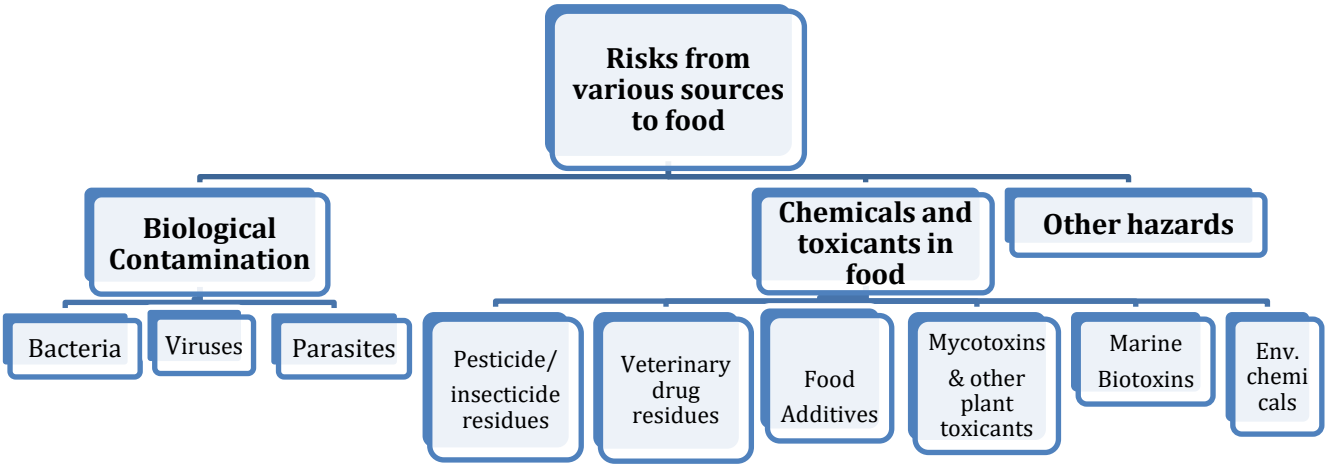
# Chapter 4

## Risk Analysis Framework for food safety in India

### 1. Introduction

4.1 There are a number of hazards associated with food and eating. Biological contaminants like bacteria, viruses, and parasites are a significant cause of foodborne diseases. There also may be physical hazards like pieces of glass in pulses; chemical hazards related to food that may either be natural chemical components of food (Lathyrus toxin in *Lathyrus sativus*) or human-made (e.g. chemical preservatives added to food) or residues of pesticides/insecticides/veterinary drugs in food etc. Food regulatory systems all over the world, therefore strive to manage the risk, i.e., the probability of something going wrong. Various types of risks associated with food are from different sources (**Figure 8**).

**Figure 8: Risks from various sources to food**



4.2 To determine the risk of a particular situation, one must know the hazard and measure the exposure to it. Therefore risk is represented as:

Risk=Hazard×Exposure

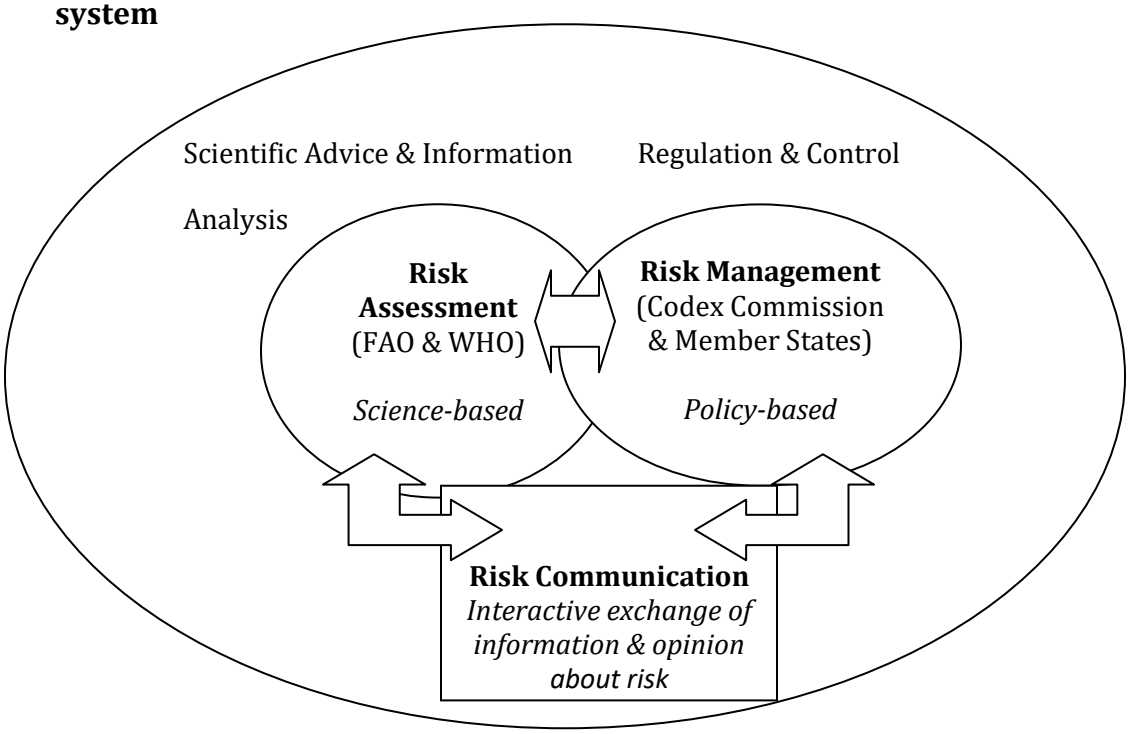
."Risk" has been defined under the FSSA *about any article of food, as the probability of an adverse effect on the health of consumers of such food and the severity of that effect, consequential to a food hazard.* "Hazard" is defined as *a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.* Risk analysis, *in relation to any article of food, means a process consisting of three components, i.e., risk assessment, risk management and risk communication.*

4.3 Risk analysis has, therefore, emerged as the foundation for developing food safety systems and policies (Buchanan 2010) as a systematic approach for making decisions related to food safety. As already elaborated, this approach has three distinct but closely linked components of risk analysis (RA, RM &RC). Three parts should have a functional separation of risk assessment and risk management, to ensure the scientific integrity of the risk assessment, to avoid confusion over the functions to be performed by risk assessors and risk managers and to reduce any conflict of interest.

4.4 It is embedded in the functioning of Codex Alimentarius Commission wherein risk assessment is carried out by joint WHO/FAO expert committees and risk management by the Commission & the Member States through its various general subject and commodity committees (**Figure 9**). The standards developed by general subject committees are generally referred to as "horizontal standards" as these

standards apply transversely[33]. These texts deal with hygienic practices, labelling, additives, inspection & certification, nutrition, contaminants and residues of veterinary drugs and pesticides. Commodity Committees are responsible for developing Codex commodity standards that refer to a specific product although increasingly Codex now develops standards for food groups i.e. one general standard for fruit juices and nectars as opposed to one per fruit[34]. They are often referred to as the "vertical standards". As on September 2017, there are ten and six active general subject and vertical committees respectively.

**Figure 9: Codex Risk Analysis paradigm-foundation for robust food regulatory system**




Source: Codex Alimentarius Commission at 50[35]

[33] http://www.fao.org/3/a-i5667e.pdf
[34] ibid
[35] https://www.foodsafetymagazine.com/magazine-archive1/aprilmay-2015/codex-alimentarius-commission-ensuring-food-safety-and-nutrition-security-for-over-50-years/

4.5 The objectives of principles of risk analysis "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius" adopted by CAC in 2003 is to guide the CAC, and the Joint FAO/WHO expert bodies and consultations, so that food safety and health aspects of Codex standards and related texts are based on risk analysis. The risk analysis used in Codex should be:

- applied consistently;
- open, transparent and documented;
- conducted in accordance with both the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken into Account* and the *Statements of Principle Relating to the Role of Food Safety Risk Assessment*; and
- evaluated and reviewed as appropriate in the light of newly generated scientific data.

4.6 The Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007), intended for implementation by Member governments, was also established. Therefore, modern food safety regulatory or control systems have risk analysis as an essential component including FSSA, 2006(**Table 1**).

**Table 1: Traditional food safety vs. Modern food safety regulatory or control system**

| S.No | Traditional Food regulatory system | Modern Food regulatory system |
|---|---|---|
| 1. | Reactive approach | Preventive approach |
| 2. | Primary responsibility of the government authorities | Addresses farm to fork continuum |
| | | Shared responsibility |
| 3. | No structured risk analysis | Science-based formal analysis |

| S.No | Traditional Food regulatory system | Modern Food regulatory system |
|---|---|---|
| | | Integrated food control |
| 4. | Relies on end product inspection & testing | Relies on process control |
| 5. | Inspection and control | Monitoring and surveillance |
| 6. | Level of risk reduction-not always satisfactory | Level of risk reduction-improved |

Source: Modified from Risk analysis of Food Additives, PFNDAI, Nov 2015

**2. Regulatory mandate for Risk Analysis under FSSA, 2006**

4.7 Risk analysis process begins with the risk management defining the problem, defining /posing questions to be answered by risk assessment. Next step would be to develop a risk profile, i.e., science-based tasks of “measuring” and “describing" nature of the risk being analysed (risk characterization) (Attrey 2016). Based on the outcome of RA, RM weighs various policy options/alternatives keeping in view the consumer health and promotion of fair trade practices. RC should be informed by knowledge of consumer risk perceptions and information needs, including individual differences in consumer preferences and requirements, and differences in these relating to a socio-historical context associated with regulation. Also, information about what is being done to identify, prevent and manage food risks need to be communicated to consumers, together with consistent messages regarding preventative programs, enforcement systems, and scientific uncertainty and variability associated with risk assessments(Cope, Frewer, et al. 2010).

4.8 Sections 12 to 18 of the FSSA mandate several structures (scientific panels, scientific committee), procedures, processes, functions, duties and general

principles including the establishment of the Risk Analysis framework. Sections 18 of the FSS Act, 2006 mandate the "General principles to be followed in the administration of the Act" which broadly cover the following points:

- Appropriate level of protection of human life and consumers' interests; fair practices in all kinds of food trade with reference to food safety standards and practices
- Risk management including taking into account results of risk assessment and other relevant factors in the matter to achieve general objectives of regulations
- Provisional risk management measures where possibility of harmful health effects but scientific uncertainty persists; must be proportionate and no more trade restrictive than is required to achieve appropriate level of protection
- The measures adopted shall be reviewed within a reasonable period of time and to conduct a more comprehensive risk assessment
- Inform consumer when food may present risk to human health

4.9 While framing rules and regulations take into account the following:

- Prevalent practice and conditions in the country, international standards, and practices
- Determine food standards based on risk analysis
- Risk assessment must be based on available scientific evidence and in an independent, objective and transparent manner

- Open & transparent public consultations; consumer interest and prevention of unfair trade practices

4.10 Risk assessment as defined under the Act is *"a scientifically based process consisting of the following steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization.*" Quantitative data from multiple sources is critical for risk assessors and Section 16.3 (b) of the FSSA, 2006 specifies that one of the duties/functions of the Food Authority is to 'search, collect, collate, analyze and summarize relevant scientific and technical data mainly relating to:

- Food consumption and exposure to risks related to consumption of food
- Incidence and prevalence of biological risk
- Contaminants in food
- Residues of various contaminants
- Identification of emerging risks
- Introduction of rapid alert system

4.11 The Risk Management process, distinct from risk assessment, *"consists of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options."*

4.12 Risk communication means *"the interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions."*

4.13 RA, RM, and RC, the components of the risk analysis framework are reflected at different places in the FSSA, 2006 as given in the table below (**Table 2**).

**Table 2: Relevant sections of the FSSA, 2006 covering components of Risk Analysis**

| Component of Risk Analysis | Activities | Relevant section in the FSSA, 2006 | Authority responsible |
|---|---|---|---|
| ***Risk-Assessment*** | Advise Food Authority on identification of potential risks | 12(c) | CAC* |
| | Advise Food Authority on pooling of knowledge | 12(d) | CAC |
| | Provision of scientific opinion to the Food Authority | 14(2) & (4) | SC@ |
| | Adoption of working procedures & harmonisation of working methods of Scientific Panels | 14(3) | SC |
| | Data collection | 16.3(b) | Food Authority |
| | Evidence of risk mainly related to food consumption; incidence and prevalence of biological risk; contaminants in foods; identification of emerging risks | 16.3(b) | Food Authority |
| | Establishment of a network of organisations to facilitate a scientific framework for exchange of information, expertise and best practices in the fields within the responsibility of food authority | 16.3 (e) | Food Authority |
| | Undertake risk assessment based on the available scientific evidence and in an independent, objective and transparent manner | 18.2 (c ) | Food Authority |

| Component of Risk Analysis | Activities | Relevant section in the FSSA, 2006 | Authority responsible |
|---|---|---|---|
| ***Risk Management*** | Laying down standards and guidelines in relation to the article of food including limits for the use of food additives and processing aids, crop contaminants, residues of pesticides/veterinary drugs, heavy metals, mycotoxins, antibiotics and pharmacologically active substances and irradiation of food. Specifying methods of sampling, analysis, and exchange of information among enforcement agencies | 16.2 (a), (b) & (f) | Food Authority |
| | Contribute to the development of international technical standards for food, sanitary and phytosanitary standards | 16.3 (j) | Food Authority |
| | Promote consistency between international technical standards & domestic food standards | 16.3 (m) | Food Authority |
| | Carry out risk management which shall take into account results of risk assessment & other factors | 18.1 (b) | Food Authority |
| | Proportionate action for risk management | 18.1 (c ) & (d) | Food Authority |
| | To take into consideration technical, economic and other factors-Regulatory Impact Analysis (RIA) | 18.1(d) | Food Authority |
| | Providing scientific advice and technical support to the Central | | |

| Component of Risk Analysis | Activities | Relevant section in the FSSA, 2006 | Authority responsible |
|---|---|---|---|
| ***Risk Communication*** | and State Governments in the areas of food safety including messages on health, nutritional risks; implementation of crisis management procedures about food safety | 16.3 (a), ( c) & (d) | Food Authority |
| | Publish Scientific opinion of the Scientific Committee and Panels; results of its scientific studies | 16.4 (a) & (c ) | Food Authority |
| ***Risk Communication*** | Provide rapid, reliable, objective and comprehensive information through appropriate means and methods to public, consumers, interested parties and all levels of Panchayats | 16.3 (g) | Food Authority |
| | Ensure there is open, transparent public consultation, directly or through representative bodies including all levels of Panchayats, during regulation-making process except in cases of food safety and health emergencies | 18.2 (d) | Food Authority |
| | Provide basis for consumers to make informed choices in relation to the food they consume | 18.2 (e) | Food Authority |

Source: Modified from Good Regulatory Practice: Regulating regulations, PFNDAI, Oct 2014

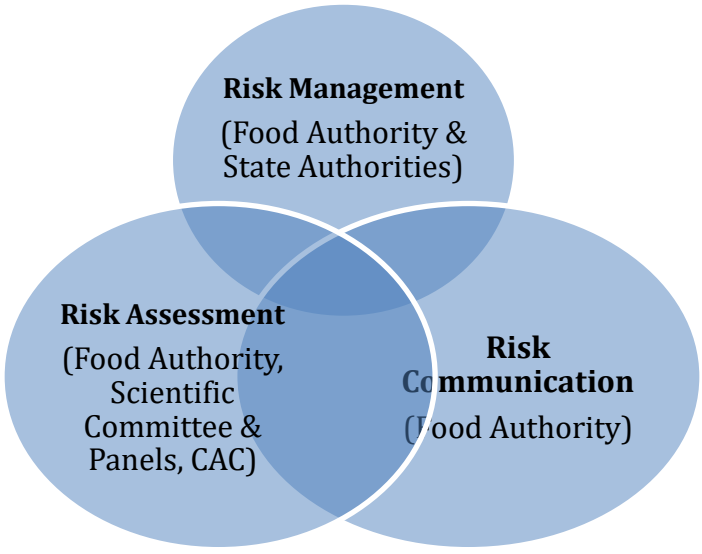
*CAC-Here it means the Central Advisory Committee of the Food Authority

@Scientific Committee of the Food Authority

### 3. Operationalization of the Risk Analysis Framework

4.14 As described in **Table 2**, the various components of risk analysis framework are clearly delineated in the Act (**Figure 10**). However, there is no separate regulation indicating the multiple activities to be undertaken for operationalising this framework except the Food Safety and Standards Authority of India (Transaction of Business and Procedures for the Scientific Committee and Scientific Panels) Regulations, 2016[36]. It replaced the Regulation 2010 on the same subject. As per the regulation, part of the risk assessment activities fall in the domain of SC & Scientific Panels (SPs) though other overlapping jurisdictions of the Food Authority and CAC on RA as given in the Act are not covered in the regulation.

**Figure 10: As per FSSA, 2006 authorities designated to carry out activities under the Risk Analysis framework**




[36] http://www.fssai.gov.in/home/fss-legislation/fss-regulations.html

4.15 As per Clause 8 of the Regulation, it is the Chief Executive Officer (CEO) of the Authority who shall make requests to the SC or SP for scientific opinion and not the Food Authority. SC and SPs also have to bring to the notice of the CEO any specific or emerging issue falling within its jurisdiction that may pose an imminent or potential risk to consumer health.

4.16 As per Clause 6 (ii), the scientific opinion has to be rendered in the format as specified in Schedule I of the regulation. Detailed assessment undertaken as well as RIA covering measurable outputs relating to mitigation of health of population in general or specific segments as identified, are to be reported in the defined format. The office of the Food Authority shall be responsible for providing necessary support to facilitate efficient functioning of the SC and the SPs.

4.17 The Food Authority and CAC meeting minutes are available on the FSSAI websites. But, minutes of the SC & SPs meetings could not be traced on the FSSAI website. Similarly, the scientific opinion rendered by the SC& SPs was also not in public domain.

4.18 Through various FSS regulations on Licensing & registration; Food Product Standards & Additives; Contaminants, toxins and residues; Packaging and labelling; Food or health supplements, Nutraceuticals, Food for special dietary use, Food for special Medical purpose, Functional foods, Novel food; Import, Food Recall procedure; Organic Food; Prohibition and restriction on sale; Laboratory and

sample analysis etc., the Food Authority has taken a number of risk management decisions[37].

4.19 Although no formal mechanism for risk communication is prescribed under any regulation, the Food Authority reaches out to consumers, industry and various other stakeholders through its various partnerships and initiatives like SNF@Home, School, Workplace, Railways, etc[38]; Food Safety Training & Certification (FoSTaC)[39]; DIET4Life[40]etc. and various publications like the pink book, yellow book, DART[41]. However, there is no formal, regular publication (monthly or quarterly) brought out by the Food Authority on the lines of monthly "Food Safety Report" brought out by CFS of the government of HKSAR.

[37] http://www.fssai.gov.in/home/fss-legislation/fss-regulations.html
[38]. http://www.fssai.gov.in/home/Safe-and-Nutritious-Food.html
[39] http://www.fssai.gov.in/home/search.html?queryStr=FoSTAC
[40] http://www.fssai.gov.in/home/search.html?queryStr=DIET4LIFE
[41] http://www.fssai.gov.in/home/capacity-building/FSSAI-Books.html