Chapter 7

Discussion and Conclusions

7.1 Food safety has become one of the core issues in the public health domain in recent years. It is closely linked to food security and nutrition too. While chronic food insecurity is associated with poverty and arises due to continuous inadequate diet, transient food insecurity is related to the risks related to the availability of food that is safe for human consumption(Vemula, Kumar, et al. 2012)[75]. Foodborne diseases are a significant cause of morbidity and mortality, and a significant impediment to socioeconomic development worldwide[76]. Foodborne disease can be defined as "any disease usually either infectious or toxic in nature, caused by agents that enter the body through ingestion of food" (Adams and Moss, 2003). The foodborne disease could be due to microbial pathogens, naturally produced toxins or other chemicals that have entered the food supply chain (Hall et al., 2008; Hui et al., 2001).

7.2 Also, world-wide there is an increase in Noncommunicable diseases (NCDs), and particularly in South-East Asia, 62% of the deaths are due to NCDs claiming an estimated 8.5 million lives each year. Tobacco use, physical inactivity, the harmful use of alcohol and *unhealthy diets* all increase the risk of dying from an NCD. According to WHO Noncommunicable Diseases Monitor, 2017, in India percentage of deaths from NCDs is 61%, in numbers translating to 5.87 million deaths annually

[75] https://doi.org/10.1108/00070701211229954
[76] http://apps.who.int/iris/bitstream/10665/200046/1/WHO_FOS_15.02_eng.pdf

with 23% risk of premature deaths from NCDs[77]. Unhealthy diets linked to NCDs are food with the High content of Fats, Sugar and Salt (HFSS). FSSAI had also constituted an expert group to look into this and provide recommendations on various aspects. The report of the expert group is in public domain[78].

7.3 As per the FSS Act 2006, FSSAI has the responsibility to handle the complex issues related to food safety and ensure *safe and wholesome food* for human consumption. Section 18 of the Act lays down what is required to achieve the public goals, its *raison d'être* namely; endeavour to achieve an appropriate level of protection of human life and health and the protection of consumer's interests, including fair practices in all kinds of food trade with reference to food safety standards and practices. This can be *only* achieved by implementing the risk analysis framework and for that FSSAI would need to put in place three essential building blocks viz., **(Figure 21)**:

i) Science-based Food Quality & Safety Standards: Formulation of new Standards and regulations based on science and also to harmonize the domestic food Standards with international Standards including the Codex Alimentarius Standards.

ii) Food Safety Regulation, Quality testing & Risk-based Surveillance: Laboratories are an integral part of the food safety system. For efficient food safety management, the existing food testing laboratories need to be strengthened; new ones' set-up, if required; and most importantly networked for the flow of information. These then have to be integrated with a robust surveillance network-

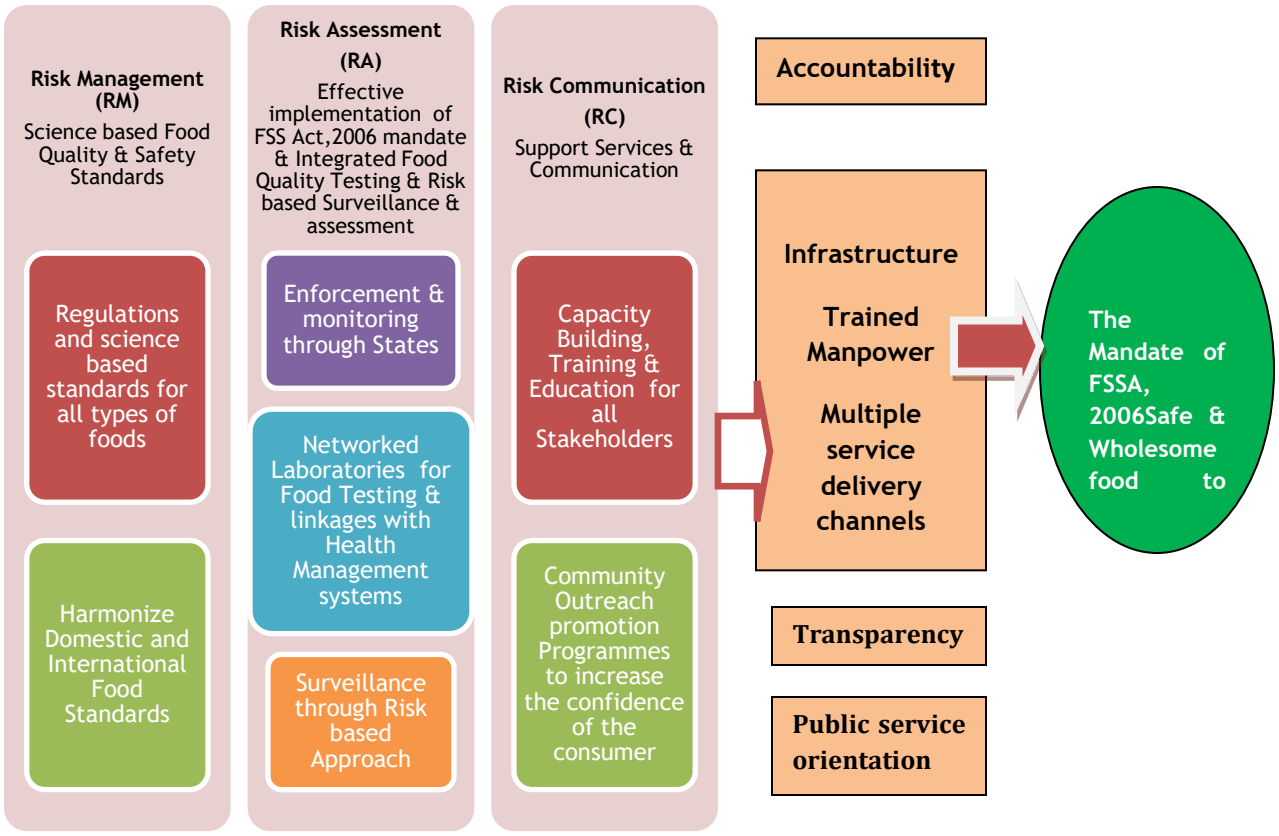
[77] http://apps.who.int/iris/bitstream/10665/258940/1/9789241513029-eng.pdf?ua=1
[78] https://fssai.gov.in/dam/jcr.../Fssai_Report_2017_Chapter_10_28_06_2017.pdf

active as well as passive, which in turn will hand shake with all the ports of entry of food and State/UT level offices. This will lead to the creation of integrated food risk assessment and surveillance network.

iii) Support services & communication: An increasingly important role for FSSAI is the delivery of information; education and advice to the stakeholders across the value chain particularly the consumers. This would involve undertaking mass awareness programmes, conducting capacity building activities and regular communication with all the stakeholders.

7.4The overriding principles guiding the functioning of the Authority would need to be accountability, transparency and public service orientation.

Figure 21: Building blocks for effective Food Safety Regulatory Framework



7.5 Based on the desk-research and survey findings, it is evident that FSSAI has made considerable progress in putting in place the 1st building block related to the formulation of science-based food quality & safety standards (RM). The food standards development is being undertaken by the SC and 17 SPs with the support of Standards Review Groups (SRGs). Ten major regulations covering various aspects of food have been notified, and around 11,000 standards of provisions of food additives adopted[79]. Some other regulations are also in the pipe-line for notification and this is in line with the consumer perception too that setting standards are FSSAI's primary responsibility.

7.6 Coming to the 3rd block of support services and communication (RC), it is evident that FSSAI has taken a number of initiatives like setting up of Food Safety Training and Certification (FoSTac)[80], a participatory program of training and capacity building for training food handlers across the value chain as well as enhancing public awareness. Project Safe and Nutritious Food (SNF) covering home; workplace; school; street food; eating out-serve safe; eating out-BHOG (Blissful Hygienic Offering to God); eating out-hospitals, eating out-safe food on track has been launched. It is a behavioral change initiative with 360-degree approach[81].For consumers other initiatives like exclusive consumer education portal, food safety display boards, consumer feedback and grievance redress (Food Safety Connect), smart consumer App, safe water portal, a tie-up with Advertising Standards Council

[79] www.fssai.gov.in/dam/jcr.../Transforming_Food_Safety_Landscape_in_India.pd
[80] Ibid,
[81] Ibid,

of India (ASCI) for processing misleading advertisements have been taken[82]. However, these activities are required on a continuous basis and there is also a need to strengthen public communication on various aspects of food safety.

7.7 Though some steps have been taken by FSSAI directed towards consumer welfare, a large number of respondents (72.4%) of the survey feel that FSSAI/ State Authorities have not been able to undertake their responsibilities appropriately. Major factors attributed to this, according to the consumers are lack of governance including corruption issues and fragmented strategy to address complex area of food safety. According to consumers, lack of funds is not a significant factor in this regard.

7.8 Consumers have highlighted the fragmented strategy of FSSAI to address complex issues of food safety as an essential reason for it not been able to take up its responsibilities appropriately. It is reflected when one examines the 2nd building block related to the implementation of the Act through enforcement, monitoring, and surveillance that eventually leads to a robust risk assessment mechanism. All the stakeholders of the survey who were posed the question related to RA mechanism in the country were unanimous in their view that it is not adequate. Chapter 4 of the study has dealt in detail with the risk analysis framework as enshrined in the Act (**Table 2**) and the authorities responsible for implementing them.

[82] ibid

7.9 In the table below based on the desk-research and findings of the survey, Table 2 is updated to assess the implementation of RA mechanism:

Table 9: Status of implementation of RA as per the mandate of FSSA, 2006

Component of Risk Analysis	Activities	Authority responsible as per FSSA,2006	Status against mandated activity
Risk-Assessment	Advise Food Authority on the identification of risks	CAC*	It can provide data on actions taken to reduce an event based on surveillance & monitoring activities. But, no formal system (IT based) in place for this
	Advise Food Authority on Pooling of knowledge	CAC	No evidence of this being done
	Provision of scientific opinion to the Food Authority	SC@	Yes, it is being done primarily in the context of standard setting. However, the outcomes of the deliberations are not placed on the FSSAI website
	Adoption of working procedures & harmonisation of working methods of Scientific Panels	SC	Governed by the Regulation,2016
	Data collection	Food Authority	No formal mechanism in place
	Evidence of risk mainly related to food consumption; incidence and prevalence of biological risk; contaminants in foods; identification of emerging risks	Food Authority	Total Diet Study has not been conducted for the country as a whole; hence data on exposure assessment is patchy. Work in other areas is being done by SPs, mainly through qualitative risk assessment
	Establishment of a network of organisations to facilitate a	Food	Food Safety Knowledge Assimilation Network

Component of Risk Analysis	Activities	Authority responsible as per FSSA,2006	Status against mandated activity
Risk-Assessment	scientific framework for the exchange of information, expertise and best practices in the fields within the responsibility of food authority	Authority	(FSKAN), a network of public & private institutions and experts has been set-up in different sectors[83]. Tangible results in the form of reports/publications yet to be seen and shift has to be on measuring its effectiveness Similarly, FSSAI has joined hands with CHIFSS (CII-HUL Initiative on Food Safety Sciences) with the purpose of driving activities related to science-based food safety in the country, to strengthen protection of consumers and create an innovative environment for the industry[84]
Risk-Assessment	Undertake risk assessment based on the available scientific evidence and in an independent, objective and transparent manner	Food Authority	This activity is being undertaken by the SC & SPs However, there is no formal independent, institutional structure that collects, collates, analyses data from various sources including health authorities and presents it to the Food Authority like it is being done in case of EFSA OR ANSES. A fragmented

[83] https://fssai.gov.in/fskan

[84] http://www.fssai.gov.in/home/partnerships/FSSAI_MOUs.html

Component of Risk Analysis	Activities	Authority responsible as per FSSA,2006	Status against mandated activity
			approach is being followed
	To take into consideration technical, economic and other factors-Regulatory Impact Analysis (RIA)	Food Authority	Not being implemented (70% of industry respondents said RIA not being performed by FSSAI)

7.10 Having an adequate laboratory and analytical facilities for food testing is an essential component of food safety regulatory system particularly, risk assessment. Laboratories for analysis (food testing) for enforcement purpose perform a different function from laboratories undertaking research. To engage in sound risk management, it is necessary to verify that food-testing laboratories produce valid, reliable data. A comprehensive oversight framework enhances the level of confidence in the data used in analyzing risk and supports sound decision making[85]. The laboratories should have adequate facilities for physical, microbiological and chemical analyses. It is not only the type of equipment that determines the accuracy and reliability of analytical results but also the qualification and skill of the analyst and the reliability of the methods used. The analytical results of a food control laboratory are used as evidence in a court of law to determine compliance with regulations or standards of the country. It is, therefore, necessary that utmost care is taken to ensure the efficient and effective performance of the laboratory.

[85]http://www.inspection.gc.ca/food/chemical-residues-microbiology/laboratory-management/qmof/eng/1342722248818/1342722485391#tc_o

7.11 On the other hand, laboratories engaged for research purpose do not undertake day to day food testing laboratories but are focused on evaluating the current as well emerging risks and provide insights for comprehensive risk management strategy.

7.12 Currently, there are 232[86] food testing laboratories in the country under the FSSA, 2006 as given:

- 72 State/Public Food testing laboratories that are used for primary analysis of food samples by food analysts
- 142 FSSAI accredited primary food-testing laboratories from both government and private sphere
- 18 referral laboratories notified by the Food Authority, out of which two are under the direct control of FSSAI, viz., FRSL, Ghaziabad, and CFL, Kolkata

Also, FSSAI has launched "Food Safety on Wheels" (FSW), which envisages the establishment of 62 mobile units across the country for food testing and reaching out to the consumers.

7.13 All the stakeholders, including the Central regulator unequivocally feel that the status of laboratory and analytical capabilities for food testing are not adequate in the country. The reasons for this range from lack of funds, to inadequate planning. However, some respondents have also highlighted the lack of trained human resources manpower in this sphere as a reason for the inadequacy of facilities.

[86] http://foodregulatory.fssai.gov.in/food-testing

Comptroller and Auditor General (CAG) of India in its Report 37 of 2017[87] on performance audit of the implementation of the FSSA, 2006 has been critical of the laboratory infrastructure in the country. It has opined that quality of testing by State food laboratories cannot be assured. It has also commented on the shortage of qualified manpower and functional food testing equipment in State food laboratories and referral laboratories.

7.14 FSSAI has launched Indian Food Laboratory Network (INFoLNET)[88], an IT solution for integrating all categories of labs which are involved in food sample testing. The intention is to create a data repository that will help in risk analysis, improvements in standards, training and capacity building. INFoLNET will be connected to a centralized system called Lab Management System (LMS). FSSAI is also planning to develop and implement the National Reference Laboratory Network (NRLN) a network of laboratories that produce analytical results used in support of the regulatory activities.

7.15 An analysis of the laboratory network in EU will reveal that EURLs aim to ensure high-quality, uniform testing in the EU and support Commission activities on risk management and risk assessment in the area of laboratory analysis. Regulation (EC) No, 882/2004 on official controls, defines tasks, duties, and requirements for all the EURLs, a list of which is provided in its Annex VII. The Commission can

[87] http://www.cag.gov.in/sites/default/files/audit_report_files/Report_No.37_of_2017_-_Performance_Audit_on_Implementation_of_Food_Safety_and_Standards_Act%2C_2006_Union_Government.pdf

[88] www.fssai.gov.in/dam/jcr.../Transforming_Food_Safety_Landscape_in_India.pd

establish new EURLs or change designation of existing ones. Reference Laboratories are tasked to[89]:

- provide National Reference Laboratories (NRLs) with analytical methods and diagnostic techniques, and coordinate their application
- train staff from National Reference Laboratories
- provide the Commission with scientific and technical expertise about laboratory analysis (e.g., assist actively in the diagnosis of animal disease outbreaks)
- collaborate with the competent laboratories in non-EU countries

7.16 There are fourteen EURLs for Animal health and twenty-seven for food and feed[90]. The reference laboratories for food and feed are designated for different areas like additives, AMR, Campylobacter, Mycotoxins, heavy metals, pesticide residues, etc.

7.17 Similarly, the technical expertise for the laboratory accreditation or approval programs is provided by CFIA laboratory staff. In addition to participating in the development of international standards and test methods, various technical experts may also be responsible for developing the criteria for laboratory approval programs, providing supplementary guidance and interpretation of standards and acting as technical assessors (TA) carrying out assessments of the non-CFIA laboratories. CFIA laboratories also provide and evaluate a number of proficiency testing (PT) programs that are used as a tool in assessing the competence of the

[89] https://ec.europa.eu/food/safety/official_controls/legislation/ref-labs_en

[90] https://ec.europa.eu/food/ref-labs_en

participating laboratories and where deemed necessary provide training in mandated methods, and certification of analysts. There are currently fourteen CFIA laboratories undertaking oversight activities. The chemical residue surveillance program of the CFIA consists of three well-defined components. The first is monitoring sampling, which probes the food supply for potential contamination and is managed under the National Chemical Residue Monitoring Program (NCRMP). The second is directed sampling which focuses on identified chemical contamination issues, and the third is compliance sampling, which seeks removal of food in violation of standards from the marketplace[91]. Similarly, CFIA operates a national microbiological monitoring program. The monitoring program includes the random selection and testing of samples for a wide variety of domestic and imported products. Sample tests are done every year to monitor the level of microbiological contamination in the food supply. The outcomes of these are published annually as reports by CFIA as reports on food microbiology and chemical residues[92].

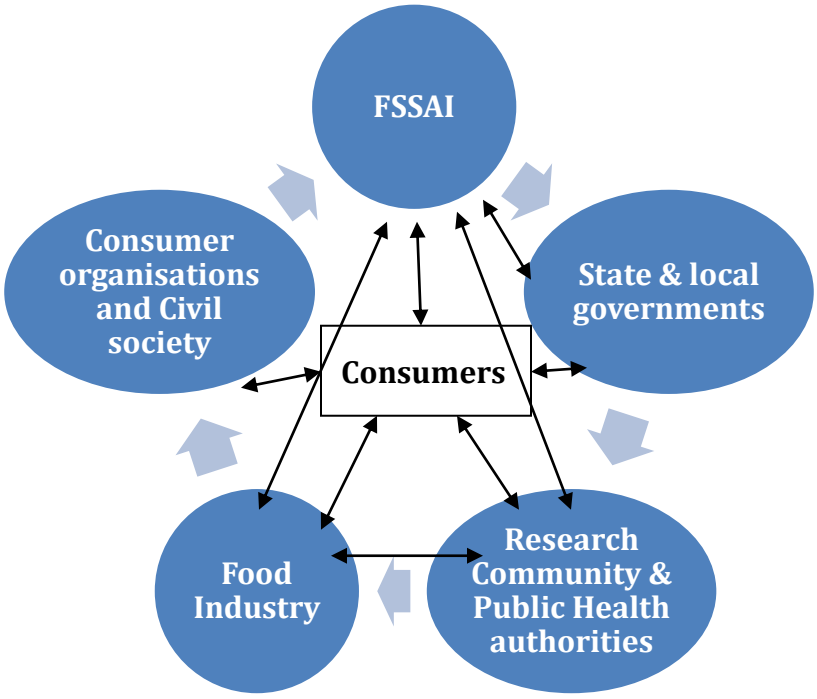
7.18 Desk research and survey findings have, however, highlighted that a fragmented approach is being followed by FSSAI. Some steps[93] like FSKAN, partnership with CHIFSS, INFOLNET, NRLN, big analytics being carried out on imports, registration & licensing data have been taken by FSSAI. But, what is lacking is an integrated, holistic approach to handle complex issue of food safety. Neither the health management systems like IDSP, HMIS nor AINPPR is integrated with any

[91] http://www.inspection.gc.ca/food/chemical-residues-microbiology/eng/1331960432334/1331962151945#foodreports
[92] ibid
[93] www.fssai.gov.in/dam/jcr.../Transforming_Food_Safety_Landscape_in_India.pdf

of current operational systems nor is it connected to any of the leading institutes like NIN, IITR, AINPPR and NCDC in a formal manner. There has to be a formal, regular and effective coordination mechanism with public health authorities too and effective flow of information amongst all the stakeholders (**Figure 22**).

7.19 However, as is evident from the survey, data is being collected by various authorities, but much of the data is "stovepiped" into stand-alone databases that are not accessible within and across government agencies. Non-standardized data collection, varied data formats, incompatible data IT systems, a sense of ownership by the group that collects the data are the factors that further worsen the problem (Taylor & Batz, 2008).

Figure 22: Major Institutions and information flows



Source: Modified from "Harnessing knowledge to ensure Food Safety: Opportunities to Improve the Nation's Food Safety Information Infrastructure".

7.20 Many types of information are required to implement a modern, science-based risk approach to food safety to prevent FBDs and assure the consumers about the safety of the food they are consuming. The wide-range of information that a modern food safety regulatory system requires is illustrated in the table below:

Table 10: Categories and types of Food Safety Information

Category	Type of information	
Human Health	Illness surveillance	Attribution
	Medical/Clinical	Health Valuation
	Host factors	
Measurement of Contamination	Microbiological contamination	Other contamination
	Chemical Contamination	Contamination of imports
Indicators of Contamination	Animal Health/Disposition	Sanitation & inspection
	Recalls and violations	
Hazard Identification	Pathogen subtyping	Food Toxicology
	Pathogen biology	
Modeling	Predictive Microbiology	Risk assessment
Total Diet Study	Hazard characterization based on food consumed	Exposure assessment
Trade and Industry	Facilities and processes	Intervention cost
	FSMS	Economic impacts
	Traceback	International Trade
	Intervention efficacy	
Consumers & Workers	Food consumption	Risk perception/communication
	Consumer & worker behaviour	Population and demographics
Food and Environment	Food composition and characteristics	Environmental characteristics

Source: Modified from "Harnessing knowledge to ensure Food Safety: Opportunities to Improve the Nation's Food Safety Information Infrastructure".

7.21 The wide-range of information illustrated above comes from a wide-range of sources, and there are multiple users of this information thus, adding to the complexity. In the Indian context too, it was found that multiple sources have different types of data/information that is of significance to multiple users. But, following was observed in the context of FSSAI based on the current research:

i. There is no overarching strategic plan focusing on food safety binding the research institutes/organisations working in the areas that have implications for ensuring safe and wholesome food to share information/data
ii. Fragmented data collection by respective institutes in their niche areas of specialization
iii. All the State authorities are not reporting their monitoring and surveillance data to FSSAI
iv. Lack of data sharing among government entities
v. The industry also is a repository of data but no linkages/access to industry data
vi. There may also be a need to bring in more stakeholders to cover the ambit of food safety like Ministries of Environment & Forests, Sanitation and Drinking Water Supply who are currently neither the part of Food Authority nor CAC

7.22 Codex Alimentarius guidelines (CAC/GL 82-2013) on principles governing NFCS have articulated 13 principles that are tabulated below. In summing up, against each principle compliance status has been indicated about food regulatory system in the country.

Table 11: Compliance w.r.t principles governing National Food Control System

S.No	Principles	Compliance status
1.	**Protection of consumers**	✓
2.	**Whole Food Chain approach:** Should cover the entire food chain	×

S.No	Principles	Compliance status
	from production to consumption	
3.	**Transparency:** All aspects of NFCS should be transparent and open to scrutiny by all stakeholders while respecting legal requirement to protect confidentiality, wherever applicable	≠
4.	**Roles and responsibilities:** Specific roles and responsibilities of participants in NFCS should be clearly defined	✓
5.	**Consistency and impartiality:** All aspects of NFCS should be applied consistently and impartially, free of improper or undue influence or conflict of interest	✓
6.	**Risk-based, science-based and evidence-based decision making:** Decisions within NFCS should be based on scientific information, evidence and/or risk analysis principles as appropriate	Ω
7.	**Cooperation and coordination between multiple competent authorities:** Competent authorities in NFCS should operate in a cooperative and coordinated manner	β
8.	**Preventive measures:** To prevent and when necessary to respond to food safety incidents	¥
9.	**Self-assessment and review procedures:** NFCS should possess the capacity and capability to undergo continuous improvement & review of its objectives	✓
10.	**Recognition of other systems (including equivalence):** Concept of recognition of systems, including equivalence should be provided for in the NFCS	✓
11.	**Legal foundation:** Fundamental legal structures should be in place	✓
12.	**Harmonisation:** Codex standards including international inter-governmental organisations to be considered	✓
13.	**Resources:** NFCS should have sufficient resources to meets its objectives	µ

Source: Principles have been taken from CAC/GL 82-2013

✓Compliant

×: Primary production is not within the purview of the FSSA

≠: All the information may not be available to the stakeholders particularly the consumers

Ω: All elements of risk analysis framework are yet to be fully implemented

β: Further improvement is required

¥: More robust mechanism needed for prevention, intervention, and response

µ: Inadequate

7.23 There is a need to articulate a comprehensive, integrated approach for risk assessment in the country with public health as an integral part. In all the case-studies that are discussed in chapter 5, the risk analysis framework is firmly linked with public health. The inputs from various standalone systems within FSSAI of licensing & registration, surveillance, imports, scientific panels, etc. along with other data has to be articulated to set up a National Food Safety Risk Assessment Centre (NFSRAC) or any such body. Recommendations emerging from the study are articulated in Chapter 8.