FROM 'FORK TO FARM'- FOOD SAFETY, TRACEABILITY, AND RECALL REGULATION IN INDIA AND U.S.A

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Abstract

In global trade and economics, food has been a seminal commodity and transparency is increasingly recognised as a cherished attribute of the global food supply chains. While articles of food are traded like any other commodity, the dynamics of international agri- food trade unveil profound socio-economic effects, including the incidence of foodborne diseases. While food systems proclaim the effective implementation of the 'farm to fork' traceability as a means to ensure transparency and food safety in food supply chains, it is only after a determination or suspicion of tampering with the safety or quality aspects of food, that the traceability exercise is undertaken which usually goes in the reverse direction i.e., from 'fork to farm'. As a risk assessment and management tool, traceability furthers the mandate of law enforcement in facilitating and targeting the recall or removal/ withdrawal of the unsafe articles of foods. In this milieu, this research is galvanised around an appraisal of the food safety, traceability, and recall regulation in India and the United States of America (U.S.A), along with an identification of the gaps, and recommendations for the way forward.

Keywords *: Food Safety, Food Laws, Traceability, Food Recalls, Regulation, Food Fraud*

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I. Introduction

IN A press release dated October 8, 2018, Carrefour, the international food retailer, became the first company to have integrated blockchain technology[1] in its supply chain for European food tracing ("Blockchain technology makes it easier to record events along the supply, processing, packaging and distribution chain."[2]). Through this concerted network between the manufacturers and the distributors, the essential product safety information, like "traceability information" apropos the origin and quality of the product, composition and nutritional claims, raw materials and their safety for the presence of any allergens, etc.[3] that benefits the consumers can be communicated. The firm has now expanded that service, which initially only covered chicken and tomatoes, to comprise Carrefour Quality Line (CQL) fresh micro-filtered full-fat milk. This has enabled checking by the consumers the exact location of the farms through the utilisation of the GPS coordinates, the time of packing and transportation, that the milk lives up to its advertised/ labelled claims; that the cows are fed Genetically modified organisms (GMO)-free food, reared on reasonably spacious farms, employing best livestock safety practices.[4]

With the rising agri-food[5] trade internationally, food safety, quality, and traceability has become a high priority globally.[6] Foodborne diseases, both local and transnational, have become a major concern worldwide.[7] The scale and ramifications of these diseases has changed through the ages,

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[1] A. Wright and P.D. Filippi, *Decentralised Blockchain Technology and the Rise of Lex Cryptographia* 4–5, 5 (March 12, 2015). Blockchain technology, is also referred to be "a distributed, shared, encrypted database that serves as *an irreversible and incorruptible public repository of information*…. enables, for the first time, unrelated people to reach consensus on the occurrence of a particular transaction or event without the need for a controlling authority [emphasis supplied]."

[2] Carrefour-Press Release, "Food traceability: Carrefour, a blockchain pioneer in Europe, has joined the IBM Food Trust platform to take action on a global scale", October 8, 2018, *available at*: https://www.carrefour.com/sites/default/files/2019-12/carrefour_press_release_81018_eng.pdf (last visited on January 21, 2021)

[3] *Ibid.*

[4] Mark Barley, "Carrefour extends blockchain traceability to milk" *Ledger Insights*, March, 2019, *available at*: https://www.ledgerinsights.com/carrefour-blockchain-food-traceability-milk/ (last visited on January 21, 2021).

[5] European Commission, "Agri-food Trade Statistical Factsheet", Directorate-General for Agriculture and Rural Development, *available* at: https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/farming/documents/agrifood-south-caucasus-3_en.pdf (last visited on January 21, 2021) - "Agri-food commodities" comprise the products enlisted in Annex 1 of the WTO Agreement on Agriculture along with the fish and fish products.

[6] Confederation of Indian Industries and GS1 India, "Food Traceability in India", 2017-18, *available at*: http://face-cii.in/sites/default/files/final_report-version_2.pdf (last visited on January 21, 2021) - Examples from other parts of the world with retail firms integrating "traceability" are Vartini Packing Company in Peru, METRO group in Europe, "IT-enabled barcode traceability systems" by ITC Spices in India.

[7] T. Yamaguchi and Shun-Nan Chiang, "Food Safety in a Global Economy: Policies and Social Issues" *Oxford Research Encyclopedia of Environmental Science* (Oxford University Press, December 23, 2019).

across regions and countries.[8] History demonstrates that the prospects for adulteration and food fraud increased with a subsequent increase in the number of links in the food supply chain and the miles travelled by the impugned articles.[9] Today, information asymmetry, between the consumers and the food they consume, permeates the global food supply chains, making them more susceptible to foodborne morbidity and mortality.[10]

In fact, today food safety is not simply a cause of concern for the consumers, the food businesses and the regulatory agencies of a particular nation. It is a universal fundamental right of all the citizens of the world. The right to food- and its implicit corollary, the right to safe food, was recognized as a fundamental human right and a binding obligation under the international law, as declared in the Universal Declaration of Human Rights as well as in the International Covenant on Economic, Social and Cultural Rights (ICESCR).[11] In 1992, the Food and Agriculture Organisation (FAO) of the United Nations and the World Health Organization (WHO) jointly recognized that access to safe and adequate food in terms of nutritional values is the right of each individual. Thus, right to safe food is derived from other universal fundamental rights such as the right to life,[12] human dignity, [13] the right to protection of health and the right of consumers to protection.[14]

In this milieu, this article intends to undertake an appraisal of the food safety, traceability, and food recall regulation in India and the United States of America (U.S.A.), along with an identification of the gaps, and recommendations for the way forward. This is germane considering that food businesses use various controls to safeguard the safety of their products. Despite employing all the safety nets, however, sometimes unsafe articles of food, or those that do not meet the legislative requisites, reach the market or with the consumers. When an unsafe

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[8] *Ibid.*

[9] Neal Fortin, "The U.S. Food Safety Modernisation Act: Implications in Transnational Governance of Food Safety, Food System Sustainability, and the Tension with Free Trade" 25(2) *Duke Environmental Law and Policy Forum* 314-336 at 313, 320 (2015); C. Coglianese, A. M. Finkel, *et.al.* (eds.), *Import Safety: Regulatory Governance in the Global Economy* (Penn Press, United States, 2009).

[10] Mariela Maidana- Eletti, "The Promises and Perils of the TBT Agreement: Food Quality, Food Labelling, and Market Access" 12 *New Zealand Yearbook of International Law* 65-76 (2014).

[11] S. Söllner, "The 'Breakthrough' of the Right to Food: The Meaning of General Comment No. 12 and the Voluntary Guidelines for the Interpretation of the Human Right to Food" 11 *Max Planck Yearbook of United Nations Law* 391–415 at 404 (2007).

[12] The Universal Declaration of Human Rights, 1948, art. 3; The European Convention on Human Rights, art. 2; The International Covenant on Civil and Political Rights, 1966, art. 2; The Treaty of the European Constitution, art. 11-62.

[13] The Universal Declaration of Human Rights, 1948, Preamble; The International Covenant on Economic, Social and Cultural Rights, 1966, art. 13.1.

[14] Miguel Angel Recuerda Girela, "Food Safety: Science, Politics and the Law" 1 *European Food and Feed Law Review* 33 (2006).

or violative article of food has left the control of any of the actors in the food supply chain, it must be traced, removed or recalled or withdrawn from the market. The exercise is vital for attaining the highest standard of public health, a core state obligation enunciated under General Comment 14, under article 12 of the ICESCR.[15]

The United States (U.S.) food-safety regulation is mainly administered by the Food and Drug Administration (USFDA) in the Department of Health and Human Services and the U.S. Department of Agriculture (USDA), although several other federal and State agencies play an important role.[16] The USFDA has been established under the Federal Food, Drug, and Cosmetic Act, 1938 (FFDCA), and regulates "the safety of all domestic and imported foods except meat and poultry". The Food Safety Inspection Service (FSIS) under the USDA regulates "meat, poultry, some egg products, and catfish".[17] The Food Safety Modernisation Act (FSMA), signed into law in January, 2011, is a major reform of the food regulatory powers of the USFDA since 1938.[18] Its implementation has been hailed to have reoriented the role of the USFDA from a "response-based or reactive intervention" to a "preventative" one in addressing food safety issues.[19]

In India, before 2006, food regulation was governed under the Prevention of Food Adulteration Act, 1954 (PFA) and several specific product orders like the Fruit Products Order, 1955, the Milk and Milk Products Order, 1992, etc. In 2006, the Indian food regulatory framework underwent a complete regulatory overhaul with the enactment of the Food Safety and Standards Act, 2006 (FSSA), which repealed and replaced the PFA and eight product orders.[20] The FSSA regulates the entire supply chain from labelling, manufacturing, packaging, distribution, sale, storage, and import and caters to the changing requirements of the food industry. It initiated harmonization of the Indian food regulation as per the international food safety standards[21], formulated by various international organizations like the Codex Alimentarius Commission

[15] UNs Committee on Economic, Social, and Cultural Rights, UNs Economic and Social Council, *General Comment 14 Substantive issues arising in the implementation of the International Covenant on Economic, Social, and Cultural Rights: The right to right to the highest attainable standard of health (article 12)*, E/C.12/2000/4, May 11, 2000.
[16] R. Johnson, "Report- RS22600-The Federal Food Safety System: A Primer" (December, 2016); United States Government Accountability Office, "GAO-11-289- Federal Food Safety Oversight" (March, 2011).
[17] *Ibid.*
[18] Renée Johnson and Agata Dabrowska, "CRS Report No. IF10974-Proposed Reorganisation of U.S. Federal Food Safety Agencies" (September, 2018).
[19] Carissa Cruse, "Food Fraud and the Food, Drug, and Cosmetic Act: Bridging a Disconnect" 74(2) *Food and Drug Law Journal* 322-347, 335 (2019).
[20] The Food Safety and Standards Act, 2006 (Act 34 of 2006), Second Schedule and s. 97.
[21] *Id.,* Statement of Objects and Reasons.

(CAC), the International Animal Health Organisation (*Office International des Epizooties*- OIE) etc. to facilitate the smooth conduct of the world agri-food trade.[22] Such standards are germane owing to the twin effects exhibited by the food safety measures in touching upon both the trade and public health. This facet has been acknowledged by both the CAC and the World Trade Organisation (WTO);[23] however, the regulatory purviews pursued by both are quite different. While the WTO focusses on the trade effects of these measures, the Codex concerns itself with their role in the protection of human health.[24] The nexus between these two organisations and their work domains is further bolstered by the fact that the Agreement on the Application of Sanitary and Phytosanitary Measures (AoSPS), under the aegis of the WTO, refers to the CAC, along with the OIE for animal health, and the Food and Agriculture Organisation's (FAO) Secretariat of the International Plant Protection Convention (IPPC) for plant health, as the "three sister" organisations which are the relevant international standard-setting bodies of the WTO.[25]

Under the FSSA, the Food Safety and Standards Authority of India (FSSAI) is responsible to take into account international standards and practices, while framing national regulations. As per Section 16 (3) (m) of the FSSA, coherence and consistency are required to be promoted by the FSSAI between the international and domestic food/ technical standards. Further, section 18 (2) (a) makes it obligatory for the FSSAI to contemplate on the international standards and practices (where they exist or are a work in progress) while framing the domestic regulations or specifying the national food safety standards.

This article is structured in the ensuing manner. To lay the groundwork, Part II serves as a backgrounder to the phenomenon of food fraud and the importance of food safety laws. Part III then proceeds to provide an overview of the importance of transparency in the food supply chain and the vitality of traceability mechanisms. The discourse in Part IV is focussed on the regulatory framework of food traceability mechanisms in India and the USA. Considering the importance of recall regulation to the execution of the rationale of traceability, Part V offers

[22] Food and Agriculture Organisation of the United Nations and World Health Organisation, "Understanding Codex" (FAO, 5th ed., 2018).
[23] The Food and Agriculture Organisation of the United Nations and the World Trade Organisation, "Trade and Food Standards" (FAO and WTO, 2017) .
[24] Lee Ann Jackson and Marion Jansen, "Risk assessment in the international food safety policy arena: Can the multilateral institutions encourage unbiased outcomes?" *WTO Staff Working Paper ERSD-2009-01*, January, 2009 (last visited on January 21, 2021).
[25] Terence P. Stewart and David S. Johanson, "The SPS Agreement of the World Trade Organisation and International Organisations: The Roles of the Codex Alimentarius Commission, the International Plant Protection Convention, and the International Office of Epizootics" 26(1) *Syracuse Journal of International Law and Commerce* 27-54 (1998).

comparative insights into the regulatory mechanisms in India and the USA. The author winds up in Part VI with an explication of the challenges in the implementation and the way forward.

II. Transnational Food Fraud and Adulteration

Food has had a long association with crime.[26] With the rising wave of liberalisation of agri-food markets, the assurance of food quality and safety has become a major concern and landed the consumers globally in a precarious position.[27] Transnational food adulteration or fraud, including economically motivated adulteration (EMA) and other categories of organised food crime(s), endangers food safety and constitute "the deliberate substitution, addition, adulteration or misrepresentation of food or food ingredients for economic gain".[28] As per the International Food Safety Authorities Network (INFOSAN), which is a "global network of national food safety authorities" administered by both the FAO and the WHO together,[29] with the global nature of agri-food supply chains, adulterated food channeled into the international trade from one country, has the potential to trigger morbidity and mortality in other countries, owing to their food safety failure(s).[30] As food travels from 'farm to the fork' or 'from boat to plate', and so on, the prospects for adulteration and fraud multiplies with every point in the food chain. Imported food can, thus, pose danger, or be lethal more than one can imagine.[31]

In the USA, in 2015, more than nine hundred people in forty states became sick with *Salmonella* poisoning, and two hundred were hospitalised resulting in six mortalities.[32] The outbreak was linked to cucumbers imported from Mexico. In India, between June and September 2015, nine types of variants of Maggi noodles were ordered, by the FSSAI to be recalled by Nestlé from the Indian market for the alleged presence of Mono Sodium Glutamate (MSG) and lead (in excess of

[26] H. Croall, "Food Crime: A Green Criminology Perspective" in N. South and A. Brisman (eds.), *Routledge International Handbook of Green Criminology* 167-183 (Taylor & Francis, London, 2013).
[27] C. Coglianese, A. M. Finkel, *et.al.* (eds.), *Import Safety: Regulatory Governance in the Global Economy* (Penn Press, United States, 2009).
[28] C.S. Tibola, S. A. da Silva, *et.al.*, "Economically Motivated Food Fraud and Adulteration in Brazil: Incidents and Alternatives to Minimise Occurrence" 83 *Journal of Food Science*, 2028-2038 (2018).
[29] The Food and Agriculture Organisation of the United Nations and the World Health Organisation, "INFOSAN: Connecting Food Safety Authorities to Reduce Foodborne Risks", *available at*: https://www.who.int/foodsafety/fs_management/infosan_brochure_en.pdf?ua=1 (last visited on January 21, 2021).
[30] Benn McGrady and Christina S. Ho, "Identifying Gaps in International Food Safety Regulation" 66(2) *Food and Drug Law Journal 183-202 (2011)*.
[31] Alexia Brunet Marks, "The Risks We Are Willing to Eat: Food Imports and Safety" 52 *Harvard Journal on Legislation* 125 (2015).
[32] Healthline Editorial Team, "Worst Foodborne Illness Outbreaks in Recent U.S. History" *Healthline*, February 6, 2017, *available at*: https://www.healthline.com/health/worst-foodborne-illness-outbreaks#prevention (last visited on January 21, 2021).

the permitted amounts).[33] Approximately thirty-eight thousand tonnes of noodles were collected by Nestlé from retail supplies. This was followed by their destruction in incinerators at eleven cement plants across India.[34] In 2016, a joint international Europol-Interpol operation, "Opson V", spanning across fifty-seven countries across the world, seized, checked, and investigated more than eleven thousand tonnes of counterfeit articles of food and drinks.[35] The operation included within its remit substandard and mislabelled products like monkey meat, misbranded and bland whiskey, cheaper and substituted seafood, "copper sulphate solution" painted olives, etc.[36]

Such incidents underscore the importance of food safety and as a corollary, mapping/ tracing the food supply chains.[37] As an assurance that food is acceptable for human[38] and animal consumption, food safety averts any exposure to food frauds and foodborne illness outbreaks therefrom. From a purely legal perspective, ensuring food safety hinges on the effective implementation of the traceability frameworks. Such a system facilitates the utilization of proactive, preventative, and remedial instruments for regulating food safety along the supply chain.

While there is no statutory recognised or stipulated definition of "food fraud",[39] some global initiatives, like the aforementioned operations by Europol, then the Michigan State University's (MSU) "Food Fraud Initiative" (MSU-FFI) in the U.S.A. etc. have developed the requisite terminology, tools, and been furthering collaboration to tackle and reduce its incidence.[40] Furthermore, based on the incidence of some high-stake food scandals, some databases and tools for the collation and scrutiny of the data also hold the ground.[41] For instance, the databases

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[33] *M/s Nestle India Limited* v. *The Food Safety and Standards Authority of India*, 2016(3)ALLMR 497, High Court of Bombay; *Nestlé India Limited* v. *Union of India*, (2016) 13 SCC 745.
[34] Sounak Mitra, "The Maggi ban: How India's favourite two-minute noodles lost 80% market share" *Livemint,* February 16, 2017, *available at*: https://www.livemint.com/Companies/1JKHsutTXLWtTcVwdIDg0H/The-Maggi-ban-How-Indias-favourite-twominute-noodles-lost.html (last visited on January 21, 2021).
[35] Europol, "Food fraud: Joint Europol-INTERPOL Operation OPSON V Results Report", (October, 2016) *available* at: https://www.europol.europa.eu/newsroom/news/food-fraud-joint-europol-interpol-operation-opson-v-results-report (last visited on October 29, 2020).
[36] *Id.* at 48.
[37] S. Setboonsarng, J. Sakai, *et. al.*, "Food Safety and ICT Traceability Systems: Lessons from Japan for Developing Countries" *ADBI Working Paper 139*, *available at*: http://www.adbi.org/working-paper/2009/05/28/3012.ict.food.traceability.system/ (last visited on January 21, 2021).
[38] The Food Safety and Standards Act, 2006 (Act 34 of 2006), s. 3 (1) (q).
[39] A. Wisniewski and A. Buschulte, "Dealing with Food Fraud: Part 1," 14(1) *European Food and Feed Law Review* 6-14 (2019).
[40] *Supra* note 19.
[41] J. Spink, B. Bedard, *et.al.*, "International Survey of Food Fraud and Related Terminology: Preliminary Results and Discussion" 84(10) *Journal of Food Science* 2705-2718, 2707 (2019).

developed by the US Pharmacopeial Convention (USP) and the Food Fraud Network of the European Commission. The USP states: "food fraud in the context of food ingredients refers to the fraudulent addition of non-authentic substances or removal or replacement of authentic substances without the purchaser's knowledge for economic gain of the seller.".[42] The MSU-FFI defines it as: "a collective term encompassing the deliberate substitution, addition, altering, or misrepresentation of articles of food, its ingredients, or packaging; or untruthful or deceptive claims made about a product for economic gain.". [43]

III. Food Safety through Traceability

Information empowers and emancipates. Access to information is an essential step in ensuring transparency and accountability in government systems and processes. Transparency is a highly regarded value, a precept enabling the public to gain information about the operations, attributes and functions of a given entity.[44] Dissemination of vital information oils the wheels of trade and commerce. Like sunlight, it serves as the best disinfectant[45] and eradicates the germs of deception, distortion, and fraud. For these reasons, transparency is increasingly recognised as a cherished and inevitable attribute of food supply chains. The reason for this increased attention is clear: consumers repose their trust in the food systems and expect safe and wholesome articles of food. An offshoot of this expectation is the existence of a robust food safety legal apparatus that underscores the rapid and precise identification, detection, positioning, and removal or withdrawal and recall of unsafe or adulterated articles of food. This is made possible through supply chain transparency and traceability *viz.* integrating traceability systems in the food supply chains.

Generally, food safety systems proclaim the effective implementation of the 'farm to fork' strategy and its variants ('boat to plate' or 'stable to the table' etc.) as a means to ensure transparency in the food supply chains. It is also argued that such a strategy is a precursor to the

[42] *Id.,* at 2708.
[43] *Id.,* at 2709.
[44] David Heald, "Varieties of transparency" in Christopher Hood and David Heald (eds.), *Transparency: The Key to Better Governance?* 23-45, 26 (Oxford: Oxford University Press, 2006); B. I. Finel and Kristin M. Lord, "The Surprising Logic of Transparency" 43 *International Studies Quarterly* 315–39, 316 (1999).
[45] A phrase used by Justice Louis Brandeis of the Supreme Court of the United States of America to emphasise upon the significance of transparency in governance. Louis D. Brandeis, *Other People's Money* 62 (1914) cited in S. Rajagopalan, "'Sunlight's the Best Disinfectant': A Review of the Right to Information Act, 2005" *Delhi Law Review* 46-72 (2005).

invocation of remedial measures like, detention, food recalls, etc. for ensuring the 'safety' of the articles of food. However, it is only after a determination or suspicion of tampering with the safety or quality aspects of food, that the traceability exercise is undertaken which usually goes in the reverse direction i.e., from 'fork to farm'. Here 'fork' could be either the point of consumption or any other point in the food supply chain to the 'farm' which could be any of the previous point(s) in the supply chain.

Traceability emerged in the mid-1930s in Europe for high-value food, as per one strand of history. Thus, the age-old method of classification and labelling of French wine and champagne points to its origins.[46] It is, per se, not an indicator of safety or quality attributes of a food product. But it plugs information asymmetry should there be a determination or suspicion of tampering with the safety or quality aspects of food. According to a study published by the *Harvard Business Review*, *"…Companies are under pressure from governments, consumers, NGOs, and other stakeholders to divulge more information about their supply chains, and the reputational cost of failing to meet these demands can be high. For example, food companies are facing more demand for supply-chain-related information about ingredients, food fraud, animal welfare, and child labour…"*[47] In this way, traceability enables the sharing of information about the provenance, safety, efficiency and sustainability of articles of food and food supplies.[48] It is a growing business imperative and requires the firms to be able to identify, at any specified stage of the food supply chain (from production to distribution) from where the food originated (one step back) and to the points where the food travelled (one step forward), the commonly known "one-up, one-down' approach (OUOD).[49]

Defining Traceability

[46] M. Fourcade, "The Vile and the Noble: On the relation between Natural and Social Classifications in the French Wine World" 53(4) *The Sociological Quarterly* 524-545 (2012); M. Power, "Infrastructures of Traceability" in M. Kornberger, G. Bowker, *et. al.* (eds.) *Thinking Infrastructures. Research in the Sociology of Organisations* 115-130 (Emerald Group Publishing Limited, Bingley, UK, 2019).

[47] Alexis Bateman and Leonardo Bonanni, "What Supply Chain Transparency Means" *Harvard Business Review*, August 20, 2019, *available at*: https://hbr.org/2019/08/what-supply-chain-transparency-really-means (last visited on January 21, 2021).

[48] World Economic Forum, "Innovation with a Purpose: Improving Traceability in Food Value Chains through Technology Innovations" (January, 2019), *available at*: http://www3.weforum.org/docs/WEF_Traceability_in_food_value_chains_Digital.pdf (last visited on January 21, 2021).

[49] L. Ruiz-Garcia, G. Steinberger, *et.al.*, "A Model and Prototype Implementation for Tracking and Tracing Agricultural Batch Products along the Food Chain" 21(2) *Food Control* 112-121 (2010).

The International Organisation for Standardisation (ISO), an autonomous non-governmental international standard-setting organisation, defines 'traceability' as meaning to "*trace the history, application and location of that which is under consideration, and for products this can include the origin of materials and parts, the processing history and the distribution and location of the product after delivery.*".[50]

International food traceability standards are set through the CAC. Traceability/product tracing is defined by the CAC as: "The traceability/product tracing tool should be able to identify at any specified stage of the food chain (from production to distribution) from where the food came (one step back) and to where the food went (one step forward), as appropriate to the objectives of the food inspection and certification system.". [51] The FAO defines traceability as "*the ability to discern, identify and follow the movement of a food or substance intended to be or expected to be incorporated into a food, through all stages of production, processing and distribution.*".[52]

The adoption of these principles is underpinned by national and international regulations. For instance, the European Parliament and the Council of European Union (EU) define 'traceability' as "*ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.*".[53]

The common denominators from these definitions emerge out as follows (Author's analysis):

Table 1: Author's Analysis of the Definitions of 'Traceability'

FOOD TRACEABILITY	**Task/ Function**	Trace (ISO and EU) the history, application and location (ISO); Origin of materials and parts, the processing history and the distribution and location of the product after delivery; and follow (FAO, EU, and Codex) the movement (FAO and Codex); Discern, identify and follow (FAO)
	Rationale	Provide information on what they are made of and what has happened to them (ISO)
	Coverage	Food, feed, food-producing animal or substance intended to be, or

[50] International Organisation for Standardisation, "ISO-12875-Traceability of finfish products-Specification on the information to be recorded in captured finfish distribution chains" (September, 2011), *available* at: https://www.sis.se/api/document/preview/913736/ (last visited on January 21, 2021)
[51] Joint Food and Agriculture Organisation (FAO) and World Health Organisation (WHO) Food Standards Programme, *Codex Alimentarius: Food Import and Export Inspection and Certification Systems* 79- 81 (FAO, 3rd ed., Rome, 2007)
[52] Food and Agriculture Organisation of the United Nations, *Food Traceability Guidance* (Santiago, 2017).
[53] Regulation (EC) No. 178/2002, art. 3 (15) (January 28, 2002).

		expected to be incorporated into a food or feed; (FAO, Codex, and EU)
	Application	Through the distribution chain from origin to destination and vice versa (ISO); All stages of production, processing and distribution (FAO, Codex, and EU)
	Drivers/ Outcomes	Food safety, quality and labelling (ISO)

IV. Food Traceability Perspectives in India and the USA

In the U.S.A, the Public Health Security and Bioterrorism Preparedness and Response Act, 2002 (Bioterrorism Act) incorporated the recordkeeping requirements for the imported food products. It was enacted to prevent, prepare for, and respond to[54] any bio-terrorism threat to the nation's food supply. The legislation is directed at the safety of food imports and increased the powers of the USFDA to ensure safe food supply in collaboration with the U.S. Customs and Border Protection (CBP). It introduced significant amendments to the FFDCA, the parent law on food safety and standards, to integrate recordkeeping as a measure to ensure food traceability. Both the FFDCA and the Bioterrorism Act do not define "bioterrorism". The US Centres for Disease Control and Prevention defines "bioterrorism" as "*a biological attack, or bioterrorism, is the intentional release of viruses, bacteria, or other germs that can sicken or kill people, livestock, or crops*.".[55]

Under the Indian law, the FSSA stipulates that no person shall import into India, *inter alia,* any unsafe or misbranded or sub-standard food or food containing extraneous matter.[56]FSSAI regulates the import of articles of food to ensure their safety. The procedure and requirements for food imports are enumerated in the Food Safety and Standards (Import) Regulations, 2017 (FSSI).

Recordkeeping for Traceability

[54] The Public Health Security and Bioterrorism Preparedness and Response Act, 2002, The Preamble.
[55] U.S. Department of Health & Human Services, "Definition- Bioterrorism" *Centers for Disease Control and Prevention*, *available at*: https://www.cdc.gov/anthrax/bioterrorism/index.html (last visited on January 21, 2021).
[56] The Food Safety and Standards Act, 2006 (Act 34 of 2006), s. 25.

The USFDA has the access to and copy of all the records relating to any article of food which may be adulterated[57] and presents a threat of "*serious adverse health consequences or death to humans or animal*" (SAHCODHA).[58] Furthermore, in pursuance of the responsibility of regulating food safety and traceability it facilitates the identification of the immediate previous sources (one step back) and the immediate subsequent recipients of food (one step forward), including its packaging. In this regard, the persons who manufacture, process, pack, transport, distribute, receive, hold, or import food have been mandated to establish and maintain records for a period not longer than two years to address credible threats of SAHCODHA.[59]

The Food Safety and Standards (Food Recall Procedure) Regulations, 2017 (FSSR) stipulates comprehensive tracking of all the constituents of the food supply chain.[60] In pursuance of the same, a Food Business Operator (FBO) is mandated to maintain food distribution records which include granular details pertaining to the names and addresses of suppliers and customers, nature of food, date of purchase, date of delivery, lot number, batch code, pack size, brand name, date of manufacture, date of expiry and best before date. Such records are to be maintained for a period of one year from the best before date or the expiry date, as applicable. To tackle any deviance therefrom, the FSSA affixes liability on the manufacturers, packers, wholesalers, distributors and sellers of the articles of food if they fail to meet the requirements of the law.[61] It is obligatory for an FBO to maintain proper recording system consisting of accurate records of recovered food and of disposition, in consequence of a recall exercise.[62]

Notice to the States

Under section 908 of the FFDCA, the USFDA, based on credible evidence or information, is mandated to give notice of any shipment of imported food posing a threat of SAHCODHA to all the States where the food is held or will be held, and to the States in which the manufacturer, packer, or distributor of the food is located.

[57] The Federal Food, Drug, and Cosmetic Act, 1938, s. 414 (a).
[58] The Public Health Security and Bioterrorism Preparedness and Response Act, 2002, s. 303 (a).
[59] The Federal Food, Drug, and Cosmetic Act, 1938, s. 414 (b).
[60] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 6.
[61] The Food Safety and Standards Act, 2006 (Act 34 of 2006), s. 27.
[62] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 10.

In India, the FSSAI shall alert all import points to maintain vigil on imports of products manufactured by the same company or similar products imported by the same importer or Custom Brokers.[63]

Some other federal legislations concerning food traceability are outlined in Appendix-I.

Other Food Traceability Systems in India

The law endows the Indian food regulator with the "*trace, alert and recall*" tools[64] at all levels of a food supply chain to regulate the safety of both the domestic as well as the imported articles of food. In *Swami Achyutanand Tirth* v. *Union of India,*[65] the Hon'ble Supreme Court of India observed as follows:

> The Food Authority shall be guided by the general principles of food safety, such as, risk analysis, risk assessment, risk management, risk communication, transparent public consultation, protection of consumers' interest, etc.

In view of the foregoing observations, it can be inferred that as a risk-assessment and management tool, traceability furthers the mandate of law enforcement in facilitating and targeting the recall or removal/ withdrawal of foods.[66] It plays a vital role in the investigative efforts of the food safety officers excavating the root causes of foodborne illnesses and epidemics. However, these observations are directed at the "FSSAI/ Food Authority" which has regulatory oversight on the entire food supply chain apropos the domestic and the imported food articles and does not regulate the food exports for their 'safety'. As a result, it does not indulge in ensuring the 'farm to the fork' or 'fork to farm' traceability of the articles of food that are exported from India.[67]

Nonetheless, the Agricultural and Processed Food Products Export Development Authority (APEDA) under the Ministry of Commerce and Industry, Government of India, has developed six web-based traceability systems for the exports of certain food products. These are the

[63] The Food Safety and Standards (Import) Regulations, 2017, reg. 9(5).
[64] The Food Safety and Standards Act, 2006 (Act 34 of 2006), s. 16 (3) (b)(vi) lists the "introduction of rapid alert system" as one of the duties of the Food Authority of India.
[65] AIR 2016 SC 3626.
[66] Michail Bitzios, Lisa Jack, *et.al.*, "Country-of-Origin Labelling, Food Traceability Drivers and Food Fraud: Lessons from Consumers' Preferences and Perceptions" *8 European Journal of Risk Regulation* 541 (2017).
[67] Export-Import Bank of India, "International Trade in Processed Foods: An Indian Perspective" *Working Paper No. 61* (March, 2017).

Basmati.Net, GrapeNet, HortiNet, Meat.Net, Peanut.Net, and TraceNet.[68] Beginning with the launch of TraceNet in June 2010, followed by Peanut.Net in 2011-12, the remaining also followed as internet-based electronic services provided by the APEDA for the ease of doing business of the stakeholders in their respective product supply chains.[69] Basmati.Net has been developed in furtherance of the legislative mandate contained in section 10A of the APEDA Act, 1985 and Section 21 of the Geographical Indications of Goods (Registration and Protection) Act, 1999.[70] HortiNet is an integrated traceability system[71] for horticulture products that include grapes, pomegranate (*anar)*, mango, betel leaves, citrus fruits and specified vegetables.[72]

V. Food Recall Regulation in India and the U.S.A.

The process of removing or withdrawing an unsafe or violative article of food from the market, using traceability is called a 'recall authority/ procedure'. To 'recall' is not to remember, but to retrieve. A News headline that a "food business recalls a significant number of adulterated or misbranded or unsafe articles of food" is not an "exercise in nostalgia"; it is an imminent and pressing concern.[73] Both India and the USA, did not have specific legal provisions regarding food recall procedures until the years 2006 and 2011, respectively. Till the enactment of the FSSA, a multiplicity of laws[74] pervaded the Indian food sector. But none of these statutory instruments mentioned about the food recall procedures for unsafe articles of food. In 2006, with

[68] From the official website of the Agricultural and Processed Food Products Export Development Authority (APEDA)

[69] Agricultural and Processed Food Products Export Development Authority, "Annual Report 2014-15" at 12 *available* at: http://apeda.gov.in/apedawebsite/Annual_Reports/Apeda_Annual_Report_English_2014-15.pdf (last visited on January 21, 2021).

[70] *Id.,* APEDA "Traceability System for Basmati Rice: A Registered GI Product of India", *available* at: http://traceability.apeda.gov.in/basmatirice (last visited on January 21, 2021); Section 10A of the APEDA Act, 1985 deals with "Functions in respect of Special products, etc." making it a duty of the APEDA to take measures for "registration and protection of the Intellectual Property rights in respect of Special products"; *Basmati* Rice, a registered Geographical Indication (GI) article is the sole entry in the Second Schedule of the APEDA Act comprising the "Special Products"; Section 21 of the Geographical Indications of Goods (Registration and Protection) Act, 1999 discusses the "Rights conferred by registration" of a GI.

[71] PIB, "Agricultural and Processed Food Products Export Development Authority's (APEDA) new progressive step: An APP to apply for farm registration and approval by State Govt. & Lab Sampling" *Press Information Bureau*, September 1, 2017, *available at*: https://pib.gov.in/newsite/printrelease.aspx?relid=170439 (last visited on January 21, 2021).

[72] The list of vegetables covered under the HortiNet System are Bitter Gourd, Bottle Gourd, Cluster Beans, etc.

[73] Eugene I. Lambert, "Voluntary Recalls or Delegated Seizures: The Legal Considerations" 27 *Food Drug and Cosmetic Law Journal* 670 (1972).

[74] The Food Safety and Standards Act, 2006 (Act 34 of 2006), Schedule II read with s. 97

the enactment of the FSSA, the primary legislation on food safety and standards in India, food recall procedures were, for the first time, legislated in the Indian food regulatory framework.[75]

Similarly, in the USA, the FFDCA nowhere made any reference to a food recall procedure (except for infant formula under section 412[76]). The recourse to the same was in the nature of an administrative action or an informal enforcement tool since the mid-1950s.[77] In the beginning, recalls were "requested only in situations of serious hazard to health"[78] and were not statutorily defined or recognised.[79] In this scenario, the nature of recalls undertaken for adulterated or substandard or misbranded articles of food was purely 'voluntary' with no obligation to undertake the same on the responsible party or the concerned food business. The first recall regulation was formalised by the USFDA in the year 1971 and finalised in 1978.[80] It was only in 2011, with the enactment of the FSMA, that amended the FFDCA, that the enforcement authority of the USFDA was broadened. For the first time, the US FDA was legally endowed with a new and wide-ranging authority of initiating a "mandatory recall" for food products, with complete traceability and recordkeeping.[81] However, this power has been used only once by the USFDA in April, 2018[82] and food recall largely remains a voluntary exercise in pursuit of self-regulatory goals.

Furthermore, to implement and administer the requirements of the primary legislations (FSSA and FFDCA), delegated or subordinate legislations have been made in both the countries. India has exclusive food recall Regulations in place *viz.* the Food Safety and Standards (Food Recall Procedure) Regulations, 2017 (FSSR) explicating the recall procedure for the articles of food.

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[75] *Ibid.*

[76] As per the mandate of the law [section 412(e)], "knowledge" of a "manufacturer of an infant formula" should reasonably support the conclusion that an infant formula processed by her and "which has left an establishment" subject to her control "may not provide the nutrients required, or "may be otherwise adulterated or misbranded". If the same materialises, the manufacturer is mandated to "promptly notify" the USFDA of such knowledge. On a determination by the Federal Agency that "the infant formula presents a risk to human health", the manufacturer is required to immediately "recall the shipments of such formula from all wholesale and retail establishments."

[77] Blake M. Harper, "Mandatory Food and Drug Recalls: An Analysis of a Developing FDA Enforcement Tool" 36 *Food Drug and Cosmetic Law Journal* 669 (1981).

[78] *Id.,* at 672.

[79] *Supra* note 77.

[80] *Supra* note 77 at 671.

[81] K. B. Armstrong and J. A. Staman, "Congressional Research Service Report- R43609, Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues", (February, 2018).

[82] Food and Drug Administration, "Constituent Update- FDA Finalises Guidance on Mandatory Recall Authority", November 5, 2018, *available at*: https://www.fda.gov/food/cfsan-constituent-updates/fda-finalizes-guidance-mandatory-recall-authority (last visited on January 21, 2021); US Food and Drug Administration, "FDA Orders Mandatory Recall for Kratom Products Due to Risk of Salmonella", April 16, 2018, *available at*: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/fda-orders-mandatory-recall-kratom-products-due-risk-salmonella-0 (last visited on January 21, 2021) (citing the instance of recall).

Whereas, in the USA, Title 21 of the Code of Federal Regulations (CFR)[83] comprises the existing federal regulatory reference for 'recall of products' generally in Chapter 1.[84] Food recalls are one of the several other regulatory enforcement actions initiated by the USFDA pursuant to the FFDCA[85] and other laws that it administers to ensure the 'safety' aspect of food.[86]

Food Recall Regulation- India

The FSSA governs the procedure for the initiation of a food recall. A 'Food recall' is defined as the action of removal of food from the market at any stage of the food chain, including when in the possession of the consumers.[87] The primary objective is to ensure the removal of articles of food under recall from all the stages of the food chain.[88] In light of the same, every actor in the food supply chain, be it the producer(s), manufacturer(s), or the distributor(s) or the importer(s), is legally responsible to assure, *inter alia*, the safety, wholesomeness,[89] and authentic labelling and presentation[90] of the articles of food to the consumers and can be held liable for any contravention(s) in this regard.[91] Further, it mandates the dissemination of such information to the concerned consumers and the retrieval, destruction or reprocessing of the article of food under recall.[92] The recall procedures apply to food or food products.[93] The basis of regulation is prima facie consideration of an article of food being unsafe and/or as may be specified by the FSSAI.

A recall shall be initiated by an Indian FBO under the law,[94] either *suo motu,* or on the direction of the authorities responsible[95] for the enforcement of the FSSA or as a result of any report(s) or complaint(s) from any of the stakeholder(s) to that effect. [96] A food recall can be initiated *suo motu* by an FBO immediately after she considers or has reasons to believe that an article of food

[83] Title 21 of the Code of Federal Regulations, s. 7.10 to s. 7.59 (specifically, s. 7.40- the "Recall Policy").
[84] *Id.,* s. 7.3 (f); A 'Product' is defined to mean '*an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use,*' (Emphasis supplied).
[85] The Federal Food, Drug, and Cosmetic Act, 1938, s. 301.
[86] Title 21 of the Code of Federal Regulations, s. 7.1.
[87] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 2 (c).
[88] *Id.*, reg. 3.
[89] The Food Safety and Standards Act, 2006 (Act 34 of 2006), s. 26.
[90] *Id.*, s. 23(2).
[91] *Id.,* s. 27.
[92] *Id.*, reg. 3(2) and (3).
[93] *Id.,* reg. 4.
[94] The Food Safety and Standards Act, 2006 (Act 34 of 2006), s. 28 read with the Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 5.
[95] The Food Safety and Standards Act, 2006 (Act 34 of 2006), s. 29 read with the Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 5(3).
[96] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 5(4).

in the food chain[97] (processed, manufactured or distributed by her) does not comply with the FSSA, or the rules or regulations, made thereunder[98] or could be unsafe[99] for the consumers. Following such a determination, an FBO shall, in fulfilment of her statutory responsibility,[100] initiate the procedure for the withdrawal of such an article of food from the market and the consumers. The decision for withdrawal should indicate the reasons therefor and shall be informed to the competent authorities along with the action(s) taken to prevent risks to the consumer(s).[101]

Furthermore, a recall may be initiated by an FBO on the direction of the Chief Executive Officer (CEO), FSSAI or the Commissioner of Food Safety (CFS) of the State or Union Territory or both[102] Such a direction can be issued by the CEO, FSSAI or the CFS either of their own volition or as a result of information regarding unresponsive behaviour of an FBO in response to a complaint/ report from any of the stakeholder(s)[103] In this regard, it may be noted that the said provision only specifies the reporting requirement by any stakeholder(s) lacking what should constitute such reporting or whether it should be as a result of non-compliance with the provisions of the FSSA or rules or regulations made thereunder, and whether it should be based on any investigation. For recalling an imported article of food in India, reliance may be placed on the reports of the health and food authorities, or from any information received from such authorities.[104]

The FSSAI has been endowed with the regulation making power[105] apropos, *inter alia,* "92. (2) …(m) *conditions and guidelines relating to food recall procedures under subsection (4) of section 28*.".[106] In pursuance thereof, it issued the "Guidelines for Food Recall"[107] (GFR) to "provide an overview of how to develop a recall plan and how to implement that plan in the event of a recall". The GFR earmarks the role of the FSSAI to the monitoring of the food recall and its progress along with an assessment of the "adequacy of the action taken" by the concerned

[97] *Id.,* reg. 2 (b).
[98] The Food Safety and Standards Act, 2006 (Act 34 of 2006), s. 28(1).
[99] *Id.,* s. 28(2).
[100] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 5(2).
[101] The Food Safety and Standards Act, 2006 (Act 34 of 2006), s. 28 (3).
[102] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 5(3).
[103] *Id.,* reg. 5(4).
[104] *Id.,* reg. 5(7).
[105] The Food Safety and Standards Act, 2006 (Act 34 of 2006), s. 92.
[106] *Id.,* s. 92 (2) read with s. 16 (2) (a) and s. 28 (4).
[107] Food Safety and Standards Authority of India, "Guidelines for Food Recall" (Uploaded on November 28, 2017) *available at*: https://www.fssai.gov.in/upload/uploadfiles/files/Guidelines_Food_Recall_28_11_2017.pdf (last visited on January 21, 2021).

FBO. Notifying the affected stakeholders post the initiation of recall is of paramount importance to achieve the intended aims of averting any risk to the consumers. For this purpose, the FSSR mandates all the FBOs and certain food retailers to have a detailed recall plan[108] as a part of their food safety management system.[109]

For the guidance of the FBOs in the preparation of a suitable "food recall plan", the GFR delineates a ten-step procedure apropos the various stages in the event of undertaking a food recall. The procedure comprises ten steps. In the *first* step, the FBO is required to assemble a "Recall Management Team" and proceed with assigning duties to the members of the said Team to conduct an effective recall. *Secondly*, information to the FSSAI or the State Food Authority should be communicated by the FBO at "at the earliest opportunity, after an incident is identified that may lead to a recall". Such information should comprise the details[110] in the nature of, *inter alia*, the name, brand, size, lot code(s) affected, the product distribution details, whether local or national, etc. The *third* step entails the identification of the article(s) "to be recalled" and the articles "directly affected" by the issue. In the *fourth* step, the FBO is required to ensure the detention and segregation of the article(s) "to be recalled" and a determination of their location(s) to prevent distribution. The preparation and distribution of the recall information to the consumer(s) and actor(s) in the food supply chain by a "Food Recall Notice" comprises the *fifth* step. This is followed by the *sixth* step where the FBO should facilitate the preparation of a "product/ article and lot code specific" distribution list. In the *seventh* step, the FBO is mandated to undertake a verification of the effectiveness of the Food Recall for a self-appraisal purpose. The controlling of the recalled articles encompasses the *eighth* step. In the *ninth* step, the FBO is required to arrive at a decision vis-à-vis destruction, reprocessing or correction. Followed by this, in the *tenth* step, the FBO is to undertake a fixation of the "cause of the recall".

The FSSR provides for the establishment of a web based 'Food Recall Portal' to be housed by the FSSAI on its website, to assign a unique identification number to each recall, to provide information to the consumers about such recall.[111] In consonance with the legislative scheme and efforts by the FSSAI, GS1 (India) has developed a food recall portal for India.[112] However, in

[108] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 7.
[109] *Id.,* reg. 7(3).
[110] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, Schedule I.
[111] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 16 (2).
[112] On November 8, 2011, a "Product Recall Pilot Meeting" was convened by the Food Safety and Standards Authority of India (FSSAI) where it was decided that "GS1 will provide the technology framework for Global Recall Portal service and facilitate training on best practices and usage of the portal"- **"**Product Recall Pilot by

violation of the provision of regulation 16 of the FSSR, the said portal is not housed on the website of the FSSAI. Further, a perusal of the same by the author, as a consumer, led to the inference that the portal does not provide any information for the consumers regarding the recently recalled articles of food. This is also in contravention of the statutory mandate enunciated in regulation 16 *viz.* to provide information to the consumers about recall. The search mechanism implanted in the portal can only be used by an Indian FBO, undergoing recall or firms having information concerning the 'Recall ID', 'FSSAI Licence No.', 'Global Trade Item Number (GTIN)'. Citizen-consumers may not have access to such specific business information like the GTIN or the Recall ID generated on a case-to-case basis.

The failure on the part of an FBO to undertake recall of unsafe articles of food may entail the triggering of enforcement actions for offences outlined in Chapter IX of the FSSA. The enunciated penalties depend on the degree of harm or injury to the victim(s) of the food offence(s), the varying degrees of harm to the very article of food, including false description, sale of substandard food, containing extraneous matter.[113]

Food Recall Regulation- U.S.A.

The federal responsibility for ensuring the safety of the food is primarily handled by the USDA and USFDA, along with fifteen other federal agencies (administering thirty laws in the area) at the vanguard.[114] The USFDA does not define a 'food recall' specifically, but defines a 'recall' generally as the removal or correction of a violative marketed product by a firm, against which it would initiate legal action, such as seizure.[115] Furthermore, the USFDA classifies 'recall' in three categories to indicate the relative degree of health hazard of the product being recalled or considered for recall by the USFDA, *viz.* Class I, II and III.[116] The federal scheme also insists on the development of a recall strategy for both the USFDA initiated as well as a firm-initiated recall.[117] It enlists some factors which the firms are required to take into consideration while formulating the same *viz., ease in identifying the product, health hazard evaluation* etc. It is germane to be noted that recall does not include a market withdrawal or a stock recovery. Recall

FSSAI (Dated: 14-11-2011)", *available at*: https://old.fssai.gov.in/Product_Recall.aspx (last visited on January 21, 2021).

[113] S. M. Solaiman and A. Noman M. Atahar Ali, "The Most Serious Offenses and Penalties concerning Unsafe Foods under the Food Safety Laws in Bangladesh, India, and Australia: A Critical Analysis" 70(3) *Food and Drug Law Journal* 409-43 (2015).

[114] R. Johnson, "Report- RS22600-The Federal Food Safety System: A Primer" (December, 2016); United States Government Accountability Office, "GAO-11-289- Federal Food Safety Oversight" (March, 2011).

[115] Title 21 of the Code of Federal Regulations, s. 7.3 (g).

[116] *Id.,* s. 7.41 (b).

[117] Title 21 of the Code of Federal Regulations, s. 7.42 (a).

stands on a different footing from a market withdrawal. A market withdrawal is the removal or correction of a distributed product by the firm that involves a minor violation that would not be subject to legal action by the USFDA.[118]

The mandatory recall authority of the USFDA has been enunciated in the FFDCA.[119] A food recall could be initiated by the USFDA in respect of information concerning a 'reportable food' (RF)[120] from the reportable food registry (housed within the USFDA)[121] or through any other means regarding a 'reasonable probability'[122] that:

- an article of food (other than infant formula) is adulterated under section 402, FFDCA and/or misbranded under section 403(w), FFDCA;[123] and
- the use of or exposure to such food would cause SAHCODHA.[124]

Before the enactment of the FSMA, endowing the USFDA with a "mandatory recall" authority, it relied on a responsible party (RP) [essentially the food facility manufacturing, processing, packing, or holding the articles of food and the person(s) 'responsible' for its registration with the USFDA][125] to voluntarily recall violative articles of food (except recalls for infant formula which are dealt with under section 412 of the FFDCA). The USFDA continues to rely on the RPs to voluntarily recall violative food products; however, the FSMA's mandatory recall authority allows the USFDA to mandate a recall when an RP chooses not to conduct it of its own volition, when the criteria under section 423, as aforementioned, is satisfied.

The USFDA may submit the instances of RF in the RFR after receiving any such report(s) from any RP or the Federal, State, or local public health official(s) through an electronic portal.[126] Such reporting may be done by an RP, after a determination that an article of food is an RF[127] or any Federal, State and local public health official(s). After an RP so determines, she is required to submit a Report to the USFDA, within twenty-four hours therefrom, through the electronic

[118] *Id.*, s. 7.3 (j).
[119] The Federal Food, Drug, and Cosmetic Act, 1938, s. 423.
[120] *Id.*, s. 423 read with s. 417 (a) (2); s. 417 (a) (2) defines a 'reportable food" to mean "an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals."
[121] *Id.,* defined in s. 417 (b) (1).
[122] David Benton, "The Impact of Mandatory Recalls on Negligence and Product Liability Litigation under the Food Safety Modernisation Act" 22 *San Joaquin Agricultural Law Review* 27 (2012).
[123] The Federal Food, Drug, and Cosmetic Act, 1938, s. 423 (a).
[124] *Ibid.*
[125] The Federal Food, Drug, and Cosmetic Act, 1938, s. 417 (a) (1).
[126] *Id.,* s. 417 (b) (1) and 417 (d) (3).
[127] *Id.,* s. 417 (d) (1) read with s. 7.46 (CFR).

portal, including certain data elements[128] to enable the identification of the impugned article of food. The RP shall also investigate the cause of adulteration if it may have originated with herself.[129] On submission of a report either by the RP or by the public health official(s), a 'unique number' shall be issued by the USFDA to the person submitting, through the electronic portal.[130]

The mandatory recall authority of the USFDA is exercised only when an RP refuses to or does not voluntarily cease the distribution or recall an impugned article of food. As a result of this refusal or failure to cease the distribution or undertake recall, a pre-hearing and a post-hearing recall order is passed by the Secretary.[131] In the former, the RP is directed to effect cessation of distribution of the impugned article of food and notify all the actors in the food supply chain (manufacturing, processing, packing, transporting, etc. such article; and to whom such article has been distributed, transported, or sold) to also effect the same.[132] This is followed by affording an informal hearing [133] to the RP, within two days of the initial order, on the actions required. The firm is also given an opportunity to argue against the impugned article being recalled.

An informal hearing can either result in a post-hearing recall order based on a determination by the Secretary that the removal of the impugned article from commerce is necessary, or a vacation (non-existence of adequate grounds to recall) or modification of the initial order. The said legislative procedure was incorporated in response to the speculations about the possibility of this system of enforcement to be susceptible to legal challenge on the ground of due process.[134]

The FFDCA mandates the issuance of public notification(s) regarding any food recall by the USFDA.[135] Such notifications could be in the form of Press Releases, Alerts and public notices to inform the relevant stakeholders *viz.,* the consumers and the retailers, of the incidence of recall, to whom such article may have been distributed. It must include, for a minimum, the

[128] *Id.,* s. 417(e).
[129] *Id.,* s. 417 (d) (1) (B).
[130] *Id.,* s. 417 (d) (4).
[131] *Id.,* s. 423 (b) and (d).
[132] *Id.,* s. 423 (b) (1) (A).
[133] *Id.,* s. 423 (c).
[134] Michael T. Roberts, "Mandatory Recall Authority: A Sensible and Minimalist Approach to Improving Food Safety" 59 *Food and Drug Law Journal* 563, 579 (2004) in Emily M. Lanza, "Food Recalls and Other FDA Administrative Enforcement Actions", *Congressional Research Service 7-5700, R43794*, November 20, 2014, *available at:* https://nationalaglawcenter.org/wp-content/uploads//assets/crs/R43794.pdf (last visited on January 21, 2021).
[135] The Federal Food, Drug, and Cosmetic Act, 1938, s. 423 (g).

name of the article of food along with a description of the risk; and if available, an image of the impugned article be published on the official website of the USFDA.[136]

In view of the foregoing, the USFDA and the FSIS have established dedicated sections on their website, titled as 'Recalls, Market Withdrawals, & Safety Alerts'. The section notifies the company announcements in a detailed manner along with the images (if available) of the product under recall and the company contact information. For instance, on September 11, 2019 House Of Spices (India) issued recall of "*MDH Sambar Masala*" due to *Salmonella* contamination.[137] Along with the company announcement concerning the recall, the product photographs were published on the website of the USFDA for the information of the consumers.

The Federal Regulations provide that the format, content, and extent of the recall communication should be commensurate with the hazard of the article of food subject to recall.[138] In addition to recall communications issued by the firm, the USFDA also informs other federal agencies and state and local governments of the recall. The USFDA records each recall and relevant information in its weekly USFDA Enforcement Report.[139] The regulations also affix a responsibility on the recipient/consignee to implement the instructions issued by the RP and extend the recall further.[140]

Comparing Food Recall Regulation in India and the U.S.A.

In the U.S., the nature of recalls undertaken for adulterated or substandard or misbranded articles of food has been purely 'voluntary'. Contrastingly, in India, the recalls of articles of food have been *mandated* by the FSSAI. Furthermore, unlike U.S., India does not have a recall classification system. Moreover, a Food Safety Commissioner in India, exercising his powers under the FSSA,[141] is a delegate of the Parliament responsible for ensuring the efficient implementation of food safety standards.[142] A direction by the CEO, FSSAI or the State food

[136] *Id.,* s. 423 (g) (3).
[137] USFDA, "House of Spices (India) Issues Recall of 'MDH Sambar Masala' due to Salmonella Contamination", September 11, 2019, *available at*: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/house-spices-india-issues-recall-mdh-sambar-masala-due-salmonella-contamination#recall-photos (last visited on January 21, 2021).
[138] The Code of Federal Regulations, s. 7.49(a)
[139] *Id.,* s. 7.50.
[140] *Id.,* s. 7.49 (d).
[141] The Food Safety and Standards Act, 2006 (Act 34 of 2006), s. 30 (2) (a).
[142] *Dhariwal Industries Ltd.* v. *State of Maharashtra*, (2013) 1 Mah LJ 461 (Bom).

safety officers towards the initiation of a recall,[143] is in furtherance of their statutory duty to play a proactive role to ensure safe and wholesome food and to prevent and eliminate any risk to public health caused by unsafe food.[144] However, the provision does not lay down the criterion for any determination leading to the direction by either the CEO, FSSAI or the Food Safety Commissioner. Therefore, there is lack of clarity regarding the basis of any such direction instigating a food recall by an FBO. In contrast, in the scheme of the FFDCA, any determination by the Secretary, USFDA, has to be based on the information gathered either through the RFR or through any other means.[145] Furthermore, the Commissioner of Food and Drugs or designee may request a recall if an article of food poses a risk of illness, injury, or gross consumer deception; the firm has not initiated a recall of the article; and agency action is required to protect public health and well-being.[146]

In both India and U.S., the food businesses may report information concerning an article of food that requires recall. In fact, a similar mechanism of reporting as contained in the FFDCA,[147] albeit through a physical means, is stipulated in FSSR (India).[148] An FBO, within twenty-four hours of an information concerning an article of food that requires recall, is required to submit such information in a prescribed manner to the concerned authority and initiate the recall exercise. Following this, the FBO is required to cease the distribution of food under recall and notify all the participants in the food supply chain to facilitate speedy identification and recall.[149] Furthermore, it is necessary for an FBO to investigate the reasons for recall.[150] This is similar to the provision for an RP in the U.S.[151]

Both the jurisdictions notify the affected stakeholders post the initiation of recall. While the FSSR mandates all the FBOs and certain food retailers to have a detailed recall plan, the federal scheme insists on the development of a recall strategy.[152] It is also relevant that while a recall plan is not reviewed by the FSSAI or the State Food Safety Authority, in the federal framework, the USFDA reviews the adequacy of a proposed recall strategy and recommend changes as

[143] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 5.
[144] *Supra* note 142.
[145] The Federal Food, Drug, and Cosmetic Act, 1938, s. 414 (See the requirements).
[146] Title 21 of the Code of Federal Regulations, s. 7.45.
[147] The Federal Food, Drug, and Cosmetic Act, 1938, s. 417(d) (1).
[148] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 6 (3).
[149] *Id.,* reg. 6 (4).
[150] *Id.,* reg. 11.
[151] *Supra* note 130.
[152] *Supra* note 118.

appropriate. The Federal Regulations also specify the elements of a recall strategy *viz.,* depth of a recall, Public Warning system and effectiveness checks.

Both the jurisdictions have devised the means of communicating a food recall. In the U.S., recall communications are informative in nature, and comprise details that, *inter alia,* identifies the product in question along with the reason(s) for the initiation and the hazard thereof.[153] In a similar vein, a 'Food Recall Notice' is required to be issued by an FBO in India to notify the consumers in an affected area of the food recall.[154] The FSSR enumerates the information to be included in such a notice issued by an FBO *viz., inter alia*, the contamination or violation in the food or reason for such recall, Health warning and action, the places or outlets where the food is found etc.

Such communication can be conveyed through the means of:

- India: written communication conspicuously marked "Food Recall", phone, e-mail, fax, print media, electronic media (TV or Radio or Internet or combination) or a combination thereof; marked "urgent".[155]
- USA: telegrams, mailgrams, or first-class letters conspicuously marked, preferably in bold red type, on the letter and the envelope: "*drug [or food, biologic, etc.] recall [or correction]";* marked: "urgent" for class I and class II recalls and, when appropriate, for class III recalls.[156]

Both the jurisdictions insist on monitoring the effectiveness of the recall as a legal responsibility of the recalling firm.[157] As a part of this monitoring exercise, the firm must submit recall status reports to the appropriate USFDA district office, generally every two to four weeks depending on the relative urgency or the gravity of the recall.[158] In India, such reports are required to be submitted to the CEO, FSSAI or the CFS.[159] These reports are an effective means to assess the progress of the recall and to apprise the food regulators with, *inter alia,* the quantity related details of the implicated product before the initiation of recall, estimated recall completion date,[160] number of individuals and FBOs notified, effectiveness checks,[161] and the response to

[153] *Id.,* s. 7.49 (a) and (c).
[154] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 8 (4).
[155] *Id.*, reg. 8 (2).
[156] Title 21 of the Code of Federal Regulations, s. 7.49 (b).
[157] The Federal Food, Drug, and Cosmetic Act, 1938, s. 423.
[158] The Code of Federal Regulations, s. 7.53(a).
[159] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 9.
[160] *Id.,* Schedule II.

the recall communication.[162] The FBOs are mandated to retain proper and complete documentation on food recall for inspection and verification by the FSSAI.[163]

In both India and the USA, a recall may be terminated either on submission of a written request in this regard by the FBO or the RP concerned or by the USFDA or the FSSAI.[164] On completion of the recall exercise, the USFDA or the FSSAI terminates a recall. The termination is preceded by a determination by the USFDA/ the FSSAI regarding the removal and disposition of the recalled products commensurate with the degree of hazard, to prevent recurrence. When the USFDA makes such a final determination, it provides a written communication (India)/ notification (USA) of the termination to the recalling firm.

VI. Mapping the Lessons for India from the U.S.A.

Food recalls are a rare occurrence in India. In a span of almost fourteen years of the coming into force of the FSSA, only four "food alerts", one each in 2014,[165] 2015, 2017[166] and 2020, have been issued by the FSSAI for food recall (and technically just two, after the coming into force of the FSSR). As per the available data on the official website of the FSSAI, recently a 'food alert notification'[167] was issued on September 1, 2020, pertaining to the contamination of imported Brazil nuts (almonds and peanuts, natural bar) with *Salmonella Sp.*[168] On earlier occasions too, the FSSAI has issued such notifications *viz.* the notification dated May 7, 2015, pertaining to the recall of the ice-cream ("Chocolate Chip Cookie Dough"), sherbet, frozen snacks and yoghurt,

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[161] *Ibid* and Title 21 of the Code of Federal Regulations, s. 7.53 (b) (5).
[162] The Code of Federal Regulations, s. 7.53(b).
[163] The Food Safety and Standards (Food Recall Procedure) Regulations, 2017, reg. 9 (4).
[164] *Id.,* reg. 12.
[165] Codex Division, FSSAI, "Recall of Probiotic Dietary Supplement for Infants and Children due to Contamination with Rhizopus oryzae- reg.", November 25, 2014, *available at*: https://old.fssai.gov.in/Portals/0/Pdf/Infosan(26.11.2014).pdf (last visited on January 21, 2021).
[166] Codex Division, FSSAI, "INFOSAN Alert on contamination of infant formula with Salmonella Agona- reg.", December19, 2017, *available* at: https://archive.fssai.gov.in/dam/jcr:f6177198-f9c5-40ef-a9ad-1a48a72115d2/INFOSAN_Alert_19_12_2017.pdf (last visited on January 21, 2021).
[167] The Food Safety and Standards (Import) Regulations, 2017, reg. 11(7).
[168] Codex Division, FSSAI, "INFOSAN Alert on contamination of Brazil nuts by-product with *Salmonella Sp.*- reg..", September 1, 2020, *available* at: https://www.fssai.gov.in/upload/advisories/2020/09/5f4e36cb14877Infosan_Alert_Brazil_Nuts_01_09_2020.pdf (last visited on January 21, 2021)

imported from Brenham Texas- Blue Bell Creameries, USA, on the ground of potential contamination with bacterium (*Listeria Monocytogenes*).[169] It is a food for thought:[170]

> That all the articles of food in India are miraculously produced with utmost perfection; That even the imported articles of food are pure and pristine with no trace of food fraud and resultant tension. That the food consignments landing from overseas are fully compliant with the domestic food laws. That there is no scope of adulteration from farm to fork and vice-versa, forget about whether intentional or inadvertent.

There is also an element of 'before and after*'* in the advent of 'food recalls' in India. Before the FSSR was promulgated, Nestlé India recalled nine variants of Maggi noodles after laboratory reports confirmed the presence of MSG and excess lead. This was in the year 2015. Followed by this, Knorr[171] and Top Ramen noodles too underwent food recalls.[172] After the promulgation of the FSSR, the year 2017 witnessed the recall of *amla* (gooseberry) juice produced by *Patanjali Ayurveda* from the Canteen Stores Department, Indian Defence Forces, for being "unfit for consumption" after failing the safety tests conducted by the Central Food Laboratory, Kolkata.[173] These food recall incidents put into spotlight the vitality of public notification and dissemination of information regarding the food recalls initiated either by the FBOs or the FSSAI. Especially so, when both *Patanjali Ayurveda* and Top Ramen are amongst the two hundred centrally licenced FBOs identified by the FSSAI for the submission of a fresh plan for food recall management.[174]However, as to the author's understanding, unlike the rhetorical 'before and after' where one does witness some transformation, the food recall system in India continues to be steeped in obscurity with no signs of embracing transparency for the wider public good.

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[169] Codex Division, FSSAI, "INFOSAN Alert on recall of ice-cream and other frozen products due to contamination with Listeria Monocytogenes-reg.", May 7, 2015, *available at:* https://old.fssai.gov.in/Portals/0/Pdf/Infosan_Alert(07.05.2015).pdf (last visited on January 21, 2021).

[170] Musings by the Author.

[171] PTI, "Maggi crisis after-effect: HUL recalls Knorr noodles" *Business Today*, June 11, 2015, *available at:* https://www.businesstoday.in/current/corporate/maggi-crisis-after-effect-hul-recalls-knorr-noodles/story/220392.html (last visited on January 21, 2021).

[172] HT Correspondent, "After Maggi and Knorr, Top Ramen noodles withdrawn from market" *The Hindustan Times*, June 30, 2015, *available at*: https://www.hindustantimes.com/india/after-maggi-and-knorr-top-ramen-noodles-withdrawn-from-market/story-oBkwbBmL6fLCOdWQ8HselL.html (last visited on January 21, 2021).

[173] Suneera Tandon, "Unstoppable at home, Ramdev's Patanjali gets a reality check in Nepal" *Quartz India*, June 22, 2017, *available at* https://qz.com/india/1011882/unstoppable-at-home-baba-ramdevs-patanjali-ayurved-gets-a-reality-check-in-nepal/ (last visited on January 21, 2021)

[174] The Food Safety and Standards Authority of India, "Letter dated March 20, 2018, Seeking Food Recall Plan from two hundred Food Businesses of India" *available at*: https://fssai.gov.in/upload/uploadfiles/files/letterregardingRecallplanof200FBOs.pdf (last visited on January 21, 2021).

Literally, either no information exists or is seldom reported either by the FBOs of their own or the FSSAI.

The approach of the apex food regulator deserves praise. However, from a public policy perspective the following issues merit consideration for the establishment of a robust food recall system in India:

i) FSSAI may consider requiring the FBOs to not only submit the recall plans with them but also to publish it on their official websites for the information of one and all. This will facilitate the examination of recall trends across different food brands, sharing the lessons learned, and impetus for behavioural research. The FBOs should not only publish the recall plans but also full description of any article of food manufactured, processed, distributed or imported by them subject to a recall.

ii) In addition, FSSAI may contemplate introducing a 'Food Recall Section' on its website notifying the FBO announcements in a detailed manner along with the images (if available) of the food article under recall and the firm contact information. This could be developed on similar lines as the USFDA and the FSIS having dedicated sections on their website, titled as '*Recalls, Market Withdrawals, & Safety Alerts*'. The section notifies the company announcements in a detailed manner along with the images (if available) of the product under recall and the company contact information.

iii) FSSAI may examine the development of a robust Food Surveillance and Recall Information Dissemination System (FSRIDS) geared towards a preventative, resource optimising, root-cause analysing and risk-based intervention in case of a food recall. The move should be directed to strengthen the public notification and communication/ dissemination in a structured and methodical manner. This can also assist in inter-agency (for example- between customs and FSSAI) or inter-state or inter-district regulatory collaboration within the country. The authorised officers at the points of entries in the States for imported articles of food should be made responsible for the supply and publication of authentic information with photographs of the recalled articles of food within their territorial jurisdictions. The FSRIDS should maintain the point or port of entry wise data in a database for rejected or recalled food consignments. Furthermore, technological interventions like the adoption of the blockchain technology, etc. in the food traceability space can bridge the information asymmetry gap.

iv) India may implement, with sufficient modifications and tweaks, the USFDA or the FSIS Model of maintaining the data pertaining to recall with delineation of the reasons, the volume/ quantity of food recalled, and the type of product. In the USA, for example, the FSIS investigates the outbreaks of foodborne illness in collaboration with the public health partners, including, *inter alia*, the CDC, the USFDA, APHIS and state authorities. FSIS publishes recall summary for meat, poultry and egg products in the following manner:

Recall Summary for Calendar Year 2019			
		Number of Recalls	Number of Pounds Recalled
Total		124	20,427,455
Recalls by Class (N=124)			
Class	I	97	19,662,158
	II	27	765,297
	III	0	
Recalls by Reason (N=124)			
Reason For Recall	STEC*	7	298,500
	Listeria monocytogenes	6	165,221
	Salmonella	3	118,830
	Undeclared Allergen	32	2,574,760
	Extraneous Material	34	15,573,818
	Processing Defect	3	32,801
	Undeclared Substance	4	76,221
	Unapproved Substance	0	
	Other**	35	1,587,304
	Recall by Species/Product (N=124)		
Species	Beef	23	695,445
	Mixed	32	618,677
	Pork	19	1,359,580
	Poultry***	37	17,126,467
	Siluriformes fish (catfish)	13	627,286

* STEC includes recalls due to Shiga toxin-producing *E. coli* (STEC). STEC organisms include *E. coli* O157:H7, *E. coli* O26, *E. coli* O45, *E. coli* O103, *E. coli* O111, *E. coli* O121, and *E. coli* O145.

**Other includes producing without inspection, failure to present for import inspection, and labeling issues, among others.

***Poultry includes egg products.

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v) Real-time notices of recalls and alerts from the USDA and the USFDA are listed in a widget maintained on the website developed by the Government of the USA for collating and assembling all the information regarding federal recalls at one place. For food products, FoodSafety.gov provides the latest information on all the food recalls and alerts as well as food illness outbreaks. India may consider mapping the lessons and consider the publishing of real time data in a similar way.

vi) To further improve the effectiveness of the food recalls, FSSAI may consider the development of new models of recall communication tapping the information and communication technologies to their highest potential. This is germane considering the fact that many articles of food are traded on e-commerce portals and timely

[175] Food Safety and Inspection Service, "Summary of Recall Cases in Calendar Year 2019" *USDA*, *available* at: https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-summaries/recall-summaries-2019 (last visited on January 21, 2021).

communicating any issue with a product may impact consumer risk perception and behaviour.

vii) India does not maintain any food recall statistics. The information concerning any ongoing recalls is not in the public domain. Many jurisdictions, including the USA collect and maintain data on food recalls. This data could be utilised for the identification of trends and complications occurring in the food industry, so that steps can be taken to prevent future issues.

The following information points to merit consideration for possible inclusion in a food recall system:

1. Classifying the severity and the risk associated with recall;
2. The time required to recall (external detection- consumer or the regulatory agency vs. internal (supplier or recalling firm);
3. The categories of food, the companies or the manufacturers involved and
4. Reasons for recall;

VII. Gazing Ahead: Conclusion

In a world marked by constant innovation and transformation, the need for articles of food to be safe and wholesome continues to be a "constant". The regulatory discourse has changed course from purely national to supranational and regional pedestals. Food safety in international food trade is an outcome of proactive decision(s) and dithering indecision of numerous participants constituting a food system, operating all across the food supply chain. These include not only those that are directly engaged in the production/manufacturing, supply and distribution, import and consumption of the articles of food, but also those who impact the enabling regulatory space of food.

In this milieu, the law, whether it be judge-made or enacted by the legislature, must have the virtue of flexibility and the capacity for continuous adjustment to the shifting conditions and changing needs. In this vein, in the food regulatory space, it is expedient to initiate a dialogue between the regulators, the regulated and the stakeholders. The food regulatory decision-making space could be utilized to build strong recall systems, indulge in regulatory policymaking and mapping the lessons which can mitigate adverse events instead of politicizing the same (a blame game). The enforcement of food safety standards has to be more stringent and the collation of food recall data more robust and transparent. A standardized mapping of information concerning

food recalls, together with stringent regulation and systemic accountability are vital for timely dissemination of precise information to the affected consumers.[176]

With food being increasingly traded across the world, there is also a need to build inclusive, robust, efficient and resilient food safety systems that tap the potential of the information and communication technologies (ICTs). With artificial intelligence (AI)[177] permeating most aspects of our modern existence, an increasing number of companies are using advanced options like a blockchain or distributed ledger technology/ internet of things (IoT)[178]/ electronic/ computer-based data storage programmes for creating a permanent digital shadow of the products.[179] Building on the utilisation of the ICTs along with AI smart and digital means of transforming the compliances with food safety laws, rules and regulations thereunder *viz.,* to license/ register the food business operators, certify and trace/ map the quality, authenticity, and safety aspect(s) of the articles of food in international trade etc., must be encouraged.

[176] Vijaya Chebolu-Subramanian and Parthajit Kayal, "Consumers deserve better product-recall norms" *The Hindu Business Line*, August 5, 2019, *available at*: https://www.thehindubusinessline.com/opinion/consumers-deserve-better-product-recall-norms/article28818925.ece (last visited on January 21, 2021).

[177] Matthew U. Scherer, "Regulating Artificial Intelligence Systems: Risks, Challenges, Competencies, and Strategies" 29 (2) *Harvard Journal of Law & Technology* 354-400 at 360 (2016). There is no "widely accepted" definition of "Artificial Intelligence (AI)". However, late Stanford pioneer Professor John McCarthy is credited to coining the expression in 1955. He defined it as "the science and engineering of making intelligent machines."; Professor Christopher Manning, "Artificial Intelligence Definitions" *Stanford University Human Centered Artificial Intelligence*, September 2020, *available at*: https://hai.stanford.edu/sites/default/files/2020-09/AI-Definitions-HAI.pdf (last visited on January 21, 2021); AI has been utilised by Japanese IT firm Fujitsu for hand wash gesture recognition in food businesses amidst the Novel Coronavirus (COVID-19) pandemic- Aaron Tan, "How AI can improve food safety", May 28, 2020, *available at*: https://www.computerweekly.com/news/252483779/How-AI-can-improve-food-safety (last visited on January 21, 2021).

[178] International Telecommunication Union, "Recommendation ITU- T Y.2060", (Geneva, 2013) *available at*: https://www.itu.int/ITU-T/recommendations/rec.aspx?rec=y.2060 (last visited on January 21, 2021) - The International Telecommunication Union (ITU) has defined the "Internet of Things (IoT)" as "a global infrastructure for the information society, enabling advanced services by interconnecting (physical and virtual) things based on existing and evolving interoperable information and communication technologies."-

[179] *Supra* note 50.

Appendix I: Other Federal Legislations- Food Traceability in the U.S.A.

Sl. No.	Legislation and Government Agency	Objective	Coverage	Recordkeeping Requirements
1.	Federal Meat Inspection Act (FMIA) Food Safety and Inspection Service (FSIS)	Prevention of adulterated[180] or misbranded[181] livestock and its food products from being traded as food; to safeguard that meat and meat food products[182]-carcasses brought into slaughtering or packing and processed under hygienic conditions.	Livestock, meat, meat products, poultry and poultry products, and eggs and egg products.	"Persons, firms and corporations to keep such records as fully and correctly disclose all transactions involved in the business"; Afford "…access to their places of business and examination of the facilities, inventory, and records thereof, to copy all such records, and to take reasonable samples of their inventory"[183] Certification of "Imported meat[184], poultry and egg products" to identify products by "…the country and plants of origin, destination, shipping marks, and amount"; health certificate
2.	Poultry Inspection Act (PIA) FSIS			
3.	Egg Products Inspection Act (EPIA); FSIS			

[180] The Federal Meat Inspection Act, 1906, s. 1 (m).
[181] *Id.,* s. 1 (n).
[182] *Id.,* s. 1 (j).
[183] *Id.,* s. 202 (a).
[184] *Id.,* s. 20.

4.	Food Safety Modernisation Act- Section 204; U.S. FDA	Enhancing "tracking and tracing of food and recordkeeping" relates to traceability-	Food Products except meat, poultry and eggs	Rapidly and effectively- • identify recipients of food; • tracking and tracing of foods for facilities; "*Develop and demonstrate appropriate technologies, that enhance the tracking and tracing of food*";[185]
5.	Perishable Agricultural Commodities Act, 1930	Promotion of "fair-trading practices" in the fruit and vegetable sector	Fruit and vegetables	Complete and accurate recordkeeping

[185] The Food Safety Modernisation Act, 2011, s. 204 (a) (2).