JIFSAN Good Aquacultural Practices Program

Food Laws and Regulations

By Brett Koonse

General Principles

People around the world are demanding that aquaculture products to be safe and wholesome. When exporting to another country, it is important to understand the import requirements of that country so that the product can move quickly. This is especially important when exporting perishables like aquaculture products.

United States Food Regulatory Scheme

The U.S. Food and Drug Administration 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 for 80 percent of the U. S. food supply.

Other U.S. Agencies

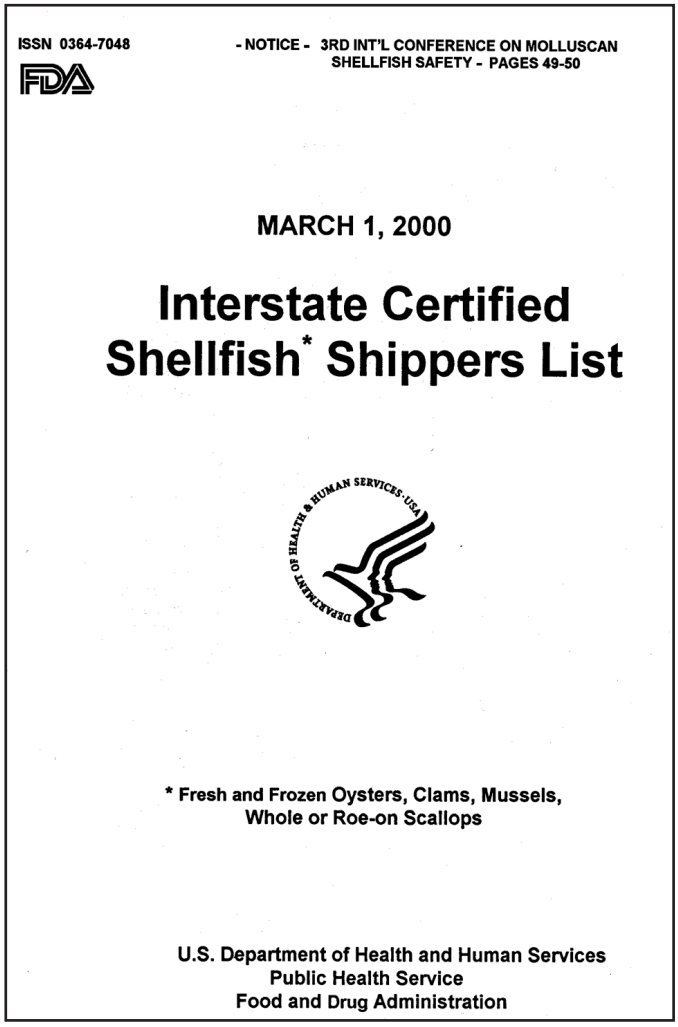
- Centers for Disease Control and Prevention (CDC)
- U.S. Department of Agriculture (USDA)
  - Agricultural Marketing Service (AMS)
  - Foreign Agricultural Service (FAS)
  - Food Safety Inspection Service (FSIS)
  - Economic Research Service (ERS)
  - Animal and Plant Health Inspection Service (APHIS)
- U.S. Environmental Protection Agency (EPA)
- U.S. Customs Service

Retail Food Code

The retail food code is a reference document for regulatory agencies, including retail outlets, restaurants, grocery stores, nursing homes, and child care providers. It is a joint publication of the FDA, the FSIS, and the CDC. It reflects the most current science and best strategies to ensure a safer food supply.

Imported Foods

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. In the U.S., food safety is a shared responsibility with several departments of the United States government sharing jurisdiction over ensuring the safety of the American food supply. These agencies assure that all foods are pure, wholesome, safe to eat, and produced under sanitary conditions. They also assure that all imported foods meet the same requirements as those produced domestically.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- NOTICE - 3RD INT'L CONFERENCE ON MOLLUSCAN SHELLFISH SAFETY - PAGES 49-50

FDA

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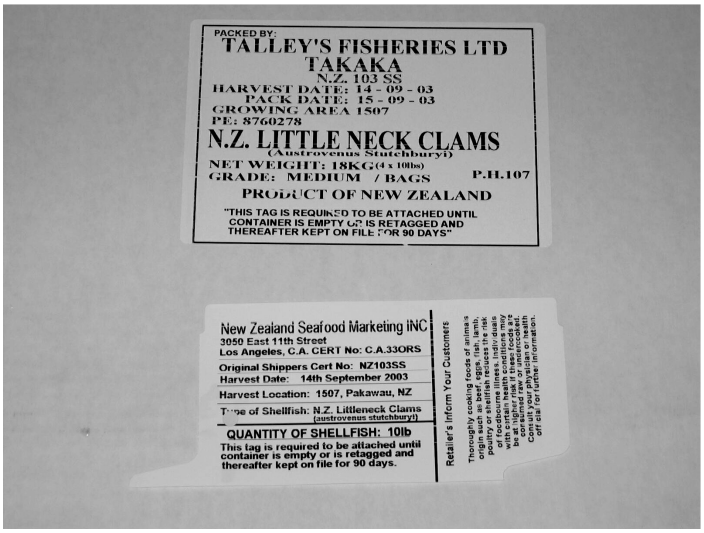
Interstate Certified Shellfish* Shippers List

* Fresh and Frozen Oysters, Clams, Mussels, Whole or Roe-on Scallops

U.S. Department of Health and Human Services
Public Health Service
Food and Drug Administration



Contaminants

The traditional focus on the safety of food itself is on whether food contains substances that may render it injurious to health, or whether the conditions of production are such that the food may contain such substances. If the answer to either question is yes, the food is "adulterated" under the Federal Food, Drug, and Cosmetic Act and thus prohibited in interstate commerce. To decide the first of these two questions (whether the food contains substances that may render it injurious), FDA sets numerical levels for those contaminants. There are over 30 such levels that apply to commercial seafood, and they address primarily microbial contaminants, toxins, and chemicals.

Bivalve Molluscan Shellfish include raw, fresh and frozen oysters, mussels, clams, and whole scallops. There are currently five nations with a Memorandum of Understanding (MOU) to import shellfish into the U.S. These are Canada, Mexico, New Zealand, Chile, and Korea. All foreign dealers certified to ship product into the U.S. are listed in the Interstate Certified Shellfish Shippers List (ICSSL).

Guidance

Fish and Fishery Products Seafood Hazards and Control Guide. Third edition.
http://www.cfsan.fda.gov/~comm/haccp4.html

Antibiotic information
www.fda.gov/cvm/index/aquaculture/aqualibtoc.htm

Retail food code
www.cfsan.fda.gov/~dms/fc01-toc.html

Seafood Safety Control

Aquaculture Controls

The FDA's Center for Veterinary Medicine approves drugs. Processors must have controls in place for drugs in HACCP plans.

- GAqP program being developed
- Mandatory GMPs
- Mandatory HACCP
- State and Federal inspections
- Importer inspections
- Same requirements for domestic/imports

International Food Import Standards

Codex Alimentarius

The Codex Alimentarius is a code of international food standards. Countries need regulations and standards to assure the safety of their food supplies. These standards vary from country to country making it difficult for producers and exporters. The stated purpose of Codex is "…to guide and promote the elaboration of definitions and requirements for foods, to assist in their harmonization, and, in doing so, to facilitate world trade."

The Codex Alimentarius Commission is the body charged with developing these standards. More than 150 countries are members. The Commission was created in 1962 by two United Nations organizations: the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). The CAC provides a forum where member countries and international organizations can meet and exchange information and ideas relative to food safety and trade issues. Its main purpose is to promote consumer protection and to facilitate world trade in foods through the development of food standards, codes of practice, and other guidelines.

Codex is first and foremost concerned with protecting the health of consumers and ensuring fair practices in the food trade. The officials who

laid the foundations for CODEX believed that if all countries harmonized their food laws and adopted internationally agreed-upon standards such issues would be dealt with naturally. Through harmonization, they envisioned fewer barriers to trade and a freer movement among creators, which would benefit farmers and their families and would also help to reduce hunger and poverty.

U.S. Codex Office

www.fsis.usda.gov/OA/codex

uscodex@fsis.usda.gov

EC's Directorate-General for Health and Consumer Protection (SANCO)

- Responsible for food safety
- CA certification
- Be on a list
- Control plan in place
- Food and vet office conducts verification inspections
- Border inspections
- http://ec.europa.eu/comm/food/international/trade/im_cond_fish_en.pdf

Drug Approval and Aquaculture Product Testing in the U.S.

Chemicals are used in aquaculture for a number of reasons. They can be used for sediment and water management, enhancement of aquatic productivity, feed formulation, manipulation and enhancement of reproduction, growth promotion, health management, improvement of survival rates, or transport of live organisms.

When used properly, chemicals in aquaculture can help to control infectious diseases. They can be used as a prophylactic measure against infections. They can also show a benefit as growth and productivity promoters.

General Food Hygiene Principles

Provisions on food hygiene applicable to all foods.

FAO Fisheries Department. Aquaculture development.

FAO Technical Guidelines for Responsible Fisheries. No. 5. Rome, FAO. 1997.

PRINCIPLES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA FOR FOODS (CHC/GL 30, 1999)

There are concerns over use or misuse of these chemicals. Producers should be concerned about residues in edible portions of the product. They should also be aware of developing bacterial resistance. Chemical use can also provoke concerns over human health implications and environmental implications.

Aquaculture Drugs

Intended use of a compound determines if a compound is a drug. Antibiotics are drugs if they treat or mitigate disease or affect structure or function. All aquaculture drugs whether for direct medication or for addition to feed must be approved for use in the U.S. Drugs are approved with respect to dosage, route of administration, species, limitation of use/indication for use, and frequency of application.

Drugs banned use in food producing animals

Chloramphenicol

Clenbuterol

Diethylstilbestrol (DES)

Dimetridazole; Ipronidazole (and other nitroimidazoles)

Furazolidone, Nitrofurazone (and other nitrofurans)

Sulfonamide drugs in lactating dairy cattle (except approved use of sulfadimethoxine, sulfabromomethazine, and sulfaethoxypyridazine)

Fluoroquinolones

Glycopeptides

Current list of drugs approved for aquaculture in U.S. (Total 7)

Chorionic gonadotropin (HCG)

Formalin

Oxytetracycline

Sulfadimethoxine-ormetoprim

Sulfamerazine

Tricaine methanesulfonate (MS-222)

Florfenicol

Drugs approved for use in shrimp in the U.S.

Formalin (control external protozoan parasites)

Some drug use under an Investigational New Animal Drug (INAD)

Aquaculture Drugs

Low Regulatory Priority

Acetic acid

Calcium chloride

Calcium oxide

Carbon dioxide gas

Fuller's earth

Garlic (whole form)

Hydrogen peroxide

Ice

Magnesium sulfate

Onion (whole form)

Papain

Potassium chloride

Povidone iodine

Sodium bicarbonate

Sodium chloride

Sodium sulfite

Thiamine hydrochloride

Urea and tannic acid

Detailed information on the approved products available at CVM's website: www.fda.gov/cvm.

FDA aquaculture drug testing program

- Shrimp
  - Chloramphenicol
  - Nitrofurans
  - Fluoroquinolones
  - Oxytetracycline
  - Quinolones: oxolinic acid and Flumequine
- Catfish/Basa
  - Fluoroquinolones
  - Malachite green
  - Quinolones: oxolinic acid and Flumequine
- Salmon
  - Quinolones: Flumequine
  - Ivermectin
  - Oxolinic acid
  - Malachite green
- Crab
  - Chloramphenicol
- Seafood products tested
  - Domestic
  - Import

Countries sampled based on where product is imported from:

- Shrimp
  - Brazil
  - China
  - Ecuador
  - India
  - Indonesia
  - Thailand
  - Vietnam

Chloramphenicol

Chloramphenicol has never been approved for use in food-producing animals. It causes aplastic anemia in humans. Adverse reactions are not dose dependent and a safe level of exposure has not been determined. The oral solution was withdrawn because of documented history of misuse in food animals.

Nitrofurans

Nitrofurans (except topical applications) were banned for use in food animals in 1991. They are considered carcinogens. They have recently been banned in topical uses for food animals due to residue concerns.

Fluoroquinolones

Fluoroquinolones arebroad spectrum drugs that are very effective against many microbes. They have never been approved for an application in aquaculture. They have also been banned for extra-label use in food producing animals. There is some concern over the development of antibacterial resistance in humans.

FDA Testing Program

Because tested compounds are not approved, presence of any residues is a violation. FDA determination of violation is based on drug residues findings with approved regulatory method (determinative or confirmatory method). All analytical methods are available at CFSAN's website: http://www.cfsan.fda.gov/~comm/labmeth.html.