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# Food Import Safety and International Trade: Comparing Regulatory Regimes in India and the U.S.A.

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## ABSTRACT

Over the years, the bilateral relations between India and the United States of America (U.S.A.) have catapulted into a “global strategic partnership”. Both the countries foster the pursuit of a plethora of shared goals, values, and beliefs, with an entrenched focus on accelerating the achievement of sustainable development. This becomes palpable in the realm of agri-food trade, where sustainability and food safety regulation enjoy a pivotal status for both the countries. While recognising the diverse culinary cultures and different origins of regulating food, they implement food import control-safety measures/standards and regulations for the welfare of the consumers. By reducing the vulnerability of their populations to transnational food-related risks through the apparatus of law, they lessen the burden on the healthcare and food systems. In this milieu, this research is anchored in comparing the regulatory mechanisms for ensuring food import safety in India and the U.S.A.

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## KEYWORDS

food safety, imports, trade facilitation, agri-food trade, mislabelling, fraud, phytosanitary measures

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## Introduction

“Tomorrow begins Today” – a family consumption campaign launched by the Almonds Board of California (ABoC), United States of America (USA), championed the strategic inclusion of almonds in the Indian dietary intake. In public policy terms, by infusing an element of “nudge”, a behavioural policy tool, the choice architecture of the individuals was pushed softly, or reframed to secure what the ABoC calls “the gift of health”. The results of this nudge infused behavioural instrument, among other things, have been incremental both for the Indian populace and for the Indo – US agri-food trade. So much so that India became the second- largest importer of Californian almonds in the year 2021, after the European Union (27 countries), accounting for half of all the United States (U.S.) almond exports [forty-seven percent (47 %)] (ABoC, 2021).

Having said that, however, to realise the “gift of health” by exporting almonds, and other agricultural commodities, to India has not been a runaway victory for the U.S.; and likewise, for the Indian agri-food exporters targeting the US consumer base. Imported food is constantly contested within the social structures while being regulated by law. In the present era of conscious consumption, necessitating food authenticity amidst the rising waves of consumer ethnocentrism and animosity (Xin & Seo, 2020), food safety is a static element in the expectations of the consumers linked to quality and sustainability in all its forms (environment, health, social relations). The nations and their consumers recognise that as food travels from ‘farm to the fork’ or ‘boat to plate’, and so on, the prospects for adulteration and fraud multiplies with every point in the food chain. Imported food, thus, poses a greater danger, or

be lethal more than one can imagine (Marks, 2015). This is complemented by the occurrence of recent food safety incidents, arising from the internationally traded articles of food, whereby a discursive conjunction of food safety risks, public health, and food trade has emerged.

With a shift in the geo-political arena with the Russia – Ukraine crisis and the Israel – Palestine conflict, both India and US have emerged as natural allies to each other on key global issues such as public health, climate change, cyber-security, counter-terrorism, etc. (Singh, 2023). To this end, the socio-economic ramifications of highly publicised food safety events on these two international markets are relevant to be considered. For instance, the 2005 Sudan Red scandal (Velázquez et al., 2023) or the “2008 Chinese milk – melamine scandal” (Hew et al., 2024) or the recent issuance of import alerts on frozen shrimp imports into the USA imposed on India (Walia, 2023) and many more similar incidents. Such incidents have underscored the considerable socio-economic costs associated with foodborne illnesses; whereby food safety failures have had a trade impeding impact on both international agri-food exports and imports. Owing to this nexus, Indo–US bilateral agri-food trade is plagued by cynicism, parochialism, and distrust, apropos food safety, ethical and religio-cultural concerns.

National distrust to an internationally traded food article is made palpably evident by the implementation of an artillery of food safety standards, laws, and regulations, peculiar to each nation. Together with the ‘nudge’, the agri-food trade policy goals of protecting public health have been achieved with the aid of traditional levers of public policy, comprised in the regulatory apparatus of the food safety legislations and trade policies of both the nations. In international trade law discourse, post the institution of the World Trade Organisation (WTO) in the year 1995, such standards, laws, and regulations, have evolved based upon sanitary and phyto-sanitary (SPS) requirements, economic interests, risk analysis, or as precautionary approach. Such regulations and standards develop steadily around the world as nation-markets respond to food safety incidents and prepare for any perceived exposure to emerging food safety risks. They are primarily moulded by: (1) countries’ experiences with food safety, (2) inherent food safety risk levels in individual country’s food supply, (3) countries and industries capability and readiness to apportion resources to control these risks, and (4) differences in consumers’ food safety perceptions and, hence, preferences for targeting risk reduction efforts (Okpala & Korzeniowska, 2023; Jin et al., 2020; Santeramo & Lamonaca, 2022).

Owing to the twin effects exhibited by such measures in touching upon both trade and public health, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (AoSPS), which is a core document in international food law, aims to ensure that such standards should be based on robust scientific principles ensuring food safety, towards affording protection to, *inter alia*, public health. Additionally, these measures should not obstruct market access, based on non-scientific grounds and hence, not function as trade-distorting or being misused for protectionist purposes (Suanin, 2023). Over the years, such food safety standards and/ or laws have been categorised as non-tariff measures (NTMs) (in contrast thereof, “tariff measures” or barriers ruled the order of the day prior to the establishment of the WTO). Due to their trade-boosting or impeding effect(s), NTMs have been delineated across two contrasting perspectives, viz., ‘standards as barriers’ perspective and “standards as catalysts” perspective. In case of former, NTMs may negatively influence trade by enforcing a stringent food safety regulation. For latter, NTMs may open avenues for harmonisation and modernisation of the supply chains, over and above bolstering the national levels of food and health standards (Santeramo & Lamonaca, 2022).

Despite the fact that the Indo – US agri-food trade pivoted slowly and steadily ever since India introduced systemic economic reforms in the year 1991, it has been a complex

phenomenon and warrants regulatory co-operation and coherence every now and then (Nakagawa, 2016). This complexity and difficulty stems from the information asymmetry in the market for food generally apropos the 'safety' aspect, regulatory heterogeneity, and the divergent domestic and supranational standards for food safety and quality. As a corollary, parallel to the conduct of increased agri-food trade are the widespread legal battles between both the countries challenging the legality of the application of any protective or trade-restrictive measures, by their trading counterpart on varied grounds, including public health and food safety. Food safety concerns in the form of NTMs have affected the trade performance of both the U.S. and India. It has been a weighty determinant of market access for both the countries, battling in the world agri-food markets for specialised and high-value articles of foods, like seafood, spices, oilseeds, fresh fruit and vegetables, milk and milk products, and nuts, etc.

In this milieu, this research employs an empirical legal research methodology in a comparative frame, centered around an appraisal of the bilateral agri-food trade relationship between the two major democracies of the world, India and the USA. It unpacks their increasingly significant strategic partnership from the prism of the principles of imported food safety regulation and public policy comprised in relevant statutes, regulations, and other legal texts. Unlike much of the extant literature that emphasizes on the trade impact(s) of NTMs barriers (Santeramo & Lamonaca 2022; Suanin, 2023), this research unveils the evolving nature of food import safety laws promulgated in India and USA. With a strong theoretical grounding, the research exposts on secondary information or data pertaining to the food control and safety system(s) operationalised by the two countries, for reporting bilateral agri-food safety concerns. The data has been gathered from several sources, primarily the official portals of the food safety regulators, online food safety databases, and partner regulatory agencies in both the countries. Marvin et al. (2017) provides a comprehensive overview of online food safety databases, which comprise information on hazard, exposure, and surveillance reports.

For USA, the data on the number of rejected food shipments destined for entry to the USA has been taken from the Import Refusal Report (IRR) published by the USFDA. The report provides information on a number of refused shipments, exporting countries, products, dates, and the underlying reasons for any refusal of admission of a product. The research assesses the utility of "food safety systems" on various parameters, for instance, the regulatory purviews, timely "information sharing", transparency in notifying the refusals of food offered for importation into India from the USA (and vice-versa) during 2018 till date etc. The year 2018 is relevant as since that year India operationalised its national system for food import safety viz., food import rejection alert (FIRA) viz., from October 31, 2018, for disseminating information apropos the non-compliances of all imported food consignments.

The article is structured in the following way. Part 2 of this article delves into the anatomy of the India – US agri-food international trade. This relationship is analysed in light of the trade disputes between both the nations at the world stage and the spillover effect caused by these disputes on the trajectory of their partnership. The safety-orientation of the food legislations in both the countries vis-à-vis the food import basket will be scrutinised in Part 3 along with a discussion on the regulatory heterogeneity in the conduct of international agri-food trade. This discourse will be complemented by leveraging the Indo – US bilateral trade data elucidating the divergent food standards and commonalities by delving into the specific nuances of food import laws in India and USA. Part 4 discusses the way forward for India and USA to shape the geopolitical landscape, spinning around cooperation and policy congruence. This is followed by the Conclusion and policy recommendations in the final part.

## 1. India – US International Agri-food Trade Relations

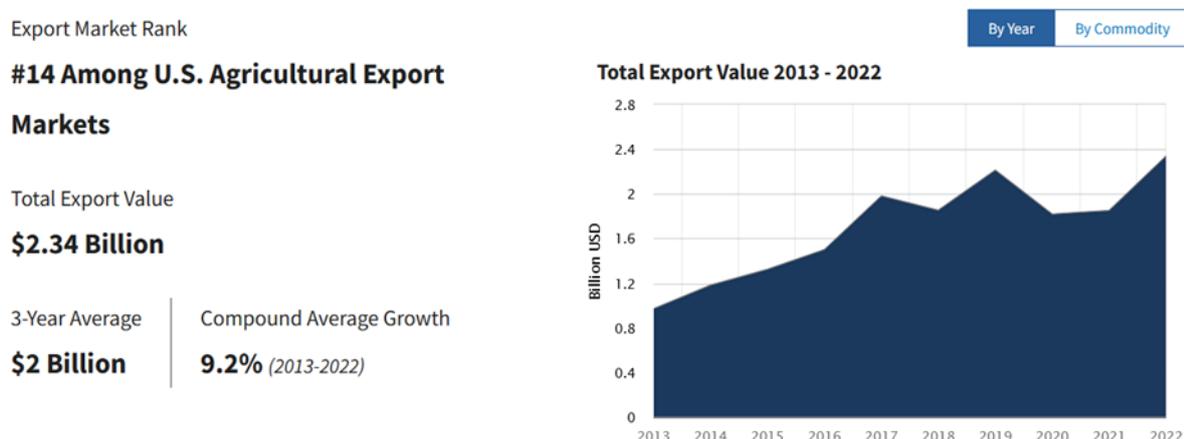
From the status of “estranged democracies” to jointly penning a “Declaration of Friendship”, U.S. and India have travelled a long road to building a strategic association for mutual benefit(s) (Vijayalakshmi, 2015; Ladwig & Mukherjee, 2019; Hornat, 2023). Trade, politico-strategy, and investment linkages form a key facet of the bilateral relations between the two nations. With every change in political leadership in both the countries, the bilateral relations evolved and strengthened from “hitting a nadir” in 1998, to India being considered, first a “counterweight to a rising China”, and then, as a “lynchpin” of the US ‘pivot’ to the Asia-Pacific during the turn of the millennium, to witnessing a qualitative transformation in 2014 – 16 of being labelled as “Enduring Global Partners in the Twenty-first Century”, and in 2020 to the status of a ‘Comprehensive Global Strategic Partnership’ (Ministry of External Affairs (MEA), India, 2020) after the 2 + 2 dialogue (2019 and 2020). Both the countries are members of the Quadrilateral Alliance (“QUAD”) alongside Australia and Japan and of I2U2 (India – Israel/ UAE – USA). India also joined the “Indo-Pacific Economic Framework for Prosperity (IPEF)” and Commercial Dialogue, the recent U.S.-led trade and economic endeavour in the Asia-Pacific region.

Established in the year 2005, the Indo – US “Trade Policy Forum (TPF)” has been integral in expanding bilateral engagement between the two countries. With so many trade complementarities, TPF was instituted to facilitate the pursuit of robust bilateral trade ties. In 2021, the TPF was revived and convened for the first time in four years on November 23, 2021 to deliberate on trade related matters. The revival led to the reactivation of the Agriculture Working Groups, as well as the relevant sub-groups, utilising science and risk-based principles to bolster overall economic relationship. The 14th Ministerial-level meeting of the India – US TPF was convened in New Delhi, India, on January 12, 2024, centered around, *inter alia*, the progress made at the 13th India – US TPF, held in Washington DC on January 11, 2023, along with trade concerns pertaining to the US imposed NTMs on agriculture items from India. In the intervening period in a spirit of bilateral bonhomie, just two days before the arrival of the U.S. President Joe Biden in New Delhi for a bilateral meeting as well as the Group of Twenty (G-20) Summit, 2023, India reduced the tariffs on the imports of major American tree nuts like California almonds (fresh or dried and shelled), cranberries, California walnuts, along with other agricultural commodities like blueberries, apples, chickpeas, turkey, duck, and lentils, effective September 6, 2023 (USDA, 2023). The development spurred the creation of new market opportunities for the U.S. agri-food producers and exporters to India, who were struggling with a period of trade tensions and measures unveiled by both the countries in the implementation of tariffs and retaliatory tariffs on their respective trade subjects during the preceding three years.

The TPF, as a joint initiative, has been instrumental in stimulating discussions on the settlement of trade disputes between India and the US along with deliberations anchored in trade facilitation by improving market access for certain agricultural products of interest for both the nations (USTR, 2024). While India exports various fresh fruits to the US, as far as mangoes and grapes are concerned there have been lingering issues related to the irradiation process, inspections, and adherence to protocols (Sen, 2023). Improving market access for these and many other agri-food products exported from India remains a vital point of discussion for the TPF, considering the fact that India and USA are leading agri-food trade markets for each other. The rapidly intensifying trade and commercial links form a vital component of their multi-faceted partnership. The U.S.A. leads the world in the export and import of the agricultural commodities and is India’s second largest trading partner and a key destination for her exports of goods and services. India is among the top ten exporters

of agricultural products in the world. It is perceived to pursue a strong growth trajectory in this realm, with its progressive economic outlook and export-oriented growth. India stood amongst the top fourteen agricultural export destinations of the U.S. in the fiscal year 2023, as per the updated dataset from the Foreign Agricultural Trade of the United States (FATUS) compilation (US-FATUS, 2023). The value of agricultural exports from the U.S. to India surged during the period from 2013 – 2022 from USD 971.33 million in FY2013 to USD 2.34 billion in FY2022, with the figure touching as high as USD 2.21 billion in FY2019 and a comparable USD 1.98 billion in FY 2017 (Figure 1), recording a “compound average growth” rate of 9.2 per cent (FAS, 2023).

## U.S. Trade with India in 2022 <sup>📌</sup>

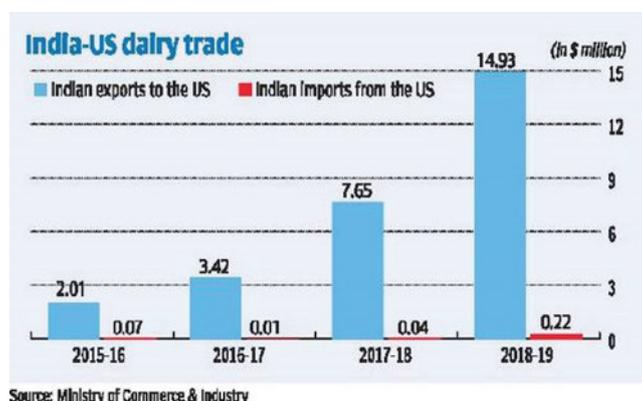


**Figure 1.** U.S. Trade with India in 2022 (FAS, 2023)

The bilateral trade exhibited a positive growth (BEA-US, 2023) owing to a continued surge in the sale of tree nuts (mainly pecans, almonds, pistachios etc.) by the U.S. valued at USD 1 billion in 2022, recording a one hundred and seventy-one percent growth rate over a period of ten years from the year 2013 (FAS, 2023). Leguminous plants, vegetables and dried pulses, Cocoa and its preparations, and fresh fruits also constituted the key agricultural commodities exported from the U.S. to India (Sawant, 2019). Some other high-value products like the dairy products also displayed progression. U.S.-origin almonds from California constituted eighty-four percent of India’s total import volume in the FY 2021 – 22 (Rosmann, 2022). Looking at the import basket (consumption) of the US, many Indian products feature prominently, including sugar and tropical products, grains and feeds, oilseeds and products, dairy, poultry, livestock, and meats (Figure 2) (Johnson, 2020). In fact, considering the volume of trade and the contribution of India to the US import basket in the past two decades, the country is poised to continue importing many specialised agri-food commodities, viz., fruits, milk and milk products, nuts, etc (Landes & Hjort, 2015).

All things considered, over the years, India has become a pivot for the US, not only geopolitically but economically. To ensure a resilient economic partnership, both the sides should consider solidifying their commercial association and negotiate sustained institutional pathways for future cooperation. While dialogue is important, the *ad hoc* nature of the current engagement could squander the prospect of deepening their economic and security relationship. To this end, both the nations have been “thinking big” apropos their engagement with strong commitments that ensure regulatory transparency and fosters long-term supply

chain and trade resilience. While both the countries were *en route* negotiating a “mini trade deal” or a Free Trade Agreement (FTA) covering all the issues of strategic importance, the negotiations hit a roadblock with, *inter alia*, the withdrawal by the US of the benefits under the Generalised System of Preferences (GSP) programme to India (Press Information Bureau, 2023).



**Figure 2.** India – US Dairy Trade. Source: Ministry of Commerce & Industry

With the global geopolitical scenario increasingly becoming anti-China, post the outbreak of COVID-19, some interesting developments in the Indo-Pacific region are also germane for the Indo – US strategic partnership. India has been aligning with the U.S., Japan, and Australia under the QUAD to safeguard the freedom of navigation and ensure peace in Indo-Pacific region where China has been trying to institute its stranglehold. This is amplified by the proposal by the U.S. (and Germany) in setting up an India – G7 partnership to help fund and support India’s transition from a “fossil-based economy to a carbon-neutral economy” (Rao, 2023). Last year, India was invited to the 49<sup>th</sup> G7 (Group of Seven) Summit in Japan. New Delhi has also unveiled new “Comprehensive Strategic” partnership with Australia, and in limelight has been the United Kingdom’s proposal of including India in the prospective D-10 alliance, joining ten democracies including South Korea, Australia, including the G7 nations to counter the burgeoning Chinese tactics of hegemony. All these developments underscore the importance of India as an evolving regional and international superpower.

## 2. Regulatory Heterogeneity and Indo – US agri-food trade Acrimonies

*“Following major trade breakthroughs in June, the United States and India will resolve the longstanding WTO poultry dispute; India will reduce tariffs on certain products.” (USTR, 2023)*

For this reason, market access and associated trade barriers (high tariff and/ or NTMs) have caused longstanding bilateral trade policy disquiets at the WTO (Akhtar & Kronstadt, 2023). The Indian trade policies and regulations have been termed as protectionary and ‘onerous’ by the U.S. (Kaushik & Sohrabji, 2022; Negi, 2020), thus, preventing greater market infiltration of their agri-food products. Similar has been the stance maintained by the Indian Government as far as market access for the Indian agri-food exporters to the US is concerned. The bilateral trade consultations were intermittently marred by trade tensions and retaliations. For instance, March 2018 witnessed the imposition of additional tariffs by the US on steel and aluminium imports from India. However, even with that patent a discrimination, only some agri-food products from the US were “identified” and no retaliation materialised until June 16, 2019. It was only when the “Generalised System of Preferences” was withdrawn by the US on the exports from India, that she imposed such tariffs on chickpeas, apples, almonds and walnuts, and lentils from the US.

With the recent change in the political leadership in both the countries, some of the bilateral trade issues have been resolved whilst exploring various ways to expand their agri-food trade ties (USTR, 2024) (Verma, 2023). The strength of this bilateral relationship has been tested by seven trade disputes raised at the WTO, four by the US and three by India (USTR, 2023). After the conclusion of the 13<sup>th</sup> India – US TPF, held in Washington DC on January 11, 2023, both the nations agreed to carve out mutually beneficial solutions to these longstanding trade disputes (Press Information Bureau, 2023). Recently, with the culmination of the G-20 Summit, New Delhi, both nations reached an agreement to resolve the seventh and last outstanding WTO dispute on the issue of “India–Measures Concerning the Importation of Certain Agricultural Products (DS 430).” Combined with this resolution, India also pledged a reduction of tariffs on specific US agri-food products, such as “frozen turkey, frozen duck, fresh blueberries, cranberries, and their frozen, processed, and dried counterparts” (Siddiqui, 2023). These tariff reductions benefit the US agricultural producers but also provide Indian consumers with more access to the American products. The following section shall delve into the specifics of the agri-food disputes between both the countries.

### **2.1. Assessment of the Avian Influenza Dispute**

The matter of *India – Measures Concerning the Importation of Certain Agricultural Products (DS-430)* involved a challenge by the U.S. to the regulatory policies (import prohibitions) enforced by the Government of India apropos the tackling of avian influenza (AI), also known as ‘avian/ bird flu’. India had not been a leading market for the poultry exports from the U.S. However, the embargo, on the imports of poultry meat, feathers, eggs, and seven other poultry products from countries reporting certain types of AI, by India, brought to prominence a number of critical legal, economic, and public policy questions (Bown & Hillman, 2016).

AI is an infectious viral disease of birds, and, in specific, wild water fowl for instance ducks and geese. While AI is mainly carried in wild birds, it can be transmitted to domestic poultry and, sporadically, humans (WHO and CDC) as well. Specially, the H5N1 and H7N9 strains holding the potential to trigger a global public health crisis (Bown & Hillman, 2016). A variety of subtypes of AI have been identified by the Scientists. The classification ranges between one of two groups according to “the propensity to cause disease, or the ‘pathogenicity’, in birds: (a) highly pathogenic avian influenza (HPAI); and (b) low pathogenicity avian influenza (LPAI)” (WTO – DS430, 2015, Para 1.3 – 1.4).

The OIE sets and defines the standards for the potential infection of poultry with AI and stipulates the suggestive safe trade measures, while averting any unfounded sanitary barriers to trade in animals and their products. The standards are published in a legal record, called the OIE Terrestrial Animal Health Code (TAHC). The country Members are required to notify the OIE of any incidence of HPAI and a few categories of LPAI in their territories. AI is defined by the TAHC as “notifiable avian influenza” (NAI) encompassing both highly pathogenic NAI (HPNAI) and low pathogenicity NAI (LPNAI). Paragraph 1, Chapter 10.4 of the OIE’s TAHC differentiates between HPNAI and LPNAI, while detailing the latest standards relating to the detection of AI in commercial poultry products, like live birds, feathers, and eggs. The basis of the differentiation between HPAI and LPAI lies in the lethal nature of a particular strain of an AI virus in its mutation (WTO – DS430, 2015, Para 1.5).

On July 5, 2001, the Live-stock Act, 1898 (India) was amended vide the Live-Stock Importation (Amendment) Act, 2001. The US interest in the extent to which the Amendment Act was applicable to their poultry exports in light of AI concerns, dates back to 2007, according to WTO SPS Committee (Minutes of the meeting). The U.S. challenged the Indian AI combat measures comprised in, *inter alia*, the Live-stock Importation Act, 1898, and Statutory

Order (S.O.) 1663 (E). The Department of Animal Husbandry, Dairying, and Fisheries (DAHDF), Government of India, issued the S.O.1663 (E) on July 19, 2011, imposing an import ban on a number of poultry-related products from countries reporting the NAI, including both the HPNAI and (notably) LPNAI. In its October 2014 report, a WTO dispute Panel agreed with the bulk of the U.S.' claims, stating that India's restrictions were not justified with the OIE TAHC (contravened and "arbitrarily and unjustifiably" discriminated between the consignments from WTO members "where identical or similar conditions prevail." On appeal by India, the Appellate Body (AB) – WTO ruled on, *inter alia*, following fronts:

a. *AoSPP Arts. 3.1 and 3.2 (harmonisation with international standards)*: The AB upheld the findings of the Panel that the Indian AI measures were "inconsistent with Art. 3.1 because they were not based on an international standard" (OIE's TAHC), and that India was not entitled to benefit from "the presumption of consistency of its AI measures" with the AoSPS and the GATT (Art. 3.2).

b. *AoSPP Arts. 5.1, 5.2 (risk assessment) and 2.2 (sufficient scientific evidence)*: The AB upheld the findings of the Panel to the effect that the "Indian measures were inconsistent with Arts. 5.1 and 5.2 because they were not based on a risk assessment."

c. *AoSPP Art. 2.3 (discrimination)*: Inconsistency with Art. 2.3 was held on the ground of being "arbitrarily and unjustifiably discriminatory between Members where identical or similar conditions prevailed and application constituted a disguised restraint on trade."

d. *AoSPP Art. 5.6 (appropriate level of protection – alternative measures)*: The measures were held to be "more trade-restrictive than required" to realise the Indian ALOP.

## **2.2. India – U.S. Mango Trade Dispute**

India, the world's largest in the cultivation of Fresh Mangoes, of about a thousand varieties, shapes, colours, and sizes, is a leading exporter of fresh mangoes to the world. During 2019 – 20, the Indian exports of fresh mangoes to the world were nearly 49,658.68 metric tonnes valued at ₹ 400.21 Crore. The major export destinations were United Arab Emirates, United Kingdom, U.S., Oman, and Qatar (APEDA, n.d. Mango). It stands just one step ahead of Mexico contributing to more than forty percent of global output. Since 1998, the U.S. has not reported any domestic mango production (Ferrier et al., 2012) and the procurement is entirely dependent on imports for its domestic demand (FAO, 2020).

Indian fresh mangoes gained greater market access to the U.S. since 2007 as a specialty crop under a bilateral agreement. The import of Indian fresh mangoes was debarred by the Animal and Plant Health Inspection Service (APHIS) in the year 1989, for the usage of pesticides in greater quantities and fear of infestation by insect pests like the fruit flies and stone weevils. For pest mitigation and control, Hot Water Treatment (HWT) was offered, as a viable measure, by India along with a reduction in the pesticide levels. However, (nuclear) irradiation treatment was sanctioned by the USDA – APHIS, as an efficient quarantine post-harvest measure for neutralisation of almost all the insect pests (Rastogi, 2011). HWT was contended by India as an effective measure lowering the likelihood of infestation by weevils and fruits flies by nearly eighty per cent. The exports restarted again in 2007 and, through 2009, India was the ninth-largest U.S. supplier of fresh mangosteens (Verma, 2023).

## **2.3. Dairy Products Trade and Issues**

Since 1998, India has been ranking first among the world's leading dairy producers – apropos milk production, with the largest bovine population in the world. It has emerged as a leading (net) exporter of milk and value-added products derived therefrom across the world. Between 1950 – 51 to 2017 – 18, India increased its milk production manifold from

17 million tonnes to 176.3 million tonnes; with the year 2016 – 17 recording a growth of 165.4 million tonnes, which was approximately 20 % of the world milk share (DAHD, 2023). In 2019, India produced nearly 146.31 million tonnes of milk, fifty per cent more than the U.S. and three times to that of China. During 2019 – 20, the Indian exports of dairy products to the world was 51,421.85 metric tonnes valued at ₹1,341.03 Crore (APEDA, n.d. Dairy Products).

Like India, the U.S. is also a net exporter of dairy and dairy products. The proportion of Indo – U.S. bilateral trade in dairy products divulges startling results. While the Indian dairy exports to the U.S. have increased by almost seven times from USD 2.1 million in 2015 – 16, USD 7.65 million in 2017 – 18, to USD 14.98 million in 2018 – 19 and USD 14.30 in 2019 – 20 (APEDA, n.d. Dairy Products). As far as imports from the U.S. are concerned the figures yield no upward trends. (see Figure 2). Deciphering the trends leads to a piercing trade surplus maintained by India from USD 1.94 million to USD 14.4 million during the said period of time against the U.S (Parida & Bhardwaj, 2020). The most critical reason for this surge in the dairy trade surplus vis-à-vis the U.S. is attributable to the Indian “religio-cultural and public moral sentiments” (Suneja, 2018). Dairy products are a recurring component of the mythological practices in India employed for worshipping the Hindu Gods and Goddesses. The attribute of ritual ‘sacredness’ and ‘purity’ ascribed to these religio-cultural and spiritual practices requires the highest standard of chastity and purification of both the devotees and the products employed in the same. For this reason, dairy products are considered ‘pure’ and ritually sound, if derived from animals which do not consume any food / feed containing internal tissues, blood meal, or tissues / organs of ruminant derivation. The market access to dairy products from the U.S. hinges on a certification by the veterinarians regarding the feed of the source animal to be free of any bovine extracts, or not exposed to bovine growth hormones (BGH) and bovine somatotropin hormones (BST) or been subjected to estrogenic treatments in last ninety days (DAHD, 2019). While other dairy exporters to India, like New Zealand, Australia, have complied with this requirement, the Federal administration has been condemning the mandatory certification since 2004 – 05 (USITC, 2009).

Bearing in mind the Indian religio-cultural apprehensions, necessary to protect the public morals, on December 24, 2019, the DAHD, issued an OM regarding the import of milk and milk products in India in conformity with the requirements stipulated in the FSS (Food Product Standards and Food Additives) Regulations, 2011. The said Regulations sanction the use of non-animal rennet type enzymes for making a variety of dairy products. In this regard, a Veterinary Certificate certifying the same is a pre-requisite for the grant of a sanitary import permit for importing dairy products into India. The matter was reviewed again on August 10, 2020, in consultation with the concerned Ministries /stakeholders (DAHD, 2020; Aradhey, 2020).

### **3. Comparing food import safety regulation in India and the USA**

With international trade in food products growing rapidly, the law too needs to keep pace with the developments in the food markets. Consequently, the regulation of imported articles of food and their policing and profiling to avert exposure from any risks therefrom has become pivotal. Both India and the USA have an independent, impartial, honest, and efficient food safety regulator. The countries cannot risk being complacent about the occurrence and recurrence of food frauds and illnesses. One must balance between preventive and corrective actions to remedy the world food safety crisis. The current trends with respect to the import regulation and refusals in India and U.S.A. are discussed in this section.

### 3.1. The Indian Food Import regulation

In India, the role of the Food Safety and Standards Authority of India (FSSAI) is multifaceted. FSSAI ensures the adherence of the foreign sourced articles with the Indian national food safety requirements comprised in the Food Safety and Standards Act, 2006 (FSSA) and the Regulations, for instance, *inter alia*, being “safe and wholesome”, compliance with labelling mandate, etc (Khanna, 2019). It leverages information and communication technologies and embraces digitalisation to facilitate the adherence to the trade obligations of India. As a modern, dynamic socio-economic legislation, the FSSA has inculcated a significantly improved sense of socio-legal discipline in food regulation generally and imported food regulation specifically. The regulatory framework instituted under the FSSA has been catalytic in dispelling information asymmetry and kindling an efficacious behavioural change in the market (Khanna, 2019).

One of the chief statutory mandates of the FSSAI is to regulate the import of articles of food and ensure the safety and wholesomeness of the imported articles of food for human consumption. The legal basis of this mandate stems from the FSSA. The statutory mandate stipulated in section 16 of the FSSA makes FSSAI duty-bound to regulate and monitor the manufacture, processing, distribution, sale, and import of food. It bears emphasis that the term ‘import’ is defined in section 3 (1) (v) of the FSSA to mean “bringing into India any article of food by land, sea or air.” As per section 25 of the FSSA, all the import of articles of food is subject to the provisions of the law. In pursuance thereof, *inter alia*, the import by any person of any unsafe [defined in section 3(1) (zz) of the FSSA], misbranded [defined in section 3(1) (zf) of the FSSA], or substandard [defined in section 3(1) (zx) of the FSSA] articles of food or food containing extraneous matter [defined in section 3(1) (i) of the FSSA], is prohibited in India. Moreover, in a bid to regulate the licensing for import qua the food business operators (FBOs) who are either food importers or are desirous of being so, it monitors and prohibits the import of articles of food, for which a licence is required under any law, without a valid import licence.

Another limb of the law enjoins the FSSAI to pursue regulation by regulations vis-à-vis the procedure and the enforcement of safety and quality control concerning any article of food imported into India [FSSA, Sec 16 (2) (d)]. In pursuance thereof, a separate delegated or subordinate legislation, the Food Safety and Standards (Import) Regulations, 2017 (FSSI) has been promulgated by the Central Government on March 9, 2017. As an exclusive and single reference point for the regulation of the food imports, the FSSI lays down detailed procedure for food import clearance in India. The FSSI have streamlined the process of clearance of imported food in an efficient and transparent manner. As many as six government departments partake, either directly or indirectly, in the regulation, clearance, and surveillance of food imports in India. These are the FSSAI, Directorate General of Foreign Trade (DGFT), Office of Legal Metrology, DPPQS, Central Board of Indirect Taxes and Customs and DAHD.

Under the FSSA read with the FSSR, for importing articles of food into India, the prospective food importers must ensure the following pre-requisites before importing:

1. Possessing a Food Import license issued by the Designated Officer / Central Licensing Authority, FSSAI under the FSS (Licensing and Registration of Food Businesses) Regulations, 2011.
2. Registration with the DGFT and having a valid Import-Export Code (IEC) issued by the same [The Foreign Trade (Development and Regulation) Act, 1992 uses the expression ‘Importer-Exporter Code Number’ for imports in India]. As per the DGFT, IEC is a key business identification number which is mandatory for import(s) to India. Following the introduction of the Goods and Services Tax (GST), the IEC issued is the same as the PAN of the concerned firm. However, it will still be based on an application and is separately issued by the DGFT.

3. An authority letter of the food importer in favour of a Custom House Agent (CHA) (as per the FSSI, reg. 2 (1) – “shall have the meaning assigned to it in clause (c) of section 2 of the Custom House Agent (Licensing) Regulations, 2004”) addressed to the Authorised Officer of the FSSAI, if the import is being handled through the CHA.

4. Imported food whose “shelf life is not less than sixty per cent at the time of clearance by the Customs Authorities” [reg. 3 (2)].

FSSAI maintains “an online system for the clearance of the food imports” known as the “Food Import Clearance System” (FICS), which is seamlessly integrated with the Customs ICE-GATE [Indian Customs Electronic Commerce/Electronic Data Interchange (EC/EDI) Gateway] under SWIFT (Single Window Interface for Facilitating Trade). The food consignments arriving from overseas are forwarded to the FSSAI for clearance by the Customs through the FICS. The consignments are subject to “scrutiny of documents, visual inspection, selective sampling and testing”, to determine their conformance with the national (Indian) safety and quality standards stipulated under various FSSR. Risk profiling is undertaken by the FSSAI under its risk-based framework and inspection process for the clearance of imported articles of food or to include them in the prohibited list. Under sub-regulation (2) of regulation 4 of the FSSI, any attempt by a food importer to import, *inter alia*, unsafe or prohibited articles of food, directly or indirectly, including re-channelling or re-packing, may entail cancellation of her Food Import License.

Recognising the increasing volume of international food trade, to put in place a robust food imports regulatory framework, and to facilitate ease of doing business, the FSSAI oversees the food imports both directly and indirectly. In case of former, it has designated its own officers as Authorised Officers (AO) [reg. 2 (b)] at six locations across India, namely Delhi, Chennai, Tuticorin, Mumbai, Cochin and Kolkata, covering twenty-two points of entries (PoE). These officers carry out food import clearance (FIC) to ensure compliance of the imported food with the provisions of the FSSA and rules and regulations made thereunder. For indirect regulation, at another three hundred and ninety six locations [Airports / Ports / Inland Container Depots (ICD) / Land Customs Stations (LCS)] throughout the country the Customs Officials (Superintendent / Appraiser / Inspector / Examiner) have been notified as AOs by the FSSAI under section 25 read with section 47(5) of the FSSA and regulation 13(1) of the FSSI (FSSAI, 2019). Another one hundred and twenty-eight PoEs have been notified by the FSSAI, w.e.f. April 1, 2020, to be dedicated food import entry points to facilitate smooth international food trade (FSSAI, 2019). Contrastingly, many countries have a few points of entry earmarked for food articles – for instance, in the United Kingdom (U.K.), there are twenty-five designated points of entry or ports approved to receive high risk food articles of non-animal origin (FSA, 2018). In the U.S.A., as on June 8, 2020, all the States have Ports of Entry and form part of the five Import Divisions under the Office of Regulatory Affairs, USFDA.

### **3.2. The U.S. Food Import regulation**

The federal responsibility for ensuring the safety of the food is primarily handled by the U.S. Department of Agriculture (USDA) and Food and Drug Administration (FDA / USFDA), along with fifteen other federal agencies (administering thirty laws in the area) at the vanguard. FDA, an agency of the Department of Health and Human Services (HHS), is responsible for ensuring “the safety of all domestic and imported foods except meat and poultry”. USDA’s Food Safety Inspection Service (FSIS) regulates “meat, poultry, some egg products, and catfish.” The FDA has been established under the Federal Food, Drug, and Cosmetic Act, 1938 (FFDCA), the principal federal legislation governing food safety. The FFDCA was amended in 2011 by the Food Safety Modernisation Act (FSMA), 2011, which is touted to be largest expansion and overhaul of the food regulatory powers of the FDA since 1938 (Johnson & Dabrowska, 2018).

The FSMA brought a paradigm shift in the regulatory role of the FDA from a “response-based or reactive intervention” to a “preventative” one in addressing food safety issues. The regulatory transition empowered the FDA to “Order and steer” mandatory recalls, enforce new produce safety standards on the local producers, and affix legal accountability on the food importers for the safety of the imported articles of food. As a result of FSMA, imported foods are held to the same standards as the domestic foods. With a dedicated focus on the safety of imported food, the FDA promulgated the rules apropos Foreign Supplier Verification Programme (FSVP) (FFDCA, s. 384a) and the Voluntary Qualified Importer Programme (FFDCA, s 384b).

The FDA also works in ‘close co-operation’ with the U.S. Customs and Border Protection (CBP) for administering the federal laws apropos imports, exports, and customs duties. The CBP also executes a preventive mandate to prohibit the entry of any of the regulated articles, that contravenes the provisions of the FFDCA, into the U.S. commerce (USFDA, 2017). It signals the FDA when an FFDCA “regulated product” arrives at a port of entry in the US. If the product’s importation would violate the Act, it is intercepted and a “Notice of Refusal of Admission” is issued by the CBP to the importer. In 2007, “Import Safety” was recognised as a “Priority Trade Issue (PTI)” by the CBP to profile and police any unsafe articles from making entry into the U.S. commerce. Through collaborations with international partners and interagency cooperation with the FDA, the Office of Trade through CBP enables the timely identification of risks to facilitate the detection, interception, and prevention of the import of violative agri-food commodities.

The onus is placed on the importers “to verify” that the articles of food coming to the U.S. from overseas are fully compliant with the domestic laws. The prevention – obligation rests chiefly on the food businesses, and applies correspondingly to both domestic and foreign facilities (Fortin, 2016). An importer is defined as “a person that brings food, or causes it to be brought, from a foreign country into the US customs territory.” [FFDCA, s. 806 (g)]. She is either “an owner or consignee of the article of food at the time such article enters into the US.” [FFDCA, s. 805(a)(2) (A)]. The US agent or representative of a foreign owner or consignee shall be the importer in absence of a US owner or consignee [FFDCA, s. 805(a)(2) (B)].

As a part of mitigating the import risks, vital information concerning the article of food must be submitted by the US importer, viz, anticipated date and port of arrival, the name of the manufacturer, for articles of food in their natural state information concerning the name and address of the grower with shipping details, including the name of any country that refused entry of the same product [ FFDCA, s. 801 (m) (1)]. This rule of giving prior notice (PN) of imported shipments, stated in section 801(m) of the FFDCA, implements the traceability requirement of the food. It requires the importers to notify the FDA of the food “imported or offered for import” into the US.

Under the FFDCA, the USFDA has the statutory authority to “refuse the admission” of any imported food product(s) if it *appears*, from the “examination of its samples” or otherwise, that it contravenes the provisions of the law (emphasis supplied). The contravention is established by reason of the imported article of food either being:

- a. Produced or packed under unhygienic conditions; or
- b. Prohibited or restricted for sale in the country of production or export; or
- c. Adulterated or misbranded; or
- d. Non-compliant with:
  - a. any recordkeeping requirements stipulated under section 204 of the FSMA or
  - b. Accompanying certifications.
- e. Importer is in violation of the “Foreign supplier verification programme”; or
- f. Prohibited from entering or being delivered into interstate commerce under section 301.

FDA depends on preventive risk-based evidence to steer the course of its actions. Acting with the concurrence of the CBP, it is authorised to 'refuse admission' of food imports that '*appear, based on an examination or otherwise*' to be adulterated or non-compliant etc. The significance of this evidentiary standard known as the '*appearance standard*' (Buzby et al. 2008), is that the FDA is NOT required to establish the occurrence of an ACTUAL VIOLATION of law or the regulations. Rather, mere existence of an 'appearance' of a potential violation will suffice the refusal of admission (Kux & Sobel, 2007). In other words, an alternative to the process of sampling and examination at the PoE is the issuance of an 'import alert' (IA). It serves to inform the CBP, the field force of the FDA and the consumers of the persuasive evidence with the FDA to automatically detain the articles of food without physical examination if they otherwise "*appear*" to lead to or are in violation of the FFDCA. Such an information applies even to the future shipments of the said article. This is known as Detention Without Physical Examination (DWPE). Before importation into the U.S., the importers are expected to know if their products form part of an import alert. The violations may pertain to the very article of food, records of the manufacturer or the shipper and/or any other material. FDA maintains a system of red, green and yellow lists for categorising the firms for the purposes of DWPE.

Once an article is detained as a result of the issuance of an IA, the owner or consignee is responsible to adduce evidence regarding the compliance and consequent admissibility of the said article in the U.S. From this information, FDA may decide to either "permit or refuse admission" of the articles' into the U.S.

### **3.3. Food Import Refusals Data**

#### **3.3.1. Indian Food Import Rejection**

As a part of its risk-based framework for the imported articles of food, sub-regulation (7) of regulation 11 of the Food Safety and Standards (Import) Regulations, 2017 attributes legislative backing to the issuance of food alert notifications by the FSSAI in the nature of the publication of food import rejection alerts (FIRA). In pursuance thereof, FSSAI publishes country-wise food import rejection status related data on the searchable online portal developed towards creating the FIRA. While it provides the details of the rejected consignments, it does not provide the details regarding the number of consignments received in India and those that are approved.

As on November 1, 2020, the home page of the FIRA, stated that the number of published import rejections is sixty (60). However, the date range or the period applicable for the said data is not provided. The database was operationalised from October 31, 2018 for capturing the non-compliances of all imported food product consignments. Therefore, it may be inferred that the initial date for reckoning the period of rejections is October 31, 2018. For U.S.A., the number of published rejections on the FIRA is seven as on November 1, 2020. The point of entry for three out of the seven rejected consignments was Chennai, followed by two each for JNPT Nhava Sheva (Mumbai) and Kolkata. The goods imported are fresh apples (Organic Red Wash, wax free premium), fermented wheat flour, pistachios, and Jack Daniel's. The details of these are provided in Figure 3.

From Figure 2, it is seen that the point of entry for the imported consignment of fresh apples from the U.S.A. was Chennai (Port). The apples were rejected for non-compliance with Regulation 9 of the FSS (Organic Foods) Regulations, 2017, notified under the provisions of section 22 of the FSSA, and the conditions stipulated in the FSSAI Orders dated July 25, 2018 and August 21, 2018. In pursuance of the mandate of the FSSAI Orders, the importer has been advised to follow the due procedure of Review as enunciated in Chapter XI of the FSS (Import) Regulations, 2017.



### Country-wise Applications Rejection Report

Selected Country Name:

USA

Show  entries

Search:

S.No.	Publish date on Portal	Point of Entry	Product Name	Manufacturer	Importer Details	Reason of Rejection	View App.
1	2018-12-24	Chennai Port	FRESH APPLES (ORGANIC RED WASH)	DOMEX SUPERFRESH GROWERS	PAZHAMUDIR NILAYAM	Import of the product FRESH APPLES (ORGANIC RED WASH) in the subject consignment is not in compliance with Regulation No.9 of the FSS (Organic Foods)Regulations,2017 and conditions specified in FSSAI Order dated 25.07.2018 issued from File No.Stds/Organic//02/2017 & FSSAI Order dated 21.08.2018 issued from File No.1-1170/FSSAI/Imports/2018 for "Food Products imported into India and claimed to be organic"	<a href="#">View</a>
2	2018-07-12	Chennai Port	FERMENTED WHEAT FLOUR	Nutek Food Science	PRATHISTA INDUSTRIES LTD	Rejection at Scrutiny stage- As per end use declaration imported product is for use as natural mould inhibitor in foods. nomenclature of the product as "Fermented Wheat Flour" is a misnomer since end product does not contain any wheat flour but is only made from glucose syrup derived from wheat flour.Also there is no standard specified for the products "natural mould inhibitors" or provision for use of the term "Fermented Wheat flour" for these products under FSS Act,2006 Regulations thereunder	<a href="#">View</a>
3	2018-09-12	Chennai Port	MY SHAKE & PS WHEY	PROSUPPS USA LLC	NOXON NUTRITION PRIVATE LIMITED	Rejection at Scrutiny stage- Products in the consignment are not in compliance with Food Safety and Standards (Health Supplements, Nutraceuticals, Food For Special Dietary Use, Food For Special Medical Purpose, Functional Food And Novel Food) Regulations, 2016 & FSS (Packaging and Labelling)Regulations,2011. Rejection reports issued for the consignment as per the request letter dated 20.11.2018 of the importer M/s Noxon Nutrition Private Limited uploaded in online FICS	<a href="#">View</a>
4	2018-12-15	JNPT NHAVA SHEVA	PISTACHIOS GRADE 3 RAW HALVES & PIECES	TRIPLE CROWN	O A OVERSEAS	SAMPLE DOES NOT CONFIRMS TO THE STANDARDS AS PER FSSR	<a href="#">View</a>
5	2018-11-06	JNPT NHAVA SHEVA	JACK DANIEL""S	Jack daniels distillaries	S.V.DISTRIBUTORS PVT. LTD.	Article does not comply with clause numbered 2.3.1. (3) Of Food Safety and Standards (Packaging and labelling) Regulations, 2011	<a href="#">View</a>
6	2018-07-05	Kolkata Seaport/Phonex Logistics Pvt Ltd	FRESH APPLES RED DELICIOUS WAXF PREMIUM SIZE	EVANS FRUIT CO. INC. WA	AMBIA SOHRAB	Referral laboratory reported presence of mould growth,rotting and multiple non permitted colours in products,which contravenes Regulation No.2.3.6 of FSS Regulations,2011.	<a href="#">View</a>
7	2018-07-05	Kolkata Seaport/Phonex Logistics Pvt Ltd	FRESH APPLES RED DELICIOUS WAXF PREMIUM SIZE	EVANS FRUIT CO. INC. WA	AMBIA SOHRAB	Referral laboratory reported presence of mould growth, rotting and multiple non permitted colours in products, which contravenes Regulation No.2.3.6 of FSS Regulations,2011.	<a href="#">View</a>

Figure 3. Country-wise Applications Rejection Report (FSSAI)

Some of the rejections of the food consignments at Chennai occurred at the 'stage of scrutiny' where the products in the consignment were held to be either beyond the standards enunciated by the FSSAI (Item no. 2 below) or in non-compliance with the FSS Regulations like the FSS (Packaging and Labelling) Regulations, 2011 (Item no. 3 below). Regulation 5 of the FSSI empowers an AO to scrutinise the Integrated Declaration Form submitted by the importer with the FICS along with the required documentary scrutiny.

Two items rejected at the JNPT Nhava Sheva are pistachios and Jack Daniel's (Whiskey). The former has been rejected for want of conformance with the standards stipulated in the regulations promulgated by the FSSAI. However, no attribution has been made to any specific set of Regulations or any provision therein. The latter has been rejected by alluding to non-compliance with clause (3) of sub-regulation (2.3.1.) of regulation 2.3 of the FSS (Packaging and Labelling) Regulations, 2011. Regulation 2.3 details about the 'manner of declaration' and clause 3 pertains to the prohibition on the making of a declaration on a package that requires to be read through any liquid commodity contained therein.

As far as the Kolkata Seaport is concerned, a consignment of fresh apples (red delicious wax free premium size) was rejected basis the contravention of Regulation 2.3.6 of the FSS Regulations, 2011. It has been stated that the products were reported by the referral laboratory for the presence of mould growth, rotting, and multiple non-permitted colours. Again, while mentioning the provision no attribution has been made to any specific set of Regulations.

### 3.3.2. The Federal Refusals of Indian Food Imports

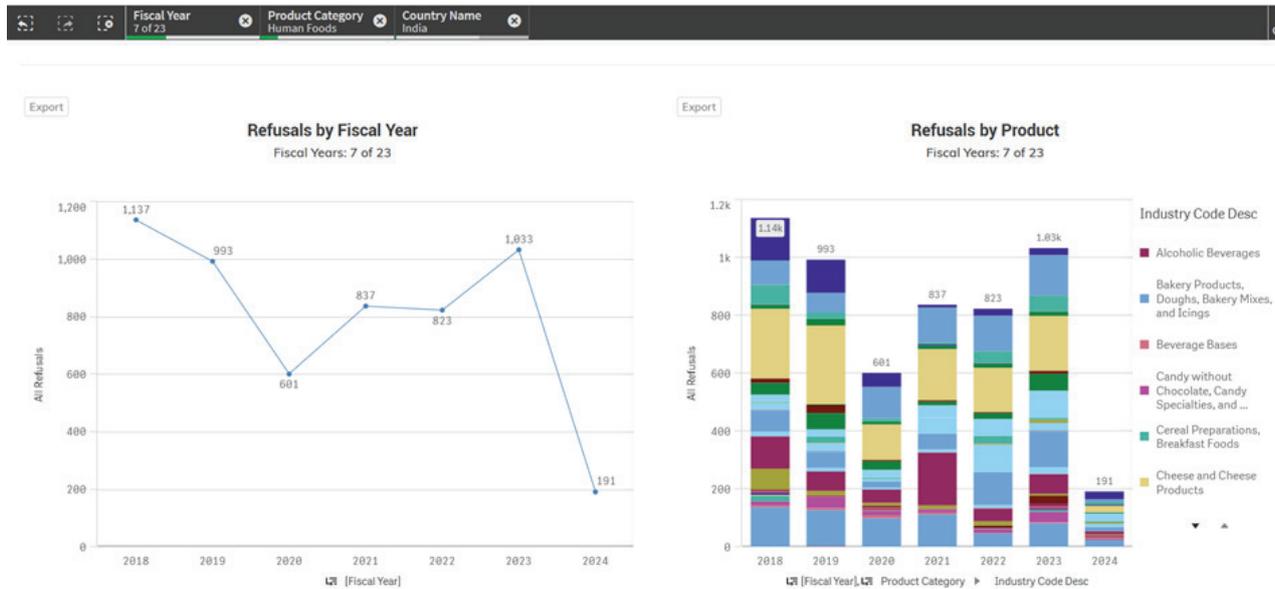
A total of 5615 "human food" export shipments from India were refused entry at US customs during the last five years (2018 – 2023), as per data collated by the USFDA. While the value of Indian food trade with the U.S. has seen an upward trend, it comes with a finding by the FDA that India together with Mexico and China, has the highest number of food import refusals in the U.S. The reasons for such refusals include, *inter alia*, filth and pesticide violations, presence of *Salmonella*, lack of nutrition labelling etc. (United States Government Accountability Office, 2016, 2019). The finding has not only led to loss of earnings for the exporters, farmers and processors, but also loss of market access for the Indian exporters who are unable to meet the U.S. food safety and health regulatory standards for various reasons.

Each month, an Import Refusal Report (IRR) is published by the FDA based on the data generated by the Operational and Administrative System for Import Support (OASIS) that records the product, its supplier, country of origin, and the reason(s) for refusal of the said product into the interstate commerce of the U.S. In the last five fiscal years beginning FY 2018-19, a total of forty thousand eight hundred and sixty-eight (40, 868) unique shipment lines were rejected by the FDA in the 'human food' category (USFDA). The data pertaining to the number of food consignment rejected Import Division wise is also published by the USFDA. Out of these, five thousand six hundred and fifteen (5615) shipments from India were rejected entry by the U.S. (Figure 4).

Conducting a conspectus of the data, the following is pertinent:

a. The year wise downward trend in the number of consignments being refused entry from India during the last five years, even though marginally. The pace of change is palpable in the figures plunging from 1137 rejected consignments in 2018 to 823 in the year 2022. This seems to indicate that the Indian agri-food exporters have been considerably securing compliance with the food safety regulatory standards stipulated by the U.S.

b. The volume of the Indian exports to the U.S. has declined amidst the ongoing COVID-19 pandemic. In view of this, the import rejections from India reaching the figure "NIL", in 2020 is relevant.



**Figure 4.** Refusals introduction “human food” from India into interstate commerce of the U.S. (USFDA)

In a revealing comparison, it is observed that unlike India, where the import refusal data has not been updated (not only for the U.S.A. but for other countries as well) since December 2018, the federal import refusal data is published both monthly and annually by the FDA and in a comprehensive manner. The publication makes known the reasons for rejection and facilitates the discerning of trends about a manufacturer(s) from a country being a perpetual defaulter so as to necessitate a DWPA or an Import Alert.

It is useful to mention here that in March 2018, the FSSAI sought the submission of “food recall plans” from two hundred “centrally licensed FBOs” to monitor their compliance with the FSSR. It is startling to observe that the analysis of the “Import Refusal Report”, published by the FDA, from *April 2018 – August 2020* reveals that many of these Indian manufacturers of food products, who are well-known and trusted brands in the domestic market and are “centrally licensed FBOs”, have frequently featured in these reports. The FDA has been utilising and invoking the “appearance standard”, as stipulated under section 801, FFDCA, for intercepting the imported articles from various countries, including India. The Indian firms MDH, Parle, Hindustan Coca-Cola etc. have been repeat offenders struggling with refusal of their products by the USFDA under the various provisions of the FFDCA. Majority of their consignments are rejected under sections 402 and 403 of the FFDCA, for, *inter alia*, misbranding (mis-labelling), followed by adulteration and presence of pathogens like *Salmonella*, and being filthy, putrid. Many a times, these firms have faced recalls in the U.S.A. The products which have been rejected due to *Salmonella* have featured in the “Import Alert 99-19- Detention without Physical Examination of Food Products due to the Presence of Salmonella” published by the FDA on May 8, 2020.

While MDH “Mahashian Di Hatti” spices are renowned in India, between April 2018 – July 2020, they have featured more than twenty-six times in the IRR, collated by the USFDA. The products intercepted included “Spices and seasoning, ground, cracked, with salt, fenugreek, whole (spice), capsicums (Cayenne Chili, Hot Peppers), Ground, cracked (spice), Curry powder, ground, cracked, without salt...”. The rejections have primarily been for non-compliance with section 402(a)(1) read with section 801(a)(3) of the FFDCA for “Adulteration” and the “charge statement” by FDA enunciates “The article is subject to refusal of admission pursuant to Section

801(a)(3) in that it appears to contain *Salmonella*, a poisonous and deleterious substance which may render it injurious to health." The refusal by the FDA of the imported articles is sufficiently justified by alluding to the relevant statutory provisions. The facet of transparency infuses their enunciation of the "Charge Statement" and the regular publication and updating of the refusals. In fact, many of the aforementioned articles feature in their recall communications and alerts, with credible information about the imported product, supported by pictures and lucid descriptions. In a revealing comparison, it is observed that unlike India, where the import refusal data has not been updated (not only for the U.S.A. but for other countries as well) since December 2018, the federal import refusal data is published both monthly and annually by the FDA and in a comprehensive manner. The publication makes known the reasons for rejection and facilitates the discerning of trends about a manufacturer(s) from a country being a perpetual defaulter so as to necessitate a DWPA or an Import Alert.

### **Conclusion and Policy Recommendations**

'Food safety' regulation is vital to afford protection to the public health of not only the national citizens-consumers, but also with the globalised food trading system, the international consumers or the global citizens. As per the International Food Safety Authorities Network (INFOSAN), with the global nature of agri-food supply chains, adulterated food channelled 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) (McGrady & Ho, 2011). For this reason, it upholds the vitality of rapid exchange of vital information between the countries to combat food safety failure(s) / economically motivated adulteration and secure both the public health as well as the economic interests of the nations.

In context of the Indo – US agri-food trade, both the nations have been coming together and slowly learning to cooperate with each other as a part of their economic engagement. There are significant challenges to the partnership but there is also great potential. They have devised food import laws, regulations, and information sharing systems to be at forefront to afford protection to the health of consumers against any transnational food safety related risks whilst ensuring fair practices in the agri-food trade. However, the Indian milieu reveals a situation of cataclysm in matters related to imported food and its safety. The Indian legal framework for protecting the consumers from hazards in imported food is at an embryonic stage. Despite the presence of laws and regulations, enforcement remains a key challenge. Even the administrative processes of importing food in India, be it the recall procedures or the import clearance/ alert systems, are recent initiatives of the Government of India and have made little to no difference to the fostering of transparency for citizens and importers alike. Contrastingly, the Federal Food Safety Programs for imported food products exhibit a developed approach to ensuring food safety of the imported food products.

Online food safety databases provide the consumers – public with information on products that have been found to appear in contravention of the respective food import laws. In India there's still no official open access to the food information database, despite the existence of online portals. The findings of this research underscore that food import safety is a variegated area of legal discourse, continually interacting with the socio-political sensitivities, existing at both the national and the supranational levels in the regulation of the manufacture, supply, and the safety of the food. The growth in regulatory standards on health, safety and consumer protection tracks the rise of the welfare state in industrialised countries. Developing countries like India, tend to have fewer standards and regulations than developed countries, like the US, and often less stringent standards and regulations when matters of quality are concerned. Yet, divergences in regulatory standards – often linked to differential levels of industrialization –

leading up to NTMs – clearly affects trade in goods and services. In a similar vein, one of the major challenges associated with contemporary food regulation is the interconnecting/ cementing of the fragmented regulatory islands in a bid to achieve harmonisation or whether one should abandon indoctrinate deference to the international standards as per the mandate of the multilateral or regional agreements. This is particularly important since compliance with international food safety standards, on the foundation of science and risk analysis, has generated a variety of legal questions that are playing out throughout the world, most notably in trade disputes between the countries on the WTO platform and thence, reaching out to the national consumers in one form or another.

A future research study could delve into the vitality of regulatory impact assessment in the realm of food import safety regulation in India and USA. Such an assessment could be utilised as a key regulatory gear employed to enhance transparency, efficacy and effectiveness of regulation. It could also appraise the viability of using new technologies to collect data related to food import safety such video monitoring and portable devices using Internet of Things, blockchain based traceability technology, etc.

### ***Policy Recommendations***

As an instrument of social change, in modern times, law aids the betterment of human civilization. Essentially, with that thought process, it is paramount to be solution-centric and legally conscious in a world increasingly dominated by infodemics and socio-economic crisis. India and the USA provide a revealing comparison of two nations that have diverse culinary cultures and different origins of regulating food. Food import safety in both of these jurisdictions enjoys a very important and pivotal status among the masses. They both have an independent, impartial, honest and efficient food safety regulator. The most challenging task for the policy makers in both the countries has been to link incidences of foodborne illnesses with a particular food commodity. It needs a strong surveillance and monitoring mechanism to unequivocally attribute a particular food commodity.

An examination of food import refusals makes the discernment of a few trends and data possible, revealing a rich set of patterns for analysis. Most importantly, such data speaks volumes about the brands or the companies or the manufacturers that strive hard to ensure compliance with the laws and the areas where the avenues for improvement lie for the exporting countries. They also reveal the reasons for missed agri-food trade opportunities for the developing and the low-income countries, when exporting their products to the U.S. Such a publication also reflects upon the value of regulatory transparency upheld by the public authorities in the country. This not only is germane for the importer/ overseas manufacturer, but also for the consumer(s). The data proves the proactiveness, diligence, prudence, and the considerateness of the regulatory agencies in affording the highest standard of public health for their populace.

To appraise the working of the food import safety law for protection of consumer rights and/or interests and other stakeholders, the following policy recommendations may be considered:

a. The widening of information asymmetry between the consumers and the competent authorities should be bridged by publishing updated data regarding the articles of food refused/rejected as a result of border inspections by the Indian Customs and agencies at the vanguard of ensuring the safety of food, animal, and plant products imported into India. Otherwise, if any such product reaches the consumers, the burden of foodborne illness may constrain the public healthcare system along with related externalities. Also, if the data is updated regularly then the exact category of food product can be pinpointed for ascertaining the industries with the most shipments refused over a period.

b. Comparisons should also be drawn between different set of periods for drawing inferences about the effect of deterrence if at all triggered by the Indian food law. This is especially relevant in case of high-risk food categories whose safety is of a significant concern.

c. Conformity with the food safety regulations and/or standards also changes the structure and modus operandi of agri-food supply chains, towards becoming more technologically sound. Digitisation of such value chains towards making food safe, trackable and of desired consumer quality needs to be accelerated and implemented at a faster pace than ever.

d. The attributes of a good regulation are not limited to legalistic rulebooks and practices but how well these are used in the regulatory realm. The law endows the food regulators and the food business operators (FBOs) with the “*trace, alert and recall*” tools at all levels of a food supply chain, to regulate the safety of both the domestic as well as the imported articles of food. Food recalls are a rare incidence in India. But implementation needs to be infused in the regulatory narrative for credible outcomes to materialise at the international trade level.

As the path towards the “world we want” is being charted by the United Nations by means of its seventeen Sustainable Development Goals, encompassed in the 2030 Agenda for Sustainable Development, it is being recognised that when food is unsafe, human development simply cannot happen. Safe supplies of food sustains a nations’ economies, tourism, trade, bolster sustainable development, and improve food and nutrition security. Unsafe food, whether traded and consumed, locally or internationally, is a potent storehouse of microbiological, or physical or chemical risks having the propensity to make people ill, triggering acute or chronic ailment, which in extreme scenarios may lead to death or permanent disability (Jaffee et al., 2019). While the SDGs do not explicitly mention food safety, it is closely related to other SDGs such as good health and well-being, gender equality, climate change, water and sanitation, sustainable production, distribution, and consumption, and elimination of poverty. In other words, without assurance as to food safety, the realisation of other SDGs becomes elusive.

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**Капур С. Безпека імпорту харчових продуктів і міжнародна торгівля: порівняльна характеристика режимів регулювання в Індії та США. – Стаття.**

Упродовж останніх років двосторонні відносини між Індією та Сполученими Штатами Америки (США) перетворилися на “глобальне стратегічне партнерство”. Обидві країни сприяють досягненню багатьох спільних цілей, цінностей і переконань із зосередженням особливої уваги на прискоренні досягнення сталого розвитку. Особливим чином це має прояв у сфері торгівлі продовольчою агропродукцією, де регулювання стійкості та безпеки харчових продуктів є ключовим для обох країн. Визнаючи різноманітність кулінарних культур та підходів до регулювання продовольчої сфери, вони реалізують заходи/стандарти та правила безпеки імпорту харчових продуктів для добробуту споживачів. Зменшуючи вразливість свого населення від транснаціональних ризиків, пов'язаних з продовольством, за допомогою правового апарату вони зменшують навантаження на системи охорони здоров'я та харчування. Враховуючи зазначене, це дослідження присвячене порівнянню регуляторних механізмів для забезпечення безпеки імпорту харчових продуктів в Індії та США.

**Ключові слова:** безпека харчових продуктів, імпорт, спрощення процедур торгівлі, торгівля продовольчою агропродукцією, неправильне маркування, шахрайство, фітосанітарні заходи.

