Chapter 5

Some International & National Food Control Institutions

1. Introduction

5.1 The globalization of trade, which has contributed to food availability and diversification throughout the world, has also increased the chances that the food produced in one place will affect the health and diet of people living in another. As a result, global food safety and nutrition measures applicable across borders, institutions, and disciplines, including the establishment of evidence-based international standards on food safety and nutrition, are more important than ever before[42]. Every year, millions of people suffer from FBD causing great socio-economic loss to the society (WHO, 2017) and this has prompted countries across the globe to strengthen their food regulatory systems. Responsiveness, outcome orientation, predictability, proportionality, and independence are the underpinnings of strong food regulatory systems (Committee, 2012).

5.2 Common to the adoption of new regulations by developed countries is the application of risk analysis principles. Under these principles, and in line with the World Trade Organization's (WTO's) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), countries should base their regulatory actions on scientific risk assessment. Also, a country should be able to explicitly link its targeted level of protection, based on a scientifically assessed risk level, to its

[42] http://www.who.int/bulletin/volumes/91/7/13-125518/en/

regulatory goals and, in turn, to its standards and inspection systems. Finally, the risk management options chosen should restrict trade as little as possible[43].

5.3 In this chapter, we examine the food regulatory systems/controls/processes of some institutions at the international level like Codex Alimentarius Commission (CAC) and European Union (EU). It will be followed by some select countries analysis at the national level viz., Canada, France and the United States of America (USA). In both cases, special emphasis is on analyzing measures put in place for risk assessment.

2. International Food Control Institutions

A. Codex Alimentarius Commission (CAC)

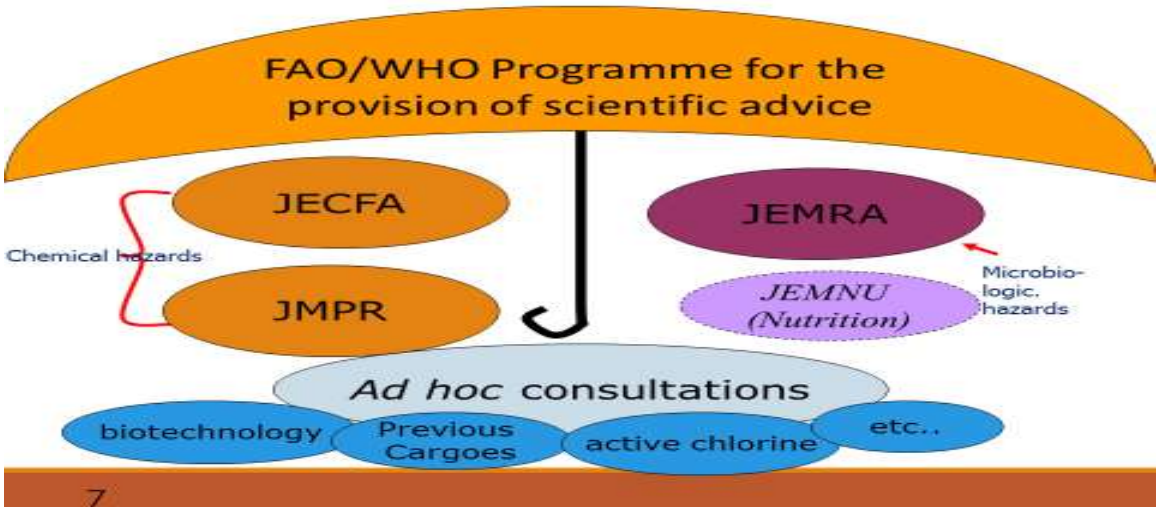
5.4 The mandate of CAC, joint FAO/WHO body, is to not only protect the health of consumers but also ensure fair practices in food trade. It shall determine priorities and initiate and guide the preparation of draft standards through and aid of the appropriate organizations (Kotwal, 2016). During the development of international standards and guidelines on foods, Codex separated the RM and RA functions and it assigned the scientific justification approach to the joint experts meeting of the Joint FAO/WHO. In this case, the general subject and vertical committees and subsidiary bodies of the CAC are described as risk managers acting based on the advice of experts from the WHO and the FAO.

5.5 The RA bodies are the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the JMPR (the Joint Meeting on pesticide residues), the JEMRA (Joint

[43] http://ageconsearch.umn.edu/bitstream/16567/1/fo031004.pdf

FAO/WHO Expert Meeting on Microbiological Risk Assessment) and other expert meetings and ad hoc consultations (**Figure 11**). They address specific requests for scientific advice on evolving, emerging and cross-cutting issues in the field of food safety.

Figure 11: FAO/WHO framework for provision of scientific advice



Source: Presentation made by Hidetaka Kobayashi on "Codex and Science" on 5th January 2o15 at FAO workshop in Dhaka

5.6 The policy of the RA elaborated by the JECFA and JMPR usually is developed by the Codex Committee. It means that the risk managers of the Codex determine the policy of the RA and not the JECFA and JMPR. It demonstrates the importance of defining the scope of the RA before its elaboration so that it serves the policy of the risk managers and the areas in which they seek the RA. Even though the food standards, guidelines and other recommendations of Codex Alimentarius are based on an analysis and objective scientific evidence, the Codex Alimentarius considers

other legitimate factors relevant for the protection of consumer's health and the promotion of fair practices in food trade[44] . Management activities related to the provision of scientific advice is shared between various units of FAO and WHO. Coordination between the two organizations shows that RA has a very close collaboration between their management activities. RA also requires close collaboration between assessors and risk managers in the field of agriculture and livestock. Moreover, even though Member States of the Codex agree that the Codex standards should be based on sound science and should rely on RA carried out by independent experts, there are some cases where "other legitimate factors" or other factors outweigh science (Chen, 2004).

B. European Commission (EC)

5.7 The European Commission (EC) has developed in 1997 a communication on consumer health and food safety to strengthen the protection of consumer health[45]. Such an approach needed a reorganization of the institutions and strengthening of the political decision-making on consumer heath. It was based on the separation between legislative responsibilities, scientific consultation, and control based on risk analysis. The new policy required as well the reorganization of the control system to cover all stages of food production from farm to table.

5.8 This communication on consumer health and food safety was followed by a Green Paper which has proposed the adoption of a simplified and modernized

[44] http://www.fao.org/docrep/006/j0776e/j0776e05.htm
[45] https://cordis.europa.eu/news/rcn/8214_en.html

European food law that attributes the primary responsibility for safe food production to industry, producers, and suppliers[46].

5.9 In 2000, the White Paper proposed the creation of an independent European Food Safety Authority (EFSA) for the elaboration of RA for the whole food chain including the primary production (manufacturers of animal feed, farmers, animal welfare and primary food operators. The responsibilities of the Authority would consist of the preparation and provision of scientific advice, the collection, and analysis of information required to underpin both that advice and the Community's decision making processes, the monitoring and surveillance of developments touching upon food safety issues and the communication of its findings to all interested parties[47].

5.10 The EC regulations 178/2002, 825/2004 and 853/2004 did not oblige the Member States to reorganize their institutional systems according to the comprehensive approach of the food safety that covers the whole food chain, but only obliged them to ensure food safety based on risk analysis. Therefore, Member States are provided with different institutional systems and is left to the Member State to choose to entrust the responsibility of the food safety system to the competent institution or authority. However, at the EU level, the RM is left to the EU institutions. The DG SANCO (The Director-General for Health and Consumer

[46] http://europa.eu/rapid/press-release_IP-97-370_en.htm
[47] https://ec.europa.eu/food/sites/food/files/safety/docs/animal-feed-pub06_en.pdf

Protection)[48] including the Food and Veterinary Office (FVO)[49] are responsible for the elaboration of the food safety RM.

Risk Assessment in EU for food safety

5.11 The EFSA, established by the article 22 of the Regulation (EC) No 178/2002[50], needs scientific and technical data in the fields that fall within its mission. Therefore, article 23 and 33 of the Regulation (EC) No 178/2002[51] provides that the authority search, collect, collate, analyze and summarize scientific and technical data in the fields within its mission and the Member States shall take the necessary measures to enable the data they collect be transmitted to the Authority. The EFSA has to harmonize scientific data and resolve the substantive divergence over scientific issues. Similarly, article 40 provides that the EFSA: "shall communicate on its own initiative in the fields within its mission without prejudice to the Commission's competence to communicate its risk management decisions." However, in case of scientific opinion divergence and uncertainty, EFSA does not have power over the final decision on measures taken based on scientific opinion and when conflict arises between the EFSA and other RA agencies of the Member States.

5.12 Therefore, the new settlement of the legislation has ensured consistent and comprehensive provisions regarding scientific expertise which includes a scientific and technical network while keeping the power to the institutions of the Community

[48] https://ec.europa.eu/info/topics/food-safety_en
[49] http://ec.europa.eu/food/fvo/how_en.print.htm
[50] http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002R0178
[51] https://www.fsai.ie/uploadedFiles/Legislation/Food_Legisation_Links/General_Principles_of_Food_Law/Reg178_2002.pdf

and the Member States on measures taken on scientific opinion. Moreover, the EFSA has no power through which it can ensure transmission of the scientific data from the Community institutions, the Member States' scientific authorities and the risk managers to it. This situation can lead to a lack of the necessary scientific information used for the RA process or sometimes to the duplication of work. Therefore, it appears that EFSA has only power on its own expertise((Ghaida, Spinnler, et al. 2014).

5.13 To enhance the control procedure of the authority and assure the food safety at all stages of the food chain, the Regulation (EC) No 178/2002 disposed of in the article 18 that the traceability: " shall be established at all stages of production, processing, and distribution." Art. 50 of the Regulation (EC) No 178/2002[52] has established a rapid alert system as a network between the commission, EFSA and the Member states for the notification of food and feed direct and indirect risks to human health. Art. 56 stipulated that in "serious direct or indirect risk, the commission shall set up a crisis unit immediately, in which the Authority shall participate, and provide scientific and technical assistance if necessary"[53]. Each EU Member State should notify the Commission through the RASFF who in turn immediately transmits to the other Members of the Network. It is the task of the national food and feed authorities to take the necessary action(Djekic, Jankovic, et al. 2017).

5.14 The Commission decides on the rapid alert system upon the scientific expertise of EFSA while it retains the responsibility for the elaboration of procedures which manage the emergency and crisis situations. However, the EFSA does not have a role in monitoring and evaluating these procedures. It has a "complementary" role to the risk managers even though the scientific information is derived from its competence. There is a functional and

[52] ibid
[53] ibid

institutional separation between RA and RM also though there is close cooperation between them. EFSA has signed separate Memoranda of Understanding with the European Center for Disease Prevention and Control (ECDC) to increase cooperation and exchange scientific information on topics of mutual interest including food safety, control of communicable diseases, infectious diseases prevention and emergency response[54]. Regulation (***EC***), No 882/2004 on official controls, defines tasks, duties, and requirements for all the EU Reference Laboratories (EURLs). EURLs aim to ensure high-quality, uniform testing in the EU and support Commission activities on risk management and risk assessment in the area of laboratory analysis[55]. There were 18 laboratories for animal health and 27 for food and feed under EURLs[56]. EFSA publishes all its scientific outputs, including its scientific opinions, in the EFSA Journal. It also issues a range of supporting publications[57].

5.15 The EU RASFF gathers and coordinates information on food borne hazards and disseminates it rapidly among member states. The system involves surveillance and monitoring, trace back, and an alert broadcast for recalls. It emphasizes support for product testing (both local and imported) off local shelves by state and local authorities in addition to testing of imported food and feed at border and ports (Zach, Doyle et al. 2012).

Risk Communication by EFSA

5.16 Communicating on risks associated with the food chain is a vital part of EFSA's mandate. The messages EFSA delivers not only have to be understood by specialist audiences, such as policymakers, the scientific community, and industry but also, on

[54] https://www.efsa.europa.eu/sites/default/files/assets/mouecdc.pdf
[55] https://ec.europa.eu/food/safety/official_controls/legislation/ref-labs_en
[56] ibid
[57] https://www.efsa.europa.eu/en/publications

a broader level, to be made relevant to the consumers of the European Union. EFSA cooperates with the Member States through its Advisory Forum. The Forum is made up of representatives from each Member State as well as Iceland and Norway, and its members advise the Authority on scientific matters, its work programme, and priorities and also address emerging risk issues as early as possible. In addition to scientific risk assessment issues, the Forum also has an important role to play in coordinating risk communications and messages. This particular aspect of its work is carried out by the Advisory Forum Communications Working Group (AFCWG), which comprises communications professionals from across Europe with expertise in food-related issues. Another important EFSA network in this area is the Advisory Group on Risk Communications (AGRC). The AGRC is made up of experts in the fields of sociology, consumer science, stakeholder relations, psychology, and communications. One of the issues addressed by this group is consumer perception of food and food-related risks. In understanding this more, EFSA can tailor communications appropriately to different target audiences to ensure their needs and concerns are met[58].

5.17 During a food-related crisis or incident, rapid, concise and clear communication is essential to manage the crisis and protect consumers. ***"Best practice for crisis communicators: How to communicate during food or feed safety incidents,"*** EFSA created the guidelines together with the EU Member States based on best practices gained from previous food-related crises and were developed in

[58] https://www.efsa.europa.eu/en/press/news/120711e

cooperation with members of EFSA's AFCWG. The best-practice advice centers on important principles such as[59]:

- Taking control of communicating about a situation.
- Communicating quickly to protect human health.
- Identifying target audiences and the tools to reach them.
- Communicating clearly and transparently.
- Collaborating with partners because food-related crises do not stop at international borders.

3. National Food Control Institutions

A. Canada

5.18 The Canadian government is an excellent example of coordinating multiple agencies in a country efficiently (Committee, 2012). The Minister of Health is responsible for maintaining and improving the health of Canadians. It is supported by the Health Portfolio which comprises Health Canada (HC), Canadian Food Inspection Agency (CFIA), the Public Health Agency of Canada (PHAC), the Canadian Institutes of Health Research (CIHR) and the Patented Medicine Prices Review Board[60].

5.19 The responsibility of the control over all stages of the food chain in Canada is the responsibility of HC, CFIA, and PHAC. Health Canada is responsible for helping Canadians maintain and improve their health. The CFIA is the Government of

[59] https://www.efsa.europa.eu/en/press/news/160315
[60] https://www.canada.ca/en/health-canada/corporate/health-portfolio.html

Canada's largest science-based regulatory agency. It has more than 6000 employees across the country, including scientists, veterinarians, administrative professionals, technical personnel, operational specialists, and many others[61]. PHAC has been created to help protect the health and safety of all Canadians. It also responds to public health emergencies and infectious disease outbreaks.

Risk assessment and Risk Management

5.20 The federal government agencies, HC and the CFIA, work with the provincial and territorial agencies to facilitate national harmonization, streamline the inspection process, and reduce regulatory pressures on industry[62]. HC is responsible for establishing policies, setting standards and providing advice and information on the safety and nutritional value of food. It administers the provisions of Food & Drug Act that relate to public health, safety, and nutrition. It conducts and invests in research to support strategic and evidence-based decision making (RA)[63]. CFIA provides all federal inspection services related to food and enforces the food safety and nutritional quality standards established by HC (RM). There is an institutional separation between RA and RM.

5.21 Primarily, CFIA is under the responsibility of the Minister of Health as of 9 October 2013 for matters concerning the food safety. However, it keeps on helping the Ministry of Agriculture and Agri-Food Canada in issues including trade and non-

[61]http://www.inspection.gc.ca/about-the-cfia/organizational-information/vision-and-mission/relationship/eng/1319480989283/1319481252700
[62]http://www.inspection.gc.ca/about-the-cfia/organizational-information/eng/1323224617636/1323224814073
[63]https://www.canada.ca/en/health-canada/services/food-nutrition/research-programs-analytical-methods.html

food safety activities as well as critical areas of animal health and plant protection. It is responsible for the elaboration of RM and is responsible for enforcing 13 Acts and their regulations (Ghaida, Spinnler, et al. 2014). It gives CFIA the coordinating role in the inspection and control measures among different components of the food chain and different sectors: agriculture, animals, animal feed, retail, and marketing.

5.22 Canada has reorganized its institutional food safety system to ensure a risk analysis that: 1 – Includes the evaluation and monitoring of health status of foodborne diseases at different levels: Federal, states, provincial, regional, territorial and local authorities (which ensure horizontal and vertical risk analysis, among all risk managers and risk assessors and within different levels). 2 – Includes the inspection system of foods including all parts of the food chain in a single agency (which ensure inspection at all levels territorial, provincial and federal and allow for a horizontal and vertical RM among different sectors and within all parts of the food chain). 3 – Ensure food inspection based on RA (when the HC evaluates the surveillance and the control programs of the CFIA) (Ghaida, Spinnler, et al. 2014).

Coordinated approach towards Food safety with Public health authorities including during crisis

5.23 The PHAC, HC, and the CFIA work closely with health authorities to protect the public against diseases following the consumption of food. Therefore, the network of organizations whose purpose is to coordinate work on RA is provided through HC, CFIA, and PHAC who play an essential role in the disease surveillance[64] and

[64] https://www.canada.ca/en/public-health/services/food-safety.html

epidemiological studies at the federal, states, provincial, regional, territorial and local authorities. Although PHAC is the first to be informed about foodborne illness incidence, HC (risk assessors) gains the full power on the prevalence of foodborne illness while working in collaboration with the CFIA (RM) and PHAC.

5.24 For rapid RM crisis management, a Foodborne Illness Outbreak Response Protocol (FIORP) was created in 2010. The FIORP allow public health and food safety authorities across Canada to respond faster, more efficiently and more effectively to national and international outbreaks[65]. During an outbreak, HC undertakes research and laboratory assessments of health risks. It also collaborates with the CFIA and PHAC and provincial regulatory authorities in the epidemiological investigation. Therefore, crisis management in Canada falls under the responsibility of HC. It accomplishes its mission on RA in collaboration with the PHAC and the CFIA although the PHAC is the first to be informed about a crisis. This system leads to rapid crisis management based on RA where the final decision on the crisis management policy falls under the responsibility of the risk assessors.

B. France

5.25 Until 1981, the General Directorate for Food of the French Agriculture Ministry (DGAL) and the General Directorate for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) that were created under the supervision of the Ministry of Agriculture (MOA) was responsible for the food safety. The role of the Ministry of Health (MOH) was limited to the control of the quality of the drinking water. The

[65]http://www.inspection.gc.ca/food/safe-food-production-systems/food-recall-and-emergency-response/fiorp/eng/1337217904403/1337217972172

risk analysis in France was distributed under the responsibility of the MOA, MOH, and the Ministry of Economy (MOE) until the approval of the Law of 1st July 1998 on the increase of sanitary supervision and control of products used by the human. This law created two public institutions. One, the French Agency for Sanitary Security of Health Products (AFSSAPS, now the drug and health products safety agency ANSM) under the supervision of the MOH which evaluates the benefits and risks related to the use of health products including drugs, insecticides, pharmaceuticals, etc. Two, the French Food Safety Agency (AFSSA) under the supervision of the MOH, MOA, and MOE, its mission is to assess the health and nutritional risks including pesticides, veterinary drugs, medicated feed, food, animal feed and others.

Risk Assessment and Risk Management in France

5.26 In 2010, the National Agency for Food, Environmental and Occupational Health and Safety (ANSES) was established. ANSES is the result of the merger of AFSSA and the French Agency for Environmental and Occupational Health Safety (AFSSET). ANSES came under the supervision of the MOH, MOA, MOE, Ministry of Environment (MOEn), and Ministry of Labor (MOL). This agency is responsible for conducting RA in the areas of environmental, labor and food. Its main task are to assess nutritional and health risks and benefits, recommend public health measures, conduct laboratory work and research projects, authorize marketing of veterinary medicinal products and conduct public health monitoring missions[66]. The ANSES assesses exposure to and risks from microbiological hazards and chemical substances

[66]https://cdn.intechopen.com/public/docs/Proceedings_of_the_special_session.pdf

through channels such as food, work, transportation, the environment, indoor and outdoor air quality. It conducts TDSs nationally as per the WHO methodology. The primary aim of TDSs is to monitor exposure of the population to chemical substances present in food, including residues of plant protection products, environmental contaminants, neoformed compounds, natural toxins, additives, trace elements or minerals[67]. They are designed to provide a snapshot of the presence of chemical contaminants in food. Till date, ANSES has conducted three TDSs, the last one specifically targeting children less than three years of age[68], from 2011-2016. It operates 11 laboratories with a number of national, European and international mandate. Every opinion is published on the ANSES website.

5.27 A clear distinction exists between the risk assessment activities of ANSES and the risk management responsibilities of the national Ministry to which it reports. The MOE, the MOA, and the MOH are responsible for the elaboration of RM While the ANSES, the ANSM and the Institute of Public Health (InVS) are responsible for the elaboration of the RA. As provided in art. R.1313-1 of the decree of 28 June 2010, ANSES ensures only close cooperation with risk managers: "The agency is informed by the competent ministries about implemented control programs and surveillance systems and accessed upon its request the results of inspections and controls that have demonstrated a risk falling within its jurisdiction". Although France has adopted a functional separation between RA and RM, it has assured close cooperation between risk assessors and risk managers. The risk managers must inform the ANSES on the results of their inspections and control programs that fall

[67] https://www.anses.fr/en/content/total-diet-studies-tdss
[68] https://www.anses.fr/en/content/diet-studies-better-protection-consumers

within the ANSES jurisdiction. This close cooperation between risk assessors and risk managers is an advanced step than the one adopted by the EC. However, ANSES has no power to access the results of inspections and controls programs of the risk managers unless in case of risk and it has no power to evaluate the RM system including inspections and control programs.

Coordinated approach towards Food safety with Public health authorities

5.28 The law of 1st July 1998 has created the Institute of Public Health (InVS) under the supervision of the Minister of Health is in charge of performing monitoring and constant observation on the states of the population health. Art. L. 792-2 of this law stipulated that the InVS should cooperate closely with other RA agencies (ANSES, ANSM, etc.) and risk managers, where the institute will be the recipient of expertise and evaluation reports, monitoring and inspecting as related to public health and food safety. As with the case of ANSES, the InVS provides the Minister of Health with information on the population health necessary to develop and conduct the health policy. It only issues recommendations to the competent authorities and does not have a role in RM.

5.29 The ANSES is involved in the national public health monitoring and alert systems, in collaboration with InVS, and other directorates of the MOA, MOE, and MOH. It is also involved in these systems at the EU level in collaboration with EFSA, ECDC, and RASFF. Responsibility for risk communication is shared between the ANSES and the ministries as appropriate.

C. United States of America (USA)

5.30 The Pure Food and Drug Act, 1906 led to the promulgation of the Food, Drug, and Cosmetic Act (FD&C Act) in 1938 to address its weaknesses. The FD&C Act required premarketing approval and proof for the safety of drugs (Fortin, 2016). This evolution had increased the responsibilities of the U.S. Bureau of Chemistry which was later on renamed as the Food, Drug and Insecticide Administration that was subsequently renamed in 1930 as the Food and Drug Administration (FDA). In 1940, the FDA was moved from the US department of Agriculture (USDA) to the Federal Security Agency who became in turn in 1953 the Department of Health, Education and Welfare. The institutional system in the USA witnessed development primarily in the provision of evidence for the safety of drugs and the determination of the tolerance rate for toxic chemical materials that could be involved in the food manufacturing (insecticides and drugs).

Risk Assessment and Risk Management in the USA

Food and Drug Administration (FDA)

5.31 The responsibility for food safety is no longer under the supervision of the USDA, but under the FDA that is a branch of the Department of Health and Human Services (HHS). FDA consists of the Office of the Commissioner and four directorates overseeing the core functions of the agency: Medical Products and Tobacco, Foods and Veterinary Medicine, Global Regulatory Operations and Policy, and Operations[69]. FDA inspects manufacturers or processors of FDA-regulated products to verify that they comply with relevant regulations. Those inspected include:

[69] https://www.fda.gov/AboutFDA/Transparency/Basics/ucm192695.htm

vaccine and drug manufacturers, blood banks, food processing facilities, dairy farms, animal feed processors, and compounding pharmacies[70]. The U.S. Food and Drug Administration's Office of Regulatory Affairs (ORA) is the lead office for all agency field activities. ORA inspects regulated products and manufacturers, conducts sample analyses of regulated products and reviews imported products offered for entry into the United States and makes available to the public certain frequently requested records of inspections in an electronic reading room[71]. The responsibility of the USDA over food was reserved to the RM over livestock and livestock products while the RA and RM on all other food products were conferred to the FDA and the US Environmental Protection Agency (EPA).

US Department of Agriculture (USDA)

5.32 The USDA has twenty-nine agencies within its ambit including includes the Animal and Plant Health Inspection Service (APHIS), the Food Safety Inspection Service (FSIS), Food & Nutrition service (FNS), Centre for Nutrition Policy and Promotion (CNPP) etc[72]. Whereby, the APHIS protects the animal and plant resources of the nations and carries out meat and inspection program and the FSIS ensures that the nation's commercial supply of meat, poultry and egg product is safe. CNPP works to improve the health and well-being by developing and promoting dietary guidance that links scientific research to the nutrition needs of consumers. FNS increases food security and reduces hunger in partnership with

[70] ibid

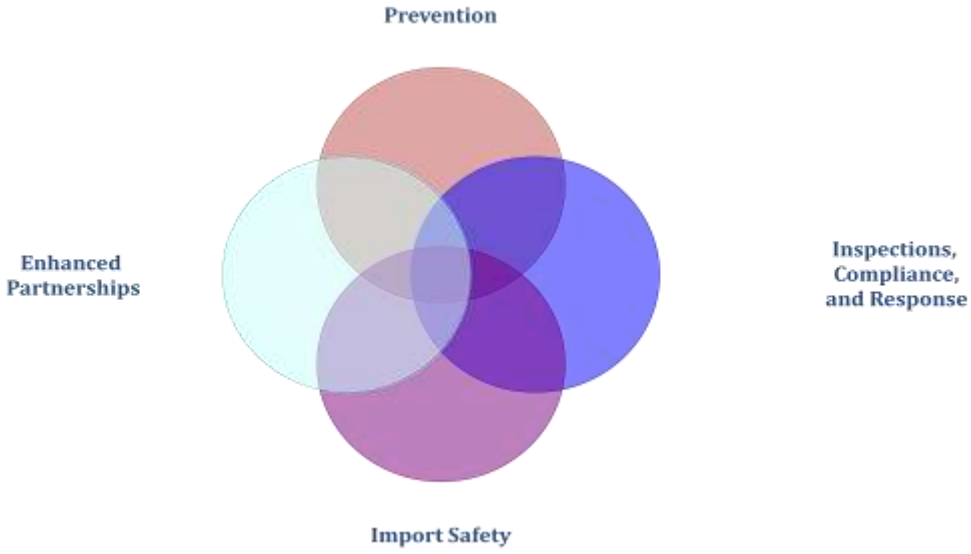
[71] https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/ucm2018295.htm

[72] https://www.usda.gov/our-agency/agencies

cooperating organizations by providing children and low-income people access to food, a healthy diet, and nutrition education.

5.33 The USA enacted the new Food Safety Modernization Act (FSMA) that was signed by President Obama on 4 January 2011(Food and Administration 2011). Instead of reorganizing the institutional system, the FSMA has restructured the previous functional food safety system. This Act emphasized on the coordination between various agencies responsible for the elaboration of risk analysis and the main themes of the legislation are: prevention; enhanced partnerships; inspection, compliance and response; and import safety (**Figure 12**).

Figure 12: Main themes of FSMA



Source: https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247546.htm

5.34 Moreover, it has stressed on the role of the Centres for Disease Control and Prevention (CDC) and the EPA as an important response to foodborne outbreaks.

Therefore, there is no institutional separation or separation between RA and RM. The HHS is primarily responsible for the elaboration of RA and RM of most foodstuffs. But control measures are distributed mainly among FDA and USDA. The FSMA tried to fill the gaps between these two central agencies and the CDC and EPA.

5.35 The FSMA has constructed a formal system of collaboration between the HHS, the Secretary of Agriculture, the CDC and the FDA, the Secretary of the Homeland Security and the EPA to provide a new food safety system based on hazard analysis and risk-based preventive controls measures as indicated below[73]:

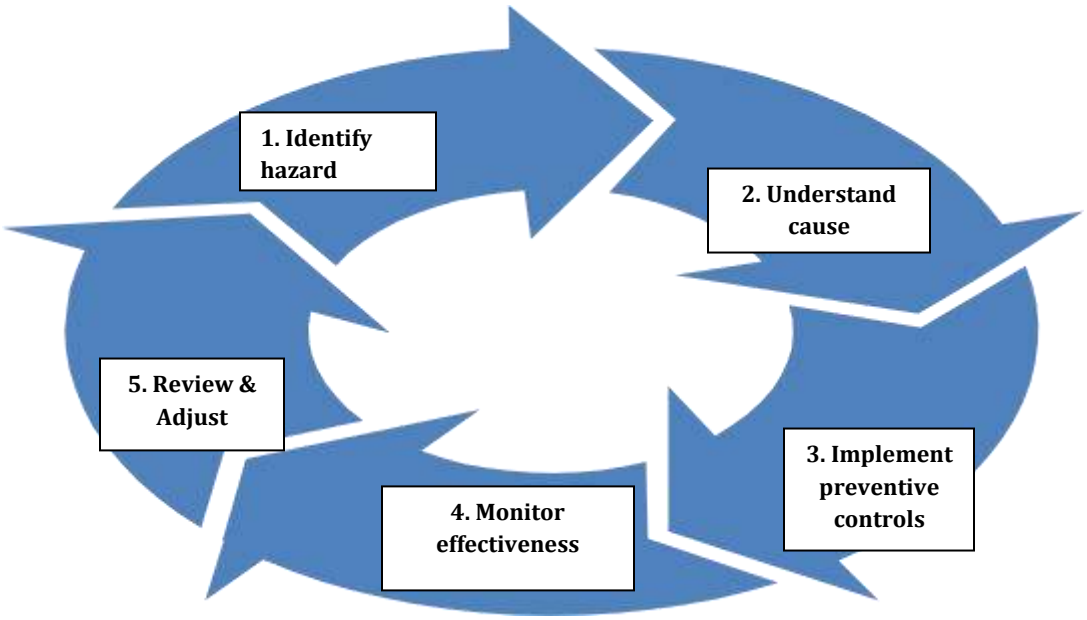
- Reliance on inspections by other agencies that meet standards
- State/local and international capacity building
- Improved foodborne illness surveillance
- National agriculture and food defense strategy
- Consortium of laboratory networks
- Easier to find recall information

5.36 Thus, FSMA has adopted a new approach based on monitoring of foodborne diseases and epidemiological studies through collaboration between federal agencies and activities of states, regional, territorial and local authorities. Here the investigations on foodborne illness are necessary for the hazard analysis and risk-based preventive controls measures and general approach to control is followed (**Figure 12**). Similarly, the Act established food and agricultural coordinating councils that improve coordination between federal, state, local and private sector

[73] https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247546.htm

on the preparation, communication and action plan in the field of agriculture and food defense. Therefore, this network whose purpose is to coordinate work on RA is mainly entrusted to the HHS through the CDC and the FDA. The CDC and FDA mission is to collaborate with the Secretaries of the Agriculture and the Homeland Security and to play an important role in disease surveillance at the federal, states, regional, territorial and local authorities.

Figure 13: General approach to controls[74]under FSMA



Source: www.fda.gov

5.37 The Sec. 2811 of the Bioterrorism Act of 2002 concerning the coordination of preparedness for response to public health emergencies, entrusted the Secretary of the HHS to coordinate: "(i) interagency interfaces between the Department of HHS and other departments, agencies, and offices of the United States; and (ii) interfaces

[74] www.fda.gov Food/Guidance Regulation/FSMA/ucm247546.htm

between the Department and State and local entities with responsibility for emergency preparedness". The purpose of this provision is to assure a smooth horizontal and vertical administration of food emergency preparedness between the federal agencies responsible for ensuring food safety and the states, local and regional authorities. As also provided with the Sec. 313: "the Secretary of the HHS shall through the Commissioner of Food and Drugs, the Director of the CDC and the Secretary of Agriculture coordinate the surveillance of zoonotic diseases."

5.38 Therefore, the Bioterrorism Act has entrusted the HHS to coordinate among agencies responsible for the elaboration of food RA and RM going from the fact that the HHS is responsible for the security of the Public Health. Moreover, with the enactment of the FSMA, the Homeland Security during crisis has been given a role to serve as a focal point for the coordination among governmental agencies without having any part on RA and RM. It is clear that the USA, has entrusted the rapid food crises management to the HHS through the FDA and the CDC along with the collaboration of the USDA, EPA and Homeland Security.