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AMERICAN FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP) – REQUIREMENTS, BENEFITS OR BURDENS FOR INDIAN FOOD COMPANIES, AND DIFFICULTIES IN THE IMPLEMENTATION®

Amerykański Program Weryfikacji Dostawców Zagranicznych (FSVP) – wymagania, korzyści lub obciążenia dla indyjskich firm spożywczych oraz trudności we wdrożeniu®

Key words: India, FSVP, food safety, importer.

The purpose of this article was to present the American Foreign Supplier Verification Program (FSVP). An importer of food is required to develop, maintain, and follow a Foreign Supplier Verification Program (FSVP) to ensure that each food product it imports meets FDA food safety standards. Specifically, an importer's FSVP must provide adequate assurances that: (a) the importer's foreign suppliers produce food with the same level of public health protection as those required by FDA for domestically produced food; and (b) the importer's foreign suppliers produce food that is not adulterated or misbranded. The FSVP regulations apply to all FDA-regulated food imported or offered for import into the United States.

Słowa kluczowe: Indie, FSVP, bezpieczeństwo żywności, importer.

Celem artykułu było przedstawienie Amerykańskiego Programu Weryfikacji Dostawców Zagranicznych (FSVP). Importer żywności jest zobowiązany do opracowania, utrzymywania i przestrzegania Programu Weryfikacji Dostawców Zagranicznych (FSVP) w celu zapewnienia, że każda importowana żywność spełnia normy bezpieczeństwa żywności FDA. W szczególności FSVP importera musi zapewnić odpowiednie gwarancje, że: (a) zagraniczni dostawcy importera produkują żywność o takim samym poziomie ochrony zdrowia publicznego, jak wymagany przez FDA dla żywności produkowanej w kraju; oraz b) zagraniczni dostawcy importera produkują żywność, która nie jest zafalszowana ani błędnie oznakowana. Przepisy FSVP mają zastosowanie do całej żywności podlegającej przepisom FDA, importowanej lub oferowanej do importu do Stanów Zjednoczonych.

INTRODUCTION TO THE FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP)

Food standards are increasingly impacting developing countries' trade balance and economic development. Over the past two decades, both public and private standards

have proliferated in global food supply chains. As the global food trade is increasing, the importance of uniform food standards for consumer protection is noticeable [29]. The most significant reform of food safety laws for developing countries in the history of the United States was the U.S. Food Safety Modernization Act (FSMA), which went into effect in September 2016 as it was signed into law by President Obama.

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Since then, the Food and Drug Administration (FDA) has been working to develop the rules that the act requires them to implement. The focus of this law is to prevent food safety issues in the U.S. food supply more effectively. The FSMA implementation is done through seven rules: (1) standards for produce safety; (2) preventive controls for human food; (3) preventive controls for food for animals; (4) a foreign supplier verification program; (5) accreditation of third-party auditors; (6) sanitary transportation of human and animal food; and (7) food protection against intentional adulteration [22, 23].

The Foreign Supplier Verification Program (FSVP) is a significant provision of FSMA [6]. The FSVP creates new requirements for importers of food for humans and animals into the United States. This regulation requires importers to perform risk-based activities to ensure that food imported into the United States was produced in accordance with applicable U.S. safety standards and that the food is not adulterated or allergen misbranded. The regulation includes standard requirements for larger importers as well as a modified set of procedures for importers who fall under the definition of “very small importer”. Modified procedures can also be used when importing food products from certain small foreign suppliers. Importer refers to the owner or consignee of a food item offered for import into the United States. If that food does not have any U.S. owner or consignee at the time of entry, then the U.S. agent or representative of the foreign owner or consignee can be the importer, as confirmed in the signed statement of consent according to 21 CFR PART 1.500 [6]. The effectiveness of a food importer’s FSVP is dependent on the calibre and knowledge of the Preventive Controls Qualified Individual (PCQI) it has chosen, the firm’s hazard analysis, its food safety plans, the food safety programs of all its foreign suppliers, and the selection, implementation, and documentation of the appropriate levels of verification. For the last three years (2019–2022), the FDA has conducted 1645 FSVP inspections, of which 17 were found to comply with FSVP regulations equalling a compliance rate of 1% [1].

Regulations under the Foreign Supplier Verification Program are designed to ensure that imported food meets the same standards of quality as food made in the United States. Therefore, the process aims to enhance food safety by improving importers’ responsibility for verifying foreign suppliers and compliance with GMPs. The FDA has released draft guidance for the Foreign Supplier Verification Program, which includes the most comprehensive set of requirements for importers to date [13]. The FSVP regulation applies to all food imported or offered into the United States. Apart from this, certain categories of imported food are not covered by the final rule which consists of certain juice, fish, and fishery products (because they are already subject to supplier verification requirements); food for research or evaluation; food for personal consumption; and alcoholic beverages and ingredients used in making alcoholic beverages, food that is transhipped through the U.S., food that is imported for processing and export, returned consignments, certain meat, poultry and egg products regulated by the FDA [7, 8].

THE FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP) – REQUIREMENTS

The FSVP rule is codified in 21 C.F.R.1, Subpart L, Sections 1.500–1.514 [6]. These regulations specify several requirements an importer must take when evaluating food and supplier for hazards and risks, including determining whom the FSVP importer is, conducting a hazard analysis of the food being imported, evaluating the foreign supplier, identifying and conducting verification activities on hazards requiring a preventive control, and re-evaluating food risks and the foreign supplier [4].

Suppliers play a significant role in the food industry sector. The quality of the final product is determined by many factors and one of them is raw materials and half-products used in the manufacturing process. Many authors emphasized the need to assess suppliers, including food importers [19, 30]. For the last 10 years, a considerable amount of research was carried out on supply chain management, especially: the selection of suppliers [5, 9, 31]. There is a similar requirement based on FSVP. The importers can only import foods from authorized foreign suppliers after assessing the risk the item poses and the supplier’s track record. However, this does not preclude importers from temporarily importing food from unapproved suppliers as long as these products are subjected to sufficient verification procedures prior to importation. The FSVP mandates that importers develop, maintain, and follow an FSVP for each food imported into the United States from each foreign supplier of that food. This suggests that a separate FSVP would be necessary if an importer purchases a specific food from a different supplier. Similarly, if an importer purchases a variety of foods from a single supplier, a separate FSVP is required for each food [21]. If certain importers, who are also manufacturers or processors, comply with the supply-chain program requirements set forth in the preventive control rules, implement preventive controls for the hazards in the food in accordance with those rules or are exempt from those rules in certain specified situations, they are deemed to be in compliance with most FSVP requirements. Examples of such situations include those where the type of food (e.g. coffee beans) could not be consumed without the use of preventive control or when the customer will be significantly reducing or preventing identified hazards and they comply with disclosure and written assurance requirements. The risk must be re-evaluated at least every three years, or whenever new information about a potential hazard or the performance of a foreign supplier becomes available. If importers receive assurances that subsequent entities in the distribution chain are processing the food for food safety, they are not required to evaluate the food or conduct supplier verification activities. Importers must, however, disclose in the documents accompanying the food that the food has not been processed to control the identified hazard [21]. Importers will be required to document the hazards requiring controls of imported foods in order to proactively mitigate or eliminate them. An importer must also assess the vulnerability of the materials/products to food fraud and must produce documentation during a Food and Drug Administration inspection (FDA).

The frequent evaluation of the performance of importers' foreign suppliers is another important requirement of the FSVP rule. Foreign manufacturers' hazard analyses, entities in charge of hazard control (foreign manufacturers or their suppliers), food safety methods, processes, and practices, compliance with relevant regulations, and food safety history should all be included. Each facility would be required to implement a written food safety plan focused on hazard prevention. The regulation requires that certain activities must be completed by a "preventive controls qualified individual (PCQI)". Importers have an explicit responsibility to verify that their foreign suppliers have adequate preventive controls in place to ensure that the food they produce is safe. There are four types of preventive controls i.e., Process preventive controls, allergen preventive controls, sanitation preventive controls, supply chain preventive controls and other controls. An importer can rely on a third party to determine and perform appropriate supplier verification activities, so long as the importer reviews and assesses the relevant documentation. Annual on-site audits of the supplier's facility are required when there is a reasonable probability that exposure to a hazard controlled by the foreign supplier will result in serious adverse health consequences or death. An importer's verification activities may provide evidence that a foreign supplier has not provided the same level of public health protection as required under the Produce Safety and Preventive Controls rules. Taking appropriate corrective action by importers is the last requirement in meeting the FSVP requirements. The appropriate corrective measure will depend on the circumstances and may include discontinuing the use of the foreign supplier. According to the FSVP rule, importers must provide the name, email address, and unique facility identifier (UFI) for each line entry of food product offered for importation into the United States. The FDA has approved the data universal numbering system (DUNS) number as a valid UFI for the FSVP.

Although the FSVP proposed rule would not itself establish safety requirements for food manufacturing and processing, it would benefit the public health by helping to ensure that imported food is produced in a manner consistent with other applicable food safety regulations [6]. The research on the measurement of the effectiveness of FSMA FSVP implementation in food manufacturing companies is still very limited. Several authors have argued that increasing food standards, including FSVP, act as barriers to developing countries' integration in global markets and lead to the exclusion or reduced bargaining power of small farmers. On the other hand, there is evidence that standards can generate important benefits for poor rural households in developing countries, either in the form of contracts with processing or exporting companies, or as employees [29].

THE FOREIGN SUPPLIER VERIFICATION PROGRAM (FSVP) – BENEFIT OR BURDEN FOR INDIAN FOOD COMPANIES

Indian food regulatory model was a complex web of multiple ministries taking care of different food laws, standards setting and enforcement and even promotional bodies for different food commodities [29]. In 2006, the

Government of India consolidated food regulations into a single act known as the 'Food Safety and Standards Act' [10]. The FSSA covered the concept of food safety across the entire supply chain from manufacturing, storage, distribution. The FSSA consolidated the laws relating to food and established the Food Safety and Standards Authority of India (FSSAI) for laying down science-based standards for food regulating their manufacturing, storage, distribution, and sale to increase food safety [11, 28].

At the same time, the standards and conformity assessment are gaining increasing importance in relation to cross-border trade. Food safety and quality, a major agenda in international trade is, therefore, receiving increased attention in the Asia-Pacific region - especially in developing countries like India. Henson and Olale, 2011 analysed the E.U. and U.S. data for food products border rejections from 2002-2008 [17]. The study analysed four groups of products against some causes of rejections. From the data, in the United States, filthy/unsanitary conditions are the highest cause of rejections in fish and fishery products followed by microbial contaminants, while pesticide residues are a major cause of rejections in fruits and vegetables, labelling issues in nuts and seeds and microbial contaminants followed by labelling in herbs and spices. Some food manufacturing entities, especially exporting countries food governing bodies are not alert to producing healthy and safe food. Due to the lack of knowledge and awareness, it is very difficult for consumers to distinguish between healthy food and unhealthy food. A food production company may try to reduce production costs by mixing low-quality materials with the high-quality ones [24]. However, the expansion of food safety standards, including FSVP, has introduced new complexity in trade policy dialogues and efforts to expand global trade in agricultural products. A loss of competitiveness due to the significant costs required to comply with these standards has arisen concern among exporting firms, particularly those in developing countries [20].

In addition, for developing countries, it is difficult to comply with the food safety standards in developed countries as they are subject to change over time in response to emerging problems, advances in scientific knowledge, consumer concerns, political pressure, etc. The majority of food exporting industries show less interest in implementing these standards if the compliance comes at a large expense. However, a well-coordinated food safety management may generate international competitiveness and awareness in the global arena [24].

The implementation of food safety requirements in India has become a significant task in recent years. However, in comparison to other countries, such as the U.S., the U.K., the E.U., and Japan, food safety requirements and inspections in the Indian food chain are still not rigorous enough [2, 3, 15]. So, it is essential that all the importing countries have some kind of risk-based verification program/ activities to ensure that the food imported into their countries has been produced in a manner that meets their food safety requirements. FSMA applies to both domestic as well as imported food hence foreign food producers will have to adhere to the same safety standards as U.S. domestic farmers and food companies. Of these, three rules of significance to food exporters are the U.S.

are Preventive Controls for Human Foods (PCHF), Foreign Supplier Verification Program (FSVP) and Accredited Third-Party Certification [25]. Rejection of consignments of food exports from India to the U.S. in 2019 especially that of basmati rice, marine products, spices and fruits and vegetables, were mostly on grounds of contamination. The U.S. rejected a total of 1674 consignments compared to 1939 rejections the year before [27].

India is one of the largest producers of many crops and food grains such as rice, wheat, pulses, oilseeds, coffee, jute, sugarcane, tea, tobacco, groundnuts, dairy products, fruits, etc. Given these advantages, India is now exporting fresh and processed food products to a number of developed and developing country markets including the United States, the European Union, Vietnam and the Middle Eastern countries [14]. India's exports of fresh fruits and vegetables to the U.S. stood at 3,018 MT valuing 8.61 million USD in 2019–20 as against 2,541 MT valuing 7.97 million USD in 2018–19 [25]. During 2021–22, the U.S. was the largest importer of Indian agricultural products at US\$ 5.7 billion with a share of 11.5% of the total exports [18].

Multinational food corporations now account for a growing portion of the global food market. Food companies are keen to keep their reputation by offering safe and high quality food. Many of these companies have built food processing factories in developing countries where food safety regulations might be less stringent than in developed countries and where the ability of the government to conduct proper monitoring may be limited [12]. In India, the food industry is regulated by numerous legislatures which monitor the permits, licensing, and sanitation issues. The government also runs the Food Safety and Standards Authority of India (FSSAI) to monitor and regulate food processing, manufacturing, storage and market distribution. Despite a monitoring body to ensure safe food, public awareness must prevail.

Food standards do not necessarily lead to new barriers to trade but can also enhance developing countries' participation in high-value global food markets and generate benefits for the poor [29]. The benefit of FSMA FSVP is higher than the efforts, financial and time expenditures associated with the installation of inspection devices. The FSVP implementation can be viewed as both an opportunity to ensure food safety and defence against harm to a company's reputation that may emerge from recall efforts. We all know that prevention is better than cure, FSVP, one of the requirements as per FSMA rule is also focused on this by verifying that imported products comply with the same activity level of health protection concerning food safety as stated by FDA regulatory food requirements. Besides, the benefits will come back to consumers and the nation in general [24].

DIFFICULTIES IN THE IMPLEMENTATION OF FSVP

The number of border detentions is an explicit indicator of the ongoing difficulties that exporters in developing countries face in meeting food safety standards in industrialized countries. Indeed, the ultimate risk for exporters is that their consignments will be turned back at the border, necessitating the destruction of the implicated products or the incurring of

additional transportation costs to bring the products home or divert them to an alternative market [16]. Access to food export markets will be based on their ability to satisfy the regulatory requirements of importing nations [24]. Building the faith and confidence of importers and consumers in the integrity of their food systems is essential to creating and maintaining demand for their food goods in international markets. Such food safety measures are crucial because the agricultural output is the core of the economies of the majority of developing nations. In India, international standards, guidelines, and recommendations are increasingly used to guide domestic as well as international trade. If the FSVP importer obtains the foreign supplier's safety plan, unless the imported food is exempt or subject to modified requirements, a thorough evaluation of each imported food item (or type of food) is required. The FSVP also requires the importer to spend additional time analysing the food safety plan of its foreign supplier. Some importers lack the technical knowledge required for such analyses, as well as the time required for review which is very common in developing countries [24]. A Preventive Control Qualified Individual should perform the FSVP verification activities, as some importers are having difficulty finding qualified employees in an already competitive labor market. Hiring a Qualified Individual as a consultant imposes a financial burden on the importer and will most likely not encourage the degree of involvement between the importer and its FSVP that is desirable [26].

Sampling and testing of food samples is another FSVP difficulty facing the food exporters, especially small/ medium scale exporters, but this activity is already costing the food processor tens of thousands of dollars prior to the FSVP implementation. In addition, the HACCP system was created in large part due to the fact that sampling and testing are not reliable methods for guaranteeing the safety of food. Next difficulty is the implementation of food safety system based on HACCP principles. Food safety has been fervently discussed throughout the world. Priority for food safety addresses issues in enhancing food safety systems in terms of exporting countries, contribution to consumers' health and protection and advancement on food regulations and standards. Not all food industrial companies are able to follow demands presented by international bodies [24]. Next are the verification issues. An onsite audit, the recommended FSVP verification method, also comes at a high expense to the importer [26]. The FDA does not allow relying on foreign suppliers' own self-audit as an appropriate verification activity. The FDA accept third-party analyses, evaluations, and activities for meeting FSVP requirements. So if the importer doesn't have local auditing staff based in his manufacturing country, hiring a professional third party might be a good compliance solution [13].

CONCLUSIONS

The Foreign Supplier Verification Program (FSVP) regulations are intended to ensure imported foods meet the same quality levels of food produced in the U.S. The FSVP process aims to improve food safety by increasing the importers' responsibility for verifying foreign suppliers and their good manufacturing practice compliance. The U.S. Food and Drug Administration Food Safety Modernization Act (FSMA) on Foreign Supplier Verification Programs

(FSVP) for Importers of Food for Humans and Animals requires that importers perform certain risk-based activities to verify that food imported into the U.S. has been produced in a manner that meets applicable U.S. safety standards. The FSVP certification allows foreign (non-U.S) suppliers to obtain certification following an audit. The FSVP program is mandatory and applicable to importers of food to the U.S. The compliance is equal to a passport for food products' entry into the U.S. market. Under the FSVP, U.S. importers are required to monitor their foreign suppliers' compliance with FDA requirements. There are difficulties in the implementation of FSVP in India. However, the benefit of FSMA FSVP is higher than the efforts, financial, and time expenditures.

WNIOSKI

Przepisy Programu Weryfikacji Dostawców Zagranicznych (FSVP) mają na celu zapewnienie, że importowana żywność spełnia ten sam poziom jakości, co żywność produkowana w USA. Proces FSVP ma na celu poprawę bezpieczeństwa

żywności poprzez zwiększenie odpowiedzialności importerów za weryfikację dostawców zagranicznych i przestrzeganie przez nich dobrych praktyk produkcyjnych. Amerykańska Ustawa o modernizacji bezpieczeństwa żywności (FSMA) Agencji ds. Żywności i Leków w sprawie Programów Weryfikacji Zagranicznych Dostawców (FSVP) dla importerów żywności dla ludzi i zwierząt wymaga, aby importerzy wykonywali określone działania oparte na ryzyku w celu sprawdzenia czy żywność importowana do USA została wyprodukowana w sposób, który spełnia obowiązujące amerykańskie standardy bezpieczeństwa. Certyfikacja FSVP umożliwi zagranicznym dostawcom (spoza USA) uzyskanie certyfikatu po audycie. Program FSVP jest obowiązkowy i dotyczy importerów żywności do USA. Zgodność jest równoznaczna z paszportem na wejście produktów spożywczych na rynek USA. W ramach FSVP importerzy amerykańscy są zobowiązani do monitorowania zgodności swoich zagranicznych dostawców z wymaganiami FDA. Istnieją trudności we wdrażaniu FSVP w Indiach. Jednak korzyści płynące z FSMA FSVP są większe niż wysiłki, koszty finansowe i czasowe.

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