CONSULTATION PAPER ON
UNIFIED AUTHORITY FOR AGRICULTURE EXPORT AND IMPORT

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CHAPTER 1
Introduction

This Consultation Paper discusses the issues that arise in developing a Unified Authority for Agriculture Export and Import regulation. Historically, efforts to regulate agriculture sales have focused on health and safety objectives emphasized by different nations. Each country has developed its national systems to address the specific needs and priorities of the country. This implies a focus on the standards which must be met by domestic production and sales, as well as for international trade.

Although governments may use a number of different policy and administrative tools to ensure safety of food[1], the core objectives of regulatory systems are similar around the world. The Food and Agriculture Organization (FAO) defines the primary objectives of a national food control system to be the following:

- Protecting public health by reducing the risk of food-borne illness;
- Protecting consumers from unsanitary, unwholesome, mis-labelled or adulterated food; and
- Contributing to economic development by maintaining consumer confidence in the food system and providing a sound regulatory foundation for domestic and international trade in food.

Despite the main focus in various countries when addressing the above objectives is similar, the standards specified to achieve these objectives differ in major ways. The standards may differ both across countries and across products within the same country (e.g., fisheries, meat and meat products, fruit and vegetables, milk and milk products, and different types of cereals). These differences have important impact on the standards relevant for international trade.

Since the import of one country is the export of another, the exporting nation has to establish systems and policies to assure the importing nation that the exported products meet the relevant standards established by the importing nation. Moreover, market access for agriculture products exported to specific nations requires discussions and negotiations with these nations. Such discussions regarding diverse products usually involve different agencies within a nation, and require co-ordination to ensure consistent and efficient steps taken by the Government.

[1] The term “food” will be used in this paper to cover both agriculture and food products.

Consistency is required both for initiatives taken with other nations as well as health and safety related activities within the country. Efficient policymaking requires a comprehensive approach that covers all the relevant parts of the "activity chain", i.e. production/processing, domestic sales, exports, and imports of agriculture products. The scope of these activities overlaps with each other, implying that the standards applicable to one part of the production/trade "chain" will have an impact on another part as well (see below). Thus, consistency and overlap of administrative activities becomes an essential part of efficient policy-making and implementation.

(a) Domestic Agriculture Production/Processing → Domestic Sales; Exports

(b) Agriculture Imports → Domestic Sales → Domestic Consumption; Domestic Processing For Further Sales → Domestic Sales; Exports

A need for consistency arises both at the sectoral as well as the overall level because the systems that deal specifically with these objectives can be sectoral, e.g., fisheries, meat and meat products, cereals, fruit and vegetables, milk and milk products. Further, typically the arrangements of food control responsibilities are shared between Government Ministries such as Health, Agriculture, Commerce, Environment, Trade and Industry, and there is a need to ensure consistency and to avoid duplication of tasks or gaps in the regulatory framework.

Experience with the established systems in different nations suggest that multi-agency systems typically have limitations such as:

- lack of overall coordination at national level;
- frequent confusion over jurisdiction and resultant inefficiencies in performance;
- differences in levels of expertise and resources across agencies and hence uneven implementation;
- conflict between public health objectives and the facilitation of trade and industry development;
- limited capacity for appropriate scientific inputs in decision-making processes;
- lack of coherence leading to over-regulation or at times, gaps in adequate regulatory activity; and
- reduced confidence of domestic consumers and foreign buyers in the credibility of the system.

For health and safety standards, as production and trade have become more complex, a number of major economies have established more co-ordinated systems, some of them like China making their changes in the recent two years or so. The major economies have a system which

consolidates the work under one or a few operational agencies. The prevailing multiple agency system in India too needs to be assessed in terms of the present needs of managing the wide-ranging activities with overall co-ordination and a structural consolidation of separate institutions that implement overlapping mandates.

It is in this background that a deeper analysis of the feasibility and efficiency of a Unified Agency for agriculture production, export and import becomes imperative. Such a change would enable greater coherence and efficiency in policy formulation, implementation and review, and pave the way for a more informed and co-ordinated interaction with foreign Governments to create greater income earning opportunities for Indian agriculture. The major significance of standards in international trade implies that the ability of Indian farmers to get access to foreign markets depends on knowledge of the relevant standards and agreements with foreign regulatory agencies on conformity of Indian products with their standards.

At present, various aspects of agriculture production, exports and imports are under the mandate of a number of agencies in India (Chapter 2 gives more detail on this). Often, there is little co-ordination in framing, regulating and implementing the policies related to agriculture export and import. The requisite co-ordination is needed between:

- the regulating agencies;
- these agencies and the farming community, domestic sales and international trade;
- these agencies and the Ministries or Departments of the Government they report to;
- these Ministries and Departments; and,
- the various national initiatives and discussions taken by India with other Governments to improve market access and international trade.

Experience suggests that deliberate efforts are required to effectively co-ordinate among each of these the tasks performed. For instance, market access for agriculture products may be provided by Indian agencies to a foreign country without any information on India's own market access request by another national agency to the foreign country concerned, or without adequate consideration of the non-tariff barriers faced by Indian agriculture exports to those markets.

Chapter 2 provides information on the relevant agencies for agriculture production and trade in India. It discusses the scope of the operation of these agencies and the effectiveness of their current operations. This would highlight possible areas with gaps or those which may need to be better co-ordinated through a change in the institutional structure. While considering the discussion in Chapter 2, certain key points must be kept in mind to address the issues that arise

in the context of unifying the co-ordination of operations of diverse agencies under one umbrella. These issues include:

- the possibility of integration of the jurisdiction of the individual agency concerned with a proposed unified agency;
- modifications required in the administrative/operational structure for this purpose;
- feasibility of combining the functions of different agencies under one umbrella agency;
- the specific legal framework required for making the relevant changes; and,
- the alternative ways to combine or co-ordinate the work of agencies that help achieve the basic objective that would be fulfilled by a unified agency.

These issues are expressed in the form of questions in Chapter 3, which builds upon the previous Chapter and provides a quick overview of the key features of the Indian food regulatory regime. Chapter 3 clarifies a number of policy-related concerns that show that the improvements required include both a move towards a co-ordinated or Unified Authority, and specific steps to address a number of gaps or overlaps/duplication in the regulatory and operational systems in India.

For insights into the framework to address these gaps or inadequate co-ordination among the relevant Bodies involved in food regulation, it is useful to examine the practices of some major economies which have faced similar concerns and have reformulated their regulatory regime and organizational structure of the operational agencies. This information is provided in Chapter 4, which covers these practices in China, USA, EU, Russia and Canada. China is a recent example of institutional changes being made for food regulation, where different agencies and their tasks have been by merged or re-organised to improve co-ordination. Similarly, insights are provided also by examining the practices of other agencies/countries that are addressing the issues raised above. These include USDA & USFDA (USA), CIFIA (Canada), DG SANTE (EU), and FSVPS (Russia). Since the issues involved cover many operational details for these countries, the details are provided also in Annexes 1 to 3 of this Paper. Chapter 4 discussed the main organizational aspects for China, US, EU and Russia, and additional points on China and US are provided in Annex 1 and 2 respectively. Annex 3 provides a description of the regime in Canada.

Chapter 4 also provides some questions for consultation, taking account of the main points that arise in the context of the efforts made by these major economies to establish a more efficient, unified approach towards food regulation.

Based on the discussion in Chapters 2 to 4 and the Annexes, Chapter 5 discusses the possibility of moving towards a Unified Authority in India. It discusses **a model scenario to achieve the objective of establishing a unified agency**, and raises the questions that need to be addressed

for establishing a more effective and co-ordinated institutional structure and mandate for the new agency. This discussion would also **identify the mechanisms for implementing the new system**. For instance, in certain cases, a **calibrated approach** has to be adopted for both establishing a seamless operational regime as well as for reaching a substantive bilateral agreement for getting market access abroad. Such a calibrated approach would need to take account of: the prevailing domestic conditions relating to production and certification; the non-tariff measures imposed by foreign markets that restrict Indian agriculture exports and imports; other specific concerns that need to be discussed or negotiated with foreign Governments; and a reasonable time that may be required for implementing the new structure.

Based on this discussion, questions for consultation are raised in Chapter 5 as well.

Since the main suggestions and questions for consultations are part of different Chapter, this paper collects them for convenience and has reproduced them in Annex 4.

CHAPTER 2

Export-Import Certification Agencies in India for Agriculture and Food products

Agricultural product standards vary considerably from one country to another even though a substantial amount of harmonization of standards has taken place because of efforts in the three international organisations (Codex, OIE and IPPC), which have been given pride of place in the WTO Agreement on Sanitary and Phytosanitary Measures.[2] Major importing countries not only insist on strict adherence to their own standards, they also sometimes specify which organization in the exporting country has to issue an export certificate for a particular product in order to be eligible to enter their markets. For some products and importing countries, the designated agency to issue an export certificate has been left open for the exporting country government to choose. Because of the gradual evolution of the certification process in India, there is an overlap in some cases in the certification responsibilities of different agencies while in some others, different parameters of the same product have to be certified by more than one agency, leading to unnecessary delays and costs. In case a consignment is detected to be not conforming to the standards of an importing country, sometimes the importing country's report is sent to the EIC in India, though the export certificate may have been issued by some other agency. In order to clearly identify such problems, it is necessary to study the roles and responsibilities of the important agencies, which have been entrusted with export and import certification work by the government.

In this chapter, we first describe in brief the statutory basis and responsibilities of different agencies and later on highlight some of the palpable areas of overlap with other agencies.

1. Export Promotion Councils and Export Certification Authorities

(1.a) Export Inspection Council

The Export Inspection Council (EIC) is the official export –certification body of India which ensures quality and safety of products exported from India. EIC was set up to ensure sound development of export trade of India through quality control and inspection and matters connected therewith. The role of EIC is to ensure that products notified under the Export (Quality Control and Inspection) Act 1963 are meeting the requirements of the importing countries in respect of their quality and safety.

EIC provides mandatory certification for various food items namely fish & fishery products, dairy products, honey, egg products, meat and meat products, poultry meat products, animal casing, Gelatine, Ossein and crushed bones and feed additive and pre-mixtures, while other food and non-food products are certified by EIC on voluntary basis. With more than four decades of

[2] See Articles 3.4, 12.3 and paragraph 3 of Definitions in the Agreement. https://www.wto.org/english/docs_e/legal_e/15-sps.pdf

experience in the field of inspection, testing and certification of food items as per the requirements of different countries, EIC enjoys wide acceptance internationally.
The functions of EIC are as follows:

- **Certification of quality of export commodities through installation of quality assurance systems (In-process Quality Control and Self-Certification) in the exporting units as well as consignment-wise inspection.**
- Certification of quality of food items for export through installation of Food Safety Management Systems in the food processing units as per international standards.
- **Issue of different types of Certificates such as Health, Authenticity etc. to exporters under various product schemes for export.**
- **Issue of Certificates of Origin to exporters under various preferential tariff schemes for export products.**
- Laboratory testing services. EIC has in-house laboratories. In addition, there are EIC approved laboratories.
- Training and technical assistance to the industry in installation of Quality and Safety
- Management Systems based on principles of Hazard Analysis Critical Control Point (HACCP), ISO-9001: 2000, ISO: 17025 and other related international standards, laboratory testing etc.
- Recognition of Inspection Agencies as per ISO 17020 and Laboratories as per ISO 17025 and utilizing them for export inspection and testing.
- In rendering the above services, EIAs are backed by qualified technical manpower, having nearly forty years of diversified experience of quality control and inspection of notified commodities including their testing as per international standards/importing countries' standards or the foreign buyers' specifications.

(1.b) Agricultural and Processed Food Products Export Development Authority (APEDA)

The Agricultural and Processed Food products Export Development Authority (APEDA) is an export promotion organization under the Ministry of Commerce & Industries, Government of India. **It is mandated with the responsibility of promotion and development of the export of its scheduled products.**

In accordance with the Agricultural and Processed Food Products Export Development Authority Act, 1985, (2 of 1986) the following functions have been assigned to the Authority:

- Development of industries relating to the scheduled products for export by way of providing financial assistance or otherwise for undertaking surveys and feasibility studies, participation in equity capital through joint ventures and other reliefs and subsidy schemes;

- Registration of persons as exporters of the scheduled products on payment of such fees as may be prescribed;
- **Fixing of standards and specifications for the scheduled products for the purpose of exports;**
- **Carrying out inspection of meat and meat products in slaughterhouses, processing plants, storage premises, conveyances or other places where such products are kept or handled for the purpose of ensuring the quality of such products;**
- Laboratories under APEDA, or accredited by APEDA have the authority to conduct conformity of standards;
- Improving of packaging of the Scheduled products;
- Improving of marketing of the Scheduled products outside India;
- **Promotion of export-oriented production and development of the Scheduled products;**
- Collection of statistics from the owners of factories or establishments engaged in the production, processing, packaging, marketing or export of the scheduled products or from such other persons as may be prescribed on any matter relating to the scheduled products and publication of the statistics so collected or of any portions thereof or extracts therefrom;
- Training in various aspects of the industries connected with the scheduled products;
- Such other matters as may be prescribed, including negotiations and follow-up on Pest Risk Analysis (PRA).

This list shows a wide-ranging list of tasks, which include development, registration, fixing standards, inspection, certification, packaging, marketing, training, negotiations, follow-up on discussions. APEDA's outreach programmes with domestic industry result in greater conformity between production and exports.

The extensive responsibilities make APEDA one of the agencies with a very wide scope of tasks.

(1.c) Marine Products Export Development Authority (MPEDA)

The Marine Products Export Development Authority (MPEDA) was set up by an Act of Parliament in 1972. MPEDA is given the mandate to promote the marine products industry with special reference to exports from the country. It is envisaged that this organization would take all actions to develop and augment the resources required for promoting the exports of "all varieties of fishery products known commercially as shrimp, prawn, lobster, crab, fish, shell-fish, other aquatic animals or plants or part thereof and any other products which the authority may, by notification in the Gazette of India, declare to be marine products for the purposes of (the) Act". The Act empowers MPEDA to regulate exports of marine products and take all measures required for ensuring sustained, quality seafood exports from the country. **MPEDA is given the authority to prescribe for itself any matters**

which the future might require for protecting and augmenting the seafood exports from the country. **It is also empowered to carry out inspection of marine products, its raw material, fixing standards, specifications, and training as well as take all necessary steps for marketing the seafood overseas.**

MPEDA is the nodal agency for the holistic development of seafood industry in India to realise its full export potential. Based on the recommendations of MPEDA, Government of India have notified new standards for fishing vessels, storage premises, processing plants and conveyances.

MPEDA's focus is mainly on Market Promotion, Capture Fisheries, Culture Fisheries, Processing Infrastructure & Value addition, Quality Control, Research and Development. In brief, these functions are as follows:

- **Registration of all entities involved in marine exports (exporters and processors), and of infrastructural facilities for seafood export trade.**
- Certification of exports.
- Collection and dissemination of trade information.
- Promotion of Indian marine products in overseas markets.
- Implementation of schemes vital to the industry by extending assistance for infrastructure development for better preservation and modernised processing.
- Promotion of aquaculture for augmenting export production through hatchery development, new farm development, diversification of species and up gradation of technology
- Promotion of deep-sea fishing projects through test fishing, joint ventures and up gradation & installation of equipment to increase the efficiency of fishing.
- Market promotional activities and publicity.
- **To carry out inspection of marine products, its raw material, fixing standards and specifications, training, regulating as well as to take all necessary steps for maintaining the quality of seafood that are marketed overseas.**
- Impart training to fishermen, fish processing workers, aquaculture farmers and other stake holders in the respective fields related to fisheries.
- Conduct research and development for the aquaculture of aquatic species having export potential through Rajiv Gandhi Centre for Aquaculture (RGCA).
- Conduct extension and awareness activities, training etc through a Network for Fish Quality Management and Sustainable Fishing (NETFISH) & National Centre for Sustainable Aquaculture (NaCSA).
- **To prescribe for itself any matters required for protecting and augmenting the seafood exports from the country in the future.**

Generally, the surveillance of standards being met is done by State level organisations.

(1.d) Tea Board

The Tea Board of India of the Government of India was established to promote the cultivation, processing, and domestic trade as well as export of tea from India. It is responsible for:

- assignment of certification numbers to exports of certain tea merchants and approval of Inspection Agencies. This certification is intended to ensure the teas' origin, which in turn would reduce the amount of fraudulent labelling on rare teas such as the ones harvested from Darjeeling tea estates. Export certification from the Tea Board is mandatory for exports to take place.
- The Tea Board provides Export License, distribution license and permanent exporter's license under Tea (Distribution & Export) Control Order 2005.
- Laboratories under the Tea Board, or accredited by the Board have the authority to conduct conformity of standards.
- It also provides financial support to research organisations and the monitoring of advances in tea packaging as it relates to health benefit aspects.
- It coordinates research institutes, the tea trade and government bodies, ensuring the technical support of the tea trade in the global industry.
- The Tea Board has developed Good Agricultural Practices, and for addressing pesticides it developed a Plant protection Code for proper use of pesticides.

(1.e) Coffee Board

The Coffee Board of India was established by the Government of India to promote coffee production in India. The Coffee Board's duties include:

- promotion of the sale and consumption of coffee in India and abroad
- conducting coffee research,
- registration of exporters,
- issue of registration-cum-membership Certificate (RCMC),
- financial assistance to establish small coffee growers,
- safeguarding working conditions for laborers, managing the surplus pool of unsold coffee and issue export permits under Rule 44(2) Coffee Act 1942, for coffee export [2].
- Export certification from the Coffee Board is mandatory for exports to take place. The Coffee Board is establishing laboratories under the Government's Trade Infrastructure for Exports Scheme (TIES).

(1.f) Spices Board

The Spices Board is the Indian government's regulatory and export promotion agency for Indian spices. It has the responsibility of:

- production/development of cardamom,
- maintenance and monitoring quality of export,
- registration, licensing of spice exporters and export promotion of 52 spices shown in the schedule of the Act[3].
- Mandatory Quality check for Export of chilli /chilli products or food products containing chilli products in whatsoever form (mandatory sampling and quality test for Aflatoxin and Sudan I, II, III and IV) and shipment is permitted by Customs only on the basis of cleared analytical report from the Spices Board.
- The above condition also applies to the export of turmeric powder to the EU, USA, Australia, New Zealand and Japan.
- As per the Spices Board (Registration of Exporters) Amendment Regulations, 2004, **export of spices is not permitted if they are in contravention of the** Geographical Indications of Goods (Registration and Protection) Act, 1999 (No. 48 of 1999) and the rules made thereunder, the Agricultural Produce (Grading and Marking) Act, 1937 (No.1 of 1937) and the rules made thereunder and the Export Quality Control and Inspection Act, 1963 (No. 22 of 1963) and the rules made thereunder.
- The Spices Board has a state-of-the-art testing laboratory at its headquarters in Kochi. There are also regional laboratories at Mumbai, Chennai, Tuticorin, Kandla, Delhi, and Guntur. **Through the laboratories, the Spices Board makes mandatory quality checks for spices exported from India.**

At present, Health certificate for spices is accepted abroad if provided by the EIC. The EU's notification has the EIC as the relevant agency in this context. Now, this situation is going to change and India's Spices Board will also be included in the notification. At present, the exporter gets a certificate from the Spices Board and resubmits it to the EIC.

(1.g) Coconut Board

Coconut Development Board is a statutory body established by the Government of India (Ministry of Agriculture and Farmers Welfare) for the integrated development of coconut production and utilization in the country with focus on productivity increase and product diversification. The Board is responsible for:

- quality testing for the products
- its certificate is not mandatory for exports
- adopting measures for the development of the coconut industry and imparting technical advice to those engaged in coconut cultivation and industry.
- providing financial and other assistance for the expansion of the area under coconut and encourages the adoption of modern technologies for processing of coconut and its products.

- **recommending measures for improving the marketing of coconut and its products and measures for regulating imports and exports of coconut and its products.**

(1.h) CHEMEXCIL

Basic Chemicals, Cosmetics & Dyes Export Promotion Council popularly known as CHEMEXCIL was set up by the Government of India with the objective of promoting exports of dyes and dye intermediates, basic inorganic & organic chemicals including agrochemicals, cosmetics, soaps, toiletries & essential oils, lubricants and castor oil from India to various countries abroad[5].

- **CHEMEXIL is the nodal agency designated by the Ministry of Commerce & Industry for compliance of REACH legislation of the European Union.**
- **It has been authorized by the Ministry of Commerce & Industry to issue Non-preferential Certificates of Origin to its member-exporters** for export of their products to various countries on the condition that the said items are covered are manufactured in India.

(1.i) CAPEXIL

CAPEXIL was setup by the Government of India to promote the export of chemical and allied products from India. It is the Competent Authority for the exports of Crushed Bones, Ossein and Gelatin (under EIC Act).

(1.j) SHEFEXIL

Shellac Export Promotion Council (SEPC) was established by the Government of India to facilitate India's exports of shellac and lac-based products. SEPC's role was enhanced as the Nodal EPC for India's Non-Timber Forest Produce, to facilitate exports of Vegetable Saps & Extracts, Guar Gum, Sesame seeds, Herbs, Niger. Seeds, Other Vegetable materials, Fixed Vegetable Oil, Cakes and more. Subsequently, SEPC was renamed as SHEFEXIL (Shellac & Forest Products Export Promotion Council) and now supports 860 individual products with $2140.94 Million of exports in 2018-19. SHEFEXIL was declared as the nodal EPC for the North Eastern Region of India, to facilitate all exports from the states of Assam, Arunachal Pradesh, Manipur, Nagaland, Meghalaya, Tripura, Mizoram & Sikkim[7].

(1.k) IOPEPC

Indian Oilseed and Produce Export Promotion Council (IOPEPC) is concerned with the promotion of various Oilseeds and Oils.

- IOPEPA is engaged in the development and promotion of exports of oilseeds, oils and oilcakes.

- Besides focusing on exports, the Council also works towards strengthening of domestic supply chain by encouraging farmers, shellers, processors, surveyors and exporters to enhance the quality of oilseeds in India.
- It provides certificates of export for countries other than the EU and Russia[8].

(1.l) Directorate of Plant Protection, Quarantine and Storage

The Directorate of Plant Protection Quarantine & Storage is an apex organization for advising the Government of India and state governments on all matters related to Plant Protection. It is an attached office of the Ministry of Agriculture and Farmers Welfare.

Plant protection activities encompasses those aimed at minimizing crop losses due to pests through integrated pest management, plant quarantine, regulation of pesticides, locust warning and control and training in desert areas besides training and capacity building in plant protection. Its main functions cover both export and import. Its mandate in brief is as follows:

- It draws and tests samples from export and import consignments for the presence of exotic pests inimical to Indian agriculture and the issue of phytosanitary certificates for export consignments.
- **To prevent introduction of exotic pests inimical to Indian agriculture by implementation of Destructive Insects and Pests Act, 1914 supported by Plant Quarantine Order (Regulation of Import into India), 2003.**
- **Export and import Certification of plants and plant products for safe global trade in agricultural commodities (certifying that standards relating to pests and diseases are met; pesticide certification is from other agencies).**
- **To advise and assist the Union Government on all matters including international obligations related to plant protection.**
- To popularize adoption of integrated pest management (IPM) through training and demonstration in crops inter-alia promotion of biological control approaches in crop protection technology.
- To ensure availability of safer and effective pesticides through regulatory measures under the Insecticides Act, 1968.
- To keep watch and control over locust in scheduled desert area.
- Human resource development in plant protection technology.
- Monitoring pesticides' residues at national level.

(1.m) Animal Quarantine & Certification Services

The purpose and scope of setting up of Quarantine Stations is to prevent the ingress of dangerous exotic diseases into the country through imported livestock and livestock products. Increased and faster international trade and travel has exposed every country to the danger of infiltration

of known and unknown transmissible diseases which have the potential of very serious and rapid spread with adverse socio-economic and human/animal health consequences. Its functions include the following:

- Implementation of the provisions of the Livestock and Livestock Products Importation Act and Central Government orders in force on the importation and exportation of livestock and livestock products.
- Detention, segregation, observation and testing of livestock and livestock products meant for import/export.
- Destruction and disposal of imported livestock and livestock products found infected and posing a threat to the national health security.
- Pre-shipment Quality control.
- To have proper liaison with Customs authorities for effective and proper implementation of Livestock and Livestock Products Importation Act.
- To be in close association with the State Directors of Animal Husbandry regarding disease position and surveillance.
- To associate with the Heads of various recognized laboratories in India for getting an expert opinion and for testing of materials.
- To supervise the production and packing of livestock products meant for exports as per the specifications of the importing countries.
- Inspection and registration of plants/mills exporting animal-by-products.

Table 2.1 below provides in summary form the mandate and export certification-related role of these main agencies.

Table 2.1. Export Certification/Promotion Agencies in India

S.No.	Name	Mandate	Certification
1.	EIC	- Notify commodities which will be subject to quality control and/ or inspection prior to export, - Establish standards of quality for such notified commodities, and - Specify the type of quality control and / or inspection to be applied to such commodities.	- Approval of plants - Issuance of Health Certificates - Issuance of certificate for Consignment Wise Inspection **Notified commodities by GoI** - Fish and Fishery products - Honey - Milk Products - Poultry - Egg Products - Animal Casings

			- Gelatine, Ossein and Crushed bones - Fruits - Peanut for EU and Malaysia (Instruction from DoC) - Basmati Rice (Authenticity certificate) - Certification of Tea to Iran **Non-Notified commodities** • Voluntary Food Scheme Non-GMO Certification
2.	APEDA	APEDA is mandated with the responsibility of export promotion and development of the following scheduled products: - Fruits, Vegetables and their Products. - Meat and Meat Products. - Poultry and Poultry Products. - Dairy Products. - Confectionery, Biscuits and Bakery Products. - Honey, Jaggery and Sugar Products. - Cocoa and its products, chocolates of all kinds. - Alcoholic and Non-Alcoholic Beverages. - Cereal and Cereal Products. - Groundnuts, Peanuts and Walnuts. - Pickles, Papads and Chutneys. - Guar Gum. - Floriculture and Floriculture Products - Herbal and Medicinal Plants	- Licensing /Registration certificate to the integrated abattoirs cum meat processing plant/meat processing plants/abattoirs. - Recognition certificate for Horticulture Produce Packhouses. - Rice certification for Iran. - Nodal agency for National Program for Organic Production (NPOP)
3.	MPEDA	Export of Marine Products	- Registration of Aquaculture farm/feed meals/hatcheries (under EIC Act) - Registration of Pre-processing Centre

			- Registration of Processing premises - Registration of cold storage - Issuance of Pre-Harvest Test report (under EIC Act) - Drawal and testing of sample under National Residue Control plan (NRCP) for aquaculture products (under EIC Act)
4.	Tea Board	Export of Tea - One of the functions is aiding Research and Development activities for augmentation of tea production and improvement of tea quality.	- Exporters License/ Distributors - License/Permanent Exporter - License/Renewal of Exporter License under Tea (Distribution & Export) control Order 2005 - Approval of Inspection Agencies (EIAs are one of the approved agencies) - HACCP Empanelment under Tea Board.
5.	Coffee Board	The core activities of Coffee Board are primarily directed towards R&D, transfer of technology, quality improvement, extending development support to growing sector, promotion of coffee in export and domestic markets. The activities of the Board are broadly aimed at: (i) Enhancement of production, productivity & quality (ii) Export promotion for achieving higher value returns for Indian coffee, and Supporting development of the domestic market.	- Registration of Exporters and Issue of Registration-cum-Membership Certificate (RCMC) - Issuing Export Permits under Rule 44(2) Coffee Act 1942, for coffee export
6.	Spices Board	Promotion of export of spices and spices products, maintenance and monitoring quality of export, Registration and Licensing of spice exporters	- Registration and Licensing Exporters Registration Auctioneer Dealer - As per Spices Board (Registration of Exporters) Amendment Regulations, 2004, export of spices in contravention of the Geographical Indications of

			Goods (Registration and Protection) Act, 1999 (No. 48 of 1999) and the rules made thereunder, the Agricultural Produce (Grading and Marking) Act, 1937 (No.1 of 1937) and the rules made thereunder and **the Export Quality Control and Inspection Act, 1963 (No. 22 of 1963) and the rules made thereunder**, is not permitted. - Mandatory Quality check for Export of chilli and chilli products or food products containing chilli products in whatsoever form (mandatory sampling and quality test for Aflatoxin and Sudan I, II, III and IV) and shipment is permitted at Customs only on the basis of cleared analytical report from the spices Board. The above condition may also apply to export of turmeric powder to EU, USA, North America, Australia, New Zealand and Japan. - Grant of Spice House **Certification to the Spice Processing Establishments**.
7.	Chemicals, Pharmaceuticals and Cosmetics Export Promotion Council (Chemexcil)	Export of the following items: - Dyes and Dye Intermediates - Basic Inorganic & Organic Chemicals, including Agrochemicals - Cosmetics, Soaps, Toiletries & Essential Oils - Specialty Chemicals, Lubricants and Castor oil	Issuance of Registration-cum-Membership Certificate (RCMC)
8.	CAPEXIL	Promote export of Chemical and Allied Products from India	- Competent authority for Crushed Bones, Ossein and Gelatin (under EIC Act) - Issuance of Registration-cum-Membership Certificate (RCMC)
9.	SHEFEXIL	Export promotion of shellac and lac-based products	

10.	Indian Oil Seeds & Produce Export Promotion Council (IOPEPC)	Promotion and development of exports of various Oilseeds and Oils from India	- Registration-cum-Membership Certificate - **Certification of warehouses and processing units** engaged in the exports of peanut and peanut products to various countries. - Grant certificate of export for countries other than EU and Russia
11.	National Plant Protection Organization (NPPO), Directorate of Plant Protection, Quarantine and Storage, MoA	- To prevent the entry, establishment and spread of exotic pests in India as per the provisions of **The Destructive Insects & Pests Act, 1914**. - Export Certification of plants and plant products for safe global trade in agricultural commodities - Providing assurance to importing countries that consignments exported from India are free from pests of quarantine significance through globally acceptable export certification as per IPPC	Phytosanitary certificate for plant origin items
12.	Animal Quarantine and Certification Services (AQCS), Department of Animal Husbandry, Dairying and Fisheries, MoA		Animal quarantine certificates
13.	Cashew Export Promotion Council of India	Promote exports of cashew kernels and cashew nut shell liquid from India	- Membership in the Council is granted to those who are engaged in export of cashew kernels/ cashew nut shell liquid, which is not mandatory. - Exports of cashew kernels from India are normally subject to voluntary quality control and pre-shipment inspection

Source: EIC research papers

2. India's Key Agencies for Import-Related Standards

(2.a) The Food Safety and Standards Authority of India (FSSAI)

The Food Safety and Standards Authority of India (FSSAI) has been established under the Food Safety and Standards Act, 2006 which consolidates various Acts and orders that had earlier handled food related issues in various Ministries and Departments. FSSAI has been created for laying down science based **domestic standards** for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption **in India**. At present, it covers 1,470 HS Codes.

FSSAI has a very wide-ranging mandate for its regulation of imports of food products, as well as food in the domestic market. It has been mandated to perform several functions, including:

- **Framing of Regulations to lay down the Standards and guidelines in relation to articles of food and specifying appropriate system of enforcing various standards thus notified.**
- **Laying down mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management system for food businesses.**
- **Laying down procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories.**
- To provide scientific advice and technical support to the Central Government and State Governments in the matters of framing the policy and rules in areas which have a direct or indirect bearing of food safety and nutrition.
- Collect and collate data regarding food consumption, incidence and prevalence of biological risk, contaminants in food, residues of various, contaminants in foods products, identification of emerging risks and introduction of rapid alert system.
- Creating an information network across the country so that the public, consumers, Panchayats etc receive rapid, reliable and objective information about food safety and issues of concern.
- Provide training programmes for persons who are involved or intend to get involved in food businesses.
- Contribute to the development of international technical standards for food, sanitary and phyto-sanitary standards.
- Promote general awareness about food safety and food standards. This includes, for example, labelling requirements and other initiatives to provide relevant information to the public.

FSSAI interacts with Customs, and examines the imports based on risk assessment or its Risk Management System. It examines about 37 to 40% of the import consignments. It is noteworthy that primary production is not under the control of FSSAI.

(2.b) Directorate of Plant Protection, Quarantine and Storage

This agency is discussed in sub-section (1.l) above. Plant quarantine examines every consignment of imports.

(2.c) Animal Quarantine & Certification Services

This agency is discussed in sub-section (1.m) above.

Conclusions

An examination of the statutory provisions governing export/import certification powers of different agencies designated/empowered by the Government of India, reveals a considerable degree of overlap, which leads to confusion among Indian exporters as well as the regulators in importing countries. It also entails delays and incurring of additional costs, thus ultimately militating against the growth of Indian agricultural exports. If agriculture is to contribute its share to GDP and exports to help India become a $5 trillion economy by 2024, it is necessary to reduce transaction costs and delays and to provide our exporters as well as foreign buyers the benefits of a credible and reliable export certification system without any further delay. The next Chapter identifies the significant concerns that arise due to the present system of food regulation in India.

CHAPTER 3

India's Regulatory Regime on Food Standards – Key Features and Concerns

This Chapter brings together the key features emerging from the discussion in Chapter 2, and discusses the concerns that bring forth the need for developing a consistent and comprehensive system of food regulation.

In India, a number of the regulatory agencies perform a wide range of tasks that cover activities relating to production, domestic sales, exports and imports, discussions or negotiations with counterpart agencies in other economies, and following up with processes to ensure that the exported products meet all the requisite conditions required for sales in the foreign market. Some other agencies perform a much more limited number of tasks. There is no uniformity in these different levels of activities by various agencies. Furthermore, there is no formal notified structure or system of operations which provide clarity to domestic and foreign stakeholders on the delegation of authority and the scope of that authority. This diversity creates the possibility of both gaps, duplication and inconsistencies in the tasks performed by different regulatory agencies.

In this background, focused attention is required to identify the areas of concern in the present system of food regulation and address them. This issue is a significant one also because the list of products covered by specified criteria or requirements to be met for domestic sales, exports and/or imports, is increasing as additional sensitive food products get added to the list. Furthermore, in a world of international trade where non-tariff measures are getting more and more an issue of special focus, an informed and consistent policy approach is essential for the policy-maker as well to examine the overall situation comprehensively and clearly, to develop the best options for improving trade opportunities for domestic producers, and health and safety for domestic consumers.

To highlight the relevant factors, this Chapter summarises the main features of the present system to help develop a comprehensive or co-ordinated approach towards food regulation. It begins by considering the different basis for the mandate of food regulatory agencies (Section A below), and then provides a summary list of the main agencies as well as the criteria which suggest different operational conditions for these agencies (section B). Section C shows the long list of different tasks performed by agencies regulating food; while some agencies cover a larger part of this list within their mandate, some others have a much smaller scope of their responsibility. These sections include inputs provided by the feedback from stakeholders.

Based on this discussion, Section D provides a summary of the organizational and operational concerns that arise for the food regulatory Bodies, the policy makers, and the producers and

traders conducting business in the domestic and international markets. These concerns clearly show a need for changing the present structure of food regulation, addressing the gaps or inconsistencies, and improve the co-ordination among agencies and institutions that make policy or conduct negotiations with other nations for improving international trade opportunities for India.

A number of questions arise in this context, reflecting the options that need to be considered before deciding the specific approach and strategy for improving the operational situation. Section E below provides some of the main questions that need to be addressed in this regard.

Additional issues for consideration include those that take account of the efforts by other major trading economies, to develop their institutions for the present end emerging scenario for food regulation. The next Chapter (i.e. Chapter 4) provides a discussion of the institutions in other major economies. Following that, Chapter 5 provides a discussion on the options and approach to be considered within the Indian context, and whether incremental changes or large changes are required to achieve the objectives of a more relevant, consistent, co-ordinated and informed approach for food regulation in India.

A. Mandates for Specific Agencies

1. Provided by Statute or Regulation
2. Delegation specified in writing by Government
3. Informal Delegation, without any notification of such delegation taking place
4. Notifications of Foreign Governments specifying a particular agency as the agency whose certification would be accepted

B. Bodies/Agencies Created for Addressing Standards Related Tasks for Exports and Imports

1. Agencies with **relatively wide ambit** of activities or products covered
   (a) Food Safety and Standards Authority of India (FSSAI)
   (b) Export Inspection Council (EIC)
   (c) Agriculture & Processed Food Products Export Development Authority (APEDA)
   (d) Marine Products Export Development Authority (MPEDA)
   (e) Indian Customs - which verify that relevant criteria for exports/imports are met
2. Agencies at **two levels of governance**: At the Center; At the State level
3. **Policy making Bodies** which inter alia oversee the main operational issues arising in food regulation: Department of Commerce; Department of Animal Husbandry, Dairying and Fisheries; Central Board of Indirect Taxes and Customs.

4. Agencies reporting to or **working under the aegis of different Ministries**: multiple agencies. The Department of Commerce conducts oversight over most of the food regulatory Bodies.
5. **Export Promotion Councils** or Commodity Boards, e.g., Spices Board, Tea Board, Coffee Board, Rubber Board, Tobacco Board
6. Export Development Authorities **with links to producers**: e.g., APEDA, MPEDA
7. Agencies **addressing Pest and Disease**: Plant Quarantine Organization of India (PQOI); Department of Animal Husbandry

C. Policy: Vision, Framework, Content, Implementation of Food Regulation

(a) Development and promotion of production, exports, links to supply chains in international trade (e.g. processing of exports for exports)

(b) Encourage quality standard of processed and manufactured products

(c) Ensure standards are met for health, safety and technical requirements by production/exports/imports

(d) Provide the basis for incentives made available by the Government for production/exports

(e) Negotiation/agreement with other countries of bilateral access for products in each other's markets, and agreement on relevant conditions for such access

(f) Registration of exporters with these Bodies, particularly to benefit from incentives provided by the Government

- Mandatory registration (for most Bodies)
- Voluntary registration (e.g. Coconut Board)

(g) Certification

- Based on internationally accepted standards - **mandated** for specified product categories
- Certification – **voluntary**, at the request from the exporter, importer or importing country based on their specific requirement

(h.1) Controller of Licenses; Issues export licenses (most Bodies, but divided responsibilities), e.g.

- MPEDA gives the certification for US and EU for fisheries and crustaceans; EIC provides the certificates for exports to Japan
- For spices, though there is a Spices Board, the health certificate is provided by EIC, because the EIC is mentioned in the notification by the EU as being the relevant Body in India
- For rice, APEDA issues the export certificate; the responsibility is now moving to EIC

(h.2) Mandatory certificates not required from the Body (Coconut Board)

(i) Develop Good Agricultural Practices, and Plant Protection Code (Tea Board)

(j) Certificate of origin is provided to exporter (Tea Board; Coffee Board)

(k) Phytosanitary certificate; pests and diseases testing (Plant Quarantine for exports and imports)

(l) Testing of pesticide level for exports (not Plant Quarantine; other agencies)

(m) Pre-harvest certification (MPEDA); Post-harvest certification (EIC)

(n) Has laboratories for testing (e.g. EIC); accredits laboratories (e.g. EIC, APEDA, Coffee Board)

(o) Production is part of mandate (e.g. cardamom for Spice Board)

(p) Primary production not under control pf the Body (FSSAI)

(q) Training of farmers (Spice Board, APEDA)

(r) Trade promotion organisation (e.g. Coconut Board, MPEDA, APEDA, Tea Board)

(s) Pest Resistance Analysis (PRA) system relevant for agriculture and horticulture products; PRA not relevant for marine products

(t) In certain cases, surveillance of standards being met, is done by State organisations (i.e. not Central organisations (e.g., marine products)

D. Concern Relating to the Responsibilities of Specific Agencies:

A number of concerns arise with respect to the operations of food regulatory Bodies in India:

D.1. Role is not clear or not consistently defined

(a) In some cases, the role of a specific the agency is not clear in terms of delegation of authority or to the exporters. For instance, while certification from some agencies are mandatory, it is not so for products covered by some other agencies. Likewise, the mandate of some agencies covers several activities while some others have a much narrower scope of operation.

(b) At times, two Acts or Regulations have delegated authority to different agencies for the same or similar task.

(c) Some agencies have been delegated their powers by Acts, but another agency conducts the delegated functions without any formal delegation of authority.

(d) While one particular agency is responsible for one role under law, oversight of exports is notified to be conducted by another agency. In certain cases, complaints are submitted to the first agency (see examples of fisheries products; meat and meat products; and processed dairy products, in Table 3.1 below)

(d) Likewise, certain activity such as certification of exports to one country is the responsibility of one agency, another agency is responsible for certification of exports to another country (see for example, the situation for basmati rice in Table 3.1 below)

D.2. Duplication of role or overlapping role

(a) In certain cases, more than one agency performs a similar role

(b) More than one agency required for an exporter to get approval for being able to export. For example, in certain cases, exporters have to approach not one but three agencies to get their relevant approval for exports. Examples include gelatin, for which the exporters have to get approvals from the EIC, CAPEXIL, and State Animal Husbandry Departments. Similarly, exporters of peanut and peanut products also have to get approvals from three different agencies.

(c) The overlap may occur because of the composition of the inputs. For instance, any animal product such as a cooking medium with animal-origin (e.g. ghee), and any component which is of vegetable origin, results in samples being demanded for verification by both plant quarantine and animal husbandry organisations.

D.3. **A linked organisation, such as Customs, is not clear about the validity of requests** from different organisations, e.g. Plant quarantine will exercise mandate for some prepared food, and Animal Quarantine too will exercise control on the grounds that the cooking material may be of animal origin, or vice versa. The linked agency (Customs) is unable to verify and complies with request of both. The result is that the same consignment for exports or imports is tested by more than one agency. This implies samples being drawn by more than one agency. A common platform would remove the need for multiple sampling, i.e. one sample could be used for all the relevant tests. This increases the efficiency of operations and saves time and costs.

D.4. Likewise, **a common platform (that does not exist at present) would**:

(a) **Enable more efficient use of staff and laboratories**.

(b) **Avoid the current confusion** which arises as mentioned above, due to two different agencies claiming that their mandate provides them the authority to test the product. A common platform could address this through a single sample.

D.5. Given the possibility of grey areas in terms of mandates being applicable, **Customs needs to be trained** more to recognize the limits of jurisdiction of different regulatory agencies.

D.6. Lack of clarity of roles or responsibilities implies a third agency such as Customs, needs to rely on a published Government Policy document. In general, Customs relies on EXIM Policy document. **All relevant agencies are not mentioned in the EXIM Policy document**, which results in gaps in the process, and increases problems faced by exporters/importers.

D.7. **Policy related jurisdictional conflicts** arise due to similar roles or lack of consistent responsibilities to any specific agency. Examples in Table 1 below.

Table 3.1. Examples of Divided or Unclear Responsibilities Resulting in Operational and Jurisdictional Conflicts Relating to Exports

Commodity	Areas of Conflict	Organization involved
Spices	EIC is the competent authority to certify export of Black Pepper from India to USA. For other spices, it is not clear who is exercising regulatory control. For complaints/import rejections related to Spices, the information is forwarded to EIC which is not in position to take action.	Spices Boards and EIC
Fisheries Products	Notified under EIC's Act however Central or State Veterinarians are sometime issuing certificates	Department of Animal Husbandry and EIC
Meat & Meat Products	Notified under EIC's Act but export is controlled by APEDA under DGFT Notification. The foreign complaints are forwarded to EIC for action.	APEDA and EIC
Honey	Despite being under compulsory certification, some export is happening without EIC's certification	Customs and EIC
Pet Food	CAPEXIL is involved in export certification but complaints are forwarded to EIC	CAPEXIL and EIC
Sesame	SHEFEXIL is involved in export certification but complaints are forwarded to EIC	SHEFEXIL and EIC
Processed Dairy Products	Products notified under EIC's Act but Animal Quarantine Certificate is issued by Department of Animal Husbandry. Complaints are forwarded to EIC.	Department of Animal Husbandry and EIC
Basmati Rice	While EIC is responsible for export certification for EU, responsibility for Iran is given to APEDA	APEDA and EIC

Source: EIC

D.8. **Delays** due to complex and/or time-consuming process

D.9. **Increase in costs** for:

(a) Producers, exporters, importers

(b) For implementing agencies

D.10. Agencies do not have adequate staff, and the **tasks have to be outsourced**. This **creates possibility of different understanding about specific requirements**, or the same task being performed in terms of varying criteria.

D.11. Foreign agencies or Governments not always clear about the relevant agencies for interaction or contact

D.12. Foreign agencies could negotiate with two Indian agencies, without each of the two knowing the details of these discussions. This is also possible when more than one Ministry has overlapping responsibilities.

D.13. Exporters or importers not always clear about the relevant requirements for trade

(a) For products not under mandatory certification, exporters are not always aware about the requirements of the importing countries. Sometimes this results in rejection of products exported, or even stronger penalties such as a ban.

(b) Adequate follow-up mechanisms that are required to address such situations, are not available or are established after delay.

(c) Appropriate action for avoiding repetition of such incidences is either not taken or no feedback is given to the importing country

E. Questions for Consultations, and Gaps Which could be Addressed Relatively Soon

We have three kinds of situations in the context of the discussion till now.

One, some questions arise to seek solutions on moving towards a unified Authority. A consideration of such a move would be more useful after examining the practices of some other major economies as well (Chapter 4). In addition to the questions given in this Chapter, questions for consultations are provided also in Chapters 4 and 5.

Two, some of the **gaps or concerns are clear and steps to address them could begin quickly. These include for example**:

(a) The EXIM Policy document does not include the names of all the agencies. This gap should be filled without a short time period, e.g. one month.

(b) Training of Customs officials to be clearer on the jurisdiction of different regulatory agencies. FSSAI and EIC could be the nodal agencies to co-ordinate such training.

(c) Likewise, training of those agencies to which responsibilities are outsourced.

(d) After a specified time period, e.g. six months, all regulatory agencies should perform their tasks based on formal delegation of authority to that agency (see questions below for addressing this issue).

(e) A list should be prepared within a short time period, to clarify the mandatory requirements for exporters and importers, and the regulatory agencies that administer these mandatory requirements.

(f) Addressing the above-mentioned concerns with respect to products not under mandatory certification:

- Centralised source of information on requirements for these products in importing countries.
- Establish follow-up mechanisms required to address trade-related problems that may arise due to non-conformity with standards in importing countries.

In this context, **there are already existing examples of success cases,** which could provide insight and some basis to identify solutions to address the gaps or develop greater coherence amongst different agencies. The **use of technology to improve efficiency or address gaps and other concerns** is also an area worth considering, particularly in light of some existing successful application of technology-based solutions. Examples include:

- The success of GrapeNet and TraceNet for outreach programmes and development of export capabilities.
- Development of consistent and harmonized standards for the organic sector, which show the possibility of developing coherent initiatives across products.
- The Coffee Board has set up a laboratory under the TIES programme which has high standards capabilities. At present, no certification is required, but this laboratory could be used for certification purposes. This would improve marketing opportunities.
- Use of BOTS by the Coffee Board to vastly reduce the time for certification, and identifying gaps which need to be addressed for completing the steps required for certification.
- BOTS has been linked with ICEGATE so that greater coherence is now possible between the Coffee Board and Customs.
- MPEDA is successfully supplying disease-free seedlings throughout the country, an initiative which requires co-ordination of several linked steps to manage such an endeavor.
- Another example is the knowledge that certain internationally recognized standards could increase the acceptability in international markets, e.g. Fairtrade, UTZ. Implementing such standards on a wide scale requires specific efforts. The steps and resources required for more extensive use of international standards could be ascertained for implementation.

The third category is the list of specific questions to be addressed in the consultation process. **These questions for consultation include:**

3.1. For areas for which clear formal delegation of authority is not provided, which method would be more appropriate to address this situation?

(a) Change of legislation? Too time consuming?

(b) Specifying the role clearly in a regulation?

(c) Through a High-Level Committee which examines all such situations, and clearly specifies the mandate for different agencies within a specified time period.

(d) Any other method that would be more efficient and quicker?

3.2. In situations where more than one agency is delegated with similar responsibility, or approval of more than one agency is required, what is the solution for removing such duplication or reducing additional effort by the exporter/importer?

(a) Relevant Ministries address the issue for Bodies which they oversee, and specify a single agency for the task for which there is duplication or approval from more than one agency is required for exports/imports?

(b) When more than one Ministry is involved in overseeing the agencies concerned, a co-ordinated meeting of the Ministries should decide within a specified time period, on one agency to perform the task?

(c) What should be the criteria to determine which of the various agencies concerned should operate as the one agency to avoid duplication?

(d) If the same task is performed by two or more agencies, e.g. export certification to one country (say EU) by one agency and to another country (e.g. Iran) by another agency, should there be a nodal Body co-ordinating this or only one agency should be given the authority to give the export certificate?

(e) Any other method that would be more efficient and quicker?

3.3. Is it possible to have a nodal or central agency which keeps information on all interaction/discussions/negotiations with foreign regulatory agencies? Should this be placed with a co-ordinating senior officials Committee comprising Commerce, Agriculture, Customs, and invited Ministries that are relevant for discussion of the agenda of specific meetings?

3.4. Is it possible to coordinate the laboratories even before a unified Authority is in place, to create a system that one sample may serve for making all relevant tests?

3.5. Similarly, is it possible to reduce the time period for approvals? Is there any specific regulatory agency whose operations could serve as a model for quick approvals? If so which one? Please provide examples of success cases in this context.

CHAPTER 4

Regulatory Regimes of Major Countries: Towards Unified or Co-ordinated Systems

National Food Control systems are designed to meet the specific criteria embodying the needs and priorities of countries. While governments may use diverse and even different policy and administrative tools to ensure the safety of food, the core elements of regulatory systems are similar among nations.

As mentioned in Chapter 1, The Food and Agriculture Organization (FAO) defines the primary objectives of a national food control system to be the following:

- Protecting public health by reducing the risk of food-borne illness;
- Protecting consumers from unsanitary, unwholesome, mis-labelled or adulterated food; and
- Contributing to economic development by maintaining consumer confidence in the food system and providing a sound regulatory foundation for domestic and international trade in food.

Food control systems also play a significant role in ensuring fair practices in trade; developing the food sector on a professional and scientific basis; preventing avoidable losses and conserving natural resources; and promoting the country's export trade. This could be through sectoral initiatives (e.g. development of the particular sector such as fisheries, meat and meat products, fruit and vegetables, milk and milk products). Such sector-specific initiatives may result in the establishment of multiple agencies with responsibilities for food control. Typically, under such arrangements the food control responsibilities are shared between several Government Ministries such as Agriculture, Commerce, Environment, Health, Trade and Industry. The specific roles and responsibilities of each of these Ministers or reporting agencies are specified in a consistent system of regulation.

Nonetheless, as the regulatory tasks have multiplied, the evidence on experience suggests the multi-agency systems to typically have limitations, for instance, lack of overall coordination at national level; frequent confusion over jurisdiction and resultant inefficiencies in performance; differences in levels of expertise and resources and hence uneven implementation; conflict between public health objectives and the facilitation of trade and industry development; limited capacity for appropriate scientific inputs in decision-making processes; lack of coherence leading to over-regulation or time gaps in adequate regulatory activity; and reductions in the confidence of domestic consumers and foreign buyers in the credibility of the system.

Given the significance of each countries institutions or regulatory infrastructure, a country-specific decision has to be taken on whether a multi-agency system or a single unified structure is better suited for implementation of the national food control strategy, while also considering the type and size of the organization(s) that are necessary to implement it.

To understand how different countries have developed their structures, this paper studies the Food Control system of five countries/regions, i.e. **Canada, China, European Union, Russian Federation, and USA.** The Chapter begins by sharing some highlights that emerge from a consideration of the regimes in these economies. The next four sections provide details on the structure of food regulation in China, USA, EU and Russia. In addition to the main features of the regulatory system, information on the co-ordination among agencies in China and the new law in the US, respectively, is provided in Annexes 1 and 2 of this Consultation Paper. Annex 3 provides the details of the regime for Canada.

SOME KEY POINTS AND HIGHLIGHTS

The regulatory regimes of countries discussed below show that:

(a) There is in general no single Body for food regulation. Only for the EU is there a single Agency or Authority responsible for developing regulatory regime and implementing it (see sub-section "A" below).

(b) Even for the EU, however, the implementation requires the relevant regulatory Bodies of members States to carry out the regulatory functions in practice. This is helped by the fact that most regulatory requirements have been harmonized for food and agriculture in the EU.

(c) Other economies discussed in this Chapter have either two or more agencies with oversight as well as more detailed responsibilities for food regulation.

(d) This level of aggregation of the number of agencies has meant:
- combining previous agencies under an agency with a broader remit,
- phasing out some agencies and re-allocating the tasks, and
- bringing in new laws to provide a basis for the new and wider ambit of the role and power of the regulatory Bodies,

(e) Even though certain agencies were transferred to become part of a larger Body, in certain cases the name of the agency was retained.

(f) Even with an aggregation of tasks into a smaller number of agencies, the products covered by individual agencies need not be comprehensive, i.e. some products may be allocated to one agency and other products to the second agency.

(g) The responsibilities in general are clearly defined, though there are overlaps in areas covered. In such situations, the framework for co-ordination and collaboration is clearly specified.

(h) In certain cases, the re-organisation was at the level of the Ministry itself, and not just for the tasks related to food regulation.

(i) This has meant that the scope of work allocated to the relevant agencies in these countries have a much wider scope than that covered by the food regulation regime of India.

(j) This in turn implies a consideration of three inter-related points:

- What should be the tasks to be considered under the re-organisation of the regulatory regimes within a framework of Unified Authority in India, i.e. even if the scope be wider than that of the Authorities at present, it is unlikely to cover the much wider level of responsibilities of a Ministry as such.
- In this context, which of the activities discussed below for the major economies, would be relevant to consider for the scope of activities of the Indian Unified Authority?
- Thus, when considering the activities covered by individual agencies of other countries, it would be useful to identify those which should be part of the Indian system, and those which at least for the present need not be part of the responsibilities of the food regulatory Bodies in India.

(k) Nonetheless, to the extent that crucial aspects of the tasks performed by the regulatory agencies involve Ministry-level actions, the Indian framework could consider an inter-Ministerial level co-ordinating Committee for higher policy level decisions, and to address areas where inter-agency conflicts of jurisdiction may arise.

(l) By aggregating several tasks under a common umbrella agency, and forming different operational parts of a single agency, mechanism have been established for co-ordinating the tasks performed by different parts of the agency, and rules of conduct be established so that conflicts do not arise?

(m) Similarly, while multiple tasks have been collected under a few (one to four) agencies, there are still other agencies outside their ambit which perform overlapping tasks. Ways of co-ordination with such agencies also have been established.

(n) Similarly, co-ordination among agencies also takes place when priority tasks are being performed, especially when negotiations/discussions take place with external agencies or Governments.

Some of the other highlights are provided below, and then a more detailed discussion of the practices in China, USA, and Canada are provided in this Chapter, and additional details on China, USA and Canada are in Annexes 1 to 3 of this Consultation paper.

A. Unified Authority

China: The responsibility of regulating safety of food and agricultural products is **shared between four agencies. No one agency has the sole right of jurisdiction**.

USA: The regulation of food and agriculture products is **carried out by the Food and Drug Administration (FDA) and the Department of Agriculture (USDA)**.

EU: The **Directorate General for Health and Food Safety, of the European Commission has the sole right of legislative initiative in EU policy on food safety and health and for monitoring the implementation** of related laws at the Union level. Member States are responsible for enforcement of regulations at the national level.

Canada: Four Federal Agencies are involved in the regulation of food and agriculture products. However, i**mplementation of the developed regulations is carried out by a single agency, the Canadian Food Inspection Agency**.

Russia: The regulation of food and agricultural products is **divided between the Eurasian Economic Commission and several ministries and agencies under the Russian Federation**.

B. Negotiators and Implementation Agencies

	Negotiator of Agreements with Trading Partners.	**Implementation of Regulations**
China	Ministry of Agriculture and Rural Affairs, General Administration for Customs of China	Co-ordinated effort between the Ministry of Agriculture and Rural Affairs, General Administration for Customs of China, State Administration for Market Regulations and the National Health Commission.
USA	Department of Agriculture (USDA) and the Office of the United States Trade Representative (USTR)	Food and Drug Administration (FDA) and USDA
EU	European Commission	European Commission and Member States.
Canada	Canadian Food Inspection Agency (CFIA)	Canadian Food Inspection Agency (Other agencies are also involved in developing the regulations, however CFIA is solely responsible for implementation.)

C. Key Points from Selected Domestic Practices

China: Notwithstanding the number of agencies involved in the regulation of food safety, the **roles and responsibilities of each agency are clearly specified and there is little room for ambiguity**.

EU: While the European Commission is responsible for ensuring that member states are effectively carrying out Union-level legislations, **each member state is individually responsible for ensuring that the goods being imported are compliant with relevant standards and requirements.** There is a high level of transparency of the importation system. Additionally, the **member states are now more harmonized in policy matters concerning food and feed**.

Canada: There is equal division of labour between the four Federal Agencies involved in the Regulation of food and agricultural products.

USA: Despite a very strong federal structure in the US, the **Food and Drug Administration (FDA) has a complete control over the food regulation in the country**. The FDA was empowered by the United States Congress to enforce the Federal Food, Drug, and Cosmetic Act, which serves as the primary focus for the Agency at both domestic and import level.

Russia: Russia focuses on both the regional level and the domestic level. **Russian national regulations continue to apply to the extent they do not contradict the Eurasian Economic Union (EAEU) regulations**. Domestically, the Ministry of Agriculture (Minselkhoz) is the federal executive body responsible for drafting and implementing government policy and legal regulation in Russia.

D. Stakeholder Consultation

China: As per the Food Safety Standards Administration Measures, the National Health Commission (NHC) develops the National Food Safety Standards and the procedure involves stakeholder consultation in the following manner:

- The procedure for national food safety standard development includes: standard development programming, planning, project initiation, drafting, comments solicitation, review, approval, coding, announcing, tracking and evaluation, and revision
- Relevant government authorities, research institutes, academies, educational institutions, industry associations, food producers, and traders can submit project initiation proposals for national food safety standards development.
- NHC also solicits comments from relevant government agencies and industries once the standard has been developed, and publishes the standard on its website to solicit comments.

USA: Any regulation that is brought out at the Federal or State level goes through a very detailed public hearing process where inputs are received.

EU: The European Food Safety Authority (EFSA), responsible for providing scientific advice to the legislators on matters related to food safety, regularly consults stakeholders. Representatives of food industry and business, farmer organisations, consumer and environment NGOs, distributors, practitioners and academia all have the opportunity to engage with EFSA. Registered stakeholders can participate in a variety of standing and ad-hoc platforms, according to their interests and expertise.

Canada: Stakeholder consultation is an integral part of policy development in Canada and the forms of communication include stakeholder meetings, direct mailing and multimedia approach.

A number of relevant points relating to the food regulation regimes of China, US, EU and Russia are reproduced below. Further details for China, US and Canada are in Annexes 1 to 3 of this Consultation Paper.

I. CHINA: Structure of the food safety and control system in China[3]

- In China, the safety of Food and Agricultural products is regulated at the ministerial level.
- The main regulatory agencies are the State Administration for Market Regulations, the General Administration for Customs of China and the Ministry of Agriculture and Rural Affairs.
- National-level laws governing the safety of imports and exports are: Food Safety Law, Animal and Plant Quarantine Law, Import and Export Commodity Inspection Law and the Quality and Safety of Agricultural Products Law, among others.

In March 2018, the 13th National People's Congress approved the "State Council Institutional Reform Plan", a part of broader reforms proposed by the Communist Party of China under the "Plan to Deepen Reform of Party and State Institutions". The objective of the plan was to streamline the governance system to meet the demands of the people and needs of development. This was to be achieved by promoting co-ordinated actions, improving levels of management and creating a better-structured, more efficient and service-oriented administration.

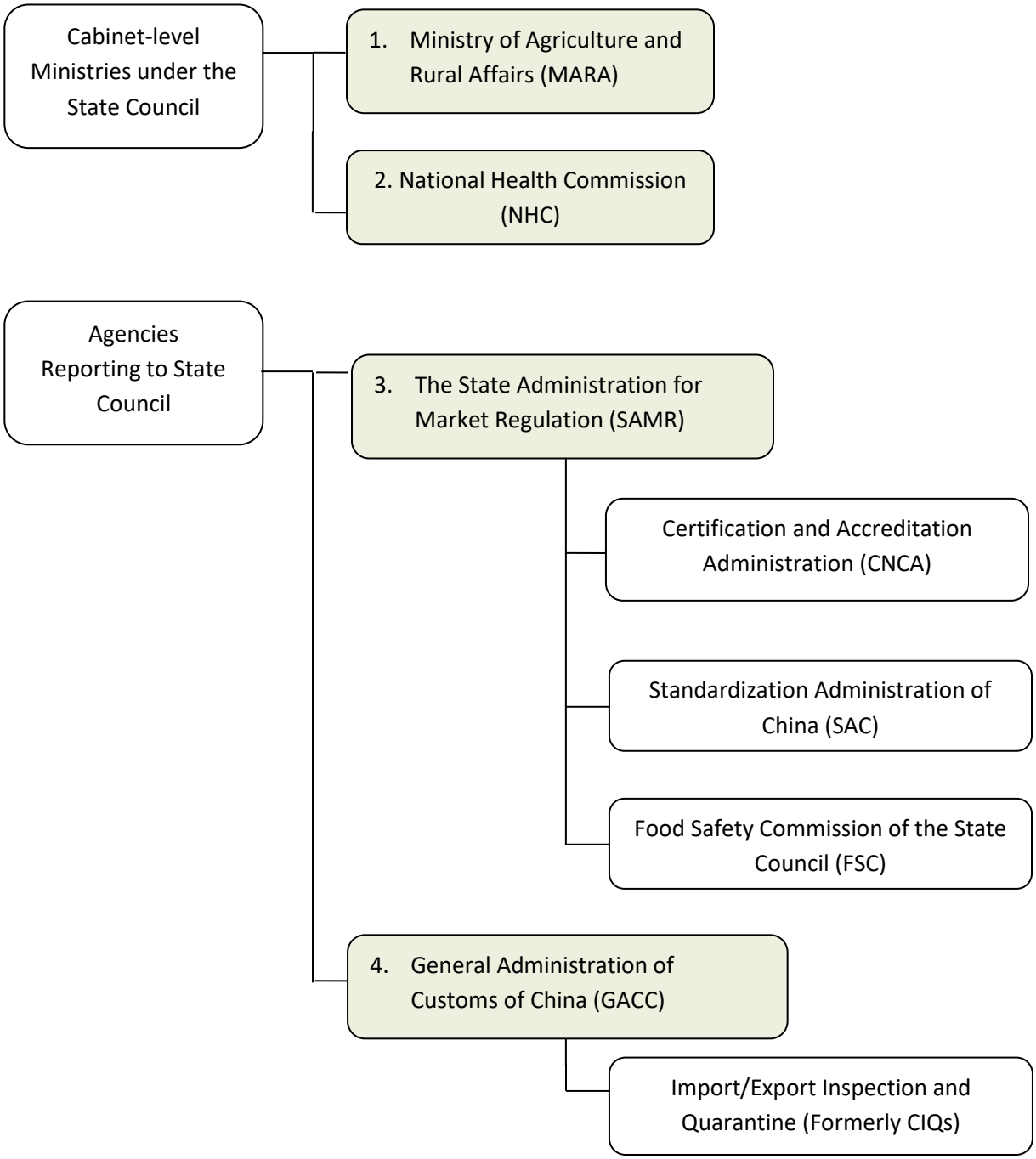
As part of the reform, there was a major reshuffle in the organizational structure of the State Council; the chief administrative authority of the People's Republic of China; leading to downsizing and reallocation of powers. Consequently, the regulatory regime for food and agricultural products also underwent significant changes, particularly with the establishment of 3 new agencies:

1. State Administration for Market Regulations (SAMR)
2. National Health Commission (NHC) (previously the National Health and Family Planning Commission)
3. Ministry of Agriculture and Rural Affairs (MARA) (previously Ministry of Agriculture)

[3] The references for this sections are: Official website of Ministry of Agriculture and Rural Affairs, China; Official website of National Health Commission, China; Official website of General Administration of Customs of China; USDA FAS GAIN report "General Administration of Customs reorganization" (Report Number- CH 18072); USDA FAS GAIN report "China Announces Revamped Market Regulation Administration" (Report Number- CH 18069); USDA FAS GAIN report "Food and Agricultural Import Regulations and Standards Report". (Report Number- CH 18086); US-China Business Council (USCBC)- Key Agencies Organization Charts.

The restructuring led to several other agencies being dismantled or being absorbed into new Ministerial structures, such as the China Food and Drug Administration (CFDA), State Administration for Industry and Commerce (SAIC) and the General Administration of Quality, Supervision, Inspection and Quarantine (AQSIQ).

In the current food regulatory regime of China, four agencies play an important role:



1. MINISTRY OF AGRICULTURE AND RURAL AFFAIRS (MARA)

- The reorganization of 2018 created the Ministry of Agriculture and Rural Affairs by consolidating the erstwhile Ministry of Agriculture (MOA) with the agricultural investment related functions previously held by the National Development and Reform Commission (NDRC), the Ministry of Finance (MOF), the Ministry of Land Resources (MLR), and the Ministry of Water Resources (MWR).
- The Ministry of Agriculture and Rural Affairs is a component of the State Council in charge of agriculture and rural economic development.
- The main functions of MARA are as follows:
  1) **To research and work out development strategies** and long-term and mid-term development plans of agriculture and rural economy
  2) To study and draw up **agricultural industry policies**
  3) To organize the **drafting of laws and provisions regarding various agricultural industries** such as crop production, animal husbandry, fishery, rural and township enterprises.
  4) To organize the **zoning of agricultural resources, ecological agriculture and sustainable agricultural development**.
  5) To **draw up technical standards** for various agricultural industries and organize their implementation thereof
  6) To organize the **implementation of quality supervision and certification of various agricultural products and green food products** and the protection of new varieties of agricultural plants
  7) To **draft laws and provisions on animal and plant diseases prevention and quarantine**, sign inter-governmental agreements and accords and formulate related standards;
  8) To **organize veterinary administrations** and veterinary medical products administration and inspection; to **organize and supervise domestic animal and plant disease prevention and quarantine**, **publicize epidemic information and organize the work of eradication**.
  9) To **undertake foreign-related agricultural affairs** and organize related international economic and technical exchanges and cooperation.
  10) The Ministry of Agriculture and Rural Welfare **develops the pesticide and veterinarian drug standards**.

2. NATIONAL HEALTH COMMISSION (NHC)

- The National Health Commission functions as a ministerial ranked department under the State Council.

- Previously called the National Health and Family Planning Commission (NHFPC), the National Health Commission (NHC) is responsible for food safety risk assessment.
- NHC **develops most National Food Safety Standards**.
- NHC is **primarily responsible for**:
    1) Formulating national health strategies, policies, and laws
    2) Promoting the reform of China's medical and health system
    3) Supervising medical sector and public health conditions
    4) Guiding family planning and aging population policy work.

- NHC also **oversees the development of the national drug management system, manages public health emergencies, and oversees the integration of medical care and pensions**.

3. STATE ADMINISTRATION FOR MARKET REGULATIONS (SAMR)

- The SAMR is a full ministerial level government agency that reports directly to the State Council of China.
- The establishment of the SAMR **consolidates in one ministry, the market regulation functions previously shared by three ministries, the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), the China Food and Drug Administration (CFDA), and the State Administration of Industry and Commerce (SAIC)**.
- The **Certification and Accreditation Administration (CNCA) and Standardization Administration of China (SAC), which were affiliated with AQSIQ, are now transferred to SAMR**. However, the names of both CNCA and SAC are retained. In this regard, CNCA is the agency r**esponsible for approving overseas manufacturing facilities for foods exported to China** (e.g., dairy products, meat products) as well as **product certification** (e.g., organic). SAC is the agency **formulating various Chinese Standards**.
- In terms of food safety, SAMR is responsible for the **comprehensive coordination of China's food safety system; the development of major food safety related laws, policies, and regulations; the implementation of market inspections; and the registration of special foods**; among other functions. All these functions were previously held by the CFDA.
- SAMR is the new **food product traceability authority**. It is also the new **food recall authority**.
- The main areas of jurisdiction and responsibilities of the SAMR are as follows (emphasis added):
    1) It is responsible for <u>comprehensive</u> market supervision and administration, by drafting the laws and regulations on market supervision and administration, formulating relevant rules, policies, and standards; organizing and implementing the policy of the great power of quality, food safety, and standardization.
    2) **<u>Unified</u> registration of market entities**.

3) It is responsible for **organizing and guiding the <u>comprehensive</u> law enforcement** in respect of market supervision and administration.
4) **<u>Unified</u> anti-monopoly enforcement**.
5) Supervision and administration of the market order.
6) It is responsible for the **supervision and administration of product quality safety**.
7) **<u>Comprehensive</u> coordination on the supervision and administration of food safety**.
8) **<u>Unified</u> administration of metrological and standardization work**.
9) **<u>Unified</u> administration, supervision, and comprehensive coordination of the national certification and accreditation work**.

- The SAMR has the following departments:
  1) General Office
  2) Comprehensive Planning Department
  3) Department of Regulations
  4) Law Enforcement and Inspection Bureau
  5) Registration Bureau
  6) Department of Credit Regulation
  7) Anti-Monopoly Bureau
  8) Price Supervision and Anti-Unfair Competition Bureau
  9) Department of Online Transaction Regulation
  10) Department of Advertising Regulation
  11) Quality Development Bureau
  12) Department of Product Quality and Safety Regulation
  13) Department of Food Safety Coordination
  14) Department of Food Production Safety Regulation
  15) Department of Food Operation Safety Regulation
  16) Department of Special Food Safety Regulation
  17) Department of Food Safety Random Inspection and Monitoring
  18) Special Equipment Safety Supervision Bureau
  19) Metrology Department
  20) Department of Technology Standards Administration
  21) Department of Standards Innovation Administration
  22) Department of Certification Regulation
  23) Department of Accreditation and Inspection Regulation
  24) Department of Publication
  25) Department of Science, Technology, and Finance
  26) Personnel Department

27) Department of International Cooperation (Office of Hong Kong, Macao, and Taiwan Affairs)

4. GENERAL ADMINISTRATION OF CUSTOMS OF CHINA (GACC)

- The reorganization of 2018 has merged most of the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) into the General Administration of Customs of the People's Republic of China (GACC). This merger includes the **integration of all former China Inspection and Quarantine (CIQ) offices located at Chinese ports into GACC's existing import/export inspection structure**. As a result, the reorganization has expanded the responsibilities of the GACC.
- GACC is primarily concerned with **public security and border protection, entry-exit inspection of goods, and collection of import and export duties and taxes**.
- With the addition of AQSIQ's food and agricultural functions and personnel, GACC is now directly responsible for a wider variety of duties, including **agricultural inspections at the port of entry and managing food and agricultural import/export policies**.
- GACC's Import and Export Food Safety Bureau is responsible for **registering foreign facilities that produce certain food and agricultural products for export to China**. This duty was previously under the purview of the Certification and Accreditation Administration (CNCA).
- In 2014, AQSIQ established the Cross Border e-Commerce (CBEC) import channel. CBEC provides the possibility of importing certain products directly from foreign suppliers through an internet platform registered by AQSIQ (now GACC), and only through certain CBEC pilot ports of entry. Since 2016, the Chinese Government (i.e., 11 ministries and commissions) maintains a "positive list," currently containing 1,321 items, of which about 150 are food or agricultural products that can enter through CBEC channels.
- The **main areas of jurisdiction and responsibilities of the GACC** are as follows:
    1) National Customs work and supervision
    2) Organization and promotion of the construction of "General Customs Clearance" at ports.
    3) Collection and administration of import/export duties and taxes. This includes conducting negotiations with foreign countries based on the multilateral and bilateral rules of origin and enforcing anti-dumping and anti-subsidy measures.
    4) Jurisdiction over entry-exit health quarantine, and the inspection and quarantine for entry-exit of animals and plants and their products
    5) Legal inspection of imported and exported commodities, including supervising and administering the identification, verification, and quality safety of imported and exported commodities.

- The GACC has the following departments:
    1) General Office (National Office of Port Administration)
    2) Department of Policy and Legal Affairs
    3) Department of Integrated Services
    4) Department of Free Trade Zone and Special Areas
    5) Department of Risk Management
    6) Department of Duty Collection
    7) Department of Health Quarantine
    8) Department of Animal and Plant Quarantine
    9) Import and Export Food Safety Bureau
    10) Department of Commodity Inspection
    11) Port Supervision Department
    12) Department of Statistical
    13) Department of Enterprise Management and Inspection
    14) Anti-Smuggling Bureau (Coordination Office of National Anti-smuggling Program)
    15) Department of International Cooperation (Office of Hong Kong, Macao, and Taiwan Affairs
    16) Department of Finance
    17) Department of Science and Technology
    18) Department of Supervision and Internal Auditing
    19) Department of Personnel and Education

The discussion on tasks of different agencies suggest major overlaps between areas of responsibility amongst the Departments. More detail on the interaction between these Department is provided in Annex 1 of this Consultation paper.

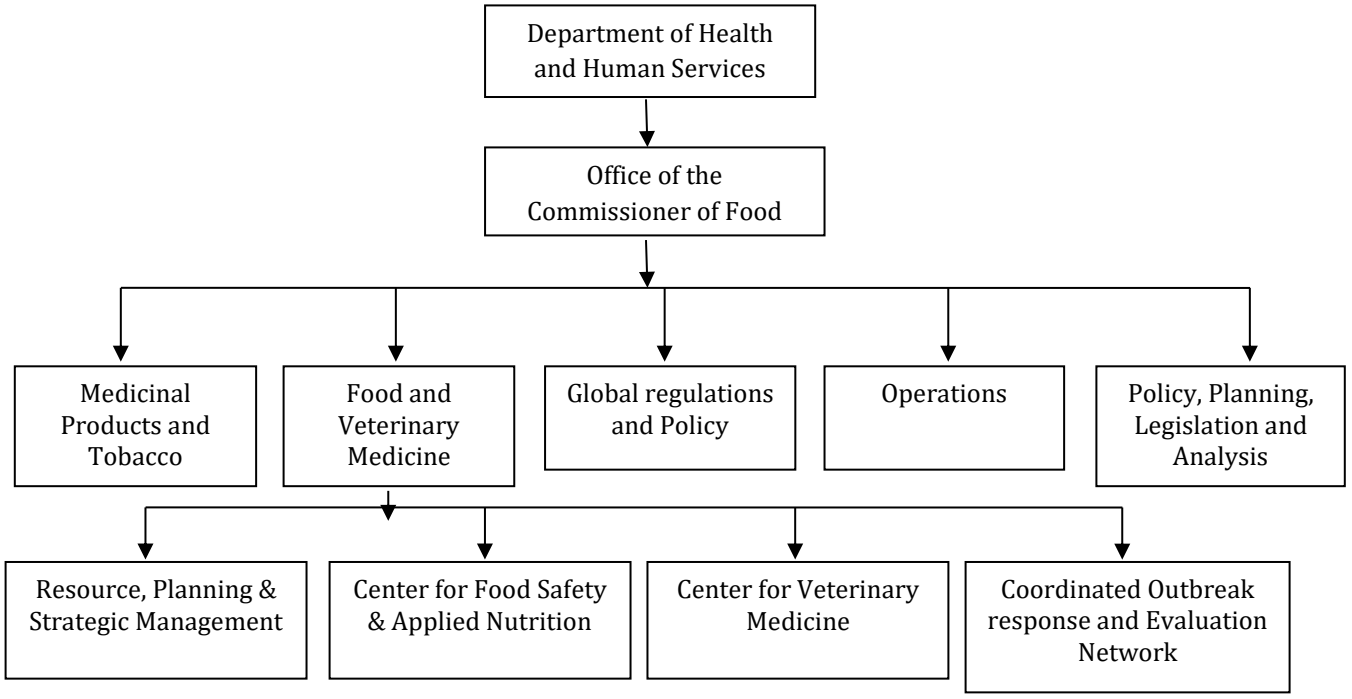
II. USA: Structure of the food safety and control system in the USA

- In USA, food regulation exists at the federal, state, and local level
- The main federal agencies are the Food and Drug Administration (FDA) and the Department of Agriculture (USDA)
- Within USDA the main agency is the Food Safety Inspection Service (FSIS)
- The FDA has responsibility for 80% of food, while FSIS regulates meat, poultry and eggs, although some overlap does occur
- Federal regulations govern interstate trade, imports and exports whilst State and local regulations govern intrastate trade
- The main federal regulations are the Food Drug and Cosmetic Act 1938, The Meat Inspection Act, The Poultry Inspection Act, The Egg Inspection Act
- The Food Safety Modernisation Act 2011 aims to improve food safety and mostly impacts on the activities of the FDA

A. Food and Drug Administration

The Food and Drug Administration (FDA) is a federal agency within the US Department of Health and Human Services (HHS).

FDA – Organisation Chart



Source: FDA website

The **responsibilities and activities of the FDA include**[4]:

- Overseeing and enforcing most (80%) of the US food supply (except for most meat and poultry products, which are regulated by the US Department of Agriculture) and for ensuring its safety and security, so protecting the public health;
- **Conducting inspections of manufacturers or processors of FDA-regulated products** (including food processing facilities; dairy farms; animal feed processors; foreign manufacturing and processing sites; imported products at the border) to verify that they comply with relevant regulations;
- Working with state, local, tribal and territorial counterparts. The **FDA funds contracts, grants and cooperative agreements for states to conduct inspections on its behalf and to build the necessary infrastructure and capacity to carry these out**; The FDA was empowered by the United States Congress to enforce the **Federal Food, Drug, and Cosmetic Act**, which serves as the primary focus for the Agency at both domestic and import level;
- FDA also enforces **other laws, notably Section 361 of the Public Health Service Act and associated regulations, many of which are not directly related to food or drugs**. These include regulating lasers, cellular phones, condoms and control of disease on products ranging from certain household pets to sperm donation for assisted reproduction.
- As per US Federal Food, Drug and Cosmetic Act, importers of food products intended for introduction into US are responsible for ensuring that the products are safe, sanitary, and labeled according to US requirements. (All imported food is considered to be interstate commerce.)
- **Providing guidance, training, program evaluation, and scientific advice and technical assistance to state and local regulatory agencies, the industries they regulate and to public health partners**. Pursuant to its obligations under the World Trade Organization (WTO), FDA **works with foreign governments and international standard-setting bodies to harmonize food safety laws, regulations and standards based on science**. FDA maintains two mechanisms in furtherance of these efforts: 1) Systems Recognition – whereby the FDA recognizes that a foreign food safety system achieves food safety outcomes comparable to those of the FDA; and 2) Equivalence – whereby the FDA recognizes that a foreign food safety system achieves the same level of public health protection as the US despite having different food safety controls.
- The scope of FDA's regulatory authority is very broad. The following is a list of product categories that fall under FDA's regulatory jurisdiction. In general, FDA regulates:

[4] The references for the section on USA include: US FDA and USDA Website; https://www.usda.gov/our-agency/about-usda/laws-and-regulations; http://www.fao.org/food/food-safety-quality/capacity-development/food-regulations/en/; https://www.fda.gov/food/food-safety-modernization-act-fsma/background-fda-food-safety-modernization-act-fsma

- Foods, including dietary supplements, bottled water, food additives, infant formulas, other food products (although the U.S. Department of Agriculture plays a lead role in regulating aspects of some meat, poultry, and egg products)
- Drugs, including prescription drugs (both brand-name and generic), non-prescription (over-the-counter) drugs.
- Biologics, including vaccines, blood and blood products, cellular and gene therapy products, tissue and tissue products, allergenics.
- **Medical Devices**, including simple items like tongue depressors and bedpans, complex technologies such as heart pacemakers, dental devices, surgical implants and prosthetics
- **Electronic Products that give off radiation**, including microwave ovens, x-ray equipment, laser products, ultrasonic therapy equipment, mercury vapor lamps, sunlamps
- **Cosmetics**, including color additives found in makeup and other personal care products, skin moisturizers and cleansers, nail polish and perfume.
- **Veterinary Products**, including livestock feeds, pet foods, veterinary drugs and devices
- **Tobacco Products**, including cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco

FDA co-ordinates with a number of other agencies, including:

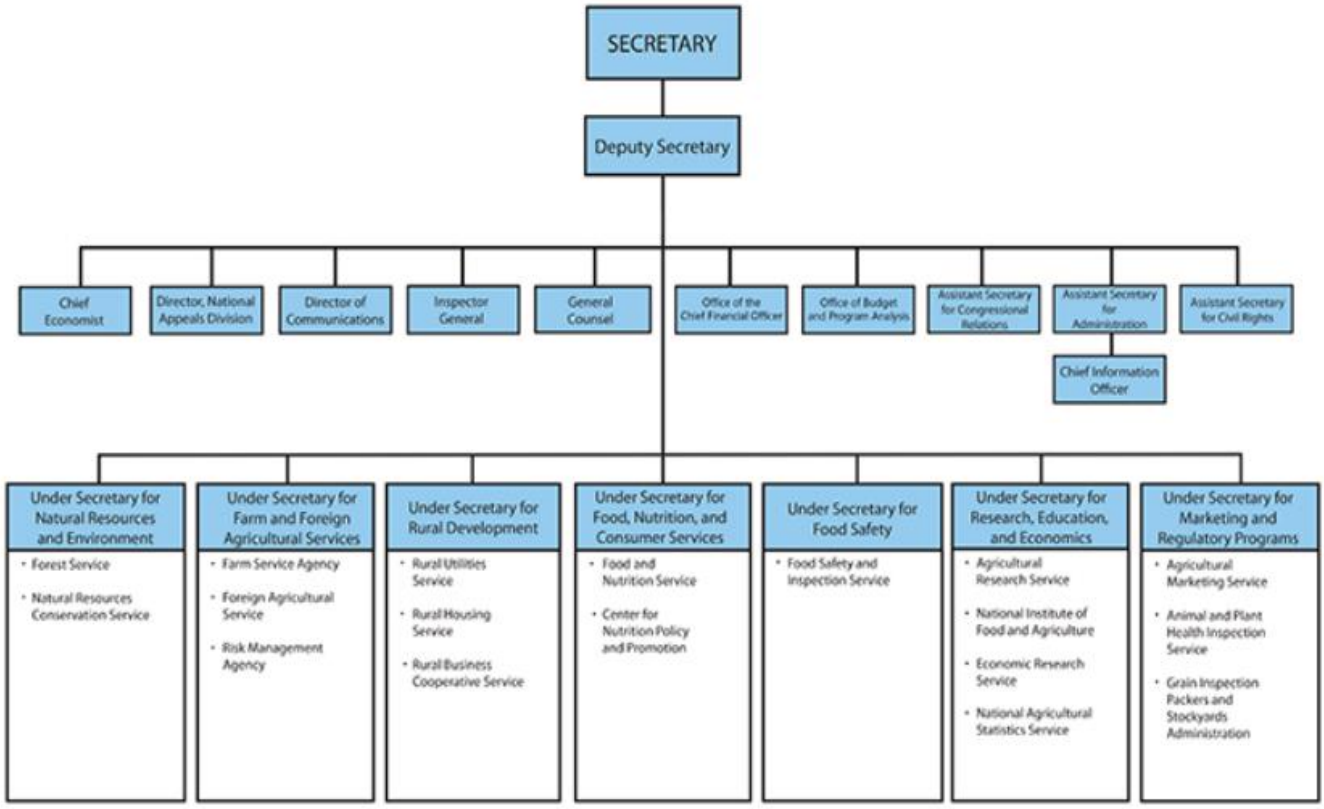
- **Advertising**: The **Federal Trade Commission** (FTC) is a federal agency that regulates many types of advertising. The FTC protects consumers by stopping unfair, deceptive or fraudulent practices in the marketplace.
- **Alcohol**: The Department of the Treasury's **Alcohol and Tobacco Tax and Trade Bureau** (TTB) regulates aspects of alcohol production, importation, wholesale distribution, labeling, and advertising.
- **Consumer Products**: The **Consumer Product Safety Commission** (CPSC) works to ensure the safety of consumer products such as toys, cribs, power tools, cigarette lighters, household chemicals, and other products that pose a fire, electrical, chemical or mechanical hazard.
- **Drugs of Abuse**: The Department of Justice's **Drug Enforcement Administration** (DEA) works to enforce the controlled substances laws and regulations of the United States, including as they pertain to the manufacture, distribution, and dispensing of legally produced controlled substances.
- **Meat and Poultry**: The **U.S. Department of Agriculture's Food Safety and Inspection Service** regulates aspects of the safety and labeling of traditional (non-game) meats, poultry, and certain egg products.
- **Pesticides**: The **Environmental Protection Agency** (EPA) regulates many aspects of pesticides. EPA sets limits on how much of a pesticide may be used on food during growing and processing, and how much can remain on the food you buy.

- **Vaccines for Animal Diseases**: The **U.S. Department of Agriculture's Animal and Plant Health Inspection Service** (APHIS), Center for Veterinary Biologics, regulates aspects of veterinary vaccines and other types of veterinary biologics.
- **Water**: The **Environmental Protection Agency** (EPA) regulates aspects of drinking water. EPA develops national standards for drinking water from municipal water supplies (tap water) to limit the levels of impurities.

B. US Department of Agriculture (USDA)

Figure 1 below shows the organizational structure of USDA.

Figure 1. USDA – Organisation Chart



Source: USDA Website

The USDA has primary responsibility for the safety of meat, poultry, and certain egg products. USDA's regulatory authority comes from the **Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act and the Humane Methods of Livestock Slaughter Act**. **USDA inspects all meat, poultry and egg products sold in interstate commerce, and re-inspects imported meat, poultry, and egg products to makes sure they meet US safety**

standards. USDA ensures food safety through a single agency i.e. the Food Safety and Inspection Service (FSIS).

- Animal and Plant Health Inspection Service (APHIS)
  APHIS is a multi-faceted agency with a **broad area of responsibility** that includes protecting and promoting US agricultural health, regulating genetically engineered organisms, administering the Animal Welfare Act and carrying out wildlife damage limitation activities.
- Agricultural Marketing Service (AMS)
  AMS is an agency within the United States Department of Agriculture (USDA), which s**upports the fair marketing of US agricultural products by providing testing, standardization, grading and market news services, overseeing marketing agreements and orders and administering research and promotion programs**. The AMS enforces certain federal laws such as the Perishable Agricultural Commodities Act and the Federal Seed Act and **also regulates organic food production**.

C. Other Partner Agencies That Work With Both FDA and USDA

- Department of Homeland Security (DHS): DHS is the primary agency responsible for integrating and coordinating efforts among federal, state, and local agencies, as well as the private sector, to protect critical infrastructure and key resources from intentional attack, including in the food and agriculture sectors. **DHS works closely with the USDA, FDA, and other federal, state, and local agencies to secure the nation's food supply through programs aimed at education, prevention, surveillance, threat detection, and rapid response**. It operates under presidential directives relating to food defence.
- Customs & Border Protection (CBP): The Customs and Border Protection Agency (CBP) is one of the Department of Homeland Securit**y's largest and most complex agencies. CBP personnel have authority to hold suspect shipments for further examination and sampling under the Bioterrorism Act**. Their laboratories and scientific services coordinate technical and scientific support to all CBP trade and border protection activities.
- Centre for Disease Control and Prevention (CDC): The Centre for Disease Control and Prevention (CDC) is part of the Department of Health and Human Services (DHHS). It is, and has historically been, involved in tracking single cases of food poisoning and outbreaks. CDC leads federal efforts to gather data on food borne illnesses, investigate food borne illnesses and outbreaks, and monitor the effectiveness of prevention and control efforts in reducing food borne illnesses. CDC also plays a key role in building state and local health department epidemiology, laboratory, and environmental health capacity to support food borne disease surveillance and outbreak response. **The Food Safety Modernisation Act (FSMA) requires CDC to strengthen the capacity of state and local health departments to respond to food borne outbreaks and improve the coordination and integration of surveillance systems and**

laboratory networks. In addition to developing a national strategy for food safety, CDC will also provide support to the Food and Drug Administration in implementing new hazard analysis, prevention, performance, and training activities required by the law.

- Environmental Protection Agency (EPA): In the US, two agencies, **EPA and FDA set limits or tolerances for pesticides to be used for food**. The **EPA sets limits for pesticides, establishing their permitted uses and use conditions including those used in food production which USDA and the FDA enforce. EPA is also responsible for setting the tolerances that define the limit on the amount of an agricultural pesticide that can legally remain in food. Pesticide use restrictions are enforced by state agencies under contract to EPA, while FDA enforces pesticide tolerances. As EPA makes far more regulatory decisions about the safety of chemicals in food than FDA or any other agency, it plays an important scientific role in establishing practices for chemical risk assessment**.

Table 1 below provides a summary of the US Food Safety Modernisation Act. More detail on this Act is provided in Annex 2 of this Paper. The Annex shows the whole range of different responsibilities given by this Act to the FDA, which implies an aggregation of several food regulatory tasks under one agency itself.

Table 1. US: Food Safety Modernisation Act – Summary

	Brief Description	**Rule Applies to**	**Additional requirements**
Produce Safety Standards	Sets enforceable standards: For the growing, harvesting, packing and holding of fruits and vegetables on farms; Considerations for how produce will be used and consumed once it leaves the farm Exceptions for those: Rarely consumed raw; For personal consumption; Destined for commercial processing from exempted farms	All unprocessed fruits and vegetables intended for human consumption, including on farm packing and holding	Training; Review of: manure standards, flexible water standard; wild animals
Preventive Controls for Human Food	Focus – preventing problems that cause human foodborne illness Requirements: Hazard analysis – written plan, to include economic adulteration Risk based preventive controls to encompass: Process, food allergen; sanitation controls and a recall plan Monitoring procedures Corrective actions Exceptions: Certain low risk activities – Process qualified On farm packing and holding	Facilities that manufacture, process, pack or hold human food. Domestic and foreign companies	Revision of current GMP controls re cross contamination and allergens

Foreign Supplier Verification Programme	Importer accountable Requires importers to: Conduct risk-based foreign supplier verification activities To determine imported food is not adulterated and is produced according to FDA's preventive control requirements and produce safety standards as applicable. Certification for high risk foods Authority to deny entry Renewal of food facility registrations	Imported food (certain exemptions apply)	Third party accreditation Voluntary qualified importer program
Preventive Controls for Animal Feed	Previously referred to human food requirements. Revised rules include the implementation of current good manufacturing practices (CGMP) rules that are more applicable to animal food producers. Takes into account feed mills associated with farms; Other changes are in line with preventative controls for human food		
Accredited Third Party Certification	Qualified third parties can certify that foreign food facilities comply with US food safety standards. Audit report available to FDA Auditor must immediately notify any serious risk to public health FDA to consider existing international standards and accreditation bodies when developing standard Prior notice to advise if food refused entry elsewhere	Imported food: Requirement based on risk of the food and any legal requirements	May deny entry to an import if foreign facility refuses FDA inspection
Mitigation against intentional adulteration	To address intentional adulteration where the intention is to cause large-scale public health harm. Targets processes within a facility that are most likely to be vulnerable, rather than specific foods or hazards.	Domestic and foreign food facilities that manufacture, process, pack or hold food	Preparation of food defence plan, Training
Transportation	To prevent practices in transport that create food safety risks such as not maintaining the integrity of the cold chain by proper refrigeration; inadequate cleaning and not properly protecting the food	Shippers, receivers, and carriers of food by road or rail and to exporters shipping food to US	Vehicle and transport equipment and operation requirements, Information exchange, training, records

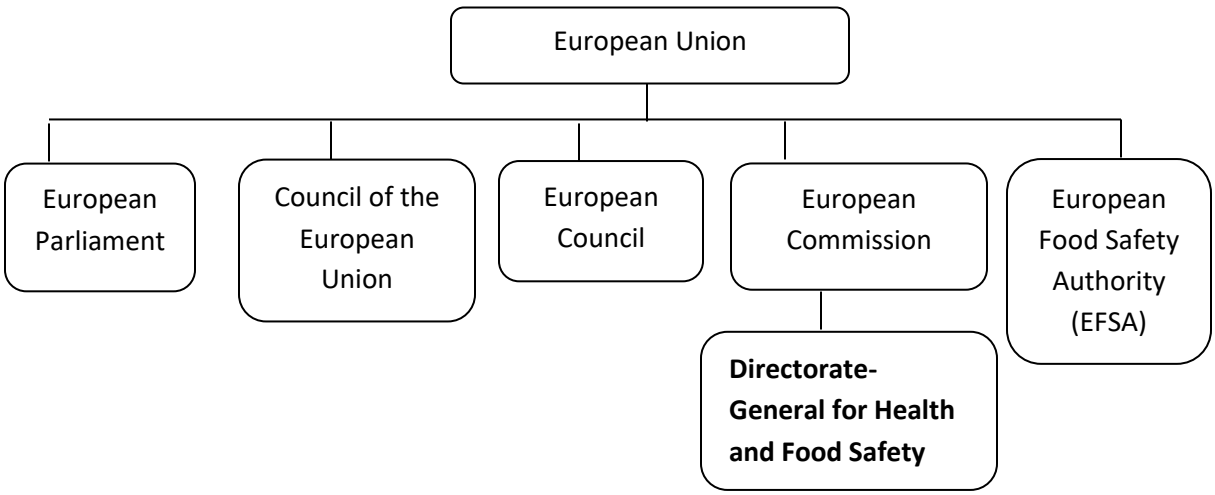
Source: FDA Website

III. EUROPEAN UNION: Structure of the food safety and control system in the EU

- In the European Union, the safety of Food and Agricultural products is regulated at the Commission level.
- The main regulatory agencies are the European Commission, the Directorate-General for Health and Food Safety as well as the Member Countries.
- Union-level law governing the safety of food is the General Food Law Regulation (Regulation (EC) No 178/2002)

The European Union (EU) is a political and economic partnership between 28 member countries. All EU Member countries accept the "Community acquis,", i.e. the entire body of EU laws and obligations associated with the treaties and agreements to which the EU is a party, including the EU laws and rules pertaining to agricultural products and processed foods. It is noteworthy that when EU-wide legislation is incomplete or absent, the laws of Member States apply, often resulting in different rules in different Member States.

For the majority of policies, including agriculture, the EU and its Member States share competences. This means that both the EU and the Member States can adopt legally binding acts. Member States exercise their competence in areas where the EU does not exercise, or has decided not to exercise its own competence.



The main institutions involved in the legislative process in EU are:[5]:

1. The **European Parliament**, which represents the EU's citizens and is directly elected by them;
2. The **Council of the European Union**, which represents the governments of the individual member countries. Governments defend their own country's national interests in the Council of the European Union. The Presidency of the Council is shared by the member states on a rotating basis.
3. The **European Council**, which brings together **EU leaders** to set the EU's **political agenda.** It represents the **highest level** of political cooperation between EU countries.
4. The **European Commission**, which represents the interests of the Union. Members are appointed by national governments.

In principle, the Commission proposes new laws, and the Parliament and Council adopt them. The Commission and the member countries then implement them, and the Commission ensures that the laws are properly applied and implemented.

FOOD REGULATIONS IN EU

The EU follows a dual approach in harmonizing food laws: "horizontal" legislation covering aspects common to all foodstuffs (such as additives, labeling, hygiene, etc.) and "vertical" legislation on specific products (e.g., wine, cocoa and chocolate products, sugars, honey, fruit juices, fruit jams, novel foods).

Where legislation has not been harmonized at EU-level, "mutual recognition" guarantees the free movement of goods in the EU. Under the principle of mutual recognition, products lawfully produced and/or marketed in one Member State should, in theory, be allowed to be marketed in any other Member State. However, certain directives allow Member States to make exceptions e.g. in cases where a country can prove public safety, health or environmental concerns about a product intended for import.

EU food legislation consists of "regulations" and "directives," and rules for their implementation. Directives lay down results that must be achieved, but each Member State is free to decide how to transpose directives into national law (usually within 2-3 years after adoption). Regulations are binding in their entirety and automatically enter into force on a set date in all Member States.

[5] The references for the section on EU are: Official website of European Commission; Official website of European Food Safety Authority; USDA FAS GAIN Report on "How the EU Works" (report number- E17059); USDA FAS GAIN Report on "Food and Agricultural Import Regulations and Standards (report number-E19004)

The General Food Law Regulation is the foundation of food and feed law. It sets out an overarching and coherent framework for the development of food and feed legislation both at Union and national levels. To this end, it lays down general **principles**, **requirements** and **procedures** that underpin decision making in matters of food and feed safety, covering all stages of food and feed production and distribution.

The General Food Law Regulation sets up an independent agency responsible for scientific advice and support, the **European Food Safety Authority** (EFSA). Moreover, it creates the main procedures and tools for the management of emergencies and crises as well as the **Rapid Alert System for Food and Feed** (RASFF).

Regulations and directives in the framework of the General Food Law have to be transposed into national legislation of individual EU Member States regarding enforcement, sanctioning and the designation of the competent authority. For instance, in the national implementation of the General Food Law the penalties must be laid down to be applied if an operator does not have an adequate traceability system and the competent authorities for inspections and controls.

National implementation of EU law must fit into national structures, such as centralized and decentralized control structures. Therefore, **most EU food safety legislation focuses on criteria and procedures rather than on detailed regulations for control.**

The agencies/institutions responsible for Food Safety in the EU are:

A. The European Commission

- The European Commission is the EU's executive and represents the interests of the EU as a whole. It is composed of "the College of Commissioners", i.e. 28 Commissioners - one from each Member State – including the President and Vice-Presidents. The President of European Commission is appointed by the European Council with the approval of the European Parliament.
- The Commission has the sole right of legislative initiative in most policy areas and monitors the Member States' application and implementation of EU legislation.
- It represents the EU in international organizations and negotiates agreements with trading partners based on a mandate from the Member State governments.
- The European Commission is divided into departments known as "Directorates-General" (DGs).

B. Directorate-General for Health and Food Safety (DG SANTE)

This department of the European Commission is responsible for EU policy on food safety and health and for monitoring implementation of related laws.

C. European Food Safety Authority (EFSA)

EFSA is a European agency funded by the European Union that operates independently of the European legislative and executive institutions (Commission, Council, and Parliament) and EU Member States. It was set up under provisions of the General Food Law Regulation. The EFSA provides scientific and technical advice to the European Commission but has no formal role in the decision-making process.

D. Standing Committee on Plants, Animal, Food and Feed

The Standing Committee on Plants, Animals, Food and Feed (**PAFF Committee**) plays a key role in ensuring that Union measures on food and feed safety, animal health & welfare as well as plant health are practical and effective. It delivers opinions on draft measures that the Commission intends to adopt. The PAFF Committee is composed by national experts as representatives of all EU countries and is presided over by a European Commission representative.

The Committee's mandate covers the entire food supply chain -from animal health issues on the farm to the product on the consumer's table. It is divided into 14 different sections: Genetically Modified Food and Feed and Environmental Risk; Phytopharmaceuticals; Plant Health; Propagating Material of Ornamental Plants; Propagating Material and Plants of Fruit Genera and Species; Seeds and Propagating Material for Agriculture and Horticulture; Forest Reproductive Material; Vine; General Food Law; Biological Safety of the Food Chain; Novel Food and Toxicological Safety; Controls and Import Conditions; Animal Nutrition; Animal Health and Animal Welfare.

1. ENFORCEMENT OF REGULATIONS

- **The EU member states are responsible for the enforcement** of agri-food chain legislation. Competent authorities organise official controls systems on their territory to verify that operators' activities and goods placed on the EU market (either EU produced or imported from non-EU countries) comply with relevant standards and requirements.
- The role of the EU Commission is to assure that the control systems at national level are effective. This is the task of **DG SANTE, through its Health and Food Audits and Analysis Directorate** (previously called "Food and Veterinary Office" – FVO). It carries out inspections in the EU countries and in non-EU countries exporting to the EU to evaluate compliance with EU standards.
- European Commission officials oversee auditing oversight of Member State performance.
- The European Commission has the power to initiate legal action in the European Court of Justice against Member States who are not complying with EU Directives and Regulations.

2. MAJOR UPCOMING REGULATIONS

In 2016 and 2017, 3 legislative developments took place in the area of food safety; the Animal Health Law, the Plant Health Law and the Official Controls Regulation were adopted. The Animal Health Law will be applicable from 21st April 2021, whereas the other two will be applicable from 14 December 2019.

The Animal Health Law and the Plant Health Law lay down some of the conditions to ensure the safety of the food chain. The compliance of these conditions and requirements will be verified through the official controls by the Competent Authorities in the Member States, performed in accordance with the Official Controls Regulation. Therefore, the application of the Official Controls Regulation will be crucial to ensure the compliance of the rules laid down in the Animal Health Law, Plant Health Law and in other legislations regulating food safety. The application date of these three legislations ensures that official controls rules will be in place to avoid legal gaps and inconsistencies of control rules.

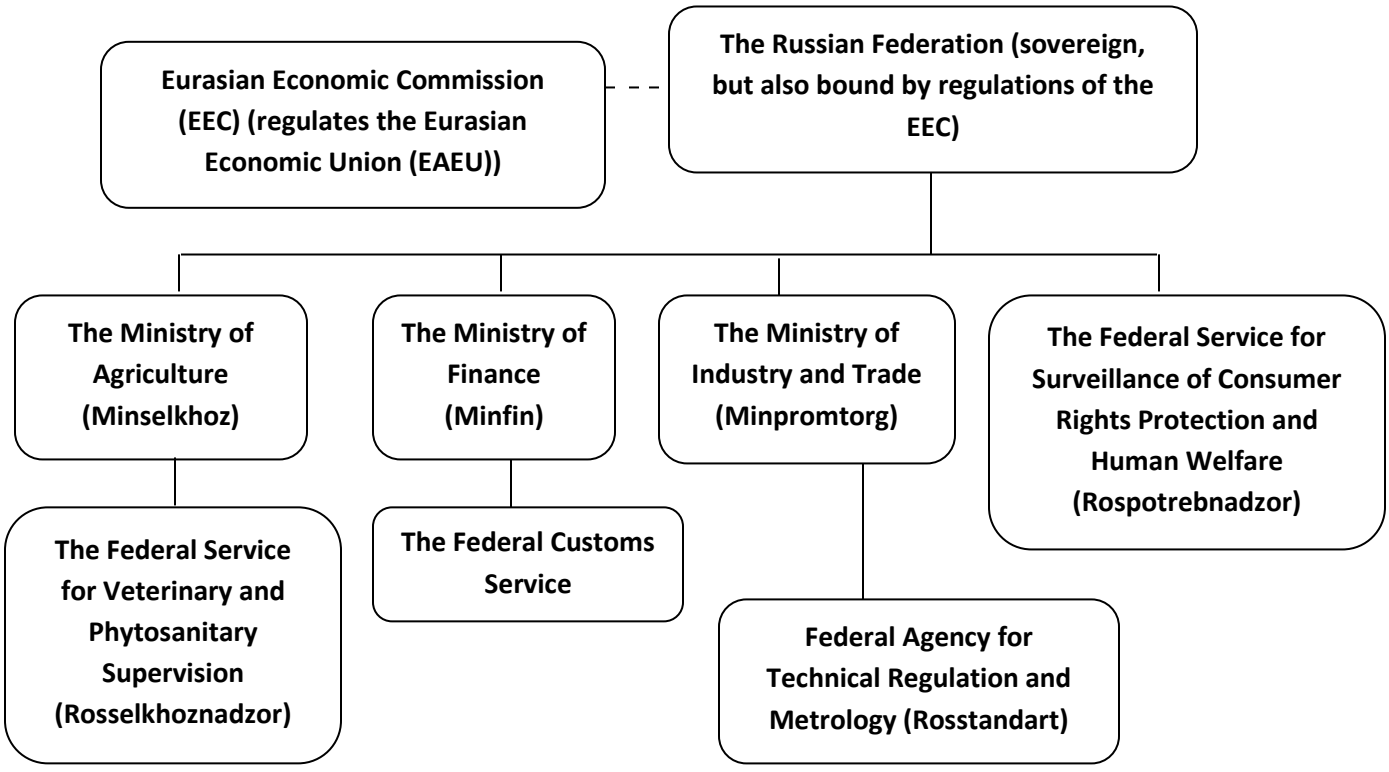
The Animal Health Law creates a single regulatory framework for transmissible animal diseases. It contains both general principles and basic rules, with a strong focus on prevention, and clarifies the responsibilities of all actors dealing with animal health. Detailed requirements are established, for instance, on the registration and approval of establishments, traceability of animals and animal health requirements for movements of animals and their products in the Union, their entry into the Union and specific measures for animal disease prevention and control.

The Plant Health Law establishes a regulatory framework for protective measures against pests of plants, also with a strong focus on prevention. It provides better instruments for a prompt control of the presence and spread of pests in Europe. For instance, it contains rules on surveys, contingency plans, plant passports and phytosanitary certificates.

IV. Russian Federation: Structure of the food safety and control system in Russion Federation

- The Russian Federation is a democratic country and is a Semi-presidential Republic.
- The main regulatory agencies are the Eurasian Economic Commission, the Ministry of Agriculture of the Russian Federation and the Ministry of Industry and Trade.
- The Eurasian Economic Union Laws, Russian Federal Laws, Government regulations as well as specific regulations of the agencies under the Russian Government are all jointly governing the safety of imports and exports of the Russian Federation.

The main agencies responsible for the regulation of imports and exports of agricultural products are[6]:



[6] The sources for information on the Russian Federation include: Official website of the Government of Russia (http://government.ru/en/); Official website of the Federal Service for Veterinary and Phytosanitary Surveillance; Official website of the Eurasian Economic Union; Official website of Eurasian Economic Commission; and, USDA FAS GAIN report "Food and Agricultural Import Regulations and Standards Report". (Report Number- RS 1838)

Russia's regulatory framework governing the import of foodstuffs consists of:
(1) Eurasian Economic Union documents,
(2) Russian Federal Laws,
(3) Russian Government documents, and
(4) Regulatory documents of the bodies of executive power of the Russian Federation.
Russian national regulations continue to apply to the extent they do not contradict the EAEU regulations.

The main regulatory agencies are as follows:

I. THE EURASIAN ECONOMIC UNION

The Eurasian Economic Union (EAEU), previously the Customs Union (CU), is an international organization for regional economic integration. It has international legal personality and is established by the Treaty on the Eurasian Economic Union. The Member-States of the EAEU are the Republic of Armenia, the Republic of Belarus, the Republic of Kazakhstan, the Kyrgyz Republic and the Russian Federation. The EAEU provides for free movement of goods, services, capital and labor, pursues coordinated, harmonized and single policy in the sectors determined by the Treaty and international agreements within the Union.

The Supreme Council is the Union's supreme authority. The Heads of the Member-States form the Supreme Council. This Intergovernmental Council is a Union's body consisting of the Heads of the Member-States Governments. (These are different from Heads of state, as is in the case of the Russian Federation, where Head of state is the President, whereas, Head of the Government is the Prime Minister)

The Eurasian Economic Commission (EEC) is a permanent supranational regulatory body of the Union, with its members appointed by the Council of the Commission and the Board of the Commission. The core tasks of the Commission are fostering the conditions to support the operation and development of the Union, and drafting proposals in the field of economic integration within the Union.

The Court of the Eurasian Economic Union is the court of justice of the Eurasian Economic Union, which ensures the uniform application of the EAEU Treaty and other Union treaties by the Union Member-States and bodies.

The EAEU maintains a unified list of goods for which import and export limitations and prohibitions apply in order to monitor and control movement of goods classified as sensitive by the member states or by the international community.

Many Russian regulations either have, or are undergoing reform as Russia continues to be involved in the process of policy integration with the EAEU. The EAEU has a mechanism for recognizing the equivalence of food safety systems of WTO members and rules on inspection of establishments in third-countries that export product to Russia and the other EAEU Member States.

II. THE MINISTRY OF AGRICULTURE (MINSELKHOZ)

The Ministry of Agriculture (Minselkhoz) is the federal executive body responsible for drafting and implementing government policy and legal regulation in a number of areas:

(i) agriculture and related industries, including livestock farming (including breeding of domesticated fish species included in the State Register of Protected Breeding Achievements)

(ii) veterinary services, including pharmaceuticals, crop production, phytosanitary control, soil improvement and fertility

(iii) regulation of the farm produce, raw materials and foodstuffs markets

- the food and food processing industry
- fisheries industry
- the production and distribution of tobacco products, and
- the sustainable development of rural areas
- The state registration of pesticides and agrochemicals falls under the purview of the Ministry of Agriculture

II(a). THE FEDERAL SERVICE FOR VETERINARY AND PHYTOSANITARY SUPERVISION/SURVEILLANCE (ROSSELKHOZNADZOR, OR FSVPS)

The Federal Service for Veterinary and Phytosanitary Supervision (Rosselkhoznadzor) is a federal executive body responsible for control and oversight in:

- the field of veterinary medicine
- the marketing of veterinary medicines
- quarantine and plant protection
- safe handling of pesticides and agricultural chemicals
- soil fertility
- quality and safety of grain
- cereals and compound animal feedstuff and components for their production
- grain milling by-products
- land relations (with regard to agricultural land), as well as
- The protection of the public from diseases shared by animals and humans.
- It also enforces Russian legal requirements for veterinary and plant health.

- Products subject to veterinary control are required to come from establishments identified on approved supplier lists. Rosselkhoznadzor often issues conditions to source from approved establishments in the import (veterinary) permit.
- The departments within this Federal Agency are**:**

Directorate for International Cooperation and Veterinary Control of Export/Import and Transportation works with the: Department for Veterinary Control within Foreign Trade Operations and during Transportation, Department for Cooperation with Foreign Countries, and Department for Cooperation with the WTO and other International Organizations.

Directorate for Domestic Veterinary Surveillance: Department for anti-epidemic measures, Department for Control and Supervision, Department for Laboratory Control, Department for Surveillance of Veterinary Drug Turnover, Information Technology Department.

Directorate for Phytosanitary Surveillance and Seed Control: Plant Quarantine Department, Department for Cooperation with International Organizations and Inspections in the Field of Plant Quarantine and Seed Control.

Directorate for Administrative and Civil Service Affairs: Department for civil service and personnel affairs, Anti-Corruption & Crime Prevention Unit, Department for Records Management, Department for Procurement and Supplies, Department for External Affairs and Protocol, and Security Unit

Directorate for Land Surveillance, Grain Quality and Safety: Department for Land Surveillance, Department for Grain Quality Surveillance.

Directorate for Finances and Support: Department for Accounting and Financial Reporting, Department for Procurement and Supplies, Department for Economic Planning, Department for Internal Financial Control, and Department for Financing.

III. THE FEDERAL SERVICE FOR SURVEILLANCE OF CONSUMER RIGHTS PROTECTION AND HUMAN WELFARE (ROSPOTREBNADZOR)

Federal Service for Surveillance of Consumer Rights Protection and Human Welfare (Rospotrebnadzor) is responsible for setting standards and sanitary-epidemiological control in Russia. It is also responsible for food safety. Based on regulations of the Eurasian Economic Union and the regulations of other national competent authorities, the Rospotrebnadzor oversees the domestic foodstuffs market in Russia. However, in practice, the Federal Service for Veterinary

and Phytosanitary Supervision (Rosselkhoznadzor) enforces sanitary-epidemiological control over products at the border when those products are also under sanitary-veterinary control.

Rospotrebnadzor may prohibit the transport and sale of products that do not meet official requirements. It may also prohibit or allow food additives based on safety tests. Rospotrebnadzor is responsible for setting tolerances of pesticides, veterinary drugs, and other contaminants in food. (However, registration is under Ministry of Agriculture and enforcement at the border is done by Rosselkhoznazdor.)

Rospotrebnadzor is also the National coordinator for WHO Regulations in the Russian Federation and is the national focal point of the International Food Safety Authorities Network (INFOSAN).
It also provides technical assistance to other nations in combating infectious diseases on a bilateral basis.

IV. MINISTRY OF INDUSTRY AND TRADE (MINPROMTORG)

The Ministry of Industry and Trade is in charge of non-tariff regulation for external economic activity including licensing and quota administration. Import licenses are issued by this Ministry in accordance with the unified licensing rules of the Eurasian Economic Union.

IV(a). FEDERAL AGENCY FOR TECHNICAL REGULATION AND METROLOGY (ROSSTANDART)

The Federal Agency for Technical Regulation and Metrology (known as Rosstandart or Rostekhregulirovaniye) is part of the Ministry of Industry and Trade. Rosstandart manages product assessment, processing, and servicing to determine if products conform to national standards and certification criteria.

V. THE FEDERAL CUSTOMS SERVICE OF RUSSIA

The Federal Customs Service of Russia (FTS), which is part of the Ministry of Finance, regulates foreign economic activity with a system of customs fees and charges, and carries out customs control.

Annex 3 provides information on the regulatory regime of **Canada**.

V. Some Questions for Consultations

4.1. Is the situation of the EU, which has one Body at the level of the European Union, similar to India that a single Body could be established for India as well?

4.2. If not, should India have two (or more) regulatory Bodies co-ordinated by an overall Board at senior level as the single Unified Authority? Should the Department of Customs also be part of this co-ordinating level?

4.3. Is there a need to phase-out some regulatory agencies and combine their functions into another agency with a larger scope? If so, which agencies should be phased out, and with which agency should their functions be combined?

4.4. Should the "single" Authority have additional functions as well which are presently performed by Departments in Ministries?

4.5. What are the co-ordinating mechanisms that will enable clear division of functions without duplication?

4.6. Which laws will need being changed to implement these changes?

4.7. Which tasks of specific agencies discussed in this Chapter (and Annexes) are most relevant to be allocated to the Unified Authority, e.g. SAMR of China or FDA or US, or any other (including tasks of more than one agency)?

Chapter 5

The Framework For Unified Authority and Questions For Consultations

Chapter 4 shows that the co-ordination of overall tasks in new regulatory structures (such as China) is at Ministerial level. This enables the system to combine and co-ordinate policy with implementation, and engage with domestic stakeholders and when discussing or negotiating with foreign Governments. Therefore, it appears that the Apex Co-ordinating Body should have representation from both policy making and implementing Bodies.

This Body could be kept informed as and when required, with the meetings taking place every three or six months. This Apex Body could include representatives from Department of Commerce, Customs, and Ministry of Agriculture as permanent members, with invited members based on the issue regulatory issues concerned.

I. The Inter-Ministerial Co-ordination Body (IMC)

The Inter-Ministerial Co-ordination Body, or IMC, would have two levels of membership, one relating to regulation issues per se, and another for co-ordination for negotiations. The nature of inter-ministerial co-ordination becomes different and wider in scope when it has to take place for negotiations with other nations.

In the context of negotiations, often the focus is a sectoral one whereby agreement on pest risk analysis (PRA) for Indian products are considered in terms of quid pro quo with PRA for foreign products, or Indian agreeing to certain market access of other demand of the foreign Government for agricultural products in return for similar benefits for Indian agricultural exports to that country. Negotiations however are not necessarily limited to a subject matter (such as PRA) or to a specific sector, e.g. agriculture. Quid pro quo in negotiations can take place across areas as well, which requires a wider scope of the relevant considerations.

Thus, for negotiations, the co-ordinating functions need to include a wider range of Government Ministries that other activities. Therefore, the Apex Body may have two parts, one focused on regulatory matters and another on negotiations.

The larger body dealing negotiations should be kept informed on all regulatory matters addressed by the Apex Body (IMC), but attendance for all meeting may be mandatory only for the Departments/Ministries that directly deal with food regulatory issues. The regulatory part of IMC should have Commerce, Agriculture and Customs as core members. The negotiating part should have these agencies as well as the External Affairs Ministry as core members, with other parts of the Government as invited members.

This Apex Body, IMC, would be analogous to the overseeing role performed by China's State Council or the EU's European Commission.

Initial establishment of such an Apex Body would not require any legislative changes, as such. It is the change in content of delegated authority or areas covered by the Unified Authority that would in certain cases require legal amendments.

II. The Main Factors Affecting the Pace and Content of Move Towards Unified Authority

The pace and content of the move towards a Unified Authority would need to take account of the main factors that affect moving from the present system to a Unified Authority. These include:

(a) Time period required for implementation,

- The short-term (within one year);
- Medium term (two to three years)
- Longer term (more than three years)

(b) In this phased-in implementation, in addition to establishing greater coherence, the focus should be on finding the gaps, duplication/overlap, and inconsistency between the work of different agencies and address them. The lessons drawn from success cases and the application of technological solutions would be very useful in this process.

(c) Changes required to address issues such as:

- Duplication/overlap of task performed
- No formal notification of delegated authority exercised by the agency
- Multiple agencies involved for exporters to get approval
- Gaps in the operational conditions, e.g. training, mentioning all relevant agencies in the EXIM Policy Document
- Indian regulatory agency notified by a foreign government as the relevant point of contact

(d) Responsibility of the regulatory agency covers:

- Imports
- Exports
- Both exports and imports
- Production

(e) Changes that require amendment in the present:

- Law for implementing the new structure

- Regulation for implementing the new structure
- Operational framework through notification of an Order by the nodal Ministry.

Changes implemented through Order or Regulation could be achieved within the short-term, which changes in law would likely take more time.

Similarly, it should be possible to bring changes in the regime for exports and/or imports within the short term, and in a few cases perhaps the medium term. For covering production, however, a longer period would be required.

Most of the issues such as duplication, gaps, notifications could be addressed within the short term, unless a change in Indian law or in foreign notifications is required. These could take more than one year or two years.

The ideal model scenario would be one where all the changes could be implemented within the short-term. However, as shown by Table 5.1, a number of actions required to have a Unified Authority would require more time than one year or two.

Table 5.1. Illustrative Indications of the Time Period Required for Various Tasks

Identify/ Address/ Change →	**Gaps**	**Duplication/ Overlap of Tasks**	**Clear Authority Delegated**	**Reduce Multiple Agencies**	**Correct Foreign Notifications**	**Regulation**	**Law**
Short term	√	√	√	√		√	
Medium term			√	√	√	√	√
Long term							√

III. Moving Towards a Comprehensive Unified Authority in Stages

Since several tasks could be implemented within the short term, i.e. within one year, a reasonable option could eb to move towards a Unified Authority in phases. **The requisite changes could be to implemented in a sequential manner so that the structure evolves over time to reach its comprehensive coverage.**

This could be initiated by announcing the vision final structure as the final goal (i.e. based on the objectives to be achieved or the changes in laws/regulations/Orders required). In the interim period, an overall structure of re-organisation could be created so that the co-ordination and informed consistent decision-making could begin within one year.

The mechanisms for implementing the system with therefore could involve a three-stage process. One, more immediate, the second one with an intermediate stage for the Authority, and third the final system which incorporates all the changes.

Even after the final, comprehensive changes take place in the structure and organization of the food regulatory system, a number of tasks would continue to require time to be implemented. Examples of such tasks include negotiating market access based on mutual equivalence or PRA, collecting information on non-tariff measures faced by Indian food exports, or establishing domestic institutions and operational conditions that would enable meeting higher (evolving) standards required for exporting to specific large markets.

The first stage would be based on the present focus of regulatory agencies in India, and the institutional models used by some major economies discussed in Chapter 4 and Annex 3.

The main areas of focus of domestic regulatory agencies are:

- exports (e.g. EIC, APEDA.MPEDA),
- imports (FSSAI), or
- both exports and imports (Quarantine Authority – Plant or Animal, Customs)

Combining these three areas into one agency may overburden the tasks of integrated agency, without necessarily increasing its efficiency. Nonetheless, it would be useful to co-ordinate the work of these agencies through a common platform where they interact at senior level to inform, share concerns and solutions, discuss options for policy facilitation, and remove inconsistencies. This could be achieved in a stage-wise manner as follows.

IV. The Implementation Co-ordination Agency (ICA)

In addition to the Apex Policy Agency (IMC) mentioned above, there could be a next level of co-ordination among the implementing agencies. This "Implementation Co-ordination Agency" (ICA) could be established with its Secretariat which would provide information on overall consistency among the **four main nodal points represented in ICA**:

- FSSAI for imports
- EIC, APEDA and MPEDA for exports,
- Quarantine agencies for both imports and exports, and
- Customs

The ICA would be part of the Inter-Ministerial Co-ordination Body (IMC), and also report to its Governing structure.

Stage 1: The Co-Ordination Stage

Stage 1 would focus primarily on co-ordination while retaining the basic workings of each agency. Other relevant agencies could become sub-Divisions of the nodal agencies, and be part of a larger set-up of the nodal points, while maintaining their existing operational systems.

The role of ICA could be to co-ordinate five kinds of tasks, which could be allocated to the five main Divisions of ICA. Each of them would have representation of the four nodal points (FSSAI; ECI, APEDA, MPEDA; Quarantine; Customs).

The five main tasks could address:

(a) **Regulatory regimes**, including testing, certification, PRA. This could also provide a basis for sharing of samples and laboratories, and to reduce the number of agencies involved in regulating or providing approval for the export of a particular product (including those mentioned in Chapter 2). Thus, the present situation where more than one agency's approval is required by exporters, could be simplified by giving a common approval.

- This part of the ICA could have as its sub-Divisions, different regulatory activities such as specification of standards, certification, and laboratories and testing It would work very closely with the Division addressing market access and negotiations of PRA with other countries
- The regulatory agencies operating at present would be associated with these sub-Divisions and the Regulatory Division as a whole, to co-ordinate and inform each other about their ongoing tasks
- For imports, the co-ordinating nodal point would be FSSAI.
- For exports, a new co-ordinating structure could be established with EIC, APEDA and MPEDA. The basic aim would be merge them over time into a Food Export Development and Regulation Authority of India (FEDRAI).
- These nodal agencies plus the nodal agencies mentioned above which regulate both exports and imports would form the overall co-ordinating Body of ICA
- The aim of such co-ordination would be to identify and help address gaps, duplication and other operational concerns, which reduce efficiency and create obstacles to trade; inform each other of operational inconsistencies, and prepare options for addressing them; identify areas which require training for the officials of specific agencies; share information on success cases and problems experienced in their operations; and share information on ongoing discussions or concerns relating to practices of other countries, and steps that have worked to improve the situation
- The Regulatory Division would also have an e-platform where producers, exporters and importers could share issues with them which need solutions. This could be operated

together with the Communications and Information Divisions mentioned under (d) and (e) below

- **One sub-Division of the Regulatory Division would work on Legal Affairs**, contributing to development of Regulations and laws to be developed for both the transition towards the Unified Authority and dealing with legal issues arising in the operational part of food regulations. To that extent, the legal Affairs sub-Division would co-ordinate with all Divisions. The reason for placing this work within the Regulatory Division would be because of the close connection between regulatory and legal issues.
- One of the initial tasks of the sub-Division on Legal Affairs would be to provide solutions to concerns such as those relating to gaps, duplication of functions, unclear delegation of authority. The starting point for this work could be Table 2.1 in Chapter 2 and the discussion in Chapter 3 of this Consultation Paper.

(b) Discussions on **market access**, keeping track of these discussions and follow up on requests for market access through discussions/negotiations.

- This Division would also keep track of the non-tariff measures faced by Indian food exports
- For export markets where certification is not mandatory, this division could be the point of information on the standards to be met by exporters selling their products to such markets
- This Division could also be a repository of all databases on regulatory issues as well as exports and imports. For that purpose, it would co-ordinate with the Regulatory Division, and with Government agencies that develop and keep trade-related data.
- The first two Divisions, i.e. (a) and (b), would closely co-ordinate with the overseeing Departments or Ministries to keep them informed of production and trade-regulation related developments
- The first two Divisions, i.e. (a) and (b), would closely co-ordinate with each other also for discussions in international Bodies such as Codex, OIE, IPPC and WTO.

(c) **Developmental work** with production units (farmers and processing units), which includes also a source for information to assist exporters that wish to know the requirements in some specific export market

- Some of the agencies, such as APEDA and the Tea Board, are already implementing outreach programmes for developmental work. Those programmes could continue and a decision could be taken on extending them for other areas as well, in a phased manner
- Training programmes would also be the responsibility of this Division, including for Government agencies which are the nodal points for ICA

(d) A **common point for receiving information and queries and passing them on** to the concerns regulatory agency

- This could be a common Division for all activities, acting similar to a communication center for ICA

(e) A **common point of reference for those who wish to know which agency, regulation or person is relevant for addressing their concerns** regarding India's food regulatory regime

- This could a be the common Division for all activities, acting similar to an information center ICA
- The last two Divisions, i.e. mentioned under (d) and (e), would co-ordinate their activities with all the other Divisions for being informed about all key activities
- The Divisions under (d) and (e) could co-ordinate to bring a quarterly or half yearly information booklet to provide current information to stakeholders. A more detailed form of this information could serve to inform the IMC, i.e. the Apex inter-ministerial co-ordination Body

The five main tasks should be allocated in such a way that the primary responsibility of each is clear and separate within the ICA. Wherever Divisions collaborate, their common goal as well as individual responsibility would need to be transparently known and monitored. This will over time pave the way for notification of an overall Body as the relevant Unified Authority for food regulation once the underlying laws, Regulation or Orders have been amended.

Stage 2: The Consolidation Stage

As the legal basis for operations of the agencies is changed, the loose federation of agencies could be incrementally combined under the nodal points under Stage 2. This could begin in the second or third year of operations for ICA. In effect, the combinations would take place under FSSAI for imports and EIC for exports. Meanwhile, APEDA and MPEDA would retain their separate identity with the possibility of a combined entity overseeing them, in view of the range of tasks which are performed by these two export development agencies.

Thus, Stage 2 would begin combining certain regulatory agencies under the nodal points as gaps, duplication and overlap of functions is reduced or removed. Stage 1 would thus pave the way for identifying and addressing these gaps and overlap, and enable greater consolidation of regulatory agencies.

Stage 3: The Integrated Stage – An Integrated Unified Authority for Food Regulation

In this Stage, the phase-in of EIC, APEDA and MPEDA into a single agency regulating and developing export related activities could be formed. Likewise, the activities of the Quarantine agencies could also be separated into exports and imports, and these initiatives work under the nodal points respectively for exports and imports. Stage 3 would see a reduction in the number of nodal points to three, i.e.

- for imports (FSSAI)
- for exports (the combined agency which would include EIC, APEDA and MPEDA), for instance, the Food Export Development and Regulation Authority of India (FEDRAI)
- Customs.

Each nodal point would work as an expert agency work on their mandated tasks within the overall framework of the Unified Authority, ICA. The two agencies, FSSAI and FEDRAI, would be part of ICA, while Customs would be a partner agency working with them on common or supporting tasks.

The five pillars of activities would continue unchanged, consolidating their experience and co-ordination work.

The framework suggested above is an example of the kind of approach that could be adopted, taking account of, and addressing, the present gaps and shortcomings of the present system. This is only a suggested framework to stimulate further thought on converging towards a structure which would be relevant for India's food regulation regime as we progress towards greater co-ordination to address increasingly complex tasks in the future.

A number of questions arise in this context. While the questions relating to this Chapter are given below, a consolidated list or questions raised in the various Chapters of this paper is provided in Annex 4.

V. Questions for Consultations

5.1. Two main level of APEX agencies are suggested, one at Ministerial level and another at Implementation level. Is this structure adequate for an efficiently functioning Unified Authority?

5.2. Should the negotiations co-ordination be considered in the wider context described for IMC, or should the scope of that be limited to areas covered by food regulatory agencies?

5.3. Is it more efficient to combine the agencies dealing with exports and imports into a single agency, or is it better to work with the suggested structure of separated yet linked two major parts of a common agency?

5.4. Are the agencies identified as nodal points under the ICA adequate for efficient and comprehensive approach to collaboration? Are there any other key agencies that should be separate nodal points, and not be working with or under the nodal agencies specified above?

5.5. The three stages for ICA are suggested so as to allow time to identify gaps and duplication, through a co-ordination mechanism which converts into and integrated operational mechanism over time. Is there any other way of sequencing which would be more efficient method on transition to an operationally Unified Authority?

5.6. Is the distribution of responsibilities to the five Divisions of ICA sufficient to prevent overlaps among agencies in such a way that duplication becomes the norm? If not, please indicate which alternative model would be better for this purpose?

5.7. Please suggest the criteria that would allow distinguishing between a situation of efficient collaboration from one with inefficient duplication of tasks?

5.8. Is the estimate of the time period required for the activities mentioned in Table 5.1, correct or not? If not, what alternative time period would be required as per your assessment?

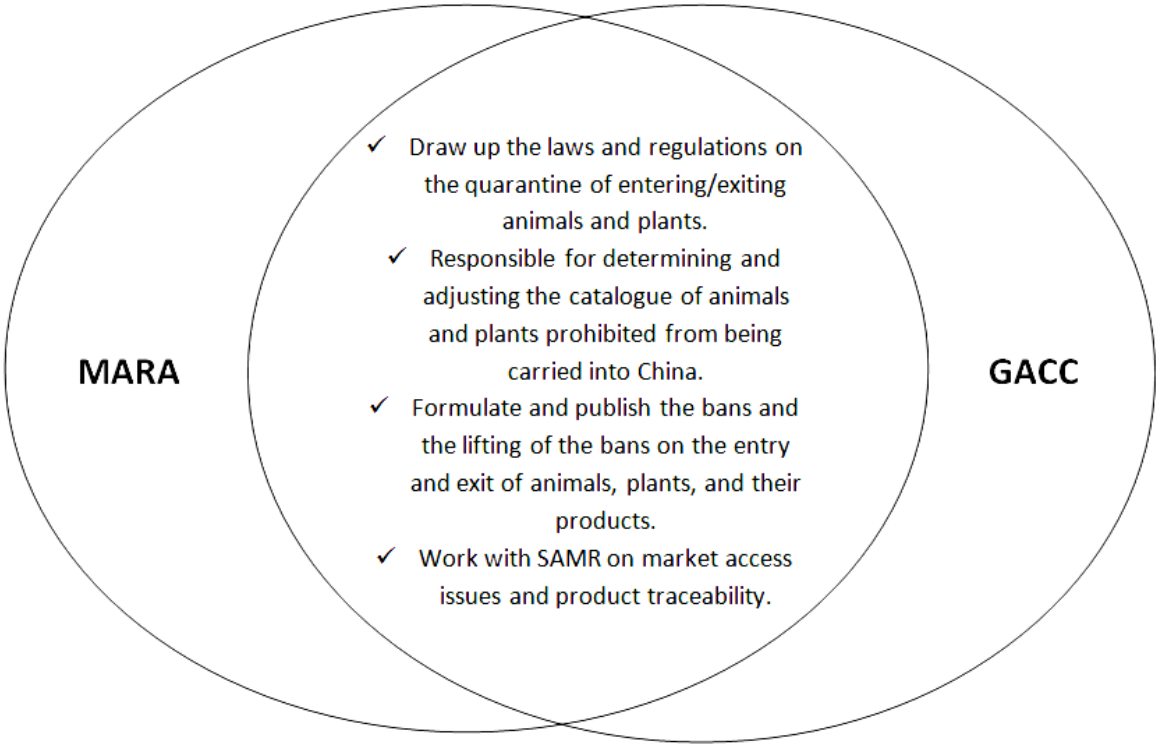
5.9. What should be the operational structure of the leadership of the Governing Bodies of IMC and ICA? Should the IMC have co-chairpersons from Department of Commerce and Ministry of Agriculture? Should the Chairperson of ICA be at the level of State Minister?

5.10. The suggested sequencing is also aimed at creating better and quicker ways to ease the operations for stakeholders, both regulatory agencies and producers/exporters/importers. Please suggest steps that would create a greater momentum towards creating quicker and more significant ease of operations for the stakeholders?

ANNEX 1. CHINA: Details of the Interaction Between Different Agencies Implementing the Food Regulatory Regime in China

DIVISION OF RESPONSIBILITIES AMONG THE AGENCIES IN AREAS OF RELATED WORK

1. **MARA & GACC**

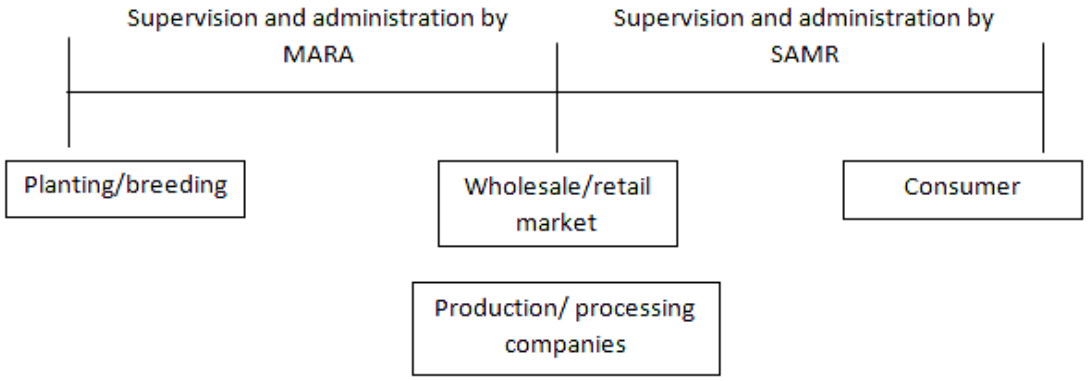


a. The Ministry of Agriculture and Rural Affairs draws up the laws and regulations on the quarantine of entering/exiting animals and plants in collaboration with the General Administration of Customs of China.
b. MARA and the GACC are responsible for determining and adjusting the catalogue of animals and plants prohibited from being carried into China and must publish it jointly.
c. The General Administration of Customs has to formulate and publish the bans and the lifting of the bans on the entry and exit of animals, plants, and their products jointly with the Ministry of Agriculture and Rural Affairs.
d. In terms of international cooperation, the Ministry of Agriculture and Rural Affairs is responsible for signing the inter-governmental agreements and treaties on animal and plant quarantine; the General Administration of Customs is responsible for signing and implementing the agreements and memorandums of agreement relating to the inter- governmental agreements and treaties on animal

and plant quarantine, and the agreements among animal and plant quarantine authorities.

e. The two Ministries have to coordinate and closely cooperate with each other and jointly carry out the quarantine for entering/exiting animals and plants.
f. MARA works with SAMR and GACC on market access issues and product traceability.

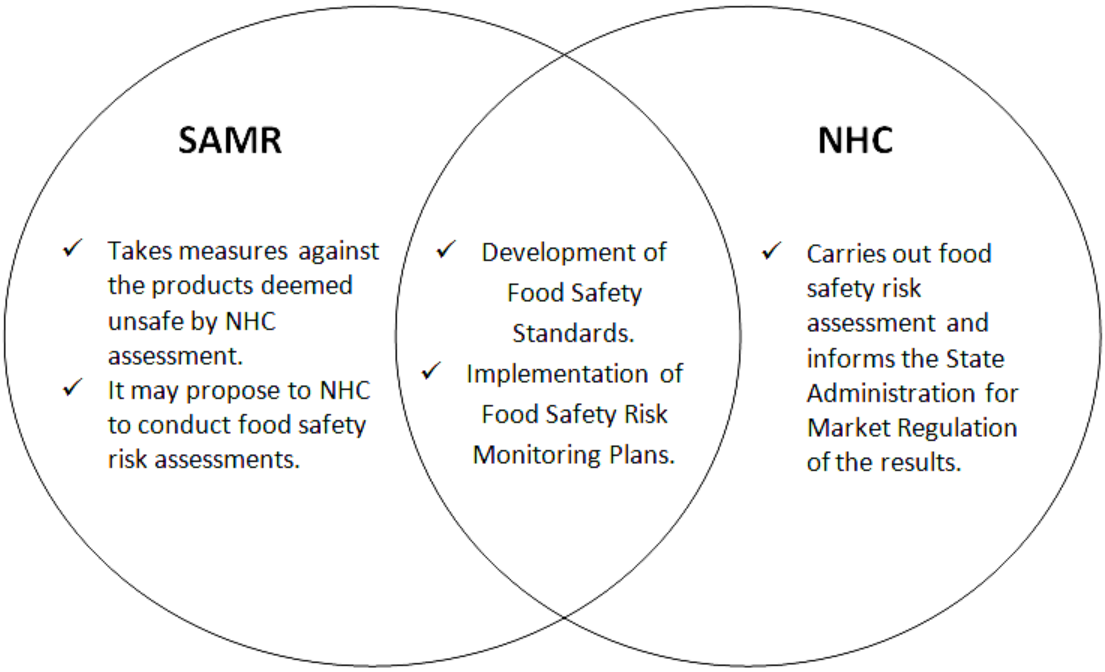
2. MARA & SAMR



Division of Supervisory and Administrative responsibilities along the production chain of Agricultural products.

a. The responsibilities are allocated based on the sequence of activities involved. The Ministry of Agriculture and Rural Affairs is responsible for supervising and administering the quality safety of edible agricultural products from planting and breeding to the wholesale and retail markets or before delivery to production process companies. The edible agricultural products are then supervised and administered by the State Administration for Market Regulation after they have been distributed to the wholesale and retail markets or the production process companies.
b. The Ministry of Agriculture and Rural Affairs is responsible for supervising and administering the quality and safety in links of animal and plant disease prevention and control, livestock and poultry slaughtering, and raw milk procurement.

3. SAMR & NHC



a. The National Health Commission, together with State Administration for Market Regulation, are the national authorities for food safety standard development and implementation.
b. The National Health Commission is responsible for food-safety risk assessment and formulates and implements food safety risk monitoring plans in collaboration with the SAMR and other departments.
c. Where the NHC finds evidence; through food safety risk monitoring or through reporting received; that food may have any potential safety hazard, it promptly organizes an inspection and carry out food safety risk assessment, and informs the SAMR of the assessment results in a timely manner.
d. The State Administration for Market Regulation then immediately takes measures for the products that are concluded to be unsafe by the NHC.

e. Where the State Administration for Market Regulation finds that it is necessary to conduct food-safety risk assessment during its supervision and administration, it shall submit a proposal in respect thereof to the National Health Commission.

4. SAMR & GACC

a. The two Administrations must establish a mechanism to avoid repeated inspection, charging, and penalties on imported and exported commodities, and imported and exported foods and cosmetics to ease the burden on enterprises.
b. The GACC is responsible for the supervision and administration of the safety of imported food. The imported food and food-related products should conform to the food-safety standards of the State. Under the Food Safety Law, China Import and Export Quarantine offices (CIQs under GACC) inspect imported food, food additives, and Food-Related Products in accordance with the NHFPC (now, National Health Commission) requirements.
c. Where a food safety incident occurring outside China may impact China or a serious food safety problem is found in the imported food, the GACC takes early warning or risk control measures in a timely manner, reports it to the SAMR, and the SAMR takes appropriate measures without delay.
d. The two administrations establish a reporting and cooperation mechanism for information on defects in imported products.

   Where the General Administration of Customs finds any substandard imported product or imported product with potential safety hazard during port inspection and supervision, it conducts technical processing, returns or destroys it, and then notifies the SAMR regarding same.

   The State Administration for Market Regulation exercises unified management over the recall of defective products. Where it is learned that any imported product is defective from consumers' reports, accident investigation, injury surveillance, and others, the SAMR shall take recall measures according to law; in case of a refusal to perform the recall obligation, the SAMR shall report it to the GACC and the GACC shall take appropriate measures according to law.

5. GACC & NHC

a. The National Health Commission is responsible for the overall prevention and control of infectious diseases and the responses to public health emergencies, as well as the preparation of the catalog of infectious diseases under frontier sanitary quarantine supervision as well.
b. The National Health Commission and the General Administration of Customs are entrusted that they must establish and improve a cooperation mechanism to deal

with port infectious diseases and public health events, a reporting and exchanging mechanism for infectious diseases and public health events, and a reporting and cooperative handling mechanism for port imported epidemics.

ANNEX 2. USA: The Food Safety Modernization Act (FSMA)

The FDA Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011 and represents the first major overhaul of food safety legislation in more than 70 years. It aims to ensure that food supply within USA is safe by shifting the focus of federal regulators from responding to contamination to preventing it.

This law affects the activities of the FDA, rather than USDA, and provides it with new enforcement and inspection authorities. The FDA conducts inspections of foreign food facilities to identify potential food safety concerns before food products reach our shores, but sometimes foreign food establishments or governments won't permit the FDA to enter the facility and inspect. Under FSMA, FDA now has the authority to refuse entry of food from such establishments.

Whilst the FDA is charged with regulating most food products, the legislation also recognizes that **food safety is a responsibility shared among US state, local, territorial, tribal, and foreign food safety agencies and therefore requires additional integration of the food control system and participation by all stakeholders**. The FSMA strategy recognizes that the food industry has the primary responsibility and capacity to produce safe food, but it calls for a new definition of public and private roles on food safety and a modern new framework for regulatory oversight, integration of government food safety efforts, and public-private collaboration. While food industry is ultimately responsible for getting the training they need to comply with the FSMA rules, the FDA recognizes the importance of its role in facilitating that training. For FDA, this means joining with public and private partners in state, federal, tribal and international governments, industry, and academia in the development and delivery of training. The vision of FSMA training began in 2010-2012 with the creation of public-private alliances funded primarily by the FDA as a resource for industry and to facilitate widespread understanding of the new standards to support compliance.

It was recognised that to build and implement a new food safety system would take time so **specific implementation dates were established in the legislation**. Initially an implementation management structure was put into place to ensure clearly defined roles and accountability for each FSMA deliverable. Implementation is focused on six major areas each headed by an Implementation Leadership Team. Task-specific working groups report to these teams and are responsible for developing the regulations, reports, guidance and processes required by the legislation.

The six implementation teams are: Prevention standards; Inspection and compliance; Imports; Federal / State Integration; Fees; Reports and Studies. Seven rules have been established since the introduction of this Act i.e.:

a) Produce Safety Standards
b) Preventive Controls for Human Food
c) Foreign Supplier Verification Programme
d) Preventive Controls for Animal Feed
e) Accredited Third Party Certification
f) Mitigation strategies to protect food from intentional adulteration
g) Sanitary transportation of human and animal food

(i) Prevention: FDA has a **mandate to require comprehensive, science-based preventive controls across the food supply.** This mandate includes:

- Mandatory preventive controls for food facilities: Food facilities are required to implement a written preventive controls plan. This involves: (1) evaluating the hazards that could affect food safety, (2) specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards, (3) specifying how the facility will monitor these controls to ensure they are working, (4) maintaining routine records of the monitoring, and (5) specifying what actions the facility will take to correct problems that arise.
- Mandatory produce safety standards: FDA must establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables. Those standards must consider naturally occurring hazards, as well as those that may be introduced either unintentionally or intentionally, and must address soil amendments (materials added to the soil such as compost), hygiene, packaging, temperature controls, animals in the growing area and water.
- Authority to prevent intentional contamination: FDA must issue regulations to protect against the intentional adulteration of food, including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points.

(ii) Inspection and Compliance: The FSMA recognizes that preventive control standards improve food safety only to the extent that producers and processors comply with them. Therefore, it will be necessary for FDA to provide oversight, ensure compliance with requirements and respond effectively when problems emerge.

FSMA provides FDA with important **new tools for inspection and compliance**, including:

- Mandated inspection frequency: The FSMA establishes a mandated inspection frequency, based on risk, for food facilities and requires the frequency of inspection to increase immediately. All high-risk domestic facilities must be inspected.
- Access to Records: FDA will have access to records, including industry food safety plans and the records firms will be required to keep documenting implementation of their plans.
- Testing by accredited laboratories: The FSMA requires certain food testing to be carried out by accredited laboratories and directs FDA to establish a program for laboratory accreditation to ensure that US food testing laboratories meet high- quality standards

The FSMA recognizes that FDA must have the **tools to respond effectively when problems emerge despite preventive controls**. New authorities include:

- Mandatory recall: The FSMA provides FDA with authority to issue a mandatory recall when a company fails to voluntarily recall unsafe food after being asked to by FDA.
- Expanded administrative detention: The FSMA provides FDA with a more flexible standard for administratively detaining products that are potentially in violation of the law (administrative detention is the procedure FDA uses to keep suspect food from being moved).
- Suspension of registration: FDA can suspend registration of a facility if it determines that the food poses a reasonable probability of serious adverse health consequences or death. A facility that is under suspension is prohibited from distributing food.
- Enhanced product tracing abilities: FDA is directed to establish a system that will enhance its ability to track and trace both domestic and imported foods. In addition, FDA is directed to establish pilot projects to explore and evaluate methods to rapidly and effectively identify recipients of food to prevent or control a food borne illness outbreak.
- Additional Recordkeeping for High Risk Foods: FDA is directed to issue proposed rulemaking to establish recordkeeping requirements for facilities that manufacture, process, pack, or hold foods that the Secretary designates as high-risk foods.

(iii) Imports: The FSMA gives FDA **unprecedented authority to better ensure that imported products meet US standards and are safe for US consumers**. It includes:

- Importer accountability: For the first time, importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe.
- Third Party Certification: The FSMA establishes a program through which qualified third parties can certify that foreign food facilities comply with US food safety standards. This certification may be used to facilitate the entry of imports.

- Certification for high risk foods: FDA has the authority to require that high-risk imported foods be accompanied by accredited third party certification or other assurance of compliance as a condition of entry into the US.
- Voluntary qualified importer program: FDA must establish a voluntary program for importers that provides for expedited review and entry of foods from participating importers. Eligibility is limited to, among other things, importers offering food from certified facilities.
- Authority to deny entry: FDA can refuse entry into the US of food from a foreign facility if FDA is denied access by the facility or the country in which the facility is located.

(iv) Enhanced Partnerships**:** The FSMA **builds a formal system of collaboration with other government agencies, both domestic and foreign**. In doing so, the statute explicitly recognizes that all food safety agencies need to work together in an integrated way to achieve the public health goals. The following are examples of enhanced collaboration:

- State and local capacity building**:** FDA must develop and implement strategies to leverage and enhance the food safety and defense capacities of State and local agencies. The FSMA provides FDA with a new multi-year grant mechanism to facilitate investment in State capacity to more efficiently achieve national food safety goals. US states have cooperative agreements with FDA, and the majority of those states received funding to build capacity to align with FSMA goals. Since FSMA became law in 2011, congressional appropriators have increased annual funding for the FDA Foods Program by $204.3 million—an increase of about 24% between FY2011 and FY2018—largely in an effort to support FDA's implementation of FSMA. The enacted FY2018 appropriation for FDA's Foods Program provided $1,041.6 million.
- Foreign capacity building**:** The law directs FDA to develop a comprehensive plan to expand the capacity of foreign governments and their industries. One component of the plan is to address training of foreign governments and food producers on US food safety requirements.
- Reliance on inspections by other agencies**:** FDA is explicitly authorized to rely on inspections of other Federal, State, local and third-party agencies including from other countries to meet its increased inspection mandate for domestic facilities. The FSMA also allows FDA to enter into interagency agreements to leverage resources with respect to the inspection of seafood facilities, both domestic and foreign, as well as seafood imports.

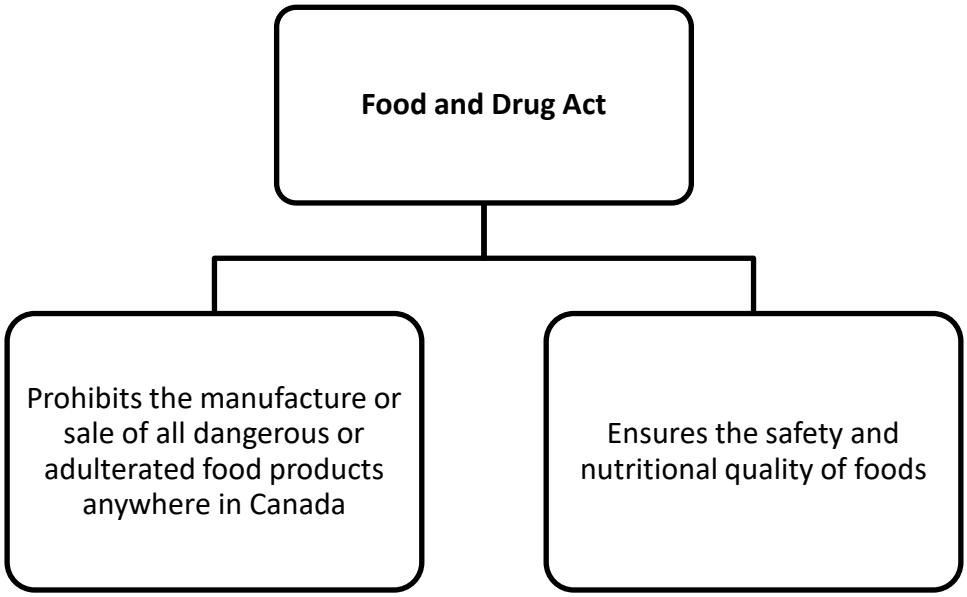
ANNEX 3. CANADA: The food safety and control system in Canada[7]

Canada's food safety system operates in a multi-jurisdictional context. It involves:

- Federal,
- Provincial/territorial (P/T) and
- Municipal authorities.

The Government of Canada has a fundamental, but not exclusive, role in health protection including food safety. Government has the primary responsibility for identifying health risks associated with the food supply, assessing the severity and probability of harm or damage, and developing national strategies to manage the risks.

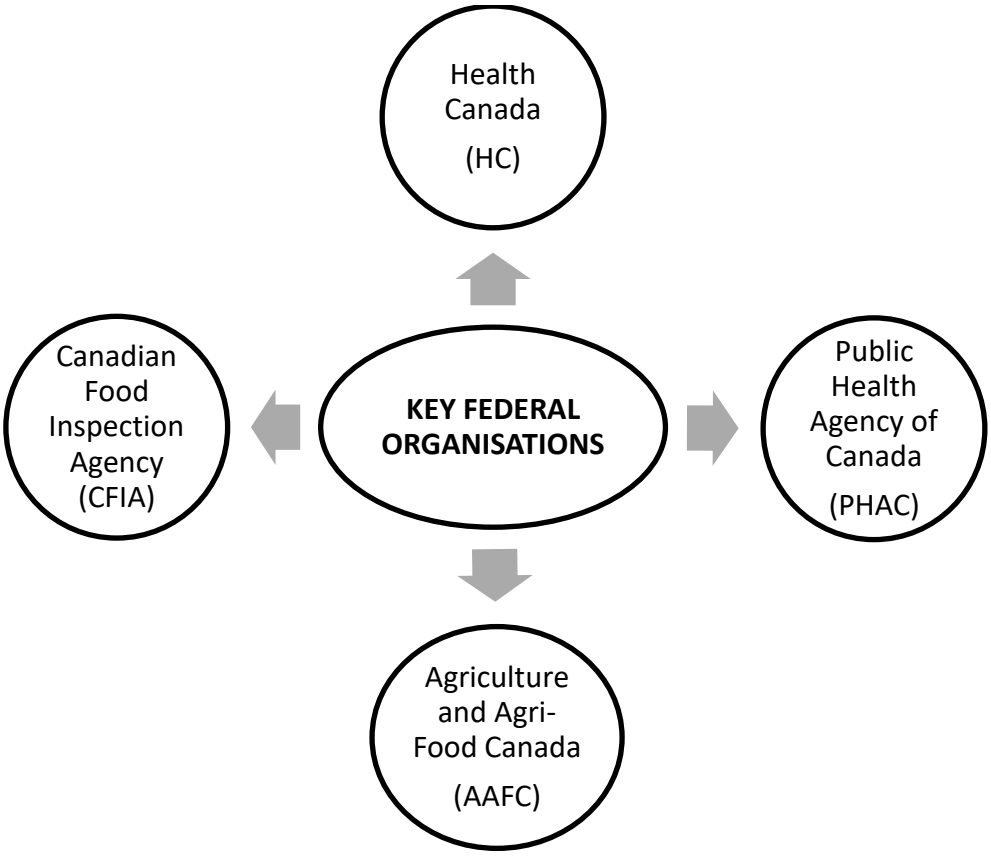
The main federal legislation covering food safety is the **Food and Drugs Act**.



Other federal trade and commerce legislation may reference the Act and stipulate additional requirements. Examples include the Canada Agricultural Products Act, Meat Inspection Act, Fish Inspection Act, Seeds Act, Fertilizer Act and Feeds Act. Also contributing to the regulatory framework is the **Pest Control Products Act**. As it is understood that animal diseases have the potential to impact the safety of food and products originating from farm animals, the Health of Animals Act, administered by the **Canadian Food Inspection Agency (CFIA)**, is also an important piece of legislation to provide further assurance of the safety of the food supply.

[7] The references for the section on Canada include: Health Canada Website; https://www.mcgill.ca/macdonald/files/macdonald/enrico_buenaventura_hc_role_in_hr_during_outbreaks_s.pdf; http://www.foodprotect.org/media/reportdate/8-07CanadaFoodSafetyPaper.pdf

KEY FEDERAL ORGANISATIONS



1. **Agriculture and Agri-Food Canada (AAFC)** – The mandate of AAFC is to provide information, research and technology, and policies and programs to achieve security of the food system, health of the environment and innovation for growth. Many CFIA programs are based on policies developed with AAFC. AAFC works with the agriculture industry to develop capacity, tools and practices through various incentives and programs towards furthering food safety objectives.
2. **Health Canada (HC)** – It establishes food safety policy and standards, assesses the effectiveness of CFIA's food safety activities, conducts health risk assessments in support of food safety investigations and informs Canadian's about potential risks to their health. HC is responsible for administering the food safety provisions of the Food and Drugs Act and Regulations. Specifically, HC engages in research, risk assessment, pre-market review and evaluation of all issues related to food safety and nutrition, and regulation and registration of pest control products and veterinary drugs. To ensure the federal system

is one with checks and balances, HC has responsibility for assessing the effectiveness of the CFIA's food safety activities.

3. **Canadian Food Inspection Agency (CFIA)** – It designs and delivery of federal food inspection programs, Monitors industry's compliance with the acts and regulations, undertakes enforcement action as necessary and food safety investigation and food recall. The CFIA is responsible for enforcing the Act and Regulations and for the administration and enforcement of the federal trade and commerce legislation regarding food safety and quality. The CFIA is responsible for enforcing those policies and standards set by HC, as well as all federally mandated food inspection, compliance and quarantine services. The CFIA designs, develops and manages inspection related programs and service standards, including supplying laboratory support. It also negotiates partnerships with other levels of government, as well as industry and trading partners, with respect to inspection and compliance programs, and supplies laboratory support for inspection, compliance and quarantine activities.

   In an effort to streamline enforcement legislation currently found in a variety of commodity statutes, the CFIA has tabled before Parliament the new Canadian Food Inspection Agency Enforcement Act that would provide statutory authority respecting the inspection powers of the CFIA and the enforcement of Acts under its responsibility.
4. **Public Health Agency of Canada (PHAC)** – The PHAC is responsible for surveillance of food-borne, water-borne and enteric human illnesses and provides comprehensive expertise and support for epidemiological and microbiological investigations. These surveillance activities provide a system for early detection and warning, and a basis for evaluating food safety control strategies.

Table: Functions and Accountability of key Federal Organisations of Canada

<table>
<tr><td rowspan="2">KEY FEDERAL ORGAN-ISATIONS</td><td colspan="6">FUNCTIONS</td></tr>
<tr><td>On-farm Food Safety Programs</td><td>Policy and Standards</td><td>Surveillance and Early Warning</td><td>Education and Outreach</td><td>Inspection and Enforcement</td><td>Public Health Surveillance</td></tr>
<tr><td rowspan="2">ACCOUNT-ABILITY</td><td>AAFC</td><td colspan="3">HC</td><td></td><td>PHAC</td></tr>
<tr><td></td><td></td><td colspan="3">CFIA</td><td></td></tr>
</table>

PROVINCIAL/TERRITORIAL (P/T)

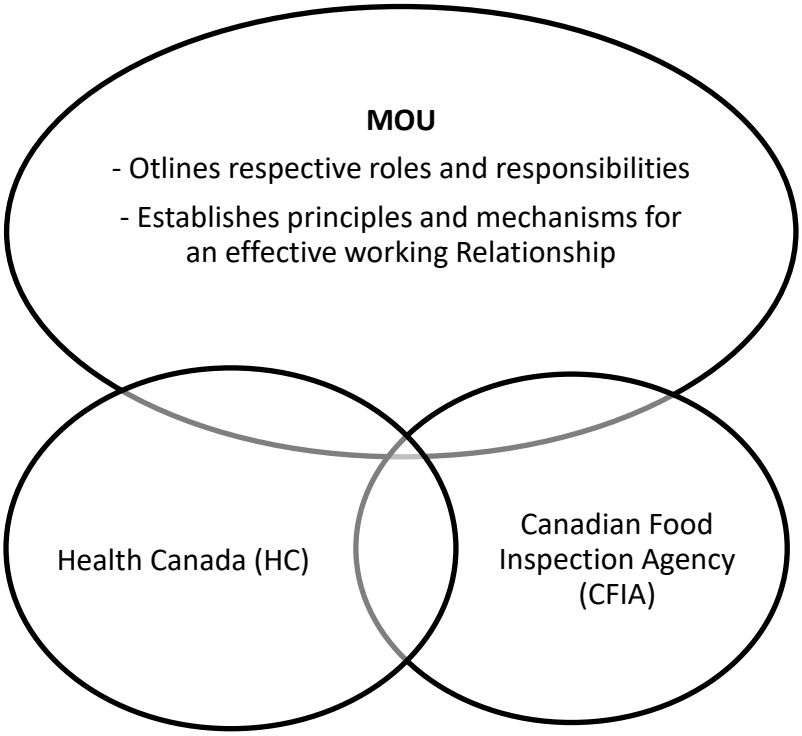
Provinces and territories enact legislation governing foods produced and sold within their own jurisdictions. These laws are complementary to federal statutes. There is also legislation to

govern animal husbandry, agricultural practices and the licensing of meat and dairy establishments selling their products intra-provincially. The inspection programs of the provinces and territories apply to food-processing and food-service establishments, food retail, hospitals, nursing homes, community kitchens and food-banks within each province. Provincial and territorial legislation also authorizes municipalities to enact bylaws affecting food inspection. Because legislative power in Canada may not be delegated from one level of government to another, governments collaborate in areas of shared jurisdiction, such as food inspection, and establish partnerships to ensure effective and efficient program delivery.

Complementary to federal, provincial/territorial legislation governs food produced and sold within their jurisdictions, including for food-safety surveillance, investigations and compliance. Often, the provinces and territories are the first to be notified of potential food-borne illnesses, and thus play an integral role in the food safety system. The success of the system depends on close working relationships among federal, provincial and territorial authorities, industry and consumers.

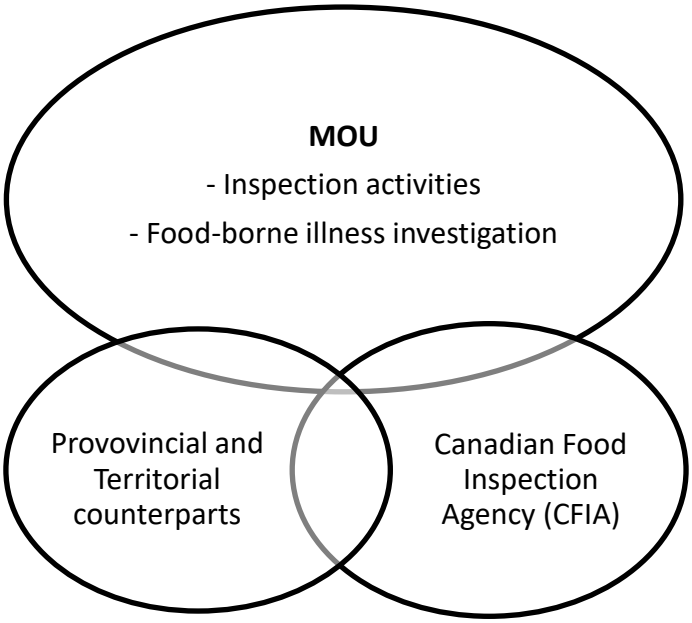
OPERATIONAL LINKAGES

Memorandum of Understanding (MOU) has been established between organisations for an effective working relationship.



A “Roles and Responsibilities Framework” details the HC/CFIA responsibilities for each program element of the federal food safety and inspection system. Collaborative mechanisms have been established between HC and the CFIA through the HC/CFIA Joint Food Safety and Nutrition Committee, which provides overall guidance and leadership on policies and strategic directions to the federal food safety and nutrition regulatory system. The Committee is at the senior management level, and is complemented by on-going cooperation and collaboration at all levels.

The CFIA has also established MOUs with provincial and territorial counterparts on shared responsibilities.



RISK ANALYSIS PROCESS

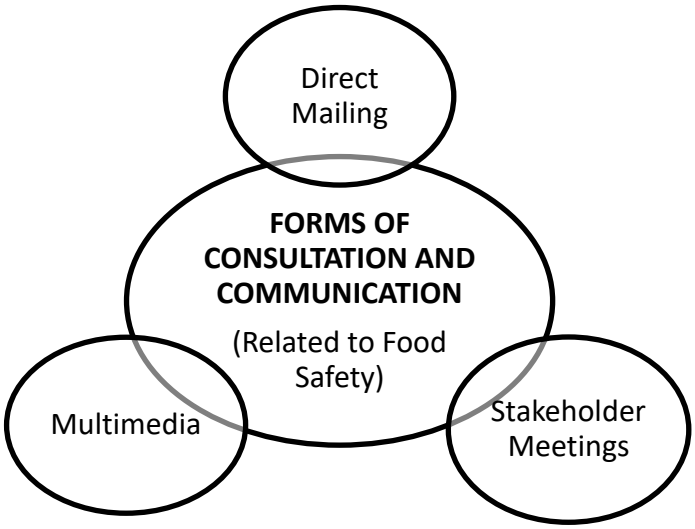
The risk analysis process is the foundation upon which Canada’s food safety policies are based.

HC's Decision-Making Framework and the CFIA's Risk Analysis Framework provide a structured, systematic approach to identifying, assessing and managing health risks, and emphasize stakeholder consultation and communication. They are compatible and consistent with approaches developed at the international level by the Codex Alimentarius Commission and with the guidance on food safety risk analysis provided by FAO/WHO.

As the **concept of precaution** is also applicable to risks other than food safety, the Government of Canada established "**A Framework for the Application of Precaution in Science-Based Decision Making About Risk"**. This framework provides guiding principles for the application of precaution to science-based decision-making for the protection of health and safety and the environment and the conservation of natural resources.

CONSULTATION

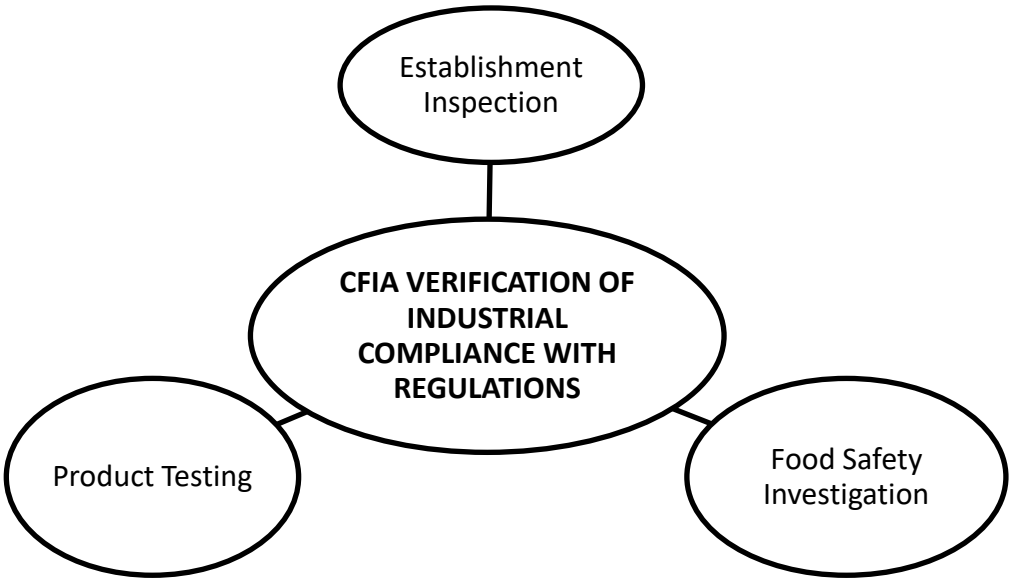
Consultation is an integral part of policy development in Canada, including the development of food safety policies and regulations. Mechanisms have been established to provide opportunities, not only for the exchange of information but, where possible, for participation in the decision-making process.



Similar consultations are conducted with Canada's major trading partners to assess the international impacts of such policies and standards and to work towards international harmonization. Canada notifies its trading partners of regulatory changes through the WTO notification system. Publication in the Canada Gazette remains the official government mechanism for notification of proposed regulatory change.

ENFORCEMENT AND COMPLIANCE

A key role of the CFIA in the Canadian food inspection system is to manage risks to human health through its compliance and enforcement activities. Once an appropriate risk management approach is selected, the CFIA works with partners/stakeholders to implement it in an effective manner.



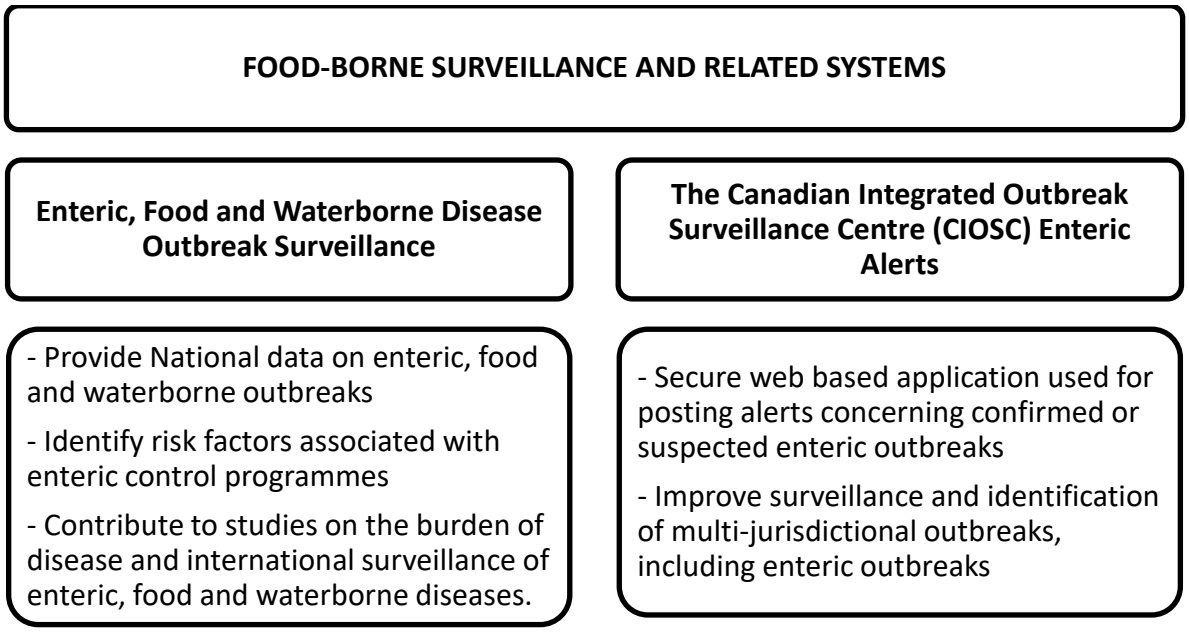
The CFIA has in place emergency response procedures aimed at protecting consumers from food involved in accidental or intentional events. It can act rapidly and effectively in response to emergencies impacting food safety, such as recalling unsafe food from the marketplace.

The CFIA's diagnostic capabilities and scientific expertise also contribute to the federal government's efforts to strengthen Canada's preparedness for, and response to, potential terrorist threats.

The CFIA has a network of 21 laboratories providing: Routine analytical services; Research; Methods development; Accreditation; and Scientific advice in support of food safety, animal health and plant protection. The CFIA also provides **training programs** across Canada to ensure key technical competencies for CFIA employees. Priorities are aligned with the key priorities of CFIA programs. As a result, inspectors across the country receive the same training, resulting in consistency of application.

FOOD-BORNE DISEASE SURVEILLANCE AND RELATED SYSTEMS

Regulatory bodies responsible for human health and food safety are responding to foodborne illness outbreaks that cross jurisdictional boundaries through the development of enhanced foodborne illness surveillance networks, and through collaboration in multi-jurisdictional outbreak investigations.



PARTNERSHIP AND SUPPORT SYSTEM

Collaboration among the different levels of government is facilitated by the creation of a new committee, "**Federal/Provincial/ Territorial Food Safety Committee"** which provides a balanced

health and agriculture perspective to manage national food safety issues along the food continuum.

The key objective of this committee is to provide federal/provincial/territorial government leadership to strengthen Canada's food safety system by coordinating the development of national food safety policy options and implementing initiatives to achieve national food safety goals and priorities.

Government-industry collaboration includes development and maintenance of food safety programs along the food continuum. AAFC provides funding opportunities for national industry associations to develop programs for food safety, quality and traceability throughout the total food chain (on-farm and post-farm), including funding for food safety projects at the national, multi-regional and regional level. These funding initiatives encourage industry to develop and implement national systems based on the use of HACCP principles/practices.

Government-academia and government-consumer collaboration include the Expert Advisory Committees and the Canadian Partnership for Consumer Food Safety Education, respectively. The Committees are established to assist in program or policy decisions through the provision of expertise in food safety and the latter provides consumers with information for safe food handling to reduce the number of food-borne illnesses and deaths associated with microbial contamination of food.

CONCLUSION

Collaboration and cooperation of all stakeholders along the food continuum is a key element for strengthening Canada's food safety system. Inter-governmental collaboration and partnerships with stakeholders, operating within a risk-based approach, ensures a comprehensive and responsive food safety system that protects Canadians from health risks associated with foods.

ANNEX 4. Main Background Suggestions and the List of Question Specified In Various Chapters of This Consultation Paper

1. Main Background Suggestions or Points for Consideration

From Chapter 2:

While considering the discussion in Chapter 2, certain key points must be kept in mind to address the issues that arise in the context of unifying the co-ordination of operations of diverse agencies under one umbrella. These issues include:

- the possibility of integration of the jurisdiction of the individual agency concerned with a proposed unified agency;
- modifications required in the administrative/operational structure for this purpose;
- feasibility of combining the functions of different agencies under one umbrella agency;
- the specific legal framework required for making the relevant changes; and,
- the alternative ways to combine or co-ordinate the work of agencies that help achieve the basic objective that would be fulfilled by a unified agency.

From Chapter 3:

Gaps or concerns that could be addressed relatively quickly:

(a) The EXIM Policy document does not include the names of all the agencies. This gap should be filled without a short time period, e.g. one month.

(b) Training of Customs officials to be clearer on the jurisdiction of different regulatory agencies. FSSAI and EIC could be the nodal agencies to co-ordinate such training.

(c) Likewise, training of those agencies to which responsibilities are outsourced.

(d) After a specified time period, e.g. six months, all regulatory agencies should perform their tasks based on formal delegation of authority to that agency (see questions below for addressing this issue).

(e) A list should be prepared within a short time period, to clarify the mandatory requirements for exporters and importers, and the regulatory agencies that administer these mandatory requirements.

(f) Collect success cases relating to co-ordination, harmonised work, or good outreach programmes to boost exports. These success cases could provide a basis to expand the scope of coherence and outreach to other activities and sectors as well. Examples include GrapeNet and TraceNet, and the experience of developing common standards for organic products.

(g) Similarly, use of technology to facilitate operations should be identified. Examples include the use of BOTS by the Coffee Board, to reduce the time period for certification, and the linking up of BOTS with ICEGATE.

(h) Addressing the above-mentioned concerns with respect to products not under mandatory certification:

- Centralised source of information on requirements for these products in importing countries.
- Establish follow-up mechanisms required to address trade-related problems that may arise due to non-conformity with standards in importing countries.

From Chapter 4:

(a) There is in general no single Body for food regulation. Only for the EU is there a single Agency or Authority responsible for developing regulatory regime and implementing it (see sub-section "A" below).

(b) Even for the EU, however, the implementation requires the relevant regulatory Bodies of members States to carry out the regulatory functions in practice. This is helped by the fact that most regulatory requirements have been harmonized for food and agriculture in the EU.

(c) Other economies discussed in this Chapter have either two or more agencies with oversight as well as more detailed responsibilities for food regulation.

(d) This level of aggregation of the number of agencies has meant:

- combining previous agencies under an agency with a broader remit,
- phasing out some agencies and re-allocating the tasks, and
- bringing in new laws to provide a basis for the new and wider ambit of the role and power of the regulatory Bodies,

(e) Even though certain agencies were transferred to become part of a larger Body, in certain cases the name of the agency was retained.

(f) Even with an aggregation of tasks into a smaller number of agencies, the products covered by individual agencies need not be comprehensive, i.e. some products may be allocated to one agency and other products to the second agency.

(g) The responsibilities in general are clearly defined, though there are overlaps in areas covered. In such situations, the framework for co-ordination and collaboration is clearly specified.

(h) In certain cases, the re-organisation was at the level of the Ministry itself, and not just for the tasks related to food regulation.

(i) This has meant that the scope of work allocated to the relevant agencies in these countries have a much wider scope than that covered by the food regulation regime of India.

(j) This in turn implies a consideration of three inter-related points:

- What should be the tasks to be considered under the re-organisation of the regulatory regimes within a framework of Unified Authority in India, i.e. even if the scope be wider

than that of the Authorities at present, it is unlikely to cover the much wider level of responsibilities of a Ministry as such.

- In this context, which of the activities discussed below for the major economies, would be relevant to consider for the scope of activities of the Indian Unified Authority?
- Thus, when considering the activities covered by individual agencies of other countries, it would be useful to identify those which should be part of the Indian system, and those which at least for the present need not be part of the responsibilities of the food regulatory Bodies in India.

(k) Nonetheless, to the extent that crucial aspects of the tasks performed by the regulatory agencies involve Ministry-level actions, the Indian framework could consider an inter-Ministerial level co-ordinating Committee for higher policy level decisions, and to address areas where inter-agency conflicts of jurisdiction may arise.

(l) By aggregating several tasks under a common umbrella agency, and forming different operational parts of a single agency, mechanism have been established for co-ordinating the tasks performed by different parts of the agency, and rules of conduct be established so that conflicts do not arise?

(m) Similarly, while multiple tasks have been collected under a few (one to four) agencies, there are still other agencies outside their ambit which perform overlapping tasks. Ways of co-ordination with such agencies also have been established.

(n) Similarly, co-ordination among agencies also takes place when priority tasks are being performed, especially when negotiations/discussions take place with external agencies or Governments.

2. Questions for Consultations Listed in Chapters 3 to 5

Chapter 3:

3.1. For areas for which clear formal delegation of authority is not provided, which method would be more appropriate to address this situation?

(a) Change of legislation? Too time consuming?

(b) Specifying the role clearly in a regulation?

(c) Through a High-Level Committee which examines all such situations, and clearly specifies the mandate for different agencies within a specified time period.

(d) Any other method that would be more efficient and quicker?

3.2. In situations where more than one agency is delegated with similar responsibility, or approval of more than one agency is required, what is the solution for removing such duplication or reducing additional effort by the exporter/importer?

(a) Relevant Ministries address the issue for Bodies which they oversee, and specify a single agency for the task for which there is duplication or approval from more than one agency is required for exports/imports?

(b) When more than one Ministry is involved in overseeing the agencies concerned, a co-ordinated meeting of the Ministries should decide within a specified time period, on one agency to perform the task?

(c) What should be the criteria to determine which of the various agencies concerned should operate as the one agency to avoid duplication?

(d) If the same task is performed by two or more agencies, e.g. export certification to one country (say EU) by one agency and to another country (e.g. Iran) by another agency, should there be a nodal Body co-ordinating this or only one agency should be given the authority to give the export certificate?

(e) Any other method that would be more efficient and quicker?

3.3. Is it possible to have a nodal or central agency which keeps information on all interaction/discussions/negotiations with foreign regulatory agencies? Should this be placed with a co-ordinating senior officials Committee comprising Commerce, Agriculture, Customs, and invited Ministries that are relevant for discussion of the agenda of specific meetings?

3.4. Is it possible to coordinate the laboratories even before a unified Authority is in place, to create a system that one sample may serve for making all relevant tests?

3.5. Similarly, is it possible to reduce the time period for approvals? Is there any specific regulatory agency whose operations could serve as a model for quick approvals? If so which one? Please provide examples of success cases in this context.

Chapter 4:

4.1. Is the situation of the EU, which has one Body at the level of the European Union, similar to India that a single Body could be established for India as well?

4.2. If not, should India have two (or more) regulatory Bodies co-ordinated by an overall Board at senior level as the single Unified Authority? Should the Department of Customs also be part of this co-ordinating level?

4.3. Is there a need to phase-out some regulatory agencies and combine their functions into another agency with a larger scope? If so, which agencies should be phased out, and with which agency should their functions be combined?

4.4. Should the “single” Authority have additional functions as well which are presently performed by Departments in Ministries?

4.5. What are the co-ordinating mechanisms that will enable clear division of functions without duplication?

4.6. Which laws will need being changed to implement these changes?

4.7. Which tasks of specific agencies discussed in this Chapter (and Annexes) are most relevant to be allocated to the Unified Authority, e.g. SAMR of China or FDA or US, or any other (including tasks of more than one agency)?

Chapter 5:

5.1. Two main level of APEX agencies are suggested, one at Ministerial level and another at Implementation level. Is this structure adequate for an efficiently functioning Unified Authority?

5.2. Should the negotiations co-ordination be considered in the wider context described for IMC, or should the scope of that be limited to areas covered by food regulatory agencies?

5.3. Is it more efficient to combine the agencies dealing with exports and imports into a single agency, or is it better to work with the suggested structure of separated yet linked two major parts of a common agency?

5.4. Are the agencies identified as nodal points under the ICA adequate for efficient and comprehensive approach to collaboration? Are there any other key agencies that should be separate nodal points, and not be working with or under the nodal agencies specified above?

5.5. The three stages for ICA are suggested so as to allow time to identify gaps and duplication, through a co-ordination mechanism which converts into and integrated operational mechanism over time. Is there any other way of sequencing which would be more efficient method on transition to an operationally Unified Authority?

5.6. Is the distribution of responsibilities to the five Divisions of ICA sufficient to prevent overlaps among agencies in such a way that duplication becomes the norm? If not, please indicate which alternative model would be better for this purpose?

5.7. Please suggest the criteria that would allow distinguishing between a situation of efficient collaboration from one with inefficient duplication of tasks?

5.8. Is the estimate of the time period required for the activities mentioned in Table 5.1, correct or not? If not, what alternative time period would be required as per your assessment?

5.9. What should be the operational structure of the leadership of the Governing Bodies of IMC and ICA? Should the IMC have co-chairpersons from Department of Commerce and Ministry of Agriculture? Should the Chairperson of ICA be at the level of State Minister?

5.10. The suggested sequencing is also aimed at creating better and quicker ways to ease the operations for stakeholders, both regulatory agencies and producers/exporters/importers. Please suggest steps that would create a greater momentum towards creating quicker and more significant ease of operations for the stakeholders?

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