

# Product Admissibility: Compliance for Food & Beverage Importers — From "Red Lane to Green Lane"

Americas Food & Beverage Virtual Show & Conference September 24, 2021



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### Find the Right Partner

- 1. Longevity
- 2. Financial stability
- 3. Reputation, recommendations
- 4. Ability to meet deadlines
- 5. Adaptability
- 6. Quality control standards
- 7. Labor standards
- 8. Security standards



### **Know Admissibility Requirements**





### Comply with FDA Requirements

	All Foods*(including dietary supplements, beverages, etc.)
	Pharmaceutical Drugs (OTC & Rx)
	Cosmetics (eye-liner, lipstick, nasal wash)
	Medical Devices (heart stent, contact lens, toothbrush)
	Biologics (Botox®, Insulin, etc.)
	Radiation-Emitting Products (CT-Scan, lasers, etc.)
	Tobacco Products (nicotine delivery device?)
* <i>Exc</i>	cept poultry & most meats



### - FDA Flags

Flag	Meaning	Examples
FD1	May or may not be regulated by FDA: If regulated by FDA, submit entry information; if not regulated by FDA, disclaim	Certain chemicals used in manufacturing drug products vs. industrial use; safety goggles for medical use vs. non-medical use
FD2	Regulated by FDA, but is not food: Submit entry information	Medical Devices, Drugs, Tobacco, and Cosmetics
FD3	May or may not be a food product: If yes, submit Prior Notice (PN) and entry information; if no, disclaim	Salt used for flavoring food vs salt used for treating road surfaces
FD4	Food product: Submit PN and entry information	Fish and seafood, live food animals, dairy products, shell eggs, fruits, vegetables, food and feed ingredients, food and feed additives, infant formula, beverages (including alcoholic beverages and bottled water), bakery goods, snack foods, candy, canned foods, and dietary supplements and dietary ingredients



- Admissibility
- FDA will decide to:
  - Release the goods
  - Obtain more information
    - Through documents
    - Through examination and/or sample collection
    - Upload documents in ITACS account management
  - Detain the good w/o exam
    - Based on lack of required affirmations
    - Based on import alert conditions



- Documents Required
- Electronic submission may not be enough
- "FDA Documents Required" message to entry filer
- What's needed:
  - CBP entry forms
  - Invoice/Packing List
  - B/L or AWB
  - Other: Affirmations of Compliance, Tests



- Examination/Sampling
- Examine products, collect samples
- "FDA Exam/Sample" message filer
- Notice of FDA Action (exam)
- Submit:
  - Entry documents
  - Availability information (where, when, contact info warehouse)
- Availability
  - At Port of Entry, or may need to redeliver



#### - Detention

- Right to provide evidence to overcome (hearing process)
- Detention will stand (refusal) or overturned (release)

### - Refusal of Admission

- If cannot bring into compliance, refuse
- Redelivery notice issues upon refusal
- Refused product export or destroy





### Meet FSMA Requirements

### Facility registration under Food Safety Modernization Act

- Registration of <u>ALL</u> foreign & domestic food facilities
- Engaged in manufacturing, processing, packing or holding food for consumption
- Re-registration every 2-years
- Consent to records and facility inspection
- U.S. Agent liable for payment of facility reinspection fees to FDA

### Registered Facilities as of January 11, 2021

Domestic (U.S.) registrations: 80,935

Foreign registrations: 101,212

• Total: 182,147



### Meet FSMA Requirements

- Other FSMA Requirements
  - Preventive controls for human food (with GMPs, Food Safety Plans)
    - Hazard: people, ingredients, environment
    - Preventive: process, allergen, sanitation, supply chain, recall
  - Produce safety
    - Water, soil, sprouts, animals, workers, equipment/tools/buildings
  - Sanitary transportation
    - Applies to shippers, receivers, loaders, carriers who transport food into U.S.



### Meet FSMA Requirements

### **Other FSMA Requirements**

- Foreign supplier verification program
  - Requires importer to document and declare FIRM is under comparable/equivalent food safety oversight and in compliance with food safety authority
  - Through qualified individual that conducts compliance review, hazard analysis, evaluation, approval and verification

### Applicability

- YES if owner, consignee, U.S. agent, representative (foreign owner/consignee)
- NOT if import only fish/fishery, juice, research/evaluation, alcoholic beverages, meat, poultry, egg; personal consumption; transshipped; processing and export; or exported/ returned w/o further manufacture abroad
- NOT low acid canned food
- NOT if compliance with Preventive Controls for Human/Animal Food (most)
- NOT if dietary supplements with CGMP (modified)
- NOT if less than \$1 million per year during preceding 3 years (modified)
- NOT if from small, qualified suppliers (PCHF/PCAF) (modified)
- NOT if from officially recognized or equivalent food safety system country (modified) © 2021 Sandler, Travis & Rosenberg, P.A. | www.strtrade.com | All rights reserved.



- Acidified Foods (AF) or Low-Acid Canned Foods (LACF)
  - Register name of establishment, principal place of business, location of each establishment of processing, processing method, list of foods processed
  - Food Canning Establishment Number (FCE)
  - Approved Scheduled Process Submission ID (SID)
  - Process for adequate acidification

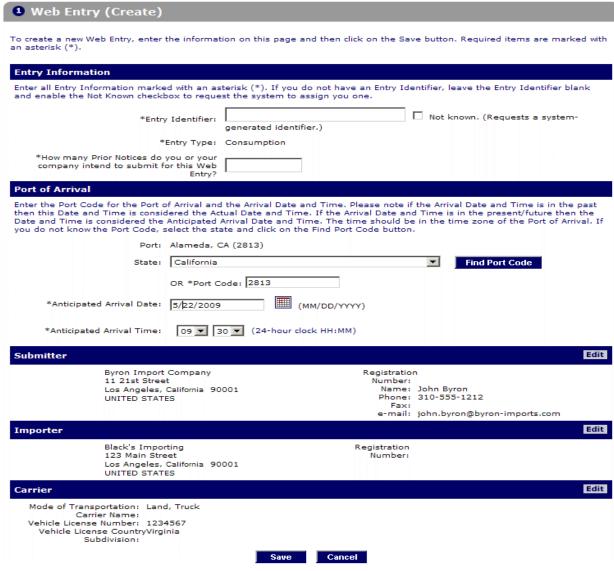




#### Prior notice

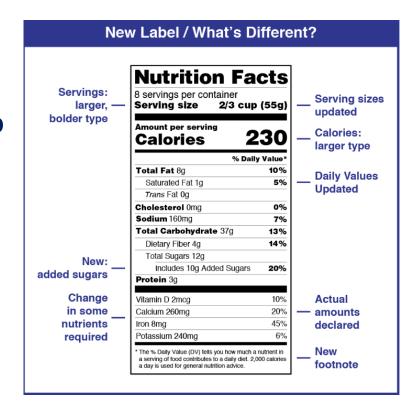
- Food for use, storage, or distribution in U.S.
- Food transshipped through U.S. to another country
- Food imported for future export
- Food for use in FTZ
- Time frames prior to arrival
  - Truck 2 hours;
  - Rail 4 hours;
  - Air 4 hours;
  - Water 8 hours







- Compliant, sufficient labeling
  - Updated in 2016 to reflect updated scientific info
  - Easier to make food choices
  - Updates -
    - 1/1/20: \$10 million or more annual sales
    - 1/1/21: Less than \$10 million annual sales





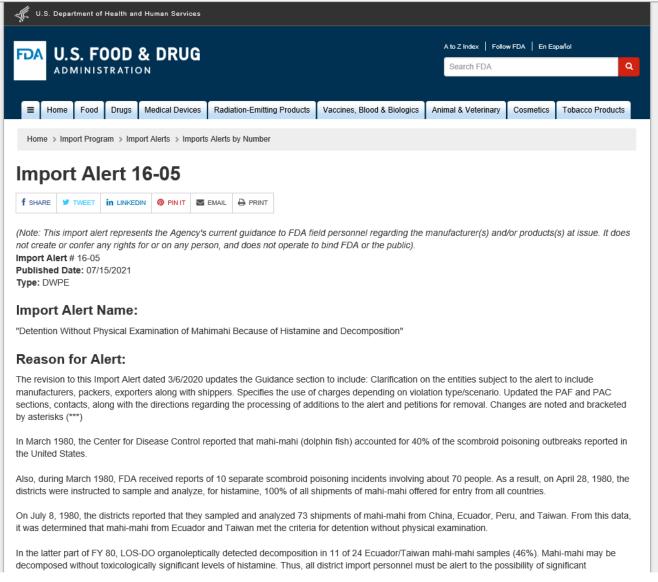
- Current Good Manufacturing Practices
  - Personal hygienic practices
  - Design, construction, maintenance food plant/grounds
  - Plant equipment
  - Sanitary operations
  - Facility sanitation
  - Production and process controls during food production



### Applicable import alerts

- History of violations regarding commodities, manufacturers/shippers, growers, geographic area, countries of origin, importers, combination of issues
- Detention Without Physical Exam based on evidence from field offices or foreign inspections; foreign gov't, state or agency
- Removal from DWPE by submitting petition (apparent violation "overcome"), reviewed by FDA with evidence usually of five non-violating shipments (may require laboratory analysis)
  - Lab testing
  - Labeling review
  - Some not at entry (GMP issues at manufacturer, unapproved food colors/ pesticides, prohibited ingredients)







Sample results as well as a number of reported illnesses attributed to imported mahi-mahi indicate continuing problems with histamines and decomposition in mahi-mahi from Ecuador.

#### Guidance:

Divisions may detain, without physical examination, all shipments of mahi-mahi from Ecuador and Taiwan, except those packers identified in the Green List to this alert.

The Red List contains individual \*\*\*packers, shippers, manufacturers and exporters\*\*\* on detention without physical examination from countries other than Ecuador or Taiwan and specifies what charge(s) are applicable to the firm.

Note: Mahi-mahi from \*\*\*packers, shippers, manufacturers and exporters\*\*\* identified in the Green List as exempt from detention without physical examination should be periodically audit sampled and analyzed for histamines.

METHODOLOGY: See Import Seafood Products Compliance Program, 7303.844.

\*\*\*Recommendations for additions to the Red List of this import alert should be forwarded to the Division of Import Operations (DIO). DIO and FDA's Center for Food Safety and Applied Nutrition (CFSAN) will evaluate regulatory packages on a case-by-case basis.\*\*\*

Release of Articles Subject to Detention without Physical Examination under This Import Alert:

In order to secure release of an individual shipment detained pursuant to this Import Alert, the importer should provide all relevant information supporting the request for release to the appropriate FDA Division compliance office

For guidance on removal from detention without physical examination, refer to FDA's Regulatory Procedures Manual, Chapter 9-8, "Detention without Physical Examination (DWPE)."

If a firm and/or a representative would like to petition for removal from detention without physical examination under this Import Alert, all relevant information supporting the request should be forwarded to the following address:

Food and Drug Administration Division of Import Operations (DIO) 12420 Parklawn Drive, ELEM-3109 Rockville. MD 20857

Or via email to: Importalerts2@fda.hhs.gov \*\*\*

\*\*\* Questions or issues involving import operations should be addressed to ORA/DIO (301) 796-0356 or FDAImportsInguiry@fda.hhs.gov

Questions or issues involving science policy, analysis, preparation, or analytical methodology, should be addressed to ORA/Office of Regulatory Science at oraorsprivatelabimportalerts@fda.hhs.gov

Questions or issues involving OASIS or PREDICT screening should be addressed to ORA/DSS/Import Systems Branch at



#### **Product Description:**

Mahi-mahi (dolphin) raw, fresh or frozen, including fillets

#### Charge:

\*\*\* For histamine: \*\*\*

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain a poisonous or deleterious substance which would ordinarily render the article injurious to health. Contains:" \*\*\*[Adulteration, Section 402(a)(1)] \*\*\*

OASIS charge code - POISONORD

and/or

\*\*\* For decomposition: \*\*\*

\*\*\*\*The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to consist in whole or in part of a filthy, putrid, or decomposed substance or be otherwise unfit for food."\*\*\* [Adulteration, Section 402(a)(3)]

OASIS charge code - FILTHY

#### Countries

#### **ECUADOR**

(16 A - - 51) Mahi Mahi

#### TAIWAN

(16 A - - 51) Mahi Mahi

Red - Firms, countries and/or products that are subject to detention without physical examination of the product identified in the criteria of the alert Yellow - List of firms and their products subject to intensified surveillance; or firms that may have satisfied GMP issues of concern, but the nature of violations may warrant further field examinations of individual entries and/or additional analyses (a.k.a. Yellow List) Green - Firms are excluded from the criteria of the alert

Go to Red List Green List



Nicalapia S.A.

Date Published: 06/15/2018

Km 34 1/2 Carretera Nueva A Leon , Frente a cementeria Hocim , Leon, Nagarote NICARAGUA

16 A - - 51 Mahi Mahi Date Published: 06/15/2018

Desc: Mahi Mahi

#### **PERU**

#### Alimentos Los Ferroles S.A.C.

Date Published: 10/28/2016

Urb. Los Ferroles, Callao, Avenida Prolongacion Centenario 1960, Callao, Callao PERU

16 A - - 51 Mahi Mahi Date Published: 10/28/2016

Desc: Mahi Mahi

Notes: Problems; Decomposition

#### DEEPER BLUE SEA LLC, SUCURSAL PERU

Date Published: 03/07/2016

Zona Industrial II, Av. Industrial Mza. R Lote. 05 Z.I., Peru, Piura PERU

16 A - - 51 Mahi Mahi Date Published: 03/07/2016

Desc: Mahi Mahi

Notes: Problems; Decomposition

#### Perla del Pacifico, S.R.L. Date Published: 07/14/2015

Parque Industrial, Av. Circunvalacion Mz. G Lote 1 y 2, Tacna, Tacna PERU

16 A - - 51 Mahi Mahi Date Published: 07/14/2015 Desc: Smoked Mahi Mahi

16 S - - 51 Mahi Mahi (Dolphin fish), Cold Smoked, Fish

Date Published: 07/14/2015 Desc: Smoked Mahi Mahi

#### **THAILAND**

Thai Ocean Venture Co., Ltd. Date Published: 09/10/2009

64, 213 Moo 7 Anupasphuketkan Rd, Muang Phuket, Phuket THAILAND

16 A - - 51 Mahi Mahi

Data Dublished: 40/04/0000



### Comply with USDA Requirements

### **United States Department of Agriculture (USDA)**

FSIS: Food Safety and Inspection Service



 Regulates imported meat, poultry and egg products (safety standards)

APHIS: Animal Plant Health Inspection Service

 Restricts some products from entering the U.S. due to animal disease conditions in country of origin (health requirements)



## Comply with USDA Requirements FSIS Refusal

### Ineligible Product

- Ineligible source/producing country
- Uncertified source, processing, preparing establishment
- Fails to comply with FSIS or APHIS regulations
- Produced when exporting country ineligible to export
- Produced when processing/preparing establishment ineligible to export
- Ineligible species from export country
- Ineligible product for export

### Failed Type of Inspection

- Certification
- Label Verification
- Physical Exams
- Lab Analysis



### Comply with USDA Requirements

#### **FSIS Small Amounts**

<u>Meat</u>: 3% or less raw meat; less than 2% cooked meat or other portions of the carcass; or 30% or less fat, tallow or meat extract, alone or in combination.

**Poultry**: less than 2% cooked poultry meat; less than 10% cooked poultry skins, giblets or fat, separately; or less than 10% cooked poultry skins, giblets, fat and poultry meat (limited to less than 2 percent) in any combination.

For dried products containing poultry, these percentages are computed on the basis of the moist cooked chicken in the ready to serve product when prepared according to the directions on the consumer package.



### Countries Eligible to Export to US

Country/Product		Beef /Veal		Lamb /Mutton		Goat		Pork		Poultry /Ratites		Egg Products
		Raw	Proc	Raw	Proc	Raw	Proc	Raw	Proc	Raw	Proc	Proc
1	Argentina	X <sub>4</sub>	X <sub>3</sub>		X <sub>3</sub>		X <sub>3</sub>		X <sub>3</sub>	) N		
2	Australia	X	X	X	X	X	X	X <sub>4</sub>	X <sub>4</sub>	X <sub>1</sub>	X <sub>1</sub>	
3	Austria	X <sub>2</sub>	X <sub>2</sub>					X <sub>4</sub>	X <sub>5</sub>			
4	Belgium	X <sub>2</sub>	X <sub>2</sub>						X <sub>4</sub>			
5	Brazil		X		X <sub>4</sub>		X <sub>4</sub>	X <sub>3</sub>	X			
6	Canada	X	X	X	X	X	X	X	X	X	X	X
7	Chile	X	X	X	X	X <sub>4</sub>	X <sub>4</sub>	X	X	X	X	
8	China										X <sub>5</sub>	
9	Costa Rica	X	X	X <sub>4</sub>	X <sub>4</sub>	X <sub>4</sub>	X <sub>4</sub>	X <sub>3</sub>	X			
10	Croatia	X <sub>2</sub>	X <sub>2</sub>		5			X <sub>3</sub>	X			
11	Czech Rep	X <sub>2</sub>	X <sub>2</sub>		1			X <sub>4</sub>	X <sub>4</sub>			
12	Denmark	X <sub>2</sub>	X <sub>2</sub>					X	X			
13	England	X <sub>2</sub>	X <sub>2</sub>					X	X			
14	Finland	X <sub>2</sub>	X <sub>2</sub>					X	X			
15	France	X <sub>7</sub>						Х	X	X <sub>4</sub>	X <sub>4</sub>	
16	°Great Britain									X <sub>4</sub>	X <sub>4</sub>	
17	Germany	X <sub>2</sub>	X <sub>2</sub>		2			X	X			
18	Honduras	X	X	X	X	X	X	X <sub>3</sub>	Χ			



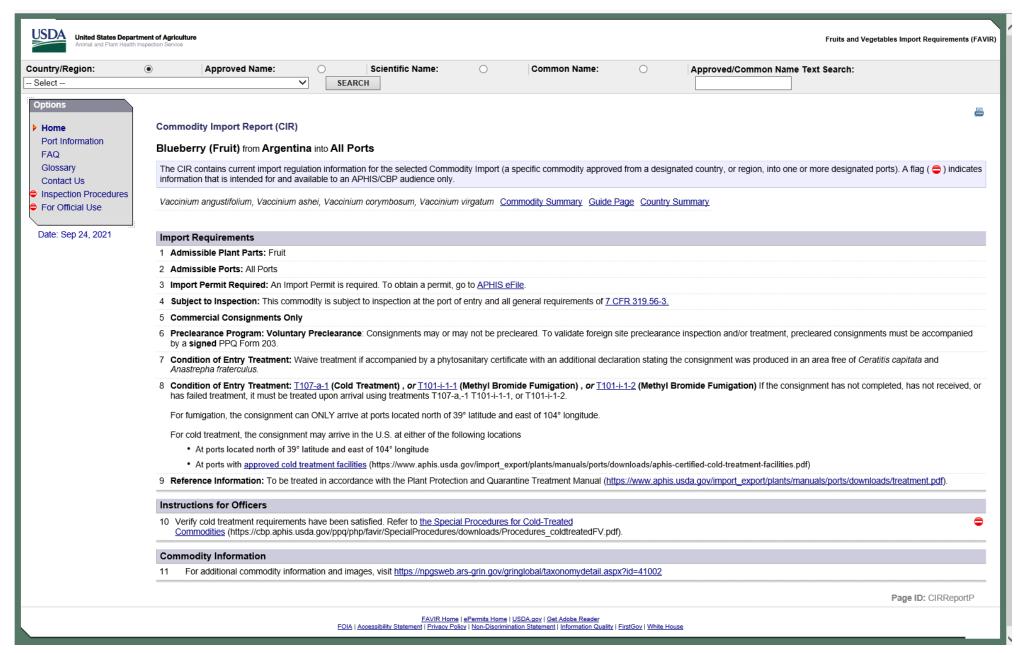
### Comply with APHIS Requirements

### Objectives:

- Animals monitor health of animals and regulate import and export of animals, animal products and biologicals.
- Plants monitor the movement of risk material, protect against the introduction of pests and regulate the import and export of plants.
- Treatments are fruit and origin specific.
- Fruit is subject to PPQ compliance inspection upon entry.
- Fruit and vegetables import requirement (FAVIR) database



### Comply with APHIS Requirements





### Comply with APHIS Requirements

### Commodity Import Approval Process:

US access for fruit/vegetable/plant or plant product that is not already an approved commodity, must initiate a commodity import request:

- Determine if the commodity is an approved commodity or currently undergoing a pest risk analysis
- If not one of the above, submit a commodity import request
- APHIS will conduct a pest risk analysis and an environmental review to determine potential pests likely to remain on the commodity upon importation and potential mitigations that may be required to avoid, reduce or eliminate the risk of pest introduction
- If APHIS determines that the commodity can be safely imported into the US, APHIS will initiate the regulatory administrative process to seek public comment



### Comply with AMS Requirements

### Section 8e Agricultural Marketing Agreement Act

- Avocados, dates, hazelnuts, grapefruit, table grapes, kiwifruit, olives, onions, oranges, Irish potatoes, pistachios, raisins, tomatoes, walnuts
- Must meet: grade, size, quality, maturity standards as domestics (inspected)

### AMS Import Certification for Organic Products:

- Protect integrity of USDA organic products
- Organic integrity from farm to table; consumer trust
- Organic Food Product Act and USDA organic regulations
- National Organic Program accredits organizations to certify farms and businesses
- Third party agents certify operations
- Buyers, sellers, importers, exporters, re-exporters, re-packagers
- Import certificate required from foreign exporters



### Comply with TTB Requirements



- Federal: Alcohol & Tobacco Tax and Trade Bureau (TTB)
- States: 50 separate markets, each with own liquor laws
  - "control" states (18) are sole wholesalers of distilled spirits and in many cases retailers, too
  - "license" states (32) regulate through licenses to industry members doing business within their states
    - -3 tier system in numerous states: importer, wholesaler/distributor, retailer



### Comply with TTB Requirements

•Exporter (Alcohol): There are certain procedures that wholesalers must follow if they wish to export alcohol – particularly if they wish to export it without payment of tax.

•Importer (Alcohol): Anyone wishing to become a beverage alcohol importer (IMP), importing into the United States beverage alcohol not for personal use, and subsequently distributing the imported beverage alcohol to wholesalers or retailers, must file this application.

•Wholesaler (Alcohol): Wholesalers (WHL), businesses which sell beverage alcohol products at wholesale to other wholesalers or retailers must first obtain a Wholesaler's Basic Permit. Producers or manufacturers of beverage alcohol products need to apply for a Wholesaler's Basic Permit only if they intend to sell beverage alcohol products which they did not produce or manufacture.

•Wholesaler/Importer (Alcohol): Businesses which require a Basic Permit for Importing (to import and distribute foreign beverage alcohol) and Wholesaling (to distribute at wholesale, domestic beverage alcohol) from the same location may reduce the required paperwork by combining the applications

TTB ensures alcohol products are created, labeled, and marketed in accordance with Federal laws and regulations.

Alcohol producers must apply for a Certification/Exemption of Label/Bottle Approval (COLA) and follow the labeling and advertising regulations.



### Questions?



### **Lenny Feldman**

**Esquire** 

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