Research Office
Legislative Council Secretariat

Fact Sheet

Regulation of imported food by the US Food and Drug Administration

FSC15/15-16

1. Introduction

1.1 In 2014, the United States ("US") imported US$126 billion (HK$977 billion) of food products, of which 58% were plant food products.[1] The rest were animal food products (27%) and beverages (15%). The top three source countries were Canada, Mexico and China, which together accounted for about 40% of the total value of food imports by the US.

1.2 The Food and Drug Administration ("FDA") and the Food Safety and Inspection Service("FSIS")[2] are the federal agencies jointly responsible for ensuring the safety of food supply in the US. FDA oversees the safety of all domestic and imported food products, except for meat, poultry and processed egg products that fall within the purview of FSIS. In this connection, FDA regulates about 80% of the food supply in the US and FSIS the remaining 20%. This fact sheet highlights the functions and organizational structure of FDA. It also covers FDA's regulatory system for imported food products, with special reference to the control measures introduced under the 2011 reform.

2. Functions and organizational structure of FDA

2.1 FDA is a federal agency established by the US Department of Health and Human Services to protect public health by assuring the safety of food products, human and veterinary drugs, biological products, medical devices, cosmetics and radiation emitting products. For food products, FDA is responsible for, among other things, ensuring that the imported food products

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1 The latest available figure from the US Department of Agriculture.

2 See FSC16/15-16 for functions and organizational structure of FSIS as well as the regulatory regime it adopts for overseeing food imports to the US.

are safe, sanitary, wholesome, accurately labelled, and up to the same safety standards that govern food products produced in the US.

2.2 FDA is headed by the Commissioner of Food and Drugs who is appointed by the US President with the advice and consent of the Senate. With a staff of about 15 700 employees, FDA is structured around the concept of the national headquarters which provides policy and decision making, together with an extensive field force of professionals throughout the country which provides additional decision making and regulatory enforcement. At the headquarters level, under the Office of the Commissioner, are four offices that oversee the core functions of FDA: (a) the Office of Foods and Veterinary Medicine; (b) the Office of Global Regulatory Operations and Policy; (c) the Office of Medical Products and Tobacco; and (d) the Office of Operations.[3] Among them, the Office of Global Regulatory Operations and Policy provides leadership for FDA's domestic and international product quality and safety efforts.

2.3 Within the Office of Global Regulatory Operations and Policy, the Office of Regulatory Affairs serves as the lead office for all FDA field activities as well as providing leadership on imports, inspections and enforcement policy. It also operates field offices across the US to enforce the relevant laws and regulations governing imported food products. These field offices are grouped into 16 districts in five regions. The San Francisco District Office in the Pacific Region is one of the larger district offices.

3. Regulatory system of imported food products

3.1 In order to better protect public health and prevent foodborne illness, the federal government reformed the food safety system in 2011 after the passage of the *FDA Food Safety Modernization Act* ("FSMA"). The objective of the reform is to strengthen the food safety system by focusing more on preventing food safety problems rather than reacting to problems after they have occurred. Under the reform, FDA has implemented a series of preventive measures to enhance the safety control system for domestic and imported food products. The measures governing imported food products include international collaboration, strengthened importers' accountability, and two-stage controls.

[3] See Abood & Burns (2015).

International collaboration

3.2 FDA adopts a global strategy for more effective control of the safety of imported food products coming from sources around the world. Under the global strategy, FDA has strengthened its international presence and co-ordination with foreign regulatory authorities by establishing offices in top exporting countries.[4] These offices conduct and facilitate inspections in foreign sites, and provide information about the safety and quality of products exported to the US to facilitate the admissibility decisions. In addition, FDA has agreements with more than 30 foreign counterpart agencies to share inspection reports and other non-public information that can help make better decisions about the safety of imported products.

Accountability of importers

3.3 FDA has established the Foreign Supplier Verification Programme to strengthen importers' accountability for the safety of their food products shipped to the US. Under this mandatory programme, importers are required to verify that their foreign suppliers have adequate preventive controls in place that ensure their food products meet the US food safety requirements.

3.4 In addition, FDA is planning to launch in 2018 the Voluntary Qualified Importer Programme to expedite entry of imported food products into the US from importers who achieve and maintain a high level of control over the safety and security of their supply chains. The programme includes the approval for importation of food from a foreign supplier who has a current food facility certification issued by a third-party auditor/certification body accredited under the *Federal Food, Drug, and Cosmetic Act* and in accordance with FDA's third-party accreditation regulations.

Two-stage control measures: pre-arrival and port-of-entry controls

3.5 FDA employs two-stage controls to ensure the safety and compliance of imported foods, both pre-arrival as well as after product arrival at the ports of entry. Pre-arrival control measures include registration of food facilities, prior notice of shipments, and screening the shipments that require inspection

[4] For example, FDA has established field offices in Beijing, Shanghai and Guangzhou as China is among the largest sources of food shipped to the US.

upon their arrival to the US. Control measures used at the port-of-entry stage include field inspection and import alert.

Pre-arrival control

3.6 All facilities, including domestic and foreign facilities, that manufacture, process, pack or keep food for human or animal consumption in the US are required to register with FDA. Registration is renewed on a biennial basis. Food products imported from facilities that are not registered with FDA will be denied entry to the US.

3.7 All registered food facilities are subject to inspection. Yet, FDA will identify high-risk domestic and foreign facilities and allocate resources to inspect them. The risk assessment is based on factors such as: (a) the known safety risks of the food manufactured; (b) compliance history of the facility; (c) the rigour and effectiveness of the hazard analysis and preventive controls taken by the facility; and (d) whether the food product or facility is certified to comply with the relevant food safety requirements.

3.8 With the support of the Customs and Border Protection ("CBP")[5], FDA also requires food importers to provide prior notice for information on each shipment to the US, including advance information such as what these shipments contain and the countries to which the products have been refused entry. FDA also makes use of the information so obtained from prior notice to screen those food products that require field examination or sampling upon their arrival to the US.[6] Screened food products with risk concern might be identified for field inspection at the ports of entry.

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[5] CBP is responsible for border management and control, combining customs, immigration, border security, and agricultural protection into one coordinated and supportive activity. It works with FDA on ensuring the safety of food products shipped to the US. For example, CBP will not release food shipments without proof that prior notice has been filed with FDA.

[6] Since 2009, FDA has adopted the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting ("PREDICT") information technology system to target field examination or sampling of imported food products with risk concern. PREDICT combines industry knowledge, data analysis, and intelligence information to predictively target import shipments for risk factors and regulatory violations.

Port-of-entry control

3.9 When the imported food products arrive at the ports of entry, FDA will notify CBP to release the shipments of those food products identified without risk concern. For imported food products requiring field examination, the FDA field staff may physically examine the products, conduct label review or collect samples for analysis. The products will be detained if examination of the samples or other evidence indicates that they are not in compliance with the relevant food laws. In the 2014 financial year, the total number of food import lines (i.e. groups of products in a shipment) was about 11 million, of which 188 578 or 1.7% were physically examined by FDA.

3.10 As another port-of-entry control measure, FDA may issue import alert, an evidence-based notification, to signal the staff at the field offices that a particular product or a range of products from a particular producer, shipper or importer may pose safety concern. Once an import alert is issued, the concerned food products can be detained at the ports of entry without examination and refused admission into the US unless the importer is able to demonstrate that the products are in compliance with the US food safety requirements.

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