



# Updates in International Food Regulation and Trade: Foreign Supplier Verification Program, Efforts in Harmonization, and the United States-Mexico-Canada Agreement

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# The Foreign Supplier Verification Program:

*A Key Part of FDA's Strategy for the Safety of Imported Food*

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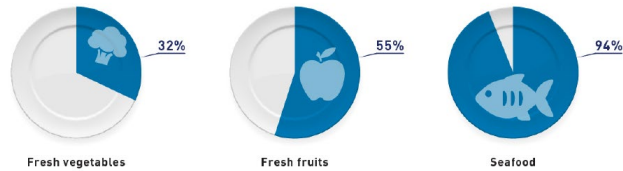
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**May 3, 2019**

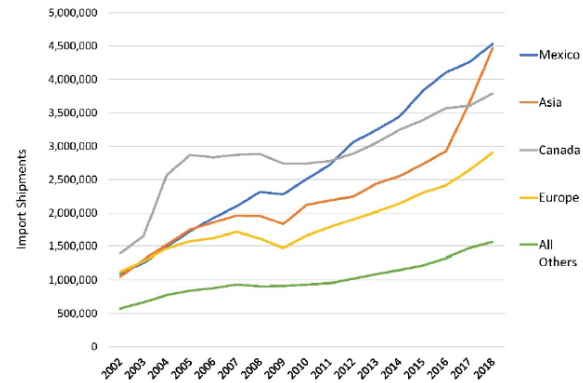


# FDA Strategy for the Safety of Imported Food (2019)

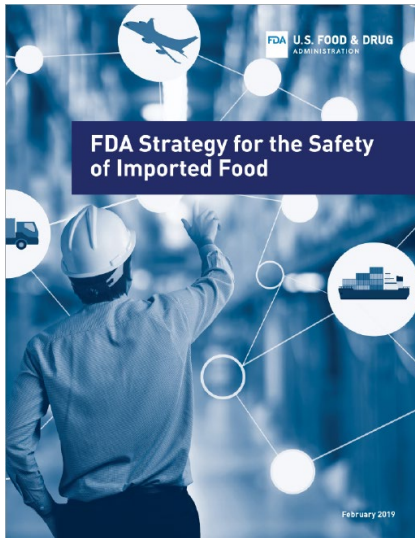
**Figure 1.** Import share of U.S. food consumption (by volume)



**Figure 2.** Number of imported food shipments by exporting country/region



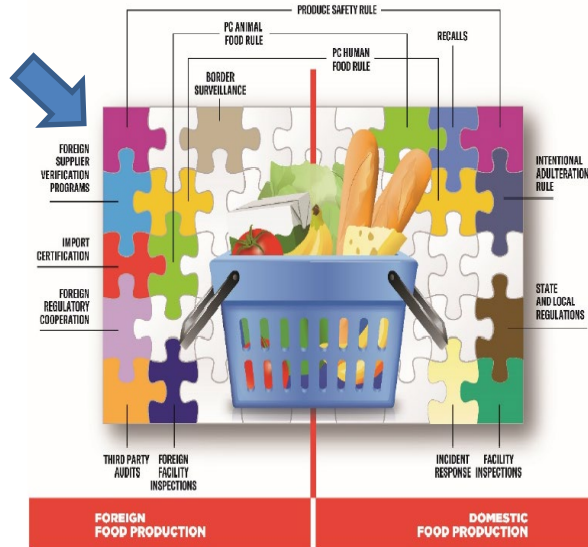
# FDA Strategy for the Safety of Imported Food (2019)



- Key Challenges:
  - Imports volume/variety & complexity of supply Economic adulteration
  - Disparate food safety systems & regulatory capacities
  - Illnesses & deaths caused by foodborne illness
- 3 Categories of Goals
  - Pre-entry prevention of food safety problems
  - Refuse entry to unsafe foods
  - Rapid response to unsafe food imports

# FDA Strategy for the Safety of Imported Food (2019)

Figure 4. Foreign and Domestic Food Safety Oversight Activities



- Goal 1: Food offered for import meets U.S. food safety requirements
  - Objective 1.2: Ensure importer use of verified foreign suppliers through effective implementation of the Foreign Supplier Verification Program

# Foreign Supplier Verification Program (FSVP) Requirements for Importers

- “[F]or each food you import, you must develop, maintain, and follow an FSVP that provides adequate assurances that your foreign supplier is producing the food in compliance with processes and procedures *that provide at least the same level of public health protection as* those required under section 418 (regarding hazard analysis and risk-based *preventive controls* for certain foods) or 419 (regarding standards for *produce safety*), if either is applicable, . . . and is producing the food in compliance with sections 402 (regarding *adulteration*) and 403(w) . . . (regarding misbranding with respect to *labeling for the presence of major food allergens*) of the [FDCA].” (Section 1.502).



# FSVP “Importers”

- “Importer” means:
  - The U.S. owner or consignee of a food offered for import into the United States; or
  - If there is no U.S. owner or consignee, the U.S. agent or representative of the foreign owner or consignee at the time of entry, as confirmed in a signed statement of consent to serve as the “importer” for FSVP purposes.



# “Importers” Subject to FDCA Sec. 418 (Preventive Controls)

- Importers subject to FDCA section 418 are “deemed” to comply with FSVP requirements if –
  - they are a “receiving facility” and
    - They comply with applicable “preventive control” requirements for the imported food\*; OR
    - They comply with the supply-chain programs requirements for the food\*\*.
  - \*Sections 117.136 (human) or 507.36 (animal)
  - \*\*Part 117 – subpart G (human) or Part 507 – subpart E (animal)





# Key FSVP Requirements for Importers

- Rely on “qualified individual”
- Conduct hazard analysis for each imported food & determine whether hazard(s) require control(s)
  - Considerations
    - Biological, chemical & physical hazards
    - Naturally occurring, introduced un-/intentionally
    - Food formulation, establishment/equipment, processing procedures, transportation practices, storage conditions, etc.

*FOOD HAZARDS*

# Key FSVP Requirements for Importers

- In approving foreign suppliers and determining the appropriate supplier verification activities that must be conducted for a foreign supplier of a type of imported food, food importers must consider --
  - The hazard analysis for the imported food
  - The entity/ies that will be responsible for minimizing/preventing each hazard requiring control or verifying that hazard has been minimized/prevented
  - The performance of the foreign supplier
    - Food safety procedures, processes & practices
    - FDA compliance track record (e.g., import alerts, warning letters, etc.)
    - Food safety track record (e.g., test results, audit results, corrective actions)

**compliance track record**

# Key FSVP Requirements for Importers

- *Approve foreign suppliers* based on the evaluation of a supplier's performance and the risk posed by the imported food.
  - Reevaluate as needed but not less than once per 3 year period
- Follow written procedures to ensure that food imports come from *approved suppliers*
  - Unapproved suppliers may be used only on a limited and temporary basis when foods are subjected to certain verification activities in accordance with FSVP requirements

APPROVED!

# Key FSVP Requirements for Importers

- Establish & follow written procedures for ensuring that – before foods are imported – appropriate foreign supplier verification (FSV) activities have been conducted
  - FSV activities must provide the assurance that the food safety hazards that require control(s) have been significantly minimized/prevented
  - FSV activities must account for the evaluation of food hazards & foreign supplier’s performance, and other key factors
  - “Appropriate” FSV activities include onsite audits, testing food samples, review of foreign supplier’s food safety records, etc.
    - For SAH/CODHA hazards, onsite audits before the initial import & at least annually thereafter = default requirement

FDA seeking source of imported melons in salmonella outbreak



Source: Produce Retailer 4.26.19

# FSVP Compliance: FY 2018 – 483s

Long Description	Frequency
You did not develop an FSVP. Specifically, ***	278

	A	B	C	D	E	F
	Citation Program Area	Cite Id	Reference Number	Short Description	Long Description	Frequency
1						
2	Foods	18254	21 CFR 1.502(a)	Develop FSVP	You did not develop an FSVP. Specifically, ***	278
	Foods	1524	21 CFR 123.11(b)	Sanitation monitoring	You are not monitoring the sanitation conditions and practices with sufficient frequency to assure conformance with Current Good Manufacturing Practices including [safety of water that comes into contact with food or food contact surfaces, including water used to manufacture ice] [condition and cleanliness of food contact surfaces] [prevention of cross-contamination from insanitary objects] [maintenance of hand washing, hand sanitizing, and toilet facilities] [protection of food, food packaging material, and food contact surfaces from adulteration] [proper labeling, storage and use of toxic chemicals] [control of employee health conditions] [exclusion of pests]. Specifically, ***	188
3	Foods	18145	21 CFR 117.35(c)	Pest Control	You did not [exclude pests from your food plant] [use pesticides under precautions and restrictions] to protect against contamination of food. Specifically, ***	183
4	Foods	18161	21 CFR 117.80(c)	Manufacturing, Processing, Packing, Holding - Controls	You did not conduct operations under conditions and controls necessary to minimize the potential for [growth of microorganisms] [allergen cross-contact] [contamination of food] [deterioration of food]. Specifically, ***	175
5	Foods	18141	21 CFR 117.35(a)	Sanitary Operations - Plant Maintenance	You did not [maintain your plant in a clean and sanitary condition] [keep your plant in repair]. Specifically, ***	167
6	Foods	18138	21 CFR 117.10	Personnel	You did not take a reasonable measure and precaution related to personnel practices. Specifically, ***	161
7	Foods	18149	21 CFR 117.40	Equipment and Utensils - Design and Maintenance	Your equipment and utensils were not designed and constructed to be adequately cleaned or maintained to protect against [allergen cross-contact] [contamination]. Specifically, ***	158
8	Foods	18148	21 CFR 117.37	Sanitary Facilities and Control	Your plant did not have adequate sanitary facilities and accommodations. Specifically, ***	143
9	Foods	18140	21 CFR 117.20(b)	Plant Construction and Design	Your plant was not [constructed] [designed] to facilitate maintenance and sanitary operations. Specifically, ***	140
10						

# Consequences for FSVP Noncompliance

- Import Refusal –
  - FDA is required to refuse admission to a food that is presented for importation when it “appears” that the importer of the food has failed to comply with FSVP requirements.
    - No U.S. owner, consignee, or agent designated
    - No FSVP that complies with FDA requirements
- Prohibited Act
  - Importation or offering for importation a food
    - if the importer fails to have compliant FSVP program
      - Criminal penalties available





*Thank You*

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**May 3, 2019**





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## Update on Canadian Food Regulation

Teresa Reguly, Partner Torys LLP



# Overview of Food Regulation

## – Health Canada

- Responsible for administering the provisions of the *Foods and Drugs Act* that relate to public health, safety and nutrition, and establishing food standards
- Establishing policies, setting standards and providing advice and information on the safety and nutritional value of food.

## – Canadian Food Inspection Agency (CFIA)

- All federal inspection services related to food facilities and enforces the food safety and nutritional quality standards established by Health Canada
- Responsible for administration and enforcement of federal legislation, including the, *Agriculture and Agri-Food Administrative Monetary Penalties Act*, *Canadian Food Inspection Agency Act*, *Health of Animals Act* and *Safe Food for Canadians Act*.

# Safe Food for Canadians Act (SFCA)

- Significant update to Canada's food regulatory space
  - In development since 2012
- SFCA and its Regulations (SFCR) came into force on January 15, 2019
- Immediate or phased-in (12-30 months) requirements depending on food commodity, type of activity and business size. In general:
  - Eggs, dairy, fish meat – licensing and other requirements in force now
  - Fresh fruit and vegetables – licensing requirements in force, other requirements will be implemented by January 2020
  - Other foods commodities have until July 2020

# Safe Food for Canadians Act (SFCA)

- SFCA replaces 14 separate sets of regulations
  - e.g. Dairy Product Regulations, Egg Regulations, Fresh Fruit and Vegetable Regulations
  - Aim to reduce unnecessary administrative burden on businesses
  - Improve consistency of rules across all types of food and food businesses
- Three fundamental new elements
  1. Licensing
  2. Preventive controls and preventative control plans
  3. Traceability

# Licensing

- Licenses from CFIA are required to:
  - Import food
  - Manufacture, process, treat, preserve, grade, package, or label food to be exported or sent across provincial or territorial borders
  - Export food that requires an export certificate, even if the site is not preparing the food
  - Slaughter food animals from which meat products are derived for export or to be sent across provincial or territorial borders
  - Store and handle a meat product in its imported condition for inspection by the CFIA

# Licensing

- Companies apply for one license to cover all establishments and activities, or apply for multiple licenses
  - Consider efficiencies vs. impact on license in event of compliance issues
  - Single license recommended for exporting businesses
  - Licence fee is \$250, and valid for two years.
- License application requires attestation to having preventive controls in place
- Existing licensed under certain other Federal legislation remain valid until expiry (fish, meat, agri-products)
  - Once expired, will need to apply for a licence under the SFCR

# Licensing – US Companies

- US company preparing food in the US for export to Canada does not require a SFC license if another entity is the importer
- Importing company must have SFC license and is responsible for compliance with SFCR
  - The importer could be located in Canada or in the US
  - US business can be a non-resident importer (NRI) and need meet the same requirements as Canadian importers, including:
    - SFC licence to import
    - Preventive control plan;
    - Procedures for handling and investigating complaints and recalls
    - Clear and complete traceability records

# Importation

- For imported food that does not meet the requirements of the SFCR
  - Food is labelled "for further preparation only", and
  - Must be brought into compliance within 3 months of arrival in Canada
- This exemption does not apply to meat products
- Can also import non-compliant foods for the purpose of export

# Preventative Controls

- Preventive food safety controls address hazards and risks in such areas as:
  - Sanitation and pest control
  - Treatments and processes
  - Equipment
  - Maintenance and operation of establishments
  - Unloading, loading and storing food
  - Employee competence
  - Employee hygiene
  - Employee health
  - Complaints and recalls



# Preventative Control Plan (PCP)

- A written document that demonstrates how risks to food and food animals are identified and controlled
  - Controls based on Hazard Analysis Critical Control Point (HACCP) principles
  - PCP must also include description of measures taken related to packaging, labelling, grades and standards of identity
  - For importers, the PCP describes how the importer and its foreign suppliers are meeting preventive food safety control requirements
    - Certified by a competent authority in a foreign state
    - Internationally recognized third-party evaluations
    - Importer evaluation

# PCP for Importers

- Description of steps to ensure SFCR compliance:
  - Sampling and testing the imported food
  - Reviewing certificates of analysis
  - Reviewing product specification
- Verification step frequency
  - Initial shipments for new supplier
  - Annual audits, certification requests, etc.
- Responsibility within the company for verification
  - Job title and qualifications of responsible individual
- Supporting documents as basis for verification steps

# Traceability

- Ability to track the movement of food one step back and one step forward
- Clear and readable records maintained for two years
  - Accessible in Canada
  - Provided to CFIA upon request
  - Electronic records must be provided in a single file and format; easily used in standard commercial software

# Traceability Documents

- **Identify the food**
  - Common name
  - Name and address of the person who manufactured, prepared, produced, stored, packaged or labelled the food,
  - Lot code or other unique identifier (purchase order number, or a bill of lading number)
- **Trace the food one step back and one step forward**
  - Person who provided the food/provided to
  - Date provided
- **If applicable**
  - Identify and trace back the ingredients, including date
  - Identify and trace back slaughtered animals

# Foreign Supplier Verification Program

- With SFCR in force, CFIA maintains list of federally licensed businesses considered in 'good standing' with Canadian regulatory requirements
  - Searchable, updated daily
  - CFIA will verify that food businesses follow their PCP and product traceability process; will be removed from list if any issues
  - CFIA will exchange information with US FDA following notices of food safety concern regarding products from licensed Canadian food establishments
    - Port-of-entry violations
    - Corrective measures taken in Canada

# Food Safety - Reporting Obligations

- *Food and Drugs Act* prohibits sale of food that contains a poisonous or harmful substance, is unfit for human consumption or is adulterated
  - No reporting obligation under the FDA or SFCA for non-compliance
- CFIA has authority to order mandatory recall where there are reasonable grounds to believe that the product poses a risk to public, animal or plant health
  - Most recalls are voluntary, initiated by manufacturer or distributor
  - CFIA guidance indicates that you should “immediately” report to CFIA if it is suspected that an unsafe product was sold

# Continued Modernization Efforts

- Food labelling
  - Ongoing consultations, no draft regulations yet
  - Alignment to Codex Alimentarius and US standards for date marking, label format, company info, statements re imported food
- Use of foreign regulatory reviews
  - Could be relied upon for the Canadian authorization process for food processing aids and additives
- No clear timeline for either initiative



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USMCA Regulatory challenges and opportunities for the food and  
beverage industries.

Alberto Campos  
Partner, Sanchez Devanny



# Food / Beverage Regulation

Food and Beverage Products importation and marketing in Mexico is highly regulated (agricultural or industrialized goods).

The main provision regarding food and beverage is the General Health Law, its Regulations for Goods and Services and Mexican Official Standards applicable to each specific kind of product or activity.

# Food / Beverage regulation

Imported and domestic food and beverage are subject to identical standards and requirements as domestic ones.

Imported food and beverage may be subject to requirements compliance not only upon marketing but also upon importation.

# Food / Beverage importation

Importation of food and beverage products is subject to:

- a. General Requirements;
- b. Tariff Requirements;
- c. Non Tariff Requirements;
- d. Disguised trade barriers.

# Tariff Importation Requirements.

All tariff importation requirements base on tariff classification of products under the Mexican Import and Export Duties Law (Tariff Schedule) and generally include:

- a. Import Duties;
- b. Dumping or countervailing duties;
- c. Value Added Tax;
- d. Excise Taxes.

# Non Tariff Requirements

Non tariff requirements are also based on the tariff classification of goods.

The most relevant are:

- a. Licenses and permits;
- b. Notices;
- c. Marketing Authorizations or Registries;
- d. Marking and labeling;
- e. Import quotas.

# Product compliance responsibility

Compliance with imported food and beverage correspond to the importer of record or marketing agent in Mexico.

Foreign manufacturers and exporters are not subject to any kind of liability arising from a product's lack of due compliance with the applicable provisions.

# Importation Under NAFTA

General import requirements.

Tariff requirements. – preferential import duties;

Non Tariff Requirements.- Specific benefits for Canadian and US goods exported to Mexico.

Particular requirements for agricultural products and finished food and beverage.

# Importation Under NAFTA

Exemptions to benefits derived from health and sanitary risks to population, animals and plants;  
Conditioning and exemption of benefits to specific agricultural products bound for the food industry (meat, grains, fruits and vegetables, etc.).



# NAFTA transformation

- 25 years of NAFTA as a trade facilitation instrument.
- Quarter of century of new technologies and products in the food and beverage industry.
- New logistics and delivery methods and technologies not existing 25 years ago.
- New manufacturing technologies, ingredients, raw materials, additives, packaging.
- Technological developments in food and beverage products.

# NAFTA - USMCA

USMCA includes considerable improvements over NAFTA and general modernization of the agreement.

Among the most relevant developments affecting food and beverage are sanitary and phito sanitary (SPS) measures, transparency, good regulatory practices and trade technical barriers (TBT), many already included in the Trans-Pacific-Partnership Agreement (TPP).

# NAFTA - USMCA

- Chapter 9: SPS Measures

“The laws, rules standards and procedures that governments employ to protect humans, animals, and plants from diseases, pests, toxins, and other contaminants” that may directly or indirectly, affect trade between the Parties (WTO SPS Agreement).

# NAFTA - USMCA

SPS measures must base on scientific principles, international standards and applied only as necessary to ensure protection and not as a disguised trade restriction.

SPS determination must be documented, provide the possibility for comments and be as unrestrictive to trade as possible.

# NAFTA - USMCA

Parties shall seek to enhance compatibility of its SPS measures with those of the other Parties, considering relevant actual or proposed measures of the other Parties and having the objective of making its SPS measures equivalent or identical to those of the other Parties.

# NAFTA - USMCA

Parties shall recognize equivalence to specific SPS measures and if feasible to groups of measures or upon systems-wide basis.

SPS measures shall be recognized even if the measures differ and it is objectively evidenced that the exporter measure achieves the importer level of protection.

A Party may initiate technical consultations with another Party to discuss matters regarding SPS that may adversely affect trade and have recourse to dispute settlement under Chapter 31

# PRACTICAL ISSUES

Probable timing for changes in domestic provisions reflecting obligations;

Different legal systems;

Implementation of direct and indirect provisions related with specific products;

Differences in infrastructure and enforcement capability.

# CONCLUSIONS

