. Tools such as multicriteria decision analysis can integrate diverse data and preferences, including health impacts, costs, and societal acceptability (140), though these methods may also introduce subjectivity in how interests are weighted. Importantly, providing policymakers with extensive options for risk-reduction interventions and their associated costs may not always lead to optimal decisions. As Mccaughey & Bruning (157) noted, policymakers and risk managers often exhibit bounded rationality and "satisficing"—choosing the first option that seems sufficient rather than the best possible one. Therefore, future efforts are needed to strengthen interdisciplinary research that incorporates social sciences, economics, life sciences, and systems biology to facilitate the development of food value chains that meet nutritional and safety needs while aligning with broader societal values. Improved communication between risk managers and assessors will also be important, ensuring that assessments and their metrics support rational, inclusive decision-making. Technological advances, such as GIS, AI, and genomics, can enhance the efficiency and precision of trade-off risk assessments (e.g., by accounting for virulence differences among strains within a given species). However, participatory and transparent approaches will be equally, if not more, essential in assuring evolving global food systems that meet safety, nutrition, sustainability, and accessibility goals.

Statements

Author contributions

MW: Conceptualization, Funding acquisition, Project administration, Supervision, Visualization, Writing – original draft, Writing – review & editing.

SS: Project administration, Visualization, Writing – original draft, Writing – review & editing.

AIM-S: Writing – original draft, Writing – review & editing.

KV: Writing – original draft, Writing – review & editing.

SJ: Funding acquisition, Writing – original draft, Writing – review & editing.

Data availability statement

The original contributions presented in the study are included in the article. Further inquiries can be directed to the corresponding author.

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Conflict of interest

MW serves as principal of Cayuga Food Safety Consulting, which includes, but is not limited to, serving on a food safety advisory council for Mars, Conagra, and Boarshead, and as a consultant for Neogen, BioMerieux, and Taylor Farms. KV is a principal of UniFAHS. The companies were not involved in the study design, collection, analysis, interpretation of data, the writing of this article, or the decision to submit it for publication.

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Appendix

APPENDIX 1 Description of terms relevant for trade-off risk assessments.

Concept	Abbreviation	Description
Agent-based model	ABM	Simulation models that represent the components of a system, such as a processing facility, as "agents" that can interact with one another based on rules or frameworks. ABMs have been used to understand factors that are involved in the transmission and control of pathogens in food processing or retail environments (109, 111).
As low as reasonably achievable	ALARA	A principle for setting food safety goals by (i) identifying what can be achieved with current risk management options and (ii) setting a goal that can thus be realistically achieved by a given risk management strategy (158).
Appropriate level of protection	ALOP	The "level of protection" considered appropriate or the level of risk that is considered acceptable or tolerable for a given food-hazard pair (158).
Food safety objective	FSO	"The maximum frequency and/or concentration of a (microbial) hazard in a food at the time of consumption that still provides the appropriate level of protection" (8).
Multi-objective optimization	MOO	An optimization approach that is used to find the best solution to a problem while considering more than one objective function (i.e., factor) with conflicting goals (159). It can be used to identify solutions to a certain objective (e.g., minimizing foodborne illness) while accounting for trade-offs of other objectives (e.g., energy use). In food safety, MOO has been used to identify a retort temperature for canned goods that minimizes nutrient loss (160).
Multi-criteria decision analysis	MCDA	An approach that uses a decision matrix to characterize potential solutions to a problem across a set of standards (i.e., criteria) (144, 159). This approach can be used to identify a preferred solution by valuing some criteria over others based on user preferences. A prior study (161) utilized MCDA to identify the preferred sanitizer for produce wash water across various stakeholder groups by considering criteria including effectiveness, consumer and worker health, and consumer acceptance.
Performance criteria	PC	"The effect of one or more control measure(s) needed to meet or contribute to meeting a PO [performance objective]" (8).
Performance objectives	POs	"The maximum frequency and/or concentration of a (microbial) hazard in a food at a specified step in the food chain before time of consumption that still provides or contributes to the achievement of an FSO or ALOP, as applicable" (8).
Quantitative microbial risk assessment	QMRA	A probabilistic framework that is typically used to estimate the population-level risk of foodborne microbial illness, considering various factors including consumption of a certain food, food processing and handling practices, or policy changes. This framework involves four steps: hazard identification, exposure assessment, dose-response characterization, and risk-characterization (60).
Qualitative microbial risk assessment	NA[1]	A framework that estimates population-level risk of microbial illness; the outcome is a risk score or category, which can be used to compare and rank practices. This approach is used either (i) as a first step during risk analysis (including to evaluate the need for a quantitative risk assessment) or (ii) if there is a lack of data, time, or resources for a quantitative microbial risk assessment. (162).
Risk-benefit analysis	RBA	Frameworks that allow for quantitative comparison of benefits and risks associated with an action, typically in a local system. RBA can also be expanded to account for global (e.g., beyond the system) benefits and risks (143). Cost-benefit analysis is a similar approach that can be used to compare the costs and benefits of an action (163).
Trade-off risk assessment	NA[1]	A tool that can be used for RBA. Trade-off risk assessments use a risk assessment framework to compare competing solutions to a risk management issue within a system by accounting for both local (i.e., within the system) and global (i.e., beyond the system) benefits and risks, including social, economic, and environmental benefits and risks.

[1] NA, not applicable.