Research Office
Legislative Council Secretariat

Fact Sheet

Regulation of imported food products in the United States

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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. The rest were animal food products (27%) and beverages (15%). The top five source countries were Canada, Mexico, China, India and France, which together accounted for about 46% of the total value of food imports.

1.2 The Food and Drug Administration ("FDA") and the Food Safety and Inspection Service ("FSIS") 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 and poultry that fall within the purview of FSIS. Currently, FDA regulates about 80%-90% of the food supply in the US and FSIS the remaining 10%-20%.[1]

1.3 In order to better protect public health and prevent foodborne illness, the federal government reformed the food safety system in 2011 by enacting 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 control measures to enhance the safety control system for domestic and imported food products. This fact sheet studies the regulatory system administered by FDA and FSIS respectively for regulating imported food products, with special reference to the control measures introduced under the 2011 reform.

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[1] See Congressional Research Service (2014).

2. Regulatory system administered by the Food and Drug Administration

2.1 FDA is a federal agency established under the US Department of Health and Human Services tasked with protecting public health by assuring the safety of food products, human and veterinary drugs, biological products, medical devices, cosmetics, and products that emit radiation. For imported food products, FDA is empowered under relevant legislation[2] to regulate them and ensure that they are safe, sanitary, wholesome and accurately labelled, and are up to the same safety standards as food products produced in the US.

2.2 The Office of Regulatory Affairs[3] of FDA 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 New York District Office in the Northeast Region and the San Francisco District Office in the Pacific Region are two of the larger district offices.[4]

2.3 To safeguard the safety of imported food products, FDA employs a multifaceted approach that includes partnerships with foreign regulatory counterparts, inspection of facilities in exporting countries, holding importers accountable for the safety of imported food products, and targeted surveillance of imported products. FDA has also planned to introduce measures stipulated in *FSMA* to strengthen preventive control on the safety of imported food products. These measures are detailed in the ensuing paragraphs.

International collaboration

2.4 FDA adopts a global strategy for more effective control of the safety of imported food products coming from sources around the world. Under the strategy, FDA has strengthened its co-ordination with foreign regulatory authorities by establishing offices in top exporting countries. These offices

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[2] The legislation includes the *Federal Food, Drug, and Cosmetic Act* as amended by *FSMA*, and the *Public Health Service Act*.

[3] The Office of Regulatory Affairs is the lead office for all FDA field activities as well as providing leadership on imports, inspections and enforcement policy.

[4] The New York and San Francisco District Offices, together with the Los Angeles and Seattle District Offices, covered about 40% of all imports regulated by FDA in 2011. See United States Food and Drug Administration (2011b).

conduct and facilitate inspections in foreign sites, and provide information about the safety and quality of products exported to the US to facilitate the making of 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

2.5 FDA has sought to hold importers accountable for introducing safe products to the US. It has planned to implement the Foreign Supplier Verification Programme to strengthen importers' accountability for the safety of imported food products. Under the 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. The proposed rule for the Programme was first issued in 2013 and the revised rule was issued in 2014 for feedback from stakeholders.

2.6 In addition, FDA has planned to introduce the Voluntary Qualified Importer Programme to expedite entry of imported food products into the US from eligible and qualified importers. To be eligible to participate in the Programme, the importers must import food products from a facility that is certified by an accredited third party. FDA also considers the risk of the imported food products in determining whether the importers concerned are eligible to participate in the Programme. The guidance for implementing the Programme has yet to be issued by FDA.

Registration and inspection of food facilities

2.7 All facilities, including domestic and foreign facilities, that manufacture, process, pack or hold 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 at the ports of entry.

2.8 All food facility registrations are required to contain an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the relevant law. FDA will consider the following factors when identifying high-risk domestic and foreign facilities and allocating resources to inspect them:

(a) known safety risks of the food manufactured, processed, packed or held at the facility;

(b) compliance history of the facility;

(c) the rigour and effectiveness of the facility's hazard analysis and risk-based preventive controls; and

(d) whether the food or facility has received a certification that assures that the food or facility concerned complies with the relevant food safety requirements.

2.9 FDA can refuse entry of imported food products from a foreign facility if FDA is denied access by the facility or the country in which the facility is located for an inspection. It is also empowered to require high-risk imported food products be accompanied by a credible third-party certification or other assurance of compliance as a condition of entry into the US. Besides, FDA has proposed to implement the Accreditation of Third-Party Auditors programme, under which FDA will recognize and allow accreditation bodies to accredit third-party auditors to conduct food safety audits and issue certifications for foreign facilities and food products. FDA issued the proposed rule for the programme in 2013.

Surveillance and control at the ports of entry

2.10 FDA requires food importers to provide prior notice for information of each shipment to the US, in a move to protect the public from terrorist attacks on the US food supply and other food-related emergencies. This requirement gives FDA advance information about when and where specific shipments will enter the US, what these shipments contain, the countries and entities where they originate, the facilities where the food was processed, and the countries to which the products have been refused entry.

2.11 With the support of the US Customs and Border Protection, FDA electronically screens all imported food products before they reach the US border. In order to effectively allocate resources for field inspection at the ports of entry, FDA screens and determines the risk level of the imported products based on factors such as:

(a) known safety risks of the imported food products;

(b) known safety risks of the countries or regions of origin and countries through which the products are transported; and

(c) compliance history of the importers.

Screened food products that are determined to be of low risk will be released at the ports of entry. For those with risk concern, the FDA staff will further investigate to determine whether a field examination or sampling is required, more information should be requested, or the products should be released.

2.12 In order to prevent entry of non-compliant imported food products, and expedite the entry of compliant products, FDA introduced the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting ("PREDICT") information technology system in 2009 and completed the rollout of the system in 2011. PREDICT uses data analytics from the entire life cycle of a product to better identify and target high-risk products for further investigation and inspection. The data analyzed include: (a) results of field examinations and sample analyses of previous entries; (b) results of facility inspections; (c) ratings of inherent product risks; and (d) accuracy of information provided by the importers.

2.13 FDA may issue import bulletins, when necessary, to alert FDA staff at the field offices to pay special attention to a particular product or a range of products from a particular producer, shipper or importer. In addition, FDA may issue import alerts for products that are considered to have food safety risks based on existing evidence, such as a history of violations. These products can be detained at the border 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.

2.14 For imported products that require field examination, FDA's 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 2012 financial year, the total number of food import lines (i.e. groups of products in a shipment) was about 11 million, of which 207 839 or 1.9% were physically examined by FDA.

3. Regulatory system administered by the Food Safety and Inspection Service

3.1 FSIS is a federal agency established under the US Department of Agriculture tasked with implementing and enforcing the relevant food laws[5] for safeguarding the safety, wholesomeness and proper labelling of domestic and imported meat and poultry.

Evaluation of the food regulatory system of the exporting countries

3.2 FSIS determines the countries that can export meat, poultry and egg products to the US. The decision is based on the equivalence determination process to evaluate whether the exporting countries have put in place a food regulatory system with equivalent sanitary measures that provide the same level of protection against food hazards as is achievable by the US regulatory system. At present, 35 countries are eligible to export meat, poultry and/or egg products to the US.

3.3 FSIS evaluates an exporting country's food regulatory system through document analysis and on-site review. FSIS conducts document analysis to evaluate the exporting country's laws, regulations and other written information. The review focuses on six risk areas, namely: (a) government oversight; (b) statutory authority and food safety regulations; (c) sanitation; (d) hazard analysis and critical control point systems; (e) chemical residues; and (f) microbiological testing programmes. If the document review process indicates that the country's system is satisfactory, a technical team of FSIS will visit the country for an on-site review. The review is to further evaluate the above six risk areas and other aspects of the food regulatory system, which include plant facilities and equipment, laboratories, training programmes and in-plant inspection operations.

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[5] These include the *Federal Meat Inspection Act*, *Poultry Products Inspection Act* and *Egg Products Inspection Act.*

3.4 After a country is determined to be eligible to export meat, poultry and egg products to the US, FSIS relies on the exporting country's responsible authorities to (a) carry out inspections of the exported food products; and (b) certify the food establishments under its jurisdiction that meet the US import requirements before they are allowed to export food products to the US.

Port-of-entry re-inspection

3.5 As mentioned above, meat, poultry and egg products must be first inspected and approved by the inspection system of their exporting countries before being shipped to the US. FSIS will conduct port-of-entry re-inspection for these products for proper certification, general condition and labelling. In addition, FSIS will conduct other types of inspection such as examination for product defects, and laboratory analysis for product composition and microbiological contamination for selected shipments according to a statistical sampling system.[6] FSIS also randomly samples products for drug and chemical residue testing.

3.6 The sampling of shipments and assignment of type of inspection are determined by the Public Health Information System ("PHIS"), a centralized computer database that stores re-inspection results from all ports of entry for each exporting country and each food establishment. Sampling is allocated by exporting country, process category, product category and species, and adjusted for each exporting country's risk-based sampling plan. The sampling plan is determined based on the volume of products imported in the previous year and the risk category of the imported products.

3.7 Products that fail re-inspection are refused entry into the US and must be re-exported, converted to non-human food or destroyed. The results of re-inspection will be recorded in PHIS and used for determining the frequency of re-inspection for future shipments from the same foreign food establishment. For example, a failure for physical defects will result in the next 10 shipments from the establishment concerned being selected for physical examination.

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[6] FSIS staff conduct re-inspection of the imported food products in approved import inspection facilities which locate in different parts of the US. The Research Office has written to FSIS requesting for information about whether these facilities are close to the ports of entry. As at the publication of this fact sheet, FSIS has not responded to the request.

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