

FSSAI's approach to Drawing up / Revision of Food Standards

1. Objectives of Developing Food Standards

- (a) To provide more effective food safety regulations and reduce the level of food borne illnesses in India.
- (b) To provide nationally uniform food safety standards for India so that food business operators in all parts of the country have only one set of requirements and a more level playing field.
- (c) To continuously review and update the standards of food in line with progress of science and its capability to understand and prevent food borne illnesses.
- (d) To develop regulations that are less prescriptive and easier to comply, which are more effectively monitored and implemented.
- (e) To encourage growth of the food sector by providing regulatory windows for innovative products to meet consumer choice and health, while providing highest level of protection to the consumer.
- (f) To assure the people of India acceptable levels of food safety and hygiene keeping in view of the variety of cuisines and eating practices.

2. **The FSSAI's approach to Risk Analysis** : The Food Safety and Standards Act, 2006 provides the following policy directions pertaining to risk analysis:

- (a) **Section 16 (2)(i)** that Food Authority may by regulations specify the manner and procedure subject to which risk analysis, risk assessment, risk communication and risk management shall be undertaken.
- (b) **Section 18** of the Act lays emphasis that the Central Government, State Governments, Food Authority and the other agencies, as the case may be, while implementing the provisions of this Act shall be guided by the general principles of Food Safety such as risk analysis, risk assessment, risk management and risk communication. The relevant sub-sections in this regard are reproduced below.

- (c) **Sub-section 18 (1) (b):** carry out risk management which shall include taking into account the results of risk assessment and other factors which in the opinion of the Food Authority are relevant to the matter under consideration and where the conditions are relevant, in order to achieve the general objectives of regulations;
- (d) **Sub-section 18 (1) (c):** where in any specific circumstances, on the basis of assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure appropriate level of health protection may be adopted, pending further scientific information for a more comprehensive risk assessment;
- (e) **Sub-section 18 (1) (d):** the measures adopted on the basis of clause c shall be proportionate and no more restrictive of trade than is required to achieve appropriate level of health protection, regard being had to technical and economic feasibility and other factors regarded as reasonable and proper in the matter under consideration.
- (f) **Sub-section 18 (1) (e):** the measures adopted shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health being identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment;
- (g) **Sub-section 18 (1) (f):** in cases where there are reasonable grounds to suspect that a food may present a risk for human health, then, depending on the nature of seriousness and extent of that risk, the Food Authority and the Commissioner of Food Safety shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or type of food, the risk it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk; and
- (h) **Sub-section 18 (2) (b):** determine food standards on the basis of risk analysis except where it is of opinion that such analysis is not appropriate to the circumstances or the nature of the case;
- (i) **Sub-section 18 (2) (c):** undertake risk assessment based on available scientific evidence and in an independent, objective and transparent manner;

Apart from this, the act under Sections 18 (2) also states “the food authority shall, while framing regulations or specifying standards under this act” take into account :

- i. Prevalent practices and conditions in the country including agricultural practices and handling, storage and transport conditions; and
- ii. International standards and practices, where international standards or practices exists or are in the process of being formulated.

3. **Underlying Principles:** The broad range of food-related risks necessitate a variety of approaches to risk analysis. It is necessary therefore to have guiding principles that ensure consistency between these different approaches. FSSAI has based it's risk analysis framework on the following principles:

Principle 1: Use the best available data and methodologies

Scientific, economic and other data and information come from both published and unpublished sources, but in both cases, FSSAI will ensure that data should be of high quality, credible and objective. Critical evaluation of the available data is an essential element in establishing the basis for the safety of food and subsequent risk management decisions. Where possible, collaboration with other experts or organizations, both national and international will be sought.

Principle 2: Recognize uncertainty in risk analysis

It is inevitable that decisions in relation to the safety of food will be made in the presence of scientific uncertainty. In deciding on the risk management options, FSSAI believes that it is appropriate to recognize, document and address scientific uncertainty. Depending on the level and nature of uncertainty, a cautious approach to proposed changes to current food regulations will be taken to ensure that the overall risk remains low and the variety of traditional cuisines is retained and promoted.

Principle 3: Tailor the risk management approach to the risk

FSSAI believes that a food chain approach to safe food enables the identification of risk factors at each step in the food production process and for controls to be put into place at various production steps to reduce risks associated with the final food. One approach used to assess new and alternative food production methods is based on the concept of *equivalence of food safety measures*. This recognizes that the same level of food safety can be achieved by a variety of control measures. This equivalence approach can ensure food safety without unnecessarily hindering innovation in food industry.

In managing food-related health risks, there are generally a number of options available, depending on the nature of the risk. Quantifying and comparing different risks is difficult, but qualitative comparisons are generally possible using criteria such as the severity of the outcome and the likelihood of the risk. FSSAI believes that in deciding on the risk management approach, consideration needs to be given to the level of potential risk which, in the case of food, will also depend on the importance of the food in the context of the total diet. Another factor influencing the level of protection in a particular case will be the level of risk which is acceptable to the community.

Principle 4: Involve interested and affected groups

The involvement of groups which have an interest in the outcome of a risk analysis can enhance the process through the provision of scientific data, by identifying relevant social, ethical and economic factors, and by suggesting alternative management approaches. While the process and rules for such involvement need to be clear, involving interested and affected groups can provide opportunities for building trust as well as helping to lend credibility to the ultimate risk management decisions leading to their successful implementation.

Principle 5: Communicate in an open and transparent manner

Documents outlining risk management options prepared in relation to food-related health risks should generally be publicly available and public submissions on these documents taken into account in the regulatory decisions. Confidential commercial information should be protected but, in general, data that support the safety assessment of the food are not considered confidential. Dialogue with industry, consumers and health professionals on food regulatory matters is integral and will be facilitated, including encouraging stakeholders to comment on documents outlining risk management options.

Principle 6: Review the regulatory response

In some cases, it is not easy to predict with certainty the outcome of a regulatory decision regarding food and it is necessary to examine the impact of the regulation after a certain period, to ensure that the predicted outcome was achieved and/or that the assumptions used in the assessment were correct. Surveys of the food supply and key groups affected by regulatory changes, such as the food industry, health professionals, enforcement officers or consumers, can generally provide information to evaluate the outcome and determine whether further regulatory action is required.

4. FSSAI's General Risk Analysis Framework is given in **Annexure-I**. This is substantially based on internationally accepted principles (FAO/Codex) of risk assessment, management and communication.

5. **Establishing the need for a Food Safety Standard**

(a) The basic purpose of establishing food safety standards is reduction of public health risks. Food standards are only one component of the strategy to address health risks, the others being proper waste management, water quality programmes, environmental safeguards, good agricultural practices, storage and distribution infrastructure etc.

(b) The standards making process recognises that where regulations are required they shall be applied at the point where maximum safety is obtained. For regulation to be effective and impact consumer safety and health, a surveillance/analysis of safety or standards failure rates, default incidents in product categories and/or industry sectors, as occurring in the market place and reliable evidence of impact of poor safety standards of food items in health will be used to determine where the regulations are most needed.

(c) While finally approving a food standard, it is necessary for the Food Authority to complete a regulatory impact assessment outlining the pros and cons of the proposed standard and how it is necessary to be developed.

(d) The Food Authority recognises that regulated industry rightfully expects enablement to meet regulatory compliance. While preparing new regulations, the Authority will take into account all compliance pre-requisites and publish the same before the enforcement date which may include among other things, analytical procedures, tolerances, guidance notes in a simple Frequently Asked Questions style explaining what current products will or will not fall under the proposed rule/regulation.

(e) It is also necessary to ensure that the regulatory burden on the public is minimised consistent with public safety. The cost of administration also needs to be kept in mind. Regulation should also be performance-based and lay down compliance strategies and enforcement.

(f) It is recognised that Food Businesses are best placed to determine the safety measures for their products and processes – Food Businesses that put in place a Food

Safety Management System may encourage non regulatory measures where such self regulation exists.

(g) No safety standard will be established by the Authority without an appropriate risk assessment according to principles adopted and approved by FSSAI. The mandate of the Authority is to ensure safety of food through establishment of appropriate standards and through effective regulations to be implemented in coordination with States and other agencies. While choosing the options for establishing standards, Authority will be guided by the consideration that not all issues of food safety can be addressed by developing standards and implementing such standards. The ability of industry to implement such standards, the feasibility of testing compliance, availability and cost of testing etc. would be critical to this choice. In many cases, guidelines and self compliance requirements would be adequate, especially when the number of Food Business Operators is large and size of units small.

6. **Review of the current Food Safety Standards and development of new standards.**

(a) The current food standards and categories which are included in the Prevention of Food Adulteration Act, 1954 have been substantially subsumed under the Food Safety and Standards Act, 2006. Many of these standards have evolved over a period of half a century due to specific developments or amendments at various points of time. The new format of Food Safety and Standards Authority's Rules and Regulations attempts to streamline the presentation of these standards in line with international best practice. However, a review of the standards has now to be carried out by the Authority keeping in view the developments in science, changes in technology and regulatory options available.

(b) While undertaking a review of the current food standards and categories, Authority will adopt an approach substantially similar to the one proposed for development of a new standard, namely, risk assessment, review of literature, consultation with stakeholders and formulation of initial draft standards/amendments before they are considered by the Scientific Panels and Committee. In a large number of cases, data on consumption, toxicity etc. may not be available with an adequate level of reliability. Data may also not available which is based on experience in India. Similar standards based on external data may be available with Codex Alimentarius and other developed countries. Wherever suitable and appropriate, codex standards could be considered for adoption with or without modifications provided they are in line with domestic industry

and consumer practices and do not have any other food safety implications. Harmonisation of standards is one of the principles mandated by the Food Safety and Standards Act. Therefore, Authority is required to explore options available for aligning itself with international best practice so as to promote international trade and higher levels of food safety.

(c) In risk analysis, very often data may not be available with the country and the applicants may submit results of risk analysis carried out by regulatory agencies in other countries or by international agencies like FAO/WHO/Codex. While due care and weightage needs to be given to such evidence, keeping in view the long period required to collect domestic data, such results need to be correlated with domestic conditions and available evidence before a regulatory option is exercised.

7. **Process of Setting Standards.** The following would be the process by which standards will be established by FSSAI:

(a) The Food Authority may of its own initiate, or based on considered evidence being presented by any stakeholder, proceed to determine if a regulatory measure is required. Amendments to the food safety standards can be initiated by anyone outside FSSAI in which case they are designated as applications or they can be initiated by FSSAI itself in which case they are designated as proposals. When considering applications, FSSAI will normally complete the process within 6 months excluding the time for the applicant to supply additional information. Proposals initiated by FSSAI itself would not have a time limit. This process may, however, be shortened by FSSAI where it is appropriate for urgent or minor issues.

(b) FSSAI proposes to structure its decision making process in such a way that more focus is placed on outcomes. In the FSSAI, technical recommendations would be made by ad hoc project teams formed for the purpose. When a project is commenced, a project manager will be appointed whether for the development of regulatory policy, to respond to an application, or to review a standard. Normally, the project manager will be a FSSAI staff member. An ad hoc project team will be assembled to bring relevant expertise to the project. Such experts may be invited from government, industry, consumer groups and appropriate professional bodies. Project managers and project teams will be required to develop and adhere to project plans that have clearly defined milestones and timelines according to FSSAI's statutory mandate.

(c) Where the Food Authority determines that a regulation may be required it will take the following steps :-

- (i) Initiate either suo moto or based on application received from stakeholders, the process to establish a food standard
- (ii) Undertake risk assessment
- (iii) Consider regulatory options and impacts
- (iv) Identify regulatory option
- (v) Draw up final assessment report for consideration of the Scientific Panel and thereafter of the Scientific Committee
- (vi) Carry out public consultation for at least 30 days
- (vii) Review the regulatory options
- (viii) Finalise the recommendations for submission to the Authority

(d) At any stage in the process, FSSAI may release discussion papers, hold consultations, organize stakeholder workshops, consult with expert panels, and seek peer review to strengthen and improve FSSAI's decision making processes.

FSSAI's Policy on open consultation.

8. Section 13(1) of the Act specifies that Authority shall establish Scientific Panels which shall consists of independent scientific experts. They shall also invite the relevant industry and consumer representatives to its deliberations. The mechanism for ensuring independence of Scientists is laid down through conflict of interest provisions under which each member declares his interests at each meeting. Scientific Committee and Panels are also required under section 15(5)(e) to associate external experts in its working groups which prepare documents for consideration of the Authority.

9. FSS Act attempts to convert food safety into a national movement rather than simply a government sponsored initiative. To make food safety a national movement, it is necessary that all stakeholders are involved. Issues are discussed openly and conflicting opinions reconciled on the basis of scientific evidence and transparent consultations with all stakeholders affected. FSSAI believes that excluding opinions which do not agree with the conventional view is not feasible in a sector which is characterised by fast pace of technological change, limited skills and competence of the regulatory agencies to decide highly complex technical issues and resource constraints.

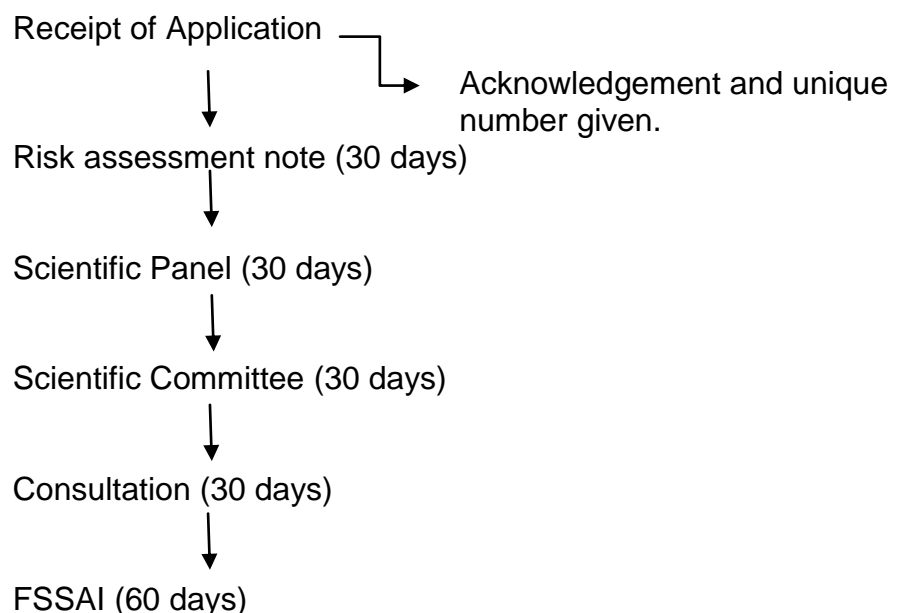
10. The scientifically established way in which potential conflict of interest is addressed is to select individuals on the basis of open, transparent criteria in the full knowledge of their affiliations, and subject to their individual competence, qualifications and experience. Scientists participate in their individual capacity and keeping in view their scientific competence. They do not represent any organisation or corporate and express scientific opinion on issues in which they have no professional interests but only intellectual interest.

11. Industry has often access to much more safety information emerging from manufacture and processing activities than the public authorities who have to take decisions affecting public health. It is, therefore, essential for public standards setting agencies such as, FSSAI to adopt an open decision making process which takes into account the information and experience available outside government. In the absence of close cooperation with the regulated industry, there is a real possibility of standards not reflecting the actual situation on the ground and resulting in ineffective regulation.

Processing of applications / proposals by FSSAI

12. As soon as an application is received in the required format, a unique acknowledgement number will be given to the applicant and the process of examination initiated. A detailed work flow of the application till the point of disposal will be developed by FSSAI. The applicant would be in a position to track his application on line through the various stages. A specific timeline would also be laid down for processing in various stages and the final disposal of application.

Suggested Workflow



Total = 180 days

13. Food Safety and Standards Authority of India has constituted 8 Scientific Panels in various areas. However, these do not fully cover the issues which have to be considered by the Authority and it may not be feasible to add more panels indiscriminately. Keeping in view the nature of expertise required for evaluation of issues and urgency of the matter, FSSAI may constitute expert committees to consider emerging issues. Expert groups will be constituted for categories of food products, sub-sectors or on policy issues cutting across various sectors in respect of which focussed attention is required to be given. The recommendations of the expert group would then be considered by the Scientific Committee.

14. FSSAI may take expert outside assistance to prepare the risk assessment, review literature, evaluate options and suggest risk management steps. The prime consideration will be scientific competence and credibility of the agency or expert selected to undertake the task.

15. All matters considered by the Scientific Committee may not go to the Authority for approval. Subject to such directions as the Authority makes, and based on recommendations of the Panels and Scientific Committee, Chairperson of the Authority may send proposals to the government. Since draft notifications undergo changes after public consultations, a copy of the final notifications will be brought to the notice of the Scientific Committee, FSSAI and Advisory Committee. Where Chairperson feels that the issue should be considered by the Authority, it may be placed before the Authority either at the concept stage, draft or final stages. Where regulatory and administrative factors necessitate amendments which have no scientific implications, such proposals may be considered by the Secretariat of FSSAI and proposals sent to government without being taken through Panels or Committee.

16. While establishing standards, FSSAI will endeavour to :

- (a) Develop standards which are easier to understand and make amendment more straightforward.
- (b) Replace standards which regulate individual foods with standards that apply across all foods or a range of foods.
- (c) Remove inconsistent/redundant regulations where new regulations are in conflict or superseded.
- (d) Resolve interface issues across various pieces of regulatory actions that arise with relation to foods.
- (e) Promote industry codes of practice to supplement regulation.

(f) Promote consumer education as a cost effective regulatory option to labelling requirements.

(g) Facilitate harmonisation of standards with India's trading partners and the international community based on best practice.

17. **Functional separation of Risk Assessment and Risk Management.** The tasks of risk assessment and risk management are best performed by different people and functional groups. It is recognised that an individual may act as both a risk manager and an assessor. However, it is necessary that activities of risk analysis process are transparent and appropriately documented.

18. Functional separation is essential for the conduct of risk analysis activities in order to maintain the scientific integrity of the risk assessment process, and to avoid pressure that would undermine the objectivity and the credibility of the conclusions. Separation of risk management and risk assessment helps to ensure that assessments are not biased by pre-conceived opinions related to management solutions. However, there is a need for frequent interaction between managers and risk assessors in order to arrive at effective risk management decisions. Active interaction is necessary to ensure that the assessment will meet the needs and answer the concerns of the risk managers. Interactions between assessors and managers do not end with the completion of the risk assessment and there will be often exchanges of information and input from assessors during subsequent risk management activities.

19. **Conclusion.** FSSAI has a significant role to play in ensuring a safe food supply by maintaining robust evidence based processes for developing food standards and responding to food safety issues which enables consumers to make informed choices and maintain public confidence in the safety of foods.

20. Incorporating the key components of risk assessment, risk management and risk communication, FSSAI's general framework for risk analysis provides a systematic and disciplined approach to risk management. The risk analysis framework provides FSSAI with information and evidence required for effective decision making to support the development of standards, manage emerging issues and to provide consumers with adequate information leading to effective food safety outcomes and improvements in public health.

21. This overarching general framework for risk analysis is further supplemented by the risk analysis policy and procedure of individual scientific panels to deal with specific issues in their areas of concern.

FSSAI's General Risk Analysis Framework

FSSAI General Risk Analysis Framework is comprised of three components: risk assessment, risk management, and risk communication.

- (a) **Risk Assessment** involves a science-based approach that utilizes experimental and other available data to characterize the risk and arrive at a conclusion regarding the potential risk associated with a food or food ingredient.
- (b) **Risk Management** assists in defining the risk assessment scope and questions to be addressed, considers options for managing identified food risks in the broader context, taking into account the potential benefits of the food as well as relevant policy, consumer behaviours and economic issues associated with use of the food.
- (c) **Risk Communication** is the interactive exchange of information and opinions regarding risks, risk-related factors, and risk perceptions among all stakeholders. It is an ongoing process that engages stakeholders and the public in decision making to the maximum extent possible.

(a) **Risk Assessment**

Risk assessment in relation to food involves assessing the likelihood that a specific adverse health effect will occur in individuals or in a population as a result of consuming food. The breadth of the assessment will depend on the circumstances, particularly the urgency of the issue, the potential severity of the adverse effect, and the likely number of affected individuals in the population.

Risk assessment is that part of risk analysis that examines the scientific data on a particular physical, chemical or microbiological hazard in food. This generally includes data from laboratory investigations (toxicological or microbiological studies) or human epidemiological studies when available, as well as data on the level of exposure from dietary and other sources. Combining these sets of data provides the risk assessment outcome, which may take the form of a quantitative assessment of the risk or a qualitative expression of the risk.

Steps in risk assessment

The risk assessment process used by FSSAI follows the Codex model and involves four steps, namely, hazard identification, hazard characterization, exposure assessment and risk characterization.

Step 1: Hazard identification

Hazard Identification is the identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods. The first step in risk assessment, hazard identification, seeks to identify the potential hazards that may occur as a result of the presence of the risk factors in food. Chemical risk assessment focuses on the *hazard* as an intrinsic property of the risk factor whereas microbiological risk assessment focuses on the *hazard* as the risk factor itself, the likelihood of its association with food, and the consequences of its presence.

The level of exposure will be the major, but not the only, factor in determining whether the hazard associated with a risk factor will manifest in a particular situation. For those chemical risk factors which also provide a benefit in food, the identification of the potential hazards and their relationship with exposure are critical in balancing the risk and benefit. While for most risk factors in food, an increased level of risk is associated with an increased level of exposure, for nutritive substances, a hazard can also occur if the exposure is too low, although in this case, the hazard is not linked with an intrinsic property of the nutritive substance, but with the absence of adequate amounts of the nutritive substance.

Step 2: Hazard characterization

Hazard characterization seeks to define the parameters that may influence whether the identified hazard will result in a health risk under the expected levels of exposure – this is often referred to as a dose-response assessment, particularly for chemicals and nutritive substances, since the level of dietary exposure/intake is the major parameter influencing the health risk. For both chemical and microbiological risk factors, hazard characterization will identify the critical health effects associated with exposure; if possible, establish a dose-response relationship; and the most appropriate dose-response model if extrapolation to the normal exposure level is required.

Step 3: Exposure/intake assessment

Exposure or intake assessment seeks to provide an estimate of the magnitude, frequency and duration of exposure to the risk factors found in the environment. Generally, this is restricted to dietary exposure but ideally exposure from all sources would be included in an exposure assessment. If possible, a quantitative estimate is sought, although in some cases, the estimate may be qualitative. Food consumption data from National Surveys, supplemented by other sources of consumption data in some instances, are combined with food chemical or nutrient concentration data to estimate dietary exposures for a 'population based' assessment.

Step 4: Risk characterization

The last step in risk assessment, risk characterization, seeks to integrate the information from the previous steps and to provide an estimate of the likely occurrence and severity of any potential adverse health effects in a given population under defined exposure conditions. This includes an analysis of the inherent uncertainties in the process, which can arise from the availability and quality of the data used, the applicability of the experimental model(s) used and the assumptions used in the absence of data. FSSAI believes that the risk characterization will provide information which can be used for risk management to manage identified risks. This information can be of a quantitative or qualitative nature depending on the nature of the issue and the quality of the available data. The information provided needs to take into account the quality, the completeness and relevance of the scientific information available, as well as the context in which this information will be used to address risk management goals.

The initial scoping of the food-related issue by both risk managers and risk assessors should establish the broad parameters to be considered in the risk characterization in order to address the risk management goals. The risk characterization can be quite broad, e.g. for the whole population or for a specific sub-population, depending on the nature of the adverse health effect and the pattern of dietary exposure. Specific risk characterization information for at risk groups e.g. infants, pregnant or lactating women, the elderly, immuno-compromised or individuals with special dietary needs, may need to be considered separately in the risk assessment.

Dealing with uncertainty and variability

Uncertainty and variability in risk assessment occur in a multitude of ways and can significantly influence the value of the risk assessment and its interpretation. Uncertainty arises when there is insufficient information available to accurately determine the value of a particular parameter within a model. Variability refers to the inherent variation in the parameters within the model. Uncertainty can be reduced through additional research and more accurate data, while variability cannot be reduced but it can be better understood. FSSAI believes that it is important, therefore, to both document the uncertainty and variability and also to make some judgment regarding their impact on the overall risk assessment.

The inherent variability within the risk assessment model should be documented, or referenced, in a risk assessment report. The uncertainties in the data and any assumptions made also need to be documented. If the level of uncertainty is too great, a decision may be taken to delay the assessment until new data are available.

(b) Risk Management

FSSAI approach to Risk management in relation to food comprises of four key phases. Each phase can have multiple steps which can vary on case to case basis.

Phase 1: Preliminary Risk Management Activities

The first phase in risk management is to examine the nature and potential impact of the food related health issue. This phase includes: defining and describing the food-related health issue; developing a risk profile, establishing risk management goals, deciding whether a risk assessment is really necessary, establishing a risk assessment policy, commissioning risk assessment, considering the results of risk assessment, and ranking food safety issues and setting priorities for risk management. FSSAI believes that it is important to attain a good understanding of the issue and to gather as much preliminary information as possible in relation to the food-safety risks being studied.

Phase 2: Identification and Selection of Risk Management Options

The second major phase involves the identification, evaluation and selection of risk management options. Although this phase ordinarily cannot be fully undertaken until a risk assessment has been completed, as a practical matter, it begins very early in a risk analysis, and is reiterated as information about the risk grows more complete and quantitative. Also, in urgent food safety situations, it may be necessary to choose and implement at least some preliminary risk management measures before a risk assessment can be carried out.

This phase also consists of several distinct sub-steps, such as: Identifying available management options, evaluating the identified management options, selecting a risk management option.

This phase considers possible risk management options and makes a risk management decision. This includes consideration of issues which may impact on the options including human health issues (risks and benefits), consideration of relevant over-arching policy guidance, practicality and enforcement of risk management options, social and consumer issues and cost and benefit analysis.

There are a range of risk management options available for preventing or reducing health risks associated with food. These options can be: regulatory, i.e. those which are specified in the Regulations, such as end product standards or outcome-based standards; or non-regulatory, such as industry codes of practice, guidelines or information/advice campaigns. Both regulatory and non-regulatory options need to be considered, particularly with regard to the need to implement minimum effective regulation.

In determining appropriate options, FSSAI gives consideration to the context of the problem (e.g. is it urgent or likely to be wide-spread in nature and involve a range of foods), the nature of the risk (e.g. low versus high and the toxicological endpoint), the likelihood and severity of the risk (e.g. low risk and low severity vs. high risk and high severity), uncertainty associated with the risk assessment and the most appropriate options (e.g. regulatory or non-regulatory). As part of the decision-making process a Regulatory Impact Statement (RIS) addressing the issue of cost effectiveness is also prepared. It analyses the benefits and efficacy of alternate (regulatory and non-regulatory) options for achieving the stated objectives. The development of risk management options for food emergencies usually require a rapid response with limited time to consider the broader issues mentioned above.

Phase 3: Implementation of Risk Management Decision

Risk management decisions are implemented by a variety of parties, including government officials, the food industry and consumers. The type of implementation varies according to the food safety issue, the specific circumstances and the parties involved.

Phase 4 : Risk Communication.

By communicating to the public in an open, transparent way based on independent scientific advice of its Scientific Committee/Panels, the Food Authority contributes to building public confidence in the system. The Food Authority will establish a

Communication Cell to address all communication on matters ranging from general information, risk assessments and position statements where required to address all communication matters the Authority will take the following steps :

- a. Establish a line and hierarchy of communicators related to information contact points, public relations, etc. These shall be notified for easy access and location
- b. Establish a Communication Advisory Group on strategy development of best practice in communications to address emerging risks/Scientific Opinions/Position Statements. The Group also covers consumer attitudes and risk perceptions related to foods.
- c. Present scientific opinions on its website contextualizing risks for a balanced understanding
- d. Proactively engaging consumers and media in novel foods and processes that are being assessed or may be introduced.
- e. Use of appropriate and effective tools such as media and press releases, position and policy statements, etc
- f. Conduct and analyze public perceptions of the Authority and its functionaries at all levels of interactions.

Phase 5 : Surveillance, Monitoring & Evaluation

SME together play an important role in providing information to help determine the link between regulatory action, resource utilization [costs] and achievement of outcomes. Surveillance is described as a systematic process of collection, analysis, interpretation and dissemination of food failures while implementing regulatory actions, while monitoring is a tracking of the changes that have been effected by the regulatory intervention over time. Where such change has taken place an evaluation measures the extent to which the objectives are being met. FSSAI will carry out surveys at various levels to monitor the safety levels, assess the impact of regulatory action and gauge the concerns of stakeholders.

FSSAI verifies that the risk mitigation measures are achieving the intended results, that there are no unintended consequences associated with the measures, and that risk management goals can be sustained in the longer term. Risk management decisions are reviewed periodically when new scientific data or insights become available, as well as when experience, such as data gathered during inspection and monitoring, warrants a review.