

Issues and Concerns with Imported Foods



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Acknowledgements

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Introduction

Due to the forces of the global economy and increased demand for traditional ethnic foods, the rate of imported foods into the United States is on the rise (Brooks, Buzby & Regni, 2009).

According to the Food & Drug Administration, the growing volumes of imported foods in the US will approach 10 million import lines in FY 2011 (FDA, 2011). This number is expected to continue to grow. As indicated by the many nationwide imported food recalls and import alerts, there has been a heightened food safety concern with imported foods for the US consumer.

Less than 1% of imported foods is physically examined; although 100% are electronically reviewed by use of a risk based targeted approach (Elder, 2010).

Once these FDA-regulated products enter the United States and are marketed domestically, they become the primary responsibility of state and local agencies to ensure the products' safety (Corby, 2010).

Surveillance of imported foods by federal, state, and local food protection agencies has resulted in many regulatory actions including food sampling and testing, food seizure or embargo, destruction of violative products, Class I, II, and III food recalls, and FDA Import Alerts.

Purpose of the Guide

This guidance document is intended for use as a quick informational resource for field inspectors. The guide gives a brief explanation of the imported food process and it discloses the agencies involved. The document also provides definitions and photo examples of violative products, unapproved ingredients, and additives.

Responsible Agencies

US Customs and Border Protection (CBP): As a first line of defense US Customs and Border Protection (CBP), under the Department of Homeland Security, is responsible for inspecting food imports for compliance with U.S. law and coordinating with the FDA to enforce food safety laws at the border, among other things. Customs cooperates with FDA and FSIS in carrying out their regulatory roles in food safety. CBP's computerized screening system processes all imported shipments, including food. CBP requires importers to (1) give a manufacturer identification number for each imported shipment and (2) post a monetary bond for formal entries to provide assurance that these shipments meet U.S. requirements, among other things. 20(1GAO, *Food Safety: Federal Efforts to Ensure the Safety of Imported Foods Are Inconsistent and Unreliable*, GAO/RCED-98-103 page 14 (Washington, D.C.: Apr. 30, 1998).

21(2GAO, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, GAO-09-873 page 2 (Washington, D.C.: Sept. 15, 2009)

Food and Drug Administration (FDA): The FDA mission is to enforce the Federal Food, Drug, and Cosmetics (FD&C) Act and other laws which are designed to protect the health and safety of U.S. consumers. FDA has jurisdiction over all food products (dairy, fruits, vegetables, and seafood), excluding meat and poultry.

United States Department of Agriculture (USDA): The United States Department of Agriculture has jurisdiction over meat, poultry, and egg products in the United States.

The USDA routinely conducts targeted enforcement actions to survey USDA regulated imported products. USDA Plant Protection Quarantine Smuggling Interdiction Trade and Compliance (USDA PPQ SITC) have the responsibility to prevent the unlawful, smuggled distribution of prohibited products that may harbor exotic plant and animal pests, diseases, or invasive species. 23(USDA.gov)

The disease status of a country determines if a meat and/or poultry item is permitted to enter the US. The USDA maintains a current list of foreign countries and their disease status on the USDA website – Appendix C. 24(USDA.gov/appendix C). Many diseases are prevalent in other countries and are not found in the United States. Such countries are banned to import meat and/or poultry products into the United States. Some of the known diseases referred to include Avian Influenza H5N1, Bovine Spongiform Encephalopathy, Classic Swine Fever, and Foot and Mouth Disease. Most imported meats, poultry, milk, and eggs require a permit from USDA APHIS veterinary services

under authority of the Animal Health Protection Act 25(AHPA; 7 U.S.C. 8301 *et seq*) and/or a health certificate from the country of origin or are banned to enter the US.

Under the Plant Protection Act 26(PPA; 7 U.S.C. 7701 *et seq*), both laws are intended to ensure that imports are free of foreign diseases or pests that would threaten the US. APHIS also requires phytosanitary certificates for many imported plants and plant product due to the possible harborage of diseases. 27(Geoffrey S. Becker – *U.S. Food & Agriculture Imports: Safeguards & Selected Issues* – page 6 March 17, 2010

<http://www.nationalaglawcenter.org/assets/crs/RL34198.pdf>)

Environmental Protection Agency (EPA): The EPA is concerned with protecting human health and the environment. Its activities include environmental research, sponsorship of educational programs, and financial support for research that can improve the scientific basis for decisions on national environmental issues. Most relevant to the food industry, the EPA sets and enforces regulations whose purpose is to maintain a certain level of environmental quality (air, water, etc.) EPA also sets the tolerance for pesticide residues in foods.

U.S. Fish & Wildlife Service: The U.S. Fish and Wildlife Service works with others to conserve, protect, and enhance fish, wildlife, plants, and their habitats for the continuing benefit of the American people.

Additional information regarding the federal agencies can be obtained at www.foodsafety.gov

Imported Food Process

The following is a brief description of the imported food process prior to domestic status.

1. The Importer or agent files entry documents with Customs.
2. The FDA Reviews documents which include CBP documents, invoice, bill of lading, packing list, etc.
3. The FDA entry review officer makes a determination on the admissibility of the product based on FDA regulation (FDA District would make decision for entries submitted for district ports.)
 - <http://www.foodsafety.gov/~lrd/import.html>
(FDA Import Procedures)
4. The FDA officer will review entry documents to determine if a physical examination is needed.

The FDA had developed the PREDICT (Predictive Risk- Based Evaluation for Dynamic Import Compliance Targeting) computer system to improve targeting screening efforts.

PREDICT considers everything from whether a product is intrinsically risky – to information acquired from previous examinations of shippers and producers. PREDICT can include information on things such as floods, hot weather, or market conditions that suggest whether a particular shipment is at risk being spoiled. 19(*“FDA and the American Public: The Safety of Foods and Medical Products in the Global Age,” remarks of Dr.Margaret Hamburg, FDA Commissioner of Food and Drugs, at the Center for Strategic and International Studies, February 4, 2010.*) More information on PREDICT can be accessed at: <http://www.fda.gov/ForIndustry/ImportProgram/ucm172743.htm>.

Definitions

Class I Recall – A situation where reasonable probability exists that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. 5(*NYSAM – Food Recalls Guidance Document, November 2007*)

Class II Recall – A situation in which use of, or exposure, to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. 6(*NYSAM – Food Recalls Guidance Document, November 2007*)

Class III Recall – A situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences. 7(*NYSAM – Food Recalls Guidance Document, November 2007*)

A recall is initiated to remove the product from commerce when there is a reason to believe it may be adulterated or misbranded. 4(*NYSAM – Food Recalls Guidance Document, November 2007*). The recall classification assigned to a product indicates the degree of health hazard presented by the recalled product.

Import Alert – Information to the FDA district offices concerning unusual or new problems affecting imports which give background and compliance guidance information for each product and problem.

Product recalls and/or Import Alerts include but are not limited to microbiological contaminants (Salmonella, Listeria, E.coli, etc.), undeclared allergens, banned antibiotics, unviscerated processed fish, lead contaminated product and packaging, unapproved colors (non FD&C certified colors),

unapproved sweetener sodium cyclamate, undeclared preservatives, mycotoxins, shelf stability, pesticide residues, economic adulteration, and the lack of English labeling.

Examples and Explanations

Provided are brief reviews and explanations of the reasons for recalled food products and/or lab analysis request. Product disposition may result in relabeling, destruction, recall, or FDA import alert.

Microbiological Contamination: Microbiological Guidelines for raw and ready to eat foods followed by New York State Department of Agriculture and Markets Food Safety and Inspection Manual. Product destruction is the typical outcome for bacteriological contaminated foods. 9(*NYSAM Inspector Manual 2006 Edition*). Some spice companies may have the capability of treating spices at their own facility or at commercial sterilizers.



Undeclared Allergens: in food products are determined through laboratory testing. The consumption of an allergen can cause mild to severe reactions in an individual and even death. There are eight foods that have been determined by the FDA to be the “Big Eight” allergens: Peanuts, milk, eggs, fish, shellfish, wheat, tree nuts, and soybeans. Products containing undeclared allergens are subject to recall and can be relabeled to identify the allergen. 10(Food Facts – February 2007FDA.govwww.fda.gov/downloads/Food/ResourcesForYou/.../UCM079428.pdf -)

Undeclared Peanuts



Undeclared Eggs



Banned Antibiotics: FDA action levels adhered. Banned antibiotics and chemicals such as chloramphenicol, sulfonamide, malachite green, and fluoroquinolones (enrofloxacin and ciprofloxacin) have been detected in imported milk, honey, shrimp, and fish products. These products are subject to destruction and FDA Import Alert.

11(www.fda.gov/.../AboutFDA/ReportsManualsForms/Reports/BudgetReports/2006FDABudgetSummary/ucm120776.pdf, page 398-399.)
www.fda.gov/NewsEvents/Testimony/ucm110728.htm



Uneviscerated Processed Fish: Is not approved for sale in the United States due to naturally occurring *Clostridium botulinum* concerns. If processed fish (cooked, dried, salted, cured, smoked) greater than 5 inches is found the product must be destroyed and will be placed on FDA import alert.



Unapproved Colors: (non FD&C certified colors) – There is a list of FD&C certified colors approved for use in food and there is also a list of non FD&C certified colors that are not approved for use in food. Non-FDA certified colors have been laboratory tested by the US FDA and found to be carcinogenic. Color additives approved in other countries may not necessarily be approved in the United States. There are also industrial dyes that are not certified for food use. Certified food dyes are very costly and industrial dyes are much cheaper. Examples of industrial dyes: Rhodamine B and Auramine are not approved for food use anywhere in the world. The colors have many different common and chemical names.

Products that may contain unapproved colors are typically candy, baked goods, beverages, and pasta. Products containing unapproved colors shall be destroyed and placed on an FDA import alert. 12(FDA 21CFRPart 70)





Unapproved E 124 (Ponceau 4R):



Contains Unapproved: Auramine O – Basic Yellow 2, Rhodamine B – Basic Violet 10, Acid Blue 1 – Sulfan Blue, Orange II – Acid Orange 7, Ponceau 4R (E 124) – Acid Red 18, Brilliant Green – Basic Green1, Crystal Violet – Basic Violet 3.

Lead Contaminated Foods and Packaging Containers: FDA action levels adhered. For FDA-regulated products, industry voluntarily stopped using lead solder in cans in the late 1970's and it was finally banned by FDA in 1995 13(21 *Code of Federal Regulations (CFR) Part 189.240*). (FDA) Lead solder detected in can seams will eventually leach into the food product. Lead is a known metabolic poison that can damage the kidneys, liver, and the nervous, reproductive, cardiovascular, immune, and gastrointestinal systems. Lead accumulates in the bones. It is particularly damaging in children and can impede intellectual development. Extremely high levels of lead in the body can cause convulsions, coma, and death. (World Health Organization) Milk, fish, and candy are some of the specific imported products and cans that were contaminated with lead.





Sodium Cyclamate: (also referred as galenical (001,004) or cyclamic acid) Artificial sweetener – banned by the FDA in 1970, cyclamates were banned due to the studies linking the sweetener to bladder cancer. 14(FDA – Volume IV – 10.2 Food and Color Additives) Examples of products containing the banned sweetener include imported candy, dried fruits, nuts, and preserved vegetables.



Undeclared Preservatives: Sulfites are added to processed foods to enhance, fix the color and to preserve the product. Certain individuals have slight to severe sensitivity to sulfites. Sulfites could be added to food products such as dried fruit, dried/ preserved vegetables, bakery items, and shrimp.



Mycotoxin: The toxin Aflatoxin - aflatoxins are very potent in minute amounts and can cause disease throughout the body including acute or chronic liver disease and liver cancer. Aflatoxins often occur in crops in the field prior to harvesting and can occur during post-harvest if there is a delay crop drying/high water and humid areas. 15(World Health Organization - www.who.int/entity/ipcs/events/2005/workshop_report.pdf, page5, www.who.int/) Food implicated contaminated with aflatoxins and note on the recalled food products list include peanuts and corn products.



Processed Fish in Oil – Shelf Stable – Clostridium Botulinum Concerns

Shelf Stability: Inspectors are trained to analyze the contents, process, and packaging of a product to make that determination. Products can be sampled and tested for “shelf stability”. In essence, the analysis will be based on the most relevant critical food safety factors, such as pH, water activity, salt content, water phase salt, etc., or perhaps the product is commercially sterile. All of these factors and parameters need to be considered to determine if the product is in fact shelf stable. Examples of products that would be sampled for shelf stability would be preserved duck eggs and salted fish. 16(*New York State Department of Agriculture and Markets; Division of Food Safety and Inspection: Inspector Manual 2006 Edition.*)





Economic Adulteration: (Fraudulent / Counterfeit) Several food commodities are intentionally adulterated for economic reasons. Historically olive oil labeled “pure / 100% olive oil” has been adulterated with soy bean oil since it is more than a third cheaper of the cost of olive oil. Honey is another product which can be adulterated with undeclared added sugars so the product is not pure honey.





English: Imported foods that lack English labels must be properly relabeled in English to include all pertinent information. Additional languages may be added to the label.



Additional Imported Food Concerns

Imported birds' nests, balut, and guinea pig - Verification of certificates and permit

USDA Permit / Health Certificate from Country of Origin required

Avian Influenza affected countries



Duck Tongue imported from China – Avian Influenza affected country (refer to USDA appendix C for updated disease status of countries.)



Illegally imported from China – Misbranded Fish Balls contain pork. Pork currently banned from China due to Swine Fever (refer to USDA appendix C for updated disease status of countries.)



Illegally imported from China – Dumpling skins containing pork.
Pork from China is currently banned due to Swine Fever (refer to USDA appendix C for updated disease status of countries.)



Beef products imported from Italy – Prohibited in the US due to disease (BSE) status of Italy at the time of importation (refer to USDA appendix C for updated disease status of countries.)



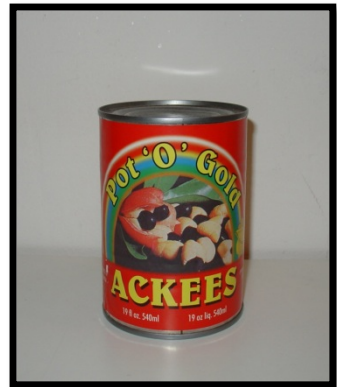
Deer tails, tendons, and sliced antlers unknown/unapproved source – Ruminant diseases (refer to USDA appendix C for updated disease status of countries.)



Imported canned Iguana soup – Must have FDA FCE number (filed scheduled process). Refer to US Fish & Wildlife to verify species of iguana is not on endangered species list.



Ackees – A canned fruit that must be harvested at the appropriate time to avoid the growth of a natural toxin that can be poisonous. Manufactures must be on an approved list



CERTIFIED COLORS PERMITTED IN FOODS

Listed color additives are subject to certification and are permanently listed (unless otherwise indicated) for use in food. Most colors are also listed for use in drugs and cosmetics as noted. None of these colors may be used in products that are for use in the area of the eye, (unless otherwise indicated).

Number	Name	Uses
FD&C Blue #1	Brilliant Blue	Food, drug and cosmetic use, including drugs for eye the area.
FD&C Blue #2	Indigotine	Food, ingested drugs and sutures.
FD&C Green #3	Fast Green	Food, drug and cosmetic use.
FD&C Red #3	Erythrosine, E127	Food and ingested drugs. May no longer be used in cosmetics, external drugs and lakes.
FD&C Red #40 & its Aluminum Lake	Allura Red AC	Food, drug and cosmetic use, including drugs and cosmetics for the eye area.
FD&C Yellow #5	Tartrazine	Food, drug and cosmetics, including drugs and cosmetics for eye the area.
FD&C Yellow #6	Sunset Yellow	Food, drug and cosmetics.
FD&C Lakes	Lakes	Provisionally listed. May be prepared from any of the above certified FD&C colors, except FD&C Red #3.
Citrus Red #2		Permanently listed for use ONLY in coloring the skins of mature oranges. Limited to ≤ 2 ppm by weight of whole fruit.
Orange B		Permanently listed for use in coloring the surfaces and casings for frankfurters or sausages. Limited to ≤ 150 ppm by weight of finished product.

Food Color Additives Banned in the USA

Listed color additives are banned in the United States of America. Products found being offered for retail sale or warehoused for further distribution containing these banned additives are to be placed under seizure and destroyed under signed waiver.

Number	Name	FD&C Number
E104	Quinoline Yellow	D&C Yellow #10
E107	Yellow 2G	
E122	Azorubine Carmoisine	
E123	Amaranth	delisted FD&C Red #2
E124	Ponceau 4R, Ponceau Red, Cochineal Red A	
E125	Ponceau SX	delisted FD&C Red #4
E131	Patent Blue V	
E142	Green S	
E151	Brilliant Black B, Black PN	
E153	Vegetable Carbon	
E154	Brown FK	
E155	Brown HT, Chocolate Brown	
	Cuttlefish Black, Cuttle Black	Not on FDA's list of permitted color additives

These colors, previously commonly used, are no longer authorized or have been restricted in their use.

FD&C Green #1	Removed from list.
FD&C Green #2	Removed from list.
FD&C Red #1	Removed from list.
FD&C Red #2	Removed from list.
FD&C Red #3	All lakes, cosmetics, and external drugs removed from list.
FD&C Red #4	Food, ingested drugs, and ingested cosmetics removed from list.
FD&C Violet #1	Removed from list.
Alkanet (Alkane)	
Calcium Carbonate	Allowed in drugs.
Carbon black	
Charcoal- NF XI	
Cudbear	

Ferric chloride	
Ferrous sulfate	
Logwood, chip & extract	Logwood extract is still permitted in sutures.

Other AFDO Publications

- ◆ A Guide to Can Defects and Basic Components of Double Seam Containers (November 2011)
- ◆ Apple Cider Processing Operations Requirements & Guidelines (February 2003, 2nd Print)
- ◆ Cured, Salted & Smoked Fish Est. GMPs Including Listeria Manual (May 2004)
- ◆ Food Code: Pocket Guide for Regulators (December 2006; August 2011, Printed)
- ◆ Food Emergency Pocket Guide (January 2007, Revised; September 2011, Revised)
- ◆ Guidelines for Exempt Slaughter and Processing Operations (June 2011)
- ◆ Guidelines for Exempt Slaughter and Processing Operations Training Manual
- ◆ Guidelines for the Transportation of Food Products (June 2005)
- ◆ Guidelines: Inspection & Enforcement of GMP Regulations for Packaged Ice
- ◆ Guidelines: Handling and Producing Packaged Ice within Foodservice and Retail Establishments
- ◆ Meat and Poultry Processing at Retail Training Manual
- ◆ Model Code for Produce Safety (November 2009)
- ◆ Model Consumer Commodity Salvage Code (February 2008)
- ◆ Model Water Vending Machine Regulation (June 1997, Revised; December 2002, Printed)
- ◆ Retail Meat and Poultry Processing Guidelines (June 2011)
- ◆ Retail Guidelines for Refrigerated Foods in Reduced Oxygen Packages
- ◆ State Food Safety Resource Survey



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