JIFSAN Good Aquacultural Practices Program

HACCP or Other Things Farmers Should Know

Processor HACCP Requirements for Aquaculture Products

In relation to aquaculture products, the processor is anyone who handles or stores, seafood. For aquaculture products, this means a producer must conduct hazard analysis and demonstrate controls for chemical and drugs.

For chemicals, a processor must determine if chemicals (e.g., pesticides) are reasonably likely to occur in the facility. The decision must be documented if the decision is **NO**. If the decision is **YES**, the farmer or grower must test and provide evidence in an HACCP plan.

The processor must also determine if drugs are reasonably likely to occur. If so, then processors must include controls in their HACCP plan. Most processors use lot certificates from farmers attesting that no drugs are used, or that the ones used are permitted and used properly. Periodic testing provides verification.

Products may come from an MOU country or have affirmative steps or evidence the processor has implemented a HACCP program. Affirmative steps include getting the foreign processors HACCP plan and sanitation monitoring records for each lot, getting a continuing or lot-by-lot certificate from a competent third party, or making an independent inspection. Alternatives are to obtain a copy of the HACCP Plan and written guarantee, get a test product and written guarantee, or something other but equivalent to one of these items.

The Food and Drug Administration is one of the nation's oldest and most respected consumer protection agencies.

Stated most simply, FDA's mission is to promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use. The Food and Drug Administration is charged with protecting consumers against food that is impure, unsafe, produced under unsanitary conditions, or fraudulently labeled. Through its Center for Food Safety and Applied Nutrition (CFSAN) the FDA regulates both domestic and imported foods, except meat and poultry, and has primary responsibility for enforcing food safety laws including food import and export regulations.

Importing/Exporting to the United States of America

All foods imported into the U.S. are required to meet the same standards as domestic products.

They must be pure, wholesome, safe to eat and produced under sanitary conditions. FDA DOES CHECK! As noted in Section 10, FDA's mission is to promote and protect the public health by helping safe and effective products reach the market in a timely way, and monitoring products for continued safety after they are in use.

Facility Registration

To register go to www.fda.gov. On the top right hand corner click on "Register a facility." Filling out the information via the internet will give you a registration number instantly. If you are having problems—call the BT help desk at 301.575.0156 (open 24/7).

FDA's Requirements for Imports

In the U.S., imports are monitored by FDA, USDA, and U.S. Customs.

- U.S. Customs monitors, controls, and collects duties and tariffs.
- USDA is responsible for meat and poultry products.
- FDA is responsible for all other food products.

Customs and FDA

- Customs notifies FDA of shipments.

- FDA then determines if product:
  - is subject to automatic detention,
  - should be sampled,
  - can be released without sampling.
- Customs will release shipment only upon written notification by FDA.

Detention Without Physical Examination (DWPE)

A product may be detained as soon as it is offered for entry into the United States based on past history and/or other information indicating the product may be in violation.

In some instances a product may be detained as soon as it is offered for entry into the U. S. This procedure is the administrative act of detaining a product without physical examination and is based on past history and/or other information indicating the product may be violative. A product may be subject to a detention without physical examination (DWPE) recommendation until the shipper or importer proves that the product meets FDA guidelines or standards. Occasionally, FDA identifies products from an entire country or geographic region for DWPE when the violative conditions appear to be geographically widespread. Detention recommendations of this breadth are rare and are initiated only after other avenues for resolving the problem have been exhausted.

It's important to remember that DWPE matters must be settled well before shipment of fresh produce. All perishable produce must adhere strictly to all import requirements. Delays of questionable items easily result in spoilage, even if the item is subsequently cleared for commerce.

Regulating Imported Foods

- Requirements for import and domestic foods are the same, but enforcement procedures vary.
- With the permission of other countries, FDA does inspect foreign food processing operations.
- Refusing an inspection may mean your firm goes on automatic detention.
- Food may enter the U.S. through a variety of "ports of entry."
- The number of entries is increasing dramatically. There are currently over one million shipments, valued at more than $20 billion annually.
- Only a small percentage of shipments are examined.

Examination of Shipments for Imports

- Sampling and examination are conducted at port of entry.
- When performing an examination, FDA considers
  - the history of product, shipper, country, importer,
  - memoranda of understanding with agencies of foreign governments, and
  - random sampling to establish compliance status.
- FDA will pay for samples found to be in compliance. Payment is not made for violative shipments.
- Bond may be posted to move perishables,
- Product cannot be distributed until released.
- There is no pre-shipment sampling.

U.S. FDA Detention Procedures for Imported Products

Detention Criteria

- Recommendation from FDA after a regulatory visit.

- Recommendation of a foreign competent authority.
- Shipment appears violative.

Types of Detention

- Detention of an individual entry--stopping a shipment of an individual entry (due to sample collection or physical examination).
- Detention without physical examination (DWPE)--stopping a shipment without collection of a physical examination.

Detention requirements—individual shipments

- Each shipment may be sampled and analyzed.
- Analysis performed by a competent private laboratory.
- Lab results reported to FDA.
- FDA reviews results.
- If not violative, the shipment is released.

Detention requirements—removal from DWPE

- Minimum 5 consecutive nonviolative shipments in a 6-month period (can be multiple ports).
- At least one shipment audited by fda to ensure analytical validity.

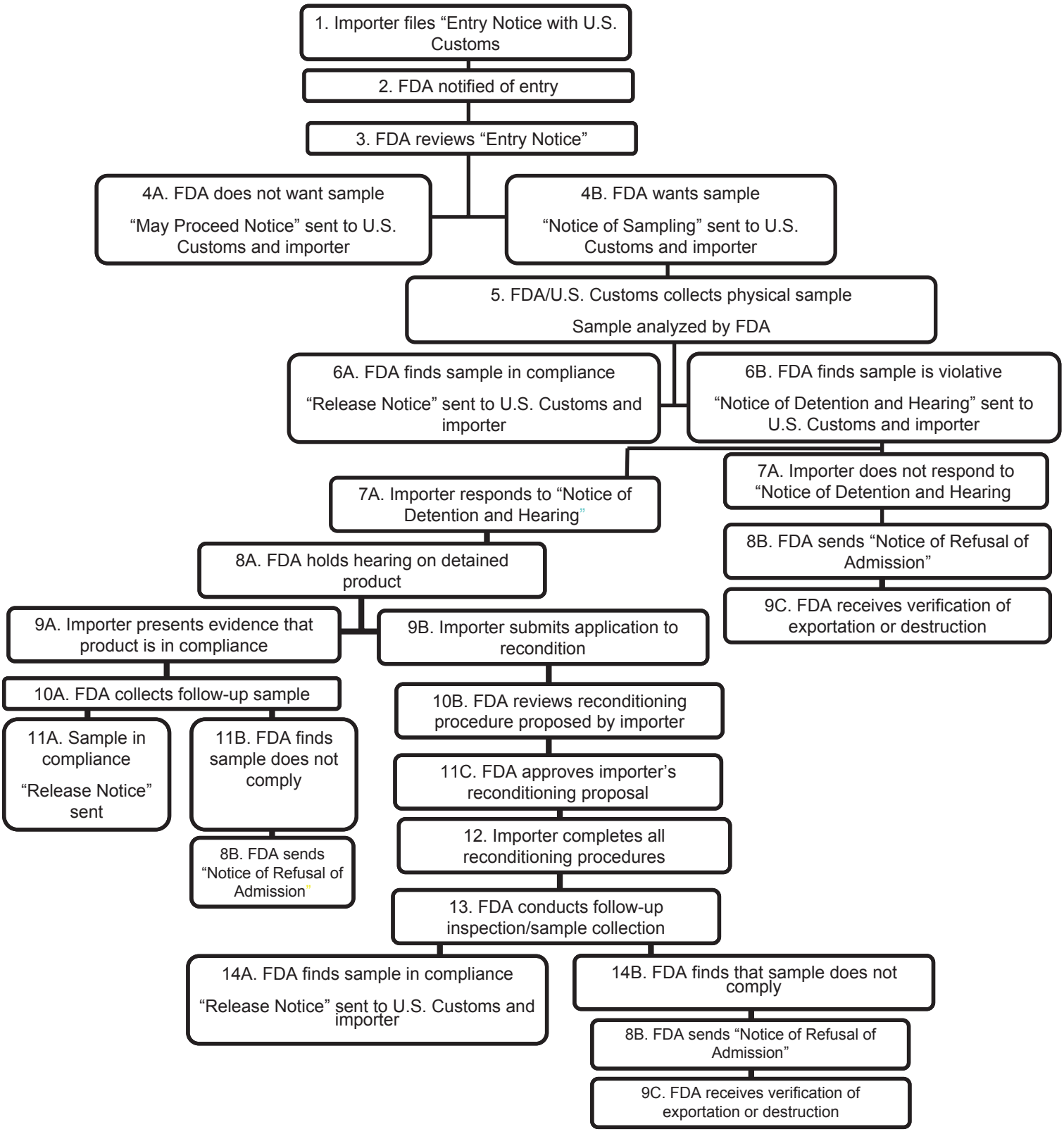
- Shipment must represent usual products and different production runs.
- FDA must be assured that firms are compliant over a reasonable period to remove from DWPE.
- FDA needs adequate product for sampling.
- FDA may request other documentation.

Enforcement tools

- Seizure if product in domestic commerce and represents potential hazard; must be supported by evidence.
- Recall for released product with potential health hazard or if distributed prior to release notice.
- Prosecution when enforcement actions have not prevented recurrence or violation warrants punishment of persons responsible.

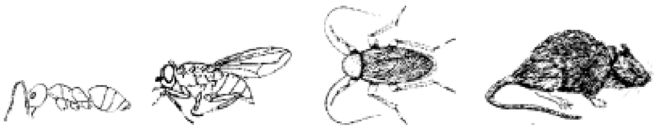
What is Decomposition/Filth?

When more than 10% of shrimp are affected by unusual odor or flavor, discoloration or texture, the shipment is considered compromised. Odor or flavor means a persistent, distinct and uncharacteristic odor or flavor including those described as ammonia, musty, yeasty, vegetable, sour, fecal, hydrogen sulphide, putrid, or other unusual or unpleasant smell. Discoloration describes shrimp that are distinctly yellow, green or black, singly or in combination, discoloration of the flesh, or shrimp with faded pigment or liver stain in association with odor or flavor of decomposition. Texture is the textural breakdown characterized by muscle structure that is mushy.



A lot will be considered defective with the presence of any material that has not been derived from shrimp and that poses a threat to human health (such as glass, etc.), or a distinct and persistent odor or flavor of any material that has not been derived from shrimp and that poses a threat to human health (such as solvents, fuel oil, etc.). A unit will be considered defective when the presence of readily detectable (without magnification) material that has not been derived from shrimp but does not pose a threat to human health (such as insect pieces, sand, etc.).

Examples of Filth:



Ant Fly Cockroach Rodent

Quality Concerns	Defects	Preventative Measures
Appearance	Blackspot	Proper application of sulfite or Everfresh
	Broken & damaged	Proper handling & icing
	Heat discoloration	Timely placement of product in ice
	Loose heads (whole product)	Proper handling of product in ice only
	Red heads	Stop feeding 48 hrs before harvest
	Soft shell (Whole and shell on product)	Harvest at the proper time based on periodic checks
	Yellowing	Proper use of sulfites
	Pitted or gritty shells	Proper use of sulfites
	Milky shrimp	Culling from the harvest
	Mixed species	Separation by species at the plant
Odor/Flavor	Decomposition	Timely placement of product on ice
	Chlorine	Use of proper concentration & exposure time
	Petrochemical smell	Prevent contamination with oil, diesel, etc.
	Choclo/earthy smell	Sensory test before harvest
	Off-flavors in the head	Sensory test before harvest
Texture	Mushy and/or soft texture	Proper shrimp to ice ratio and timely placement of product in ice
Processing defects	Short weight	Routine checks for proper specification
	Off counts	
	Uniformity	
	Dehydration	Proper glazing
	Extraneous materials	Proper culling