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Science Behind Food Regulations

Mainstreaming Risk Assessment for Robust and Resilient Food Systems

White Paper

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PREFACE

This white paper on 'Mainstreaming Risk Asessment for Robust and Resilient Food Systems' has been prepared with an intent to strengthen application of risk assessment methodology for advancing science-based food safety measures. The paper outlines the merits of a Risk based approach rather than a hazard based one which is very important for ensuring consumer safety and health. While hazard-based approaches focus merely on the presence of potential dangers without evaluating the likelihood and severity of actual harm, risk-based methodologies provide a comprehensive assessment of both the probability and the potential consequences of adverse events. This perspective enables more effective prioritization and management of food safety interventions, optimizing resource allocation and mitigating real-world risks. Risk analysis comprising of Risk Assessment, Risk Management and Risk Communication provide policymakers and stakeholders in the food control ecosystem with the necessary information and evidence for effective and transparent decision-making, leading to enhanced food safety outcomes and public health improvements. The four critical steps central to risk assessment are - (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and, (iv) risk characterization. These steps along with globally available risk assessment tools with the help of case studies, help capture the opportunities available in the Food control eco-system to evolve and adopt such principles and approaches.

This document is envisaged to be used for orienting various stakeholders like scientific panels and experts, government, regulators, industry to risk based regulatory framework and will be shared with the wider food safety stakeholder communities.

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- **Mr Sanjay Dave,** Former Chairperson of Codex Alimentarius Commission & Advisor of FSSAI; Chairperson of FSSAI Expert Committee on Codex and WTO-SPS matters
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EXECUTIVE SUMMARY

Adequate, nutritious, safe food is essential to human survival. The nation's agriculture and food marketing systems have evolved to provide food to a growing and increasingly sophisticated population. But food can also cause or convey risks to health and even life itself. Although estimates vary widely, there is agreement that foodborne illness is a serious problem.

Complex processes built on advances in science and technology have been developed to evaluate and manage the risks associated with the changing nature of the food supply. Well-established systems control many food risks, but serious hazards to public health remain.[1]

This paper presents a comprehensive examination of hazard-based and risk-based approaches in food safety regulation, advocating for a science-driven transition toward mainstreaming risk assessment within India's food safety framework.

This paper briefly examines hazard analysis and its assessment based on research data, and outlines both hazard-based and risk-based approaches to food safety. It emphasizes the need for a science-driven transition toward mainstreaming risk assessment within India's food safety regulatory framework.

The report also explains core risk assessment principles, outlines global regulatory best practices (including those from the EU, Codex, and WHO/FAO), and evaluates modern tools such as Matrix , Decision tree, FDA-iRISK, and Risk Ranger. Additionally, it outlines key do's and don'ts for policymakers and food business operators (FBOs) to support the development of an effective and practical risk analysis framework.

Case studies from India and abroad—ranging from aflatoxin contamination in groundnuts to arsenic exposure through rice—demonstrate the real-world applicability of these frameworks. These analyses underscore how risk-based systems can better protect vulnerable populations, optimize resource allocation, reduce unnecessary trade disruptions, and prevent food waste.

Key Insights:

Institutionalizing Risk based Approach

- Constitution of multi-stakeholder forum
- Development of some risk ranking tool or Adoption of globally accepted tools

Strengthening Data Infrastructure and Scientific tools

- Compilation and consolidation of comprehensive data
- Total Diet Study under Indian dietary patterns
- Standardization of format to capture FBO data
- Need for strengthening of food authority infrastructure

Building Capacity and Transparency

- Establish structured Public consultation
- Structured protocol for evaluation of scientific evidence towards any regulatory decision
- Establish a transparent, evidence-based, and participatory frameworks for conducting risk assessments

LIST OF TABLES

ABBREVIATIONS

- ADI- Acceptable Daily Intake
- AFB1- Aflatoxin B1
- AOP- Adverse Outcome Pathways
- ARfD- Acute Reference Dose
- BCoDE- Burden of Communicable Diseases in Europe
- BIOHAZ- Panel on Biological Hazards
- BMD- Bench Mark Dose
- BMD- Benchmark Dose
- CART- Classification and Regression Tree
- CCP- Critical Control Point
- CFU- Colony Forming Unit
- CLP- Classification, Labelling and Packaging
- CMR- Carcinogenicity, Mutagenicity and Toxicity to reproduction
- DALY- Disability Adjusted Life Years
- EC- European Commission
- ECHA- The European Chemicals Agency
- EFoNAO-RRT- EFSA Food of Non-Animal Origin Risk Ranking Tool
- EU- European Union
- FAO- Food and Agriculturual Organisation
- FBO- Food Business Operator
- FSS Act- Food Safety and Standards Act
- FSSAI- Food Safety & Standards Authority of India
- GAP- Good Agricultural Practices
- GF- Gluten Free
- GHP- Good Hygienic Practices
- GI- Gastro- intestinal
- GMO- Generically Modified Organisms
- GMP- Good Manufacturing Practices
- HACCP- Hazard Analysis Critical Control Point
- HBV- Hepatitis B Virus
- HCC- Hepatocellular Carcinoma
- HRI- Health Risk Index
- iAs- Inorganic Arsenics
- IPM- Integrated Pest Management
- IQ- Intelligence Quotient
- JMPR- Joint FAO/WHO Meeting on Pesticide Residues.
- kg- Killogram
- LOAEL- Lowest Observed Adverse Effect Level
- MCDA- Multi-Criteria Decision Analysis
- MRA- Microbiological Risk Assessment
- MRL- Maximum Residue Limit
- NAM- New Approach Methodologies
- NHANES- National Health and Nutrition Examination Survey
- NOAEL- No Observed Adverse Effect Level
- P3ARRT- Pathogen–Produce Pair Attribution Risk Ranking Tool
- ppb- Parts per billion
- QMRA- Quantitative Microbial Risk Assessment
- QoL- Quality of Life
- RAC- Risk Assessment Cell
- REACH- Registration, Evaluation, Authorisation and Restriction of Chemicals
- SPRINT- Scalable Parallelizable Induction of decision Trees
- SQMRA- Swift Quantitative Microbial Risk Assessment
- TDI- Tolerable Daily Intake
- UK- United Kingdom
- USFDA- United States Food and Drugs Administration
- WHO- World Health Organisartion
- WTO- World Trade Organization

BACKGROUND

Food safety is a critical global priority because it involves practices and measures that ensure the food we consume is safe and free from harmful contaminants. Despite its importance, the widespread impact of foodborne diseases is frequently underestimated. These diseases can result from consuming food contaminated with pathogens like bacteria, viruses, or parasites. The consequences can range from mild gastrointestinal discomfort to severe, life-threatening illnesses, affecting millions of people worldwide each year. Additionally, foodborne diseases can have significant economic impacts, including healthcare costs, lost productivity, and trade disruptions. Raising awareness about the actual scale and severity of foodborne illnesses is essential to implementing effective prevention strategies and to encourage global efforts to improve food safety standards and practices.

According to the World Health Organization (WHO), unsafe food causes an estimated 600 million cases of foodborne illnesses and 420,000 deaths annually, resulting in the loss of approximately 33 million healthy life years (DALYs). Alarmingly, about 30% of these deaths occur in children under the age of five—a figure that is likely underestimated. These statistics highlight the urgent need for all stakeholders across the food chain to recognize the significance of their roles, the impact of their decisions on public health, and their collective responsibility in ensuring food safety and security [2-5].

In India, the incidence of foodborne illnesses is significant, attributed to a combination of poor food handling practices, lack of awareness among consumers and vendors, and inadequate sanitation facilities, particularly in rural and semi-urban areas.

With rapid advancements in science and technology, food safety is undergoing a significant transformation. Various approaches such as New Approach Methodologies (NAMs), that are being adopted and implemented by authorities and countries like EFSA, USFDA and others—including in silico models, in vitro assays, omics technologies, and Adverse Outcome Pathways (AOPs)—are transforming food safety and chemical risk assessment by offering more human-relevant data and reducing reliance on animal testing. These tools are particularly valuable for evaluating novel foods such as plant-based proteins, lab-grown meat, and insect-based products, which often lack historical consumption data. Despite their scientific promise, the integration of NAMs into regulatory frameworks remains slow, revealing a gap between innovation and policy [6-8].

A tiered approach integrating in vitro and in vivo testing for food contaminants offers a scientifically robust, resource-efficient, and ethically responsible framework for hazard identification and risk assessment. This begins with Tier 0, involving in silico methods such as QSAR models, read-across, and molecular docking to predict potential toxicities, followed by Tier 1 high-throughput in vitro screening using cell-based assays to detect cytotoxicity, endocrine disruption, or oxidative stress. In Tier 2, more mechanistic and physiologically relevant in vitro models such as 3D organoids, co-culture systems, and gut-liver axis simulations help elucidate dose-response relationships and bioavailability. Confirmatory Tier 3 in vivo studies are then limited to high-priority contaminants, focusing on complex endpoints like systemic toxicity, reproduction, and metabolism, while Tier 4 includes human biomonitoring and epidemiological data to contextualize public health relevance. In the Indian context, this approach aligns with FSSAI's emphasis on scientific risk assessment and the 3Rs principle, with opportunities to incorporate in vitro assays into regulatory workflows, especially for high-risk contaminants such as aflatoxins, pesticide residues, and heavy metals. By integrating data across tiers using weight-of-evidence and mode-of-action frameworks, this strategy supports more predictive, humane, and globally harmonized food safety evaluations.[9]

With the shift in consumer preferences, the food safety frameworks must adapt to address emerging risks and complexities with more responsive and targeted safety strategies. The rise in demand for ready-to-eat meals and online food delivery has increased concerns around microbial contamination, cold chain maintenance, and traceability of ingredients and extended handling chains. Similarly, the growing interest in organic and natural foods introduces distinct risks such as spoilage and pest exposure, requiring specialized risk models. Heightened awareness of allergens and specific diets for target population such as vegan, gluten free, lactose free etc. has led to stricter labeling and greater emphasis on preventing cross-contamination. In this evolving landscape, food safety assessments must incorporate global data, harmonized protocols, and consumer-driven trends, aligning with the global principles of Risk Analysis to continuously build a safer, stronger and resilient food safety network.

1

Fundamentals of Hazard and Risk

A fundamental starting point to food safety is understanding the distinction between hazard and risk. Defined during the 1995 FAO/WHO expert consultation, these concepts are critical to designing preventive strategies[10]. Hazard and risk are two central principles for assessing and designing an effective Food Control/safety System towards the benefit of the population and the country. Identification of hazards and estimation of the risk concerned are central components in ensuring food safety and safeguarding public health. Table I identifies the types of hazards relating to food and their potential risks.

- A hazard refers to any biological, chemical, or physical agent in food that has the potential to cause adverse health effects.
- A risk is the probability and severity of harm resulting from exposure to a hazard.

Table I: Examples of food related hazards and their potential risks

Type	Hazard	Risk
Biological	Presence of Salmonella in raw poultry.	If poultry is undercooked, consumers may contract salmonellosis, leading to gastrointestinal illness, especially in vulnerable populations like children and the elderly.
Chemical	Pesticide residues on fruits and vegetables.	Chronic exposure to pesticide residues above acceptable daily intake values may lead to long-term health effects such as hormonal disruption or cancer
Physical	Metal fragments in processed food due to equipment failure	Ingestion of metal fragments can cause physical injury, such as cuts or internal damage
Allergenic	Undeclared peanuts in a food product	For individuals with peanut allergies, even a small amount can trigger severe allergic reactions, including anaphylaxis.

Hazard ≠ Risk

Hazard does not equal risk. Understanding hazard and risk allows to make informed- and data-driven decisions.

For example, Salmonella cells potentially present in a product is an example of hazards while the probability of contracting salmonellosis after consuming the food product is a risk (Zwietering, et al. 2021). [11]

2

Hazard and Risk Based Approach towards Food Safety

The food safety management systems should distinguish between hazard and risks and apply risk-based approaches to address food safety and/or designing food policies. The table below outlines the key thematic differences between hazard-based and risk-based approaches in food safety management, highlighting how a shift toward risk-based systems can lead to more effective, efficient, and science-driven decision-making:

Theme	Hazard Based Approach	Risk Based Approach
Core Focus	Presence of a hazard regardless of context or level	Likelihood of harm and severity based on exposure
Decision-Making Basis	Precautionary—tends to ban or restrict based on mere presence	Scientific assessment—evaluates both probability and impact
Regulatory Impact	Often leads to over-regulation and inefficiencies	Enables targeted and proportionate regulation
Impact on Farmers	May result in crop rejection due to rigid standards, regardless of actual risk	Supports farmer livelihoods by focusing only on significant risks
Food Wastage and Security	Higher food wastage due to blanket bans or rejections	Reduces waste by focusing on scientifically validated risks
Consumer Benefit	May mislead or alarm consumers over minimal threats	Builds trust through transparency and evidence-based protection
Scientific Tools Used	Largely qualitative; relies on hazard identification	Uses toxicology, dose-response, exposure assessment (e.g., NOAEL, LOAEL, ADI, TDI),
Example Framework	HACCP (Hazard Analysis and Critical Control Point) — focuses on identifying and controlling hazards	Risk Analysis Framework — incorporates scientific evidence and probability to guide decisions

Hazard Based Approach

Traditional hazard-based approaches often lead to over-cautious decisions, regulatory inefficiencies, and misallocation of resources by focusing solely on the presence of hazards, without considering the actual likelihood or severity of harm that these hazards can create. This can result in unintended negative consequences, such as livelihood loss for farmers whose crops fail to meet rigid hazard-based standards despite posing no or minimal actual risk. Such rejections can also lead to significant food wastage, impacting food security and sustainability. Moreover, consumers may not gain any tangible health benefit, as the approach may target extremely low-risk hazards while overlooking more significant issues. It is therefore imperative that the focus of stakeholders – be it policy makers, enforcement agencies, Industry or consumers – should be on risk and not merely hazard for an efficient food safety management. This is extremely critical to be able to identify the actual risk rather than spreading the resource across all hazards[11-19].

Hazard based approach mainly consist of HACCP (Hazard Analysis and Critical Control Point) system, a framework for identifying hazards and establishing critical control points (CCPs) to manage them. While HACCP remains a cornerstone in food safety, it is primarily hazard-focused and qualitative. The ultimate aim of HACCP is to prevent or substantially reduce the occurrence of food safety hazards by applying scientific principles to food processing and production. This ensures that food products are not only compliant with regulatory standards but are also safe for consumers. A broader, more quantitative approach—risk analysis—is needed to effectively address food safety challenges on a global scale[10].

The following are illustrative examples from the United Kingdom (FSA) where policy decisions were driven by a hazard-based approach,:

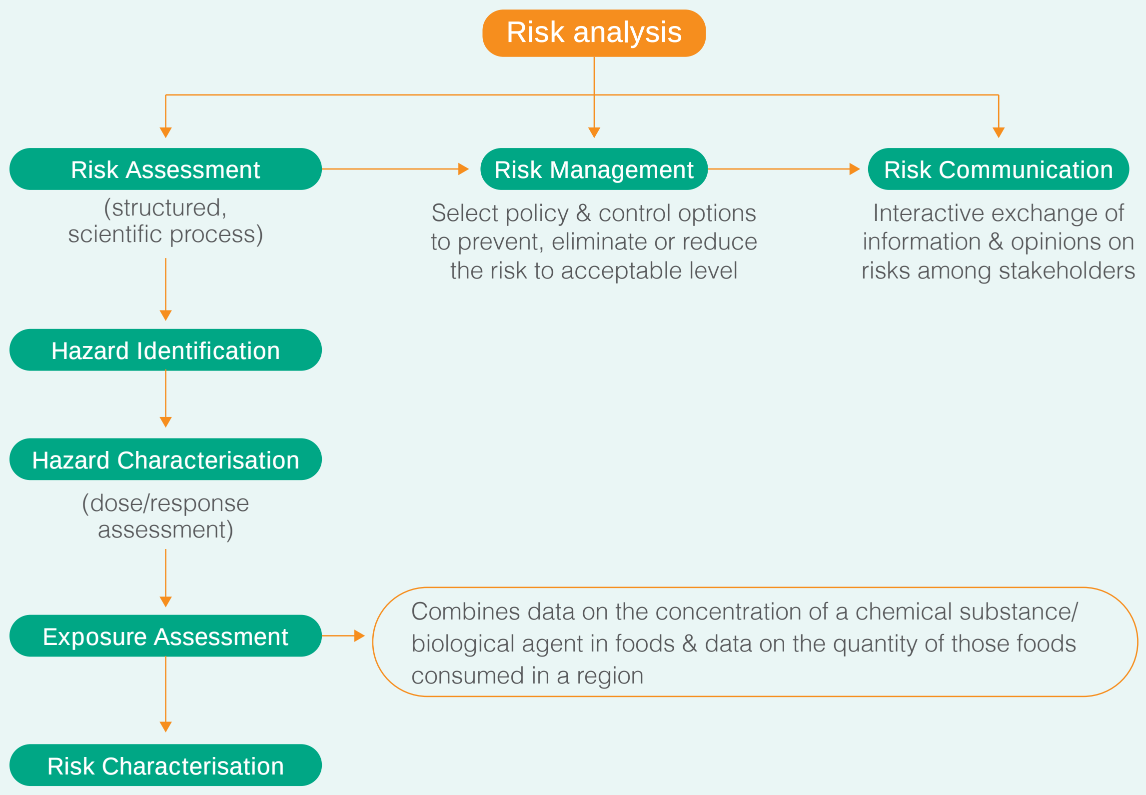
Instances of Hazard Based Approach	
Instance	**Implications**
The Sudan Red Recall in the United Kingdom (2005) The “Sudan Red recall” in the UK is an example of a zero-tolerance hazard-based approach. In laboratory animals, this dye has been shown to cause cancer. There’s no evidence that it is a human carcinogen, although the evidence is not definitive. [11]	A) In laboratory animals, this dye has been shown to cause cancer. There’s no evidence that it is a human carcinogen, although the evidence is not definitive [11] B) The UK and Europe banned foodstuffs containing the dye in 2003 to be on the safe side. [11]
Worcestershire sauce Recall in the United Kingdom (2005) In 2005, a consignment of Worcestershire sauce was found to contain chili powder contaminated with the dye. Many foods used the sauce as an ingredient. it triggered the largest recall in UK history to that point in time. [11]	A) Because the amounts of the dye in these products was so small, and because the link to cancer in humans hadn’t been proven, the overall risk to health was small. [11] B) No amount was considered safe and products were recalled based on their traceability rather than on the risk they posed to the public (Overbosch, 2013). [11]

Risk Based Approach

Risk-based systems prioritize interventions using scientific assessments of both probability and impact, enabling smarter regulations, targeted controls, and more meaningful protection of public health. In resource-constrained and developing countries like India, this distinction is especially important, as a risk-based model helps optimize limited resources, address emerging hazards effectively, support farmer livelihoods, reduce unnecessary food losses, and build consumer trust through transparent, evidence-driven decision-making. The risk-based approach is structured around a comprehensive risk analysis system, comprising three key components: **Risk assessment, Risk management, and Risk communication,** each of which is described below.

Risk Analysis

Risk Analysis is a systematic process used to ensure food safety and protect public health. It provides a scientific and structured framework for making decisions related to food safety, based on evidence and transparency. It consists of three interconnected components:



Components of classical risk analysis
Adapted from: Cheftel, J. C. (2011). [20].

Risk Assessment

Risk assessment is the science-based component of risk analysis that concerns itself with characterizing the probability of exposure to a hazard and the consequences of exposure for the consumer. It is a set of logical, systematic, evidence-based, analytical activities designed to gain an understanding of specific risks and to measure/ describe them. A risk assessment intends to answer questions about the identified risks and provides the objective information needed for decision making. It describes and addresses uncertainty in intentional ways and then characterizes the relevant uncertainty encountered in the assessment that could influence the decision or change decision outcomes

It is a process intended to calculate or estimate the risk to a given target organism, system, or (sub) population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system.

This process relies on sound, scientifically derived information and established procedures conducted transparently and comprises of 4 stages:

Table II: Stages for Risk Assessment

Stage 1	Stage 2	Stage 3	Stage 4
Hazard identification	**Hazard Characterization**	**Exposure Assessment**	**Risk Characterization**
Analyzing if the food or its ingredients be potentially hazardous Biological/ chemical); This is usually done by existing literature on the food and its ingredients by risk assessors.	If biological/chemical hazards are evident, the levels at which they could turn into risk are determined.	Determining the population that could be exposed to these hazards and the real-world levels of potential exposure (dose and duration).	Determining the level of exposure that causes harm and the level of actual exposure; exposure close to or greater than the level that causes harm triggers a safety concern.

Qualitative and Quantitative Assessments

Risk assessments can be qualitative or quantitative. When sufficient data and resources are available, a quantitative assessment is preferred. Quantitative risk assessment relies on numerical expressions of risk, which are generally more informative than qualitative estimates. They can be deterministic or probabilistic. Decision on qualitative/ quantitative assessment shall be made based on available data, the nature of the uncertainties, the skills of the assessors, the effectiveness of outputs in informing and supporting decision makers, and the number and robustness of the assumptions made in the assessment. When quantitative risk assessment is not possible or necessary, nonnumerical qualitative risk assessment can be a viable and valuable option. It is especially useful:

- For noncontroversial and routine tasks,
- When transparency and consistency in handling risk are desired,
- When theory, data, time, or expertise are limited,
- For broadly defined problems, where quantitative risk assessment is impractical, and
- As the first iteration of a risk assessment, uncertainty is great.

Qualitative risk estimates rely primarily on ratings (high, medium, and low), rankings (first, second, and third), and narrative descriptions. There is no internationally agreed approach to conduct a qualitative risk assessment. Much of the relevant evidence in any given risk assessment is not numerical. Thus, a qualitative assessment compiles the available evidence and combines it in a logical and transparent manner that supports a statement of risk. Qualitative assessments reveal data gaps and can be useful in directing resources to productive areas of research. Their value stems from the ability to inform and support risk management decision making in complex situations.[21]

To strengthen food safety, FSSAI has set up a Risk Assessment Cell (RAC) under Sections 10, 16(1)(i)(c), and 18(1)(2)(b)(c). RAC conducts risk assessments to support risk management and communication, focusing on products, processes, and activities that may pose health risks. [22]

Risk Management

Risk management in food production focuses on systematically identifying, evaluating, and mitigating risks to maintain the highest possible safety standards. This proactive approach is essential for preventing incidents that can harm consumers and damage a business' reputation and/or detrimental to public health at large.

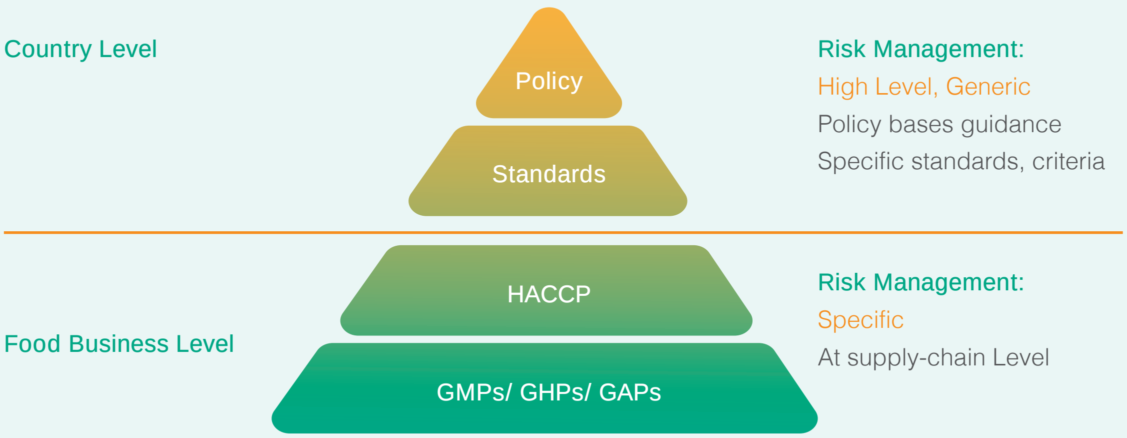
It is the process of evaluating policy alternatives in consultation with stakeholders, considering risk assessment outcomes, and selecting appropriate prevention and control measures to protect public health, which includes the following key functions:

- Develop Standards and Controls
    - Establish regulations, food safety standards, codes of practice, and mitigation protocols based on scientific risk assessments.

- Implement monitoring, inspection, and enforcement mechanisms to ensure compliance.
- Design contingency plans and emergency responses for food safety incidents.

Tailor Strategies to Context

- Integrate socio-economic, cultural, and regional factors into decision-making to ensure feasibility and acceptance.
- Maintain scientific integrity while adapting strategies to local realities, such as resource availability, dietary habits, and trade dynamics.



Adapted From: Marthi, (2023). Illustration of food safety management at country level and FBO level. Food Safety Risk Assessment I [23]

The outcome of the risk assessment, when considered alongside available risk management options, leads to an informed decision on how the risk should be managed. Once a risk management measure is implemented, its effectiveness must be monitored to assess its actual impact on reducing risk to the exposed consumer.[22]

Risk Communication

Risk communication bridges the gap between scientific risk assessments and public understanding, playing a crucial role in the successful implementation of food safety policies. It is an interactive exchange of information and opinions concerning food-related risks among risk assessors, risk managers, stakeholders, and the public. The tools for risk communication include training, press releases, publications, food labels (for example: allergen declaration), etc. It plays a crucial role in building trust and ensuring the effectiveness of food safety systems.

Core objectives:

- Foster trust and transparency
- Establish open, honest, and timely communication to build credibility among all stakeholders.
- Ensure that scientific findings, uncertainties, and decisions are clearly communicated in accessible language.
- Engage stakeholders collaboratively
- Involve government agencies, industry, academia, consumer groups, and international bodies in a two-way dialogue.
- Support inclusive decision-making that reflects diverse perspectives and values.
- Inform and empower the public
- Share the outcomes of risk assessments, especially with at-risk or vulnerable populations (e.G., Infants, elderly, immunocompromised individuals).
- Embed fact based mass communication and education to consumers for informed choice
- Provide clear guidance on actions consumers can take to prevent, reduce, or minimize food-related risks.

World Health Organization (WHO) and the Food and Agriculture Organization (FAO),	The U.S. Food and Drug Administration (FDA)	Food Safety and Standards Authority of India (FSSAI)
Effective risk communication ensures that all stakeholders are informed about the nature of food-related risks, the rationale behind risk management decisions, and the actions they can take to mitigate those risks.[24]	Emphasizes that risk communication is a strategic policy tool that supports public health objectives by informing and influencing behaviors related to food safety.[25]	Provides for a two- way communication approach wherein the authority communicates the potential risks after thorough risk assessments both internally and to external stakeholders and general public.[22]

Different strategies for transmission of messages related to food safety in risk communicaton

Different strategies for transmission of messages related to food safety in risk communication
Adapted from: Baba and Esfandiari (2023).[26]

Instances of Risk Based Approach

Instance	Implications
Risk assessments of unavoidable contaminants that are genotoxic and carcinogenic, using the margin of exposure approach, can indicate which (sub) populations and what foods/food products should be targeted for risk reduction measures, e.g. acrylamide.[27]	When there are sufficient data, risk-based approaches provide practical information concerning the likely or probable risk to the exposed population, rather than a hypothetical indicator of harm which may never be realised.[27]
Derivation of health-based guidance values (ADI, TDI, etc) for substances that are deliberately added, or present as residues or as contaminants in food.[27]	Quantitative approaches can give insight into the magnitude of risks and can be used as a basis for deriving “safe” levels of exposure.[27]
Consumer advisories on methylmercury in fish.[27]	Can inform on the level of risk reduction that can be achieved, guiding risk management decisions and consumer choice.[27]

In most cases, global regulatory regimes includes a mix of both hazard-based and risk-based approaches for ensuring food safety. While hazard-based approaches are used in some contexts (e.g. for acute and potent hazards, avoidable contaminants, genotoxic substances, allergenic ingredients, etc), risk-based approaches are most widely used around the world for chemical substances like heavy metals, pesticides, food additives in food, and the value of risk-based approaches in areas hitherto rooted on the foundational hazard-based approaches (e.g. food allergens, microbiological risks) is being increasingly recognized.[21]

3

Risk Analysis in the Food Industry: Tools & Methodologies

Risk analysis evaluates each risk by examining its nature, severity, and consequences, considering factors like uncertainty, likelihood, and consumption scenarios. Table III shows the Risk assessment systems which are essential in food safety management, enabling regulators, policymakers, and industry stakeholders to systematically evaluate, prioritize, and respond to potential hazards. These systems help allocate resources effectively by distinguishing high-risk issues from those of lower concern. Depending on the context, data availability, and decision-making needs, a range of risk ranking tools discussed in Table IV can be applied.

Table III: Risk Assessment Systems

Risk Ranking Tool	Description	Key Features	Use/Application
Magnitude/ Likelihood Matrix	Semi-quantitative matrix combining severity and probability	- Simple to use - Color-coded visualization - Uses numerical scales	- Preliminary screening - Risk communication - Prioritization of hazards
Risk Scoring and Ranking Systems	Numerical scores assigned to multiple factors to rank risks	- Data-driven- Customizable criteria - Tools like iRISK, Risk Ranger	- Comparing food-pathogen risks - Regulatory decision-making
Multi-Criteria Decision Analysis (MCDA)	Evaluates risks using multiple weighted factors (health, economic, social)	- Integrates quantitative & qualitative data-Stakeholder inclusive	- Complex decisions with many variables- Policy prioritization
Quantitative Microbial Risk Assessment (QMRA)	Mathematical modeling of microbial hazards in food	- Highly quantitative-Pathogen-specific-Based on exposure and dose-response	- In-depth assessment of microbial risks - Codex/WHO-aligned safety strategies
Expert Elicitation / Delphi Method	Structured gathering of expert opinions for risk estimation	- Useful in data-poor contexts - Consensus-based-Qualitative and semi-quantitative	- Emerging risks - Rapid prioritization where empirical data is lacking

Adapted from FAO/WHO (2006). Food Safety Risk Analysis: A Guide for National Food Safety Authorities (FAO Food and Nutrition Paper 87). Available at: https://www.fao.org/3/a0822e/a0822e.pdf

Table IV: Comparison of risk assessment tools

Tool	Type	Purpose/Focus	Key Features	Data Requirement	Output/Use
Decision Tree	Qualitative/ Semi-quantitative	Step-by-step logic-based hazard prioritization	Simple- Visual logic- Transparent criteria	Low to moderate	Basic risk sorting and decision support
P3ARRT(Pathogen–Produce Pair Attribution Risk Ranking Tool)	Quantitative	Ranks risks from pathogens in produce (U.S. FDA tool)	- Attribution model- Based on outbreak and consumption data	Moderate to high	Ranking of produce-pathogen pairs by public health risk
EFoNAO-RRT (EFSA Food of Non-Animal Origin Risk Ranking Tool)	Semi-quantitative	Prioritizes microbiological risks from plant-based foods	- Based on exposure and severity- Focused on EU produce safety	Moderate	EU-oriented prioritization for non-animal-origin foods
Risk Ranger	Semi-quantitative	General food safety risk ranking	- Easy interface- User inputs scenarios- Produces risk scores	Low to moderate	Compare risks across food-pathogen combinations
MicroHibro	Quantitative	Web-based QMRA tool for microbial hazards	- Dose- response and exposure modeling- User-customizable	High	Detailed risk estimates and simulations
sQMRA (Swift Quantitative Microbial Risk Assessment)	Quantitative	Rapid, flexible microbial risk assessment	- Spreadsheet-based- Simplified QMRA- Transparent assumptions	Moderate	Screening tool for quick assessments
FDA-iRISK	Quantitative	Comprehensive food safety risk ranking platform	- Models exposure, dose-response, and burden- Comparative scenario analysis	High	Informed decision-making and intervention planning
BCoDE Toolkit (Burden of Communicable Diseases in Europe)	Quantitative	Estimates disease burden (DALYs) for infectious diseases	- Includes foodborne transmission- Public health burden estimation	High	Policy planning, public health prioritization in Europe

Ref: Evaluation by Panel on Biological Hazards (BIOHAZ) of the European Food Safety Authority (EFSA)

Risk Assessment Tools and Techniques

There are options on the tools and techniques that can be seamlessly incorporated into a business' process. The four common risk assessment tools are: Risk Matrix, Decision Tree, Failure Modes And Effects Analysis (FMEA), Risk Ranger, FDA-iRisk And Bowtie Model. Other risk assessment techniques include the What-If Analysis, Failure Tree Analysis, Layer of Protection Analysis (LOPA) and Hazard and Operability (HAZOP) analysis.

Among the various tools available, the Risk Matrix remains the simplest and most widely adopted across industries. However, tools such as the Decision Tree, Risk Ranger, and FDA-iRisk are also frequently utilized, particularly in the field of microbiological risk assessment. A brief overview of these tools is provided below.[28]

The Risk Matrix remains the simplest and most widely adopted tool.

Risk Matrix

A commonly used tool is the magnitude/likelihood matrix (Table V), which assigns numerical values to the magnitude (harm severity) and likelihood (probability) of risks to calculate an overall risk level (Risk Level = Magnitude × Likelihood). This matrix uses color coding (green for low, yellow for medium, and red for high risk) (Table VI) to help authorities prioritize risks and focus on appropriate preventive measures.[28]

Table V: Magnitude and likelihood scales [7]

Rating	Magnitude	Likelihood
5	Lethal	Expected Likely
4	↓	↓
3		
2		
1	Irrelevant Illness	Extremely unlikely

Table VI: Magnitude/likelihood matrix and risk level. Red, high risk; yellow, medium risk; green, low risk.

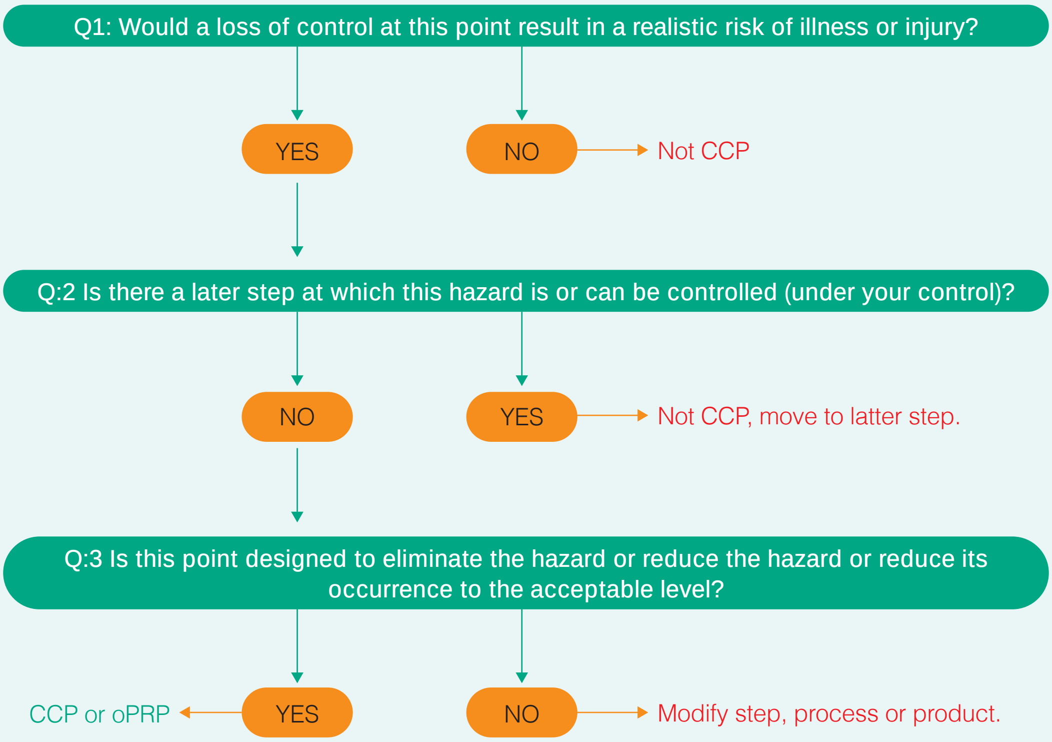
Magnitude Rating						
	5	5	10	15	20	25
	4	4	8	12	16	20
	3	3	6	9	12	15
	2	2	4	6	8	10
	1	1	2	3	4	5
		1	2	3	4	5
		Likelihood rating				

According to above matrix, authorities and participants of the food chain will focus on the higher risk level to find the right preventive strategies and to reduce the risk to an acceptable level.

Decision Tree

A Decision Tree is a tool used to determine which among your food processing operations are considered as a critical control point (CCP) or not to produce safe food products. Any controllable processing step of your whole food chain where preventive measures can be applied for the elimination of hazards can be considered as a CCP. [29]

Some examples of CCPs may include correct cooking temperature, proper conditions of storage, monitoring the integrity of packaging material, and others. A HACCP decision tree helps you decide whether a process step requires the critical limit establishment and a focused set of monitoring procedures for the control of food safety. [29]

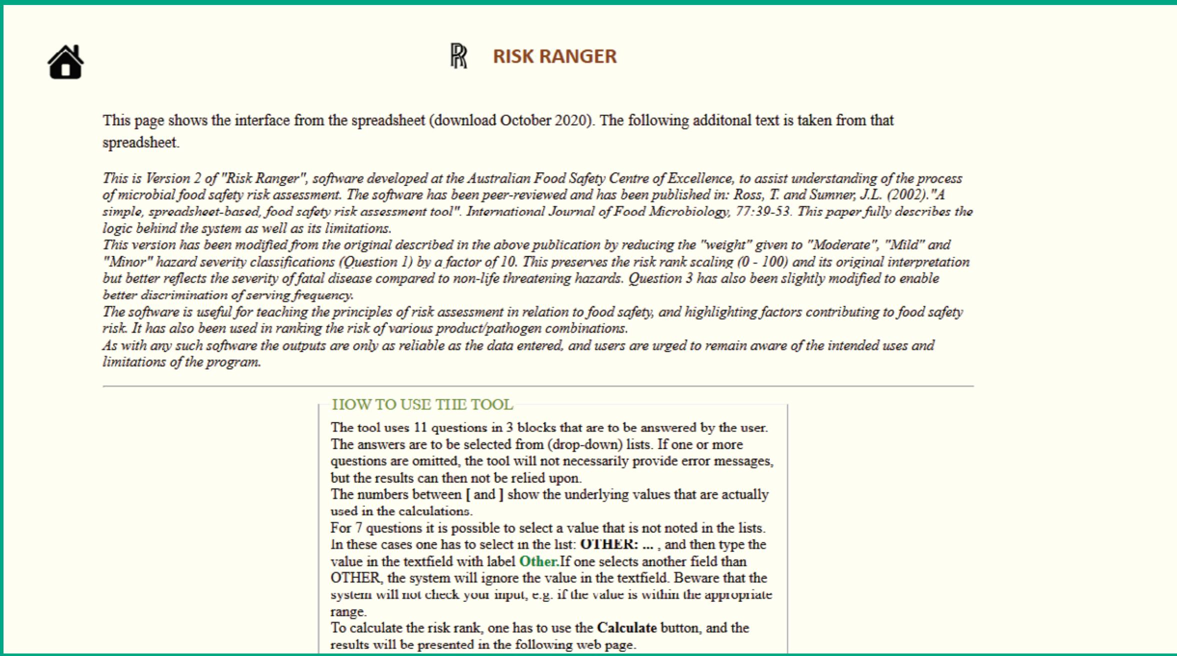


Example of a decision tree to identify critical control points (CCPs). The questions shall be answered in sequence.
Adapted from: Liivat (2025). Food Docs[30]

Risk Ranger

Risk Ranger calculates a (relative) risk ranking on the basis of a description of food contamination with pathogens. It originates from the Australia's food safety information portal. The tool uses below 11 questions that are to be answered by the user. [31]

1. Hazard severity (severe, moderate, mild, or minor hazard, depending on the need for medical intervention and/or patients' death).
2. How susceptible the population of interest is, to better define the target of the pathogens (from general population to some groups).



RISK RANGER

This page shows the interface from the spreadsheet (download October 2020). The following additonal text is taken from that spreadsheet.

This is Version 2 of "Risk Ranger", software developed at the Australian Food Safety Centre of Excellence, to assist understanding of the process of microbial food safety risk assessment. The software has been peer-reviewed and has been published in: Ross, T. and Sumner, J.L. (2002)."A simple, spreadsheet-based, food safety risk assessment tool". International Journal of Food Microbiology, 77:39-53. This paper fully describes the logic behind the system as well as its limitations.
This version has been modified from the original described in the above publication by reducing the "weight" given to "Moderate", "Mild" and "Minor" hazard severity classifications (Question 1) by a factor of 10. This preserves the risk rank scaling (0 - 100) and its original interpretation but better reflects the severity of fatal disease compared to non-life threatening hazards. Question 3 has also been slightly modified to enable better discrimination of serving frequency.
The software is useful for teaching the principles of risk assessment in relation to food safety, and highlighting factors contributing to food safety risk. It has also been used in ranking the risk of various product/pathogen combinations.
As with any such software the outputs are only as reliable as the data entered, and users are urged to remain aware of the intended uses and limitations of the program.

HOW TO USE THE TOOL

The tool uses 11 questions in 3 blocks that are to be answered by the user. The answers are to be selected from (drop-down) lists. If one or more questions are omitted, the tool will not necessarily provide error messages, but the results can then not be relied upon.
The numbers between [and] show the underlying values that are actually used in the calculations.
For 7 questions it is possible to select a value that is not noted in the lists. In these cases one has to select in the list: **OTHER: ...** , and then type the value in the textfield with label **Other.** If one selects another field than OTHER, the system will ignore the value in the textfield. Beware that the system will not check your input, e.g. if the value is within the appropriate range.
To calculate the risk rank, one has to use the **Calculate** button, and the results will be presented in the following web page.

Adapted from: Theelen, M., PhD. (n.d.).[31]

3. Frequency of consumption (daily, weekly, monthly, a few times per year or other measures given by user).

4. Proportion of the consuming population (from a low percentage of the target population to 100%).

5. Size of the consuming population, where the user can add the size of the population of interest.

6. Probability of contamination of raw product per serving (from less than 0.01% to the worst scenario approach, where the raw material is always contaminated; that is, 100%).

7. Effects of food processing, with the possibility of a focus on the flowchart and on the existence of some steps able to significantly reduce or increase levels of the pathogen.

8. Potential post-processing recontamination (yes or no, depending on the flowchart).

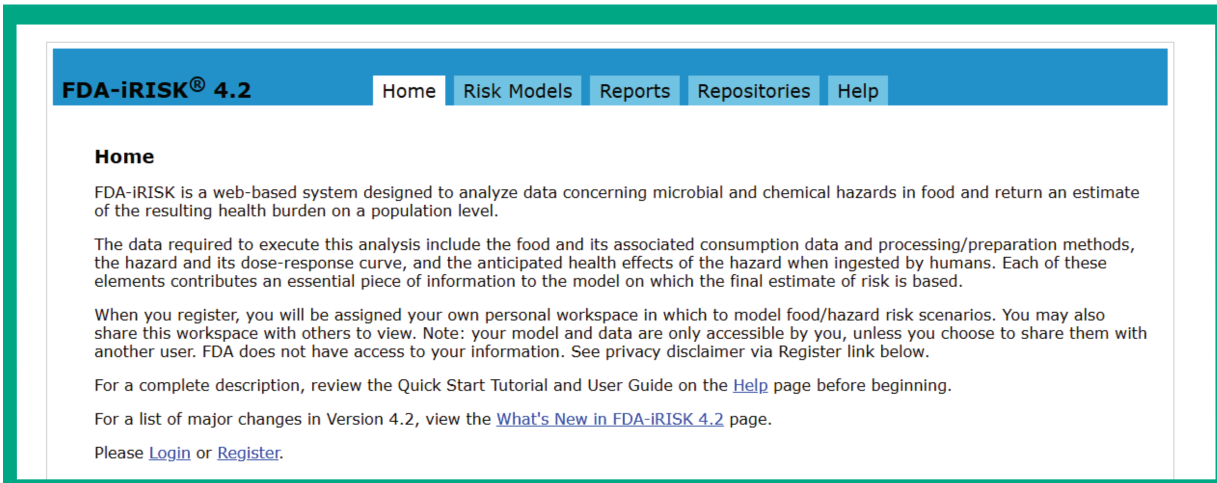
9. Importance of control processes after food processing (from “well controlled” to “gross abuse occurs”, depending on how the product is stored before preparationand consumption).

10. Level of increase in post-processing contamination increase level (the increase in the pathogen level during post-processing which can cause negative effects to average consumers).

11. Effect of preparation before eating (if a kind of preparation is required before consumption).

FDA-iRisk

FDA-iRisk is a quantitative risk assessment tool developed by the US Food and Drug Administration (FDA) with the support of American and foreign group of experts, and it is useful for estimating microbial and chemical risks. [33]



FDA-iRISK® 4.2

Home | Risk Models | Reports | Repositories | Help

Home

FDA-iRISK is a web-based system designed to analyze data concerning microbial and chemical hazards in food and return an estimate of the resulting health burden on a population level.

The data required to execute this analysis include the food and its associated consumption data and processing/preparation methods, the hazard and its dose-response curve, and the anticipated health effects of the hazard when ingested by humans. Each of these elements contributes an essential piece of information to the model on which the final estimate of risk is based.

When you register, you will be assigned your own personal workspace in which to model food/hazard risk scenarios. You may also share this workspace with others to view. Note: your model and data are only accessible by you, unless you choose to share them with another user. FDA does not have access to your information. See privacy disclaimer via Register link below.

For a complete description, review the Quick Start Tutorial and User Guide on the Help page before beginning.

For a list of major changes in Version 4.2, view the What's New in FDA-iRISK 4.2 page.

Please Login or Register.

Adapted from: FDA-IRISK - home. (n.d.)[32]

It is based on process models (initial contamination, production/processing/ handling steps), logical connections, dose-response relationships, probability density, growth or inactivation models for microorganisms and Monte Carlo simulations. [33]

- FDA-iRISK supports the following risk (exposure) scenarios:
  - Acute exposure to microbial hazards in a single food.
  - Acute exposure to chemical hazards in a single food.
  - Chronic exposure to chemical hazards in a single food.
  - Chronic exposure to chemical hazards in multiple foods (Multifood).

Risk assessors choose the type of risk scenario and set it by addressing seven elements, which are completely editable according to necessity and the available data (Figure 2); the

- Seven Elements are:
  - Food
  - Hazard
  - Population of consumers.
  - Process model (i.e., food production, processing and handling practices).
  - Consumption pattern(s) in the population.
  - Dose-response relationship(s).
  - Burden of disease measures associated with different adverse health effects from the hazard (i.e., a health metric such as losses in DALYs).

- FDA-iRisk generates two types of outputs:[33]
  - Risk Estimates and Scenario Ranking: this creates a report with risk estimates and ranking results for one or more scenarios, including full documentation of model inputs.
  - Summary of Model Elements: this creates a report summarizing model elements with no risk estimates. The scenarios are not computed.

4

International Benchmark in Risk Analysis

Risk Analysis in the food sector is not a one-time statutory exercise but a dynamic and evolving process, a long-term study of emerging risks. A forward-looking approach is adopted by establishing dedicated portals, expert committees, predictive modeling frameworks, and systematic analysis of data sources such as the Rapid Alert System for Food and Feed (RASFF).

A robust mechanism exist to identify, prioritize, and communicate potential food safety threats across the supply chain. continuous research, stakeholder engagement, and transparent dissemination of findings, ensures that emerging risks are not only monitored but also effectively managed.[34]

Key features of a transparent, evidence-based, and participatory frameworks for conducting risk assessments.

- **Transparent Communication:** Define and publish methodologies, engagement with independent scientific panels, and share findings openly with stakeholders and the public.
- **Comprehensive Data Collection:** Call for data from various stakeholders including industry and assessment of data applications and usage with proven scientific principles.
- **Realistic Timelines:** On average, comprehensive risk assessment studies may take 1.5 to 3 years, accounting for extensive data collection, toxicological evaluations, public consultations, and peer reviews.

For example, a brief of milestone achieved by EFSA in terms of emergency toxins are shown overleaf:

Milestones

2007

EFSA produces definition and description of ‘emerging risks’ within its mandate

2009

EFSA developed IT tools for identifying emerging risks through routine analysis of data from the Rapid Alert System on Food and Feed (RASFF) of the European Commission and databases of trade statistics from the EU’s Comtext and the UN’s Comtrade databases.

2010

EFSA developed IT tools to support the development of web monitoring systems for the detection of emerging risks.

2011

EFSA’s 15th Scientific Colloquium covers its work on emerging risks, while the 16th looks at emerging risks in plant health.

EFSA pilots a new process for emerging risks identification, and evaluates a system for scanning Eurostat data to detect trends in trade.

2012

EFSA supports a project on modelling, predicting and mapping the emergence of aflatoxins in cereals in the EU due to climate change. See also EFSA’s activities on Emerging Risks 2012–2013.

2014

EFSA finalises a systematic procedure for the identification of emerging chemical risks in the food/feed chain and identifies drivers and interactions of emerging biological risks. See also: EFSA’s Activities on Emerging Risks in 2014.

2015

An EFSA funded project reviews and analyses cyanobacteria toxins in food while EFSA appraises its procedures and future directions for identification of emerging risks. See also EFSA’s Activities on Emerging Risks in 2015.

2016

EFSA tests a text mining tool for emerging risk identification, a media monitoring tool MedISys for plant health threats and a procedure for identifying emerging chemical risks in the food chain. See also EFSA’s Activities on Emerging Risks in 2016.

2017

EFSA organises a session of the IAFP 2017 European Symposium on food safety. See also EFSA’s Activities on Emerging Risks in 2017.

2018

EFSA develops the concept for the DEMETER project: an Emerging Risks Knowledge Exchange Platform (ERKEP) Framework. See also EFSA's Activities on Emerging Risks in 2018.

2019

EFSA publishes reports on identifying emerging risks and drivers using food chain analysis on aquaculture of Atlantic salmon and potential emerging chemical risks in the food chain of substances under REACH 2. See also EFSA's Activities on Emerging Risks in 2019.

2020

EFSA publishes the results of the CLEFSA Project (see also separate topic) describing a methodology for identifying and characterising the possible effects of climate change on emerging risks in the food safety area, and holds an info session.

2021

A series of four external scientific reports on ciguatera in Europe signal the completion of the first phase of the EuroCigua project.

2022

Phase two of the EuroCigua project kicks off. (See our topic on Ciguatoxins and other marine biotoxins for the full story.)

Adapted from: European Food Safety Authority. (2025, February 5)[35]

✓ Do's for Effective Risk Analysis

Policymakers

- Set up of Centralized transparent risk assessment body(Like JECFA, JEMRA, EFSA).
- Public availability of risk assessment studies (Exposure assessments, MRL derivations , Total Diet Study etc)
- Integration of both hazard and Risk based approach to ensure scientific rigor and practical relevance
- Support Evidence based policy decision making
- Development of tools like risk ranger, FDAiRISK to ensure transparency
- Regular stakeholder consultations to ensure feasible evaluation

Food Business Operators

- Be proactive, not reactive.
- Implement Hazard Analysis and Critical Control Point (HACCP)
- Conduct regular Risk assessments
- Don't delay adopting food safety standards until enforcement arrives.
- Stay informed about the regulatory updates and emerging risk
- Revise risk management practices in light of new evidence or incidents to ensure food safety.
- Ensure the availability of skilled and trained technical teams to manage risk effectively

CASE STUDIES

This white paper includes case studies - four Indian and two International, where the principles of risk analysis are applied.

CASE STUDY 1

QMRA of Salmonella in Eggs[36]

Objective

Salmonella is one of the most significant foodborne pathogens globally. Eggs are a recognized vehicle for Salmonella transmission. This study aimed to perform a Quantitative Microbial Risk Assessment (QMRA) to estimate the risk of Salmonella infection from egg consumption in South Korea, factoring in different cooking methods.

Sample and Methodology

- Sample Size: 201 egg samples collected from retail markets.
- Microbial Testing: Detection of Salmonella spp.
- Result: No Salmonella detected in any sample.

Environmental Monitoring

- Time-Temperature Data: Collected during:
  - Transit
  - Storage
  - Retail display
- This was used to model bacterial growth or reduction.

Predictive Microbial Modeling

- Model Purpose: Characterize Salmonella behavior in eggs during distribution and storage.
- Kinetic Data: Growth/survival models developed.
- Goodness-of-Fit:
  - Dry-heat model: R^2 = 0.898
  - Moist-heat model: R^2 = 0.922
- Initial Contamination Level Assumed: –4.0 Log CFU/g, based on non-detection and Poisson-based probability distribution.

Consumption Data

Eggs were consumed in the following ways:

Cooking Method	Consumption Rate	Avg. Consumption (g)
Raw	1.5%	39.2 g
Dry-heat	57.5%	43.0 g
Moist-heat	41.0%	36.1 g

Exposure and Risk Estimation

- Simulation: Monte Carlo methods used to estimate exposure and illness probability.
- Risk Outcomes:
  - Cooked eggs: 6.8×10^{-10} probability of foodborne illness.
  - Raw eggs (no cooking applied): 1.9×10^{-7} probability.

Interpretation and Risk Characterization

- Cooking significantly reduces risk:
  - ~1,000× reduction in illness probability after thermal treatment.
- Dry-heat and moist-heat cooking are effective in reducing Salmonella to safe levels.
- Even under worst-case simulation scenarios, risk remains negligible for cooked eggs.

Conclusion

This QMRA concludes that the risk of Salmonella infection from egg consumption in South Korea is low, especially when eggs are properly cooked. Continuous monitoring, combined with public education on safe egg handling and cooking, can maintain or further reduce this risk.

Recommendations

- **Consumer Guidelines:**
  - Avoid consuming raw or undercooked eggs, particularly for vulnerable populations (elderly, children, pregnant women).
  - Maintain cold chain from purchase to storage.
- **Industry Practices:**
  - Strengthen hygienic practices in egg handling, storage, and transportation.
  - Promote labeling that encourages cooking before consumption.
- **Policy Suggestions:**
  - Routine surveillance and QMRA updates using recent consumption trends and pathogen prevalence data.

CASE STUDY 2

Pesticide Residues in Vegetables in Haryana, India[37]

Background

In Haryana, a study analyzed 102 vegetable samples, along with associated soil and water, for pesticide residues. The analysis revealed frequent detection of pesticides like chlorpyrifos, cypermethrin, pendimethalin, and butachlor, with health risk indices for triazophos and chlorpyrifos ranging from 1.16 to 2.76 mg/kg, raising concerns about consumer safety.

Chlorpyrifos: An organophosphate insecticide that inhibits acetylcholinesterase, leading to nervous system disruptions. It has been associated with developmental neurotoxicity and endocrine disruption. It is banned or restricted in several countries.

Triazophos: Another organophosphate insecticide, moderately hazardous (WHO Class II), with neurotoxic effects similar to chlorpyrifos.

Objective

Assess the potential health risks associated with consumption of vegetables contaminated with pesticide residues.

Target Population: General adult population (average body weight: 60 kg) in Haryana consuming locally grown vegetables.

Pesticides Assessed: Focus on chlorpyrifos and triazophos, due to elevated health risk indices.

Methodology

3.1 Dose Response Assessment

3.2 Exposure Assessment

3.3 Risk Characterization

3.4 Health Risk Index (HRI)

3.5 Uncertainty Analysis

Predictive Microbial Modeling

- Model Purpose: Characterize Salmonella behavior in eggs during distribution and storage.
- Kinetic Data: Growth/survival models developed.
- Goodness-of-Fit:
  - Dry-heat model: $R^2 = 0.898$
  - Moist-heat model: $R^2 = 0.922$
- Initial Contamination Level Assumed: –4.0 Log CFU/g, based on non-detection and Poisson-based probability distribution.

Result

Dose-Response Assessment	Chlorpyrifos: ADI = 0.001 mg/kg bw/day, ARfD = 0.005 mg/kg bw (WHO/JMPR) Triazophos: ADI = 0.004 mg/kg bw/day, ARfD = 0.01 mg/kg bw (EFSA/FAO)
Exposure Assessment	Assumptions: - Average adult vegetable consumption: 300g/day (0.3 kg/day) - Body weight: 60 kg - Residue concentrations: - Chlorpyrifos: 0.1 to 0.25 mg/kg - Triazophos: 0.15 to 0.3 mg/kg Estimated Daily Intake (EDI): - Chlorpyrifos: 0.0005 to 0.00125 mg/kg bw/day - Triazophos: 0.00075 to 0.0015 mg/kg bw/day
Risk Characterization	Chlorpyrifos: High-end EDI exceeds the ADI, indicating potential chronic risk. Triazophos: EDI remains within ADI limits, indicating low chronic risk
Health Risk Index (HRI)	HRI = EDI / ADI - Chlorpyrifos: 0.5 to 1.25 Risk when HRI > 1 - Triazophos: 0.19 to 0.375 Acceptable (HRI < 1)
Uncertainty Analysis	Limited data on regional dietary habits and pesticide application practices. - EDI based on average values; peak exposures not accounted for. - Combined effects of multiple pesticides not assessed.

Conclusion

The Haryana study indicates significant contamination, particularly from chlorpyrifos, which exceeds ADI levels and poses chronic health risks. While triazophos remains within acceptable levels, the presence of multiple pesticide residues necessitates immediate regulatory and public health interventions.

Recommendations

- Regular testing of vegetables and water sources.
- Farmer education on safe pesticide use and pre-harvest intervals.
- Consumer guidance on washing and preparing vegetables.
- Policy enforcement of MRLs and promotion of Integrated Pest Management (IPM).

CASE STUDY 3

Aflatoxin Contamination in Groundnuts – Risk Assessment using Risk Ranger

Objective

To study aflatoxin contamination in groundnuts using Risk Ranger tool

Methodology

Risk Ranger is a semi-quantitative risk assessment tool designed for food companies to evaluate microbiological hazards in a user-friendly and structured manner. It combines a logical interface with a solid mathematical foundation, making it ideal for risk managers to assess and simulate food safety scenarios.

The tool guides users through 11 structured questions divided into three categories:

- Hazard and Population Factors – Includes severity of the pathogen and susceptibility of the population.
- Exposure Factors – Covers frequency and proportion of consumption, population size, and likelihood of contamination.
- Dose and Processing Factors – Evaluates food processing effects, post-processing contamination, control measures, and preparation before consumption.

Based on mostly qualitative inputs, Risk Ranger calculates a risk ranking score from 0 to 100, representing the relative likelihood and impact of illness. Additional outputs include:

- Probability of illness per consumer per day
- Predicted annual illnesses in the population
- Comparative risk across different scenarios

Its intuitive design enables practical risk-based decision-making, and supports the evaluation of intervention strategies throughout the food supply chain.

As discussed earlier, Risk Ranger was concluded to be a more suitable tool for a food company because of its ready-to-use characteristics and the statistical values of the outputs than decision trees and FDA-iRisk, [33]

Scenario Details

- Food Product: Groundnuts (peanuts)
- Hazard: Aflatoxin B_1
- Target Population: General population, with emphasis on HBV-positive individuals (increased susceptibility)
- Population Size: 1,000,000
- Consumption Frequency: Daily
- Contamination Level: Average of 20 µg/kg (moderate)
- Processing Impact: Minimal (aflatoxins are heat-stable)
- Control Measures: Moderate (manual sorting is only partially effective)

Risk Ranger Input Summary

Factor	Input
Hazard Severity	Severe (carcinogenic)
Population Susceptibility	Partially susceptible (HBV+ individuals)
Frequency of Consumption	Daily
Proportion of Consuming Population	80–100%
Population Size	1,000,000
Probability of Contamination	Moderate
Effect of Processing	Minimal
Post-Processing Recontamination	No
Control Measures	Moderate
Contamination Increase Post-Processing	Low
Preparation Before Eating	None (eaten as-is or lightly roasted)

Results (Risk Ranger Interpretation)

- **Risk Ranking Score:** High (estimated 70–85 out of 100)
- **Estimated Illnesses:** 8–10 liver cancer cases per million population annually
- **Risk Drivers:** Daily consumption, lack of effective processing, chronic exposure, population susceptibility

Conclusion

The Risk Ranger-based assessment confirms that aflatoxin contamination in groundnuts represents a high-priority food safety risk in India, particularly for vulnerable subpopulations. This structured, semi-quantitative tool supports food safety managers and regulators in identifying, prioritizing, and mitigating such risks effectively.

Recommendations

- Enforce regulatory limits on aflatoxin (e.g., <20 µg/kg as per FSSAI).
- Promote better drying and storage technologies post-harvest.
- Screen and reject contaminated batches using rapid test kits.
- Raise awareness among consumers and vendors about health risks.
- Encourage dietary diversity to reduce cumulative aflatoxin exposure.

CASE STUDY 4

Gluten Contamination In Gluten-free Products – Risk Assessment Using Fda I-risk[38]

Objective

To study gluten contamination in gluten free products using FDA I-Risk tool

Methodology

2.1. Hazard Identification

- Hazard: Gluten (primarily gliadin), a protein causing autoimmune reactions in individuals with celiac disease
- Health Outcome: Chronic inflammation, intestinal damage, malabsorption, anemia, growth retardation (in children), and risk of GI malignancies

2.2. Food–Hazard Combination

- Foods:
  - Labelled gluten-free grains (e.g., rice flour, jowar flour)
  - Naturally gluten-free grains (e.g., whole millets, rice, ragi)
- Product Characteristics: Varied packaging—some in sealed packets, others sold in bulk or loose form

2.3. Exposure Assessment

- Consumer Population: Southern Indian consumers with diagnosed celiac disease or gluten sensitivity
- Consumption Rate: ~80 g/day of GF grains (typical diet)
- Gluten Detection from Study:
  - 30% of labelled GF products >20 ppm gluten
  - 32% of naturally GF products >20 ppm gluten
- Estimated Intake:
  - At 20 ppm in 80 g — 1.6 mg gluten/day (may exceed tolerable threshold for sensitive individuals, often cited as ~10 mg/day)

2.4. Dose-Response

- No single threshold for celiac disease exists, but:
  - <10 mg/day of gluten is generally considered safe
  - Chronic exposure to >20 ppm poses long-term clinical risks even in low daily doses

RESULT

Result

Risk Characterization (iRisk Outputs Hypothetical)

Parameter	Value
Probability of contamination results)	30–32% (based on test
Average gluten intake in contaminated foods	1.6–3 mg/day
Frequency of consumption	Daily
Population size (at-risk in region) celiac/gluten-sensitive individuals in South India	Estimated ~100,000
Estimated Annual Illnesses subclinical or clinical cases from exposure	~15,000–20,000 chronic
Severity Score (Health Impact) on intestinal damage, QoL loss)	Moderate to High (based

Risk Mitigation Scenarios Modelled

Scenario	Outcome (Projected Risk Reduction)
Mandatory gluten testing & certification	Reduces contamination prevalence by 80%
Use of dedicated GF milling equipment	Reduces cross-contact risk significantly
Consumer awareness campaigns	Reduces consumption of loose/unregulated grains

Conclusion

Using FDA-iRisk [32] modelling principles, the study indicates that undiagnosed and unmanaged gluten contamination poses a measurable and preventable public health risk in sensitive populations. Applying iRisk allows for quantitative scenario analysis that supports regulatory decision-making and industry reform.

CASE STUDY 5

A Case Study of Three Pathogen-food Combinations Using Risk Ranger Tool

Objective

This study aimed to evaluate the microbiological risks associated with three specific pathogen-food combinations using the Risk Ranger tool. The objective was to assess and compare the relative risk levels, estimate potential illness burden, and examine the critical points in the food chain that influence pathogen exposure.

- The three case studies analysed were:
- Listeria monocytogenes in ready-to-use lettuce[39]
- Escherichia coli in chicken salad[40]
- Staphylococcus aureus in fresh egg pasta [41]

These foods were chosen due to their common consumption patterns and potential for harbouring foodborne pathogens.

Methodology

Risk Ranger- Risk Ranger calculates a (relative) risk ranking on the basis of a description of food contamination with pathogens. The "Risk Ranking" value is a simplified measure of relative risk of hazardous effects of microbiological agents, as can be read at the end of this page. It originates from the Australia's food safety information portal but today the site lacks references to it. To calculate the rank, a computer tool was developed. The tool is called "Risk Ranger: A Simple Food Safety Risk Calculation Tool". FAO supports this tool and provides you with an example for which the tool was used to evaluate the quality of fish. The various questions addressed in the tool are explained in detail in that example, and how different choices might affect the outcome.

The tool uses 11 questions in 3 blocks that are to be answered by the user.:

1. Hazard severity (severe, moderate, mild, or minor hazard, depending on the need for medical intervention and/or patients' death).
2. How susceptible the population of interest is, to better define the target of the pathogens (from general population to some groups).
3. Frequency of consumption (daily, weekly, monthly, a few times per year or other measures given by user).
4. Proportion of the consuming population (from a low percentage of the target population to 100%).
5. Size of the consuming population, where the user can add the size of the population of interest.
6. Probability of contamination of raw product per serving (from less than 0.01% to the worst scenario approach, where the raw material is always contaminated; that is, 100%).
7. Effects of food processing, with the possibility of a focus on the flowchart and on the existence of some steps able to significantly reduce or increase levels of the pathogen.
8. Potential post-processing recontamination (yes or no, depending on the flowchart).
9. Importance of control processes after food processing (from "well controlled" to "gross abuse occurs", depending on how the product is stored before preparation and consumption).
10. Level of increase in post-processing contamination increase level (the increase in the pathogen level during post-processing which can cause negative effects to average consumers).
11. Effect of preparation before eating (if a kind of preparation is required before consumption).

As per the case study , Table 5 shows the answers set by assessors, and the outputs of the tool; generally, the choices for the different questions were based on worldwide habits while the target was set to the Italian population to gain relevant results.

Result

Table 5. Answers to the questions in Risk Ranger. Answers given following authors' knowledge and information. Simulation was performed for a general audience; the exception was for question 5 (size of consuming population), where the input was based on the Italian population to gain realistic outputs.

L. monocytogenes in Ready-to-Use Lettuce	E. coli in Chicken Salad	Staph. aureus in Fresh Egg Pasta
Susceptibility and Severity		
1. Hazard severity		
Moderate hazard The risk is medium because Listeriosis requires hospitalisation in most cases.	**Minor hazard** The patient rarely requires medical assistance	**Mild hazard** The patient rarely requires medical assistance
2. Susceptibility of the population of interest		
Slight or very The subjects mostly affected are pregnant women/ foetuses and aged people.	**General** The pathogen can affect in a similar way all members of the population.	**General** The pathogen can affect in a similar way all members of the population.
Probability of exposure to food		
3. Frequency of Consumption		
Other (100 days per year, i.e., twice a week).	**Weekly** Consumption is generally once a week (average of consumers' habits worldwide).	**Weekly** Fresh egg pasta is not consumed daily.
4. Proportion of consuming population		
Most Lettuce is eaten by most of the population	**Most** Chicken salad is eaten by most of the population	**Most** Fresh egg pasta is eaten by most of the population, at least for countries where pasta is generally consumed
5. Size of Consuming Population		
60,000,000: the test was carried out taking into consideration the population of Italy		

L. monocytogenes in Ready-to-Use Lettuce	E. coli in Chicken Salad	Staph. aureus in Fresh Egg Pasta
Probability of food containing an infectious dose		
11. Effect of preparation before eating		
No effect Lettuce does not require any processing before being consumed.	No effect Since the chicken is pre-cooked, it would not require preparation before eating.	Usually eliminates The boiling before consumption eliminates all bacteria; if a simulation on toxin is performed, it is worth mentioning that toxins are thermostable and cannot be eliminated during cooking.
Risk Ranking		
59	40	40
Probability of illness per consumer per day		
$2.50 * 10^{-6}$	$4.27 * 10^{-7}$	$4.27 * 10^{-7}$
Total predicted illness per annum in the population of interest		
$1.17 * 10^{5}$	$7.02 * 10^{3}$	$7.02 * 10^{3}$
Comparative risk in the population of interest		
$5.34 * 10^{-8}$	$3.21 * 10^{-11}$	$3.21 * 10^{-11}$

1) The output is the "total predicted illness per annum in the population of interest" (from 7.02*103 in pasta/Staph. aureus to 1.17 _ 105 for L. monocytogenes/lettuce);this index is probably the most understandable measure as it offers a prediction of the possible cases of illness due to that food. For the conditions presented in this paper, the output was probably overestimated due to some input conditions and to the use of a worst scenario approach.

2) Finally, the "comparative risk" is a measure of relative risk, independent of the size of the population, but it relies on the size of the consuming population (75%). This last output is probably the most useful factor for measuring the risk for different combinations of pathogen/food, as well as for different populations.

Table 5 shows some examples of the use of Risk Ranger and how the different inputs could strongly affect outputs. It is worth mentioning that the correct use of this tool should be based on a higher number of food/pathogen combinations, and different pathogens should be evaluated for each food to assess the effective risk ranking and the pathogen requiring urgent controlling or preventive measures.

As an example, for chicken salad, the simulation was also performed for Campylobacter spp. [36,37], E. coli O157:H7 [38], and Salmonella sp. [39]; for the first two pathogens, the severity was set to moderate, while for Salmonella sp., the choice was set to "mild". The risk ranking was 52 for Campylobacter spp. and E. coli O157:H7 and 40 for Salmonella sp., with a comparative risk from 3.21*10-9 to 3.21 *10-11, suggesting that, at least for the pathogens hereby reported, Campylobacter spp. and E. coli O157:H7 are limiting for chicken salad safety.

Conclusion

- The final ranking was 59 for L. monocytogenes in lettuce, which means a risk level requiring controlling measures; this rank probably depends on certain inputs (frequency of consumption, proportion of consuming population, post-processing, and possibility of recontamination).
- For the E. coli in chicken salad and Staph. aureus in fresh pasta, the risk ranking was 40, which means a lower risk level requiring some preventive or controlling measures.
- The hazard was set to minor for Staph. aureus, due to the low grade of hospitalization and disease severity, and mild for E. coli, as the focus was on the overall strains and not only on the O157:H7 serotype.
- On the other hand, for L. monocytogenes, the choice was "moderate", as the targets mostly exposed are pregnant women/foetuses and aged people.
- Based on the average habits for Western countries, the frequency of consumption was set to "weekly" for fresh egg pasta and chicken salad, and twice a week for lettuce.
- For the contamination of raw material, the option "sometimes" or "infrequent" was set, depending on the authors' knowledge of the epidemiology of the three pathogens, while the other inputs take into account that pasta and chicken are usually cooked, while lettuce is not.
- Additional information tool givers: The tool offers other outputs, namely, the probability of illness per consumer per day, the total predicted illness per annum in the population of interest, and the comparative risk in the population of interest. The probability of illness per consumer per day is not strictly a measure of risk, because it does not consider the severity of disease, and it is only based on the "probability of a disease-causing dose being present in a portion of the product of interest" and on the exposure; it is in the range of 0–1 and measures the probability of a customer being affected by the disease. In the conditions used in this paper, the value was the highest for the combination of L. monocytogenes/lettuce (2.50 *10-6) and the lowest for Staph. aureus/pasta (4.27 *10-7).

CASE STUDY 6

Study Carried out by FDA IRISK tool: Arsenic in Rice and Rice Products Risk Assessment Report[42]

Objective

The objectives of this risk assessment are to assess the risk of adverse health effects associated with exposure to arsenic from consumption of rice grain and rice products and to examine how that risk may be mitigated. This risk assessment provides a scientific basis for the development of risk-management policy and consumer options for reducing exposure to arsenic from consumption of rice grain and rice products.

Methodology

2.1 Data Collection:

- Over 1,300 samples of rice and rice-based products were collected from 2011 to 2013 across the U.S.

  These included:

  White rice (enriched and unenriched)

  Brown rice

  Rice-based infant cereals

  Rice cakes and crackers

  Rice beverages (rice milk)

  Multi-ingredient foods containing rice

  Each sample was tested to determine the concentration of total arsenic and inorganic arsenic (iAs) using advanced analytical methods.

  Brown rice consistently showed higher iAs levels compared to white rice, due to the presence of arsenic in the outer bran layers, which are retained in brown rice.

2.2 Exposure Assessment:

- Estimated the amount of iAs consumed by different age and population groups through dietary intake of rice products.
- Dietary data was drawn from the National Health and Nutrition Examination Survey (NHANES).
- Special attention was given to infants and young children (0–3 years), who consume relatively more rice (per body weight), especially through infant cereals.
- The average daily intake of inorganic arsenic was calculated based on consumption patterns and product-specific arsenic levels.
- Exposure estimates were modeled both for typical consumers and for high-end (95th percentile) consumers.

2.3 Hazard Identification & Dose-Response Assessment:

- The FDA reviewed epidemiological and toxicological studies to identify health risks associated with iAs exposure.
- Key health outcomes considered included:

  Cancer risks – primarily lung and bladder cancer

  Non-cancer effects – including neurodevelopmental delays, immune suppression, reproductive toxicity, hypertension, and cardiovascular effects

2.4 A Benchmark Dose (BMD) approach was used to evaluate the dose-response relationship – i.e., the level of exposure associated with increased risk of disease.

The increased cancer risk was assessed based on a lifetime exposure model, while non-cancer endpoints were assessed based on sensitive life stages (e.g., infancy, pregnancy).

2.5 Risk Characterization:

Combined exposure data with dose-response data to estimate quantitative risk levels.

Monte Carlo simulations were used to handle uncertainty and variability in both consumption patterns and arsenic content.

Results

3.1 Inorganic Arsenic Levels in Rice Products:

Product	Mean iAs Level (ppb)
White Rice (enriched)	~ 92
Brown Rice	~ 154
Infant Rice Cereal	~ 103
Rice Cakes	~ 101
Rice Beverages	~ 10–50 (varied)

- Brown rice generally had 50–80% higher iAs levels than white rice.
- Rice drinks and cakes also contributed to arsenic intake.
- Estimated Dietary Exposure:
- Infants (0–3 years):
  - Highest exposure: ~ 0.64 μg/kg body weight/day
  - Mostly due to rice-based cereals and snacks.
- Adults (19–50 years):
  - Lower exposure: ~ 0.22 μg/kg body weight/day
  - More varied diets resulted in diluted arsenic intake.
- Health Risk Assessment:
  - Cancer Risk:
  - Long-term exposure at high levels may increase bladder and lung cancer risk.
  - Estimated additional cancer risk from rice product consumption ranged from 1 in 10,000 to 5 in 100,000, depending on age group and product type.
  - Non-Cancer Effects:
  - Neurodevelopmental effects such as lower IQ scores have been associated with early-life iAs exposure.
  - Developmental effects (e.g., fetal growth restriction) noted in some population studies.
  - Infants and pregnant women considered most vulnerable to these effects.

- Arsenic Levels in Products:
  - Brown rice had consistently higher inorganic arsenic levels than white rice due to arsenic accumulation in the outer bran layer.
  - Infant rice cereals and other processed rice products also contained measurable amounts of iAs, contributing to early-life exposure.
- Estimated Dietary Exposure:
  - Young children (especially ages 0–3) had the highest exposure relative to body weight, largely due to consumption of rice cereals and snacks.
  - Estimated cancer risks were found to range from low to moderate, depending on the amount and type of rice consumed.
- Health Risk Assessment:
  - Chronic exposure to iAs through regular consumption of rice could increase long-term cancer risk.
  - Non-cancer risks such as developmental and neurocognitive effects were particularly concerning in infants and children.

Conclusion

Based on the comprehensive risk assessment conducted by the USFDA, the following conclusions were drawn:

- Inorganic arsenic (iAs) is present in rice and rice-based products at varying levels, with brown rice and rice cereals showing consistently higher concentrations than white rice and other processed rice products.
- Long-term dietary exposure to inorganic arsenic through rice consumption poses a potential public health concern, especially for vulnerable populations such as infants, young children, and pregnant women. Their smaller body size and higher rice intake (per kg body weight) increase their risk of adverse health effects.
- The estimated lifetime cancer risk associated with chronic exposure to inorganic arsenic in rice falls within a low to moderate range, with the potential to contribute to an increase in lung and bladder cancer cases in the population if mitigation strategies are not implemented.

- Non-cancer health effects, including developmental, neurocognitive, cardiovascular, and immune system impacts, are also associated with prolonged exposure to inorganic arsenic. Infants and young children are particularly at risk for these effects, especially due to their reliance on rice-based infant cereals.
- Risk is highly variable depending on the type of rice product, the amount consumed, and individual factors such as age, body weight, and dietary diversity. Therefore, individualized risk mitigation strategies may be needed alongside general public guidance.
- The FDA emphasizes the importance of mitigation measures such as:
  - Encouraging dietary diversification to reduce dependency on rice.
  - Working with industry and agricultural stakeholders to develop low-arsenic rice varieties and improved farming techniques.
  - Considering the establishment of regulatory limits for iAs in rice products, especially those consumed by infants and children.
  - Overall, while most adults are not at significant risk from rice consumption in typical amounts, targeted interventions are essential to reduce exposure in high-risk groups and ensure long-term public health safety.

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