한국산식품의 對美수출시 유의사항

– Exporting Foods to the United States –

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필자주 본고는 저자가 수차에 걸쳐서 미국내의 한국식품 수입업자 또는 국내의 식품업계 여러분들로 부터 문의되어온 한국식품의 대미수출에 관한 질문들을 간추려서 정리한 것으로 한국산 식품을 미국에 수출하는데 필요한 미국의 식품법과 규정을 간단히 소개하여 우리나라 식품업계에 조그마한 도움이 되기 위한 것이 주목적입니다.
실제로 식품을 미국에 수출하는 단계의 필요한 과정과 수속에 관한 자세한 절차는 나열한 소속기관에 문의하여 그에 따르도록 하여야 합니다.

Many foreign businesses dealing with food want to export products to the United States (U.S.) because the U.S. is perceived to be a wealthy country with a large, and diverse population, and with good distribution systems.

One general overriding principle which underlies the importation of foods is : the importation of food into the U.S. is a privilege and not a right. Remembering this will make understanding procedures easier.

The U.S. has specific food laws regarding the preparation and selling of food that are different from many other countries. Two actions that must be undertaken almost simultaneously are to obtain a broker or agent in the U.S. who is willing to represent you and also to communicate with the appropriate U.S. government agency(ies) that will handle your product(s). If meat products are to be exported, the Food Safety Inspection Service(FSIS) of the United states Department of Agriculture(USDA), should be contacted. If a preserved food other than a meat product is to be exported, then the U.S. Food and Drug Administration(FDA) in the Department of Health and Human Services(HHS) should be approached. If the product in question is fresh fruit or vegetable or floricultural product, then both the FDA and the USDA should be contacted. The FDA is also interested in pesticide residues and the USDA APHIS (Animal Plant Health Inspection Service) is concerned with animal and plant diseases.

Although the U.S. has many laws and regulations, copies are inexpensive to buy and easily obtainabls from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. Telephone 202–523–5230.

Specific Food Laws and Regulations

The primary food law that of interest to potential exporters is the U.S. Federal Food, Drug, and Cosmetic Act(FD&C), of which the interpretation and execution is carried out by the FDA. The interpretation of the Act is published in the U.S. Code of Federal Regulations(CFR) under Title 21. There are three volumes of Title 21 for anyone involved in the U.S. food business; Volume 1(or Title 21 CFR Parts 1~99) covers FDA administration and color additives, Volume 2(or Title 21 CFR Parts 100~169) covers food labeling, quality standards, standards of identity, emergency permit control, current good manufacturing practices in manufacturing, packing, or holding human food, thermally processed low-acid foods packaged in hermetically sealed containers, and acidified foods, and Volume 3(or Title 21 CFR 170~199) covers food additives.

Of particular interest to an exporter of processed foods to the U.S. would be the following Parts of the CFR : Part 108-Emergency Permit Control - Section 108.25(c)(1) Plant registration, (c)(2) Process filing, (c)(3)(ii) Process and pH information availability, and Imports for Acidified Foods. Section 108.35 Thermal processing of low-acid foods packaged in hermetically sealed containers. Section 108.35 (c)(1) Plant registration and (c)(2) Processing filing. These Parts are for those who wish to distribute Acidified or Low-acid foods packaged in hermentically sealed containers and must register with the FDA and file their proposed process. The filing of the process does not imply approval of processing procedures by the FDA.

Part 110 deals with all aspects of current Good Manufacturing Practices(GMP), primarily sanitation, in the manufacturing, packing or holding human food.

Part 113 specifically describes equipment and operating procedures, product preparation, establishing a scheduled process, operations in the thermal processing room, deviations in processing, venting or control of critical factors, personnel trainning, and the keeping of processing and production records in the preparation of thermally processed low-acid foods packaged in hermetically sealed containers.

Part 114 deals with processes and controls, establishing scheduled processes, deviations from scheduled procedures, training of personnel, and methodology to be used in the preparation of acidified foods in hermetically sealed containers.

In addition to the above specific requirements in the preparation of thermally processed "canned foods" for export, there are several other applicable regulations.

Chapter VIII Section 801 of the US Federal Food, Drug, and Cosmetic Act states in part that :

> "The Secretary of the Department of the Treasury(Customs) shall deliver to the Secretary of Health and Human Services(FDA) upon his request, samples of food which are being imported or offered for import in the US, giving notice thereof to the owner or consignee, who may appear before the Secretary of HHS and have the right to introduce testimony. The Secretary of HHS shall furnish to the Secretary of the Treasure a list of establishments registered. If it appears from the examination of such samples or otherwise that such article has been manufactured, processed or packed under insanitary conditions, or such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or such article is adulterated, misbranded then such article shall be refused admission. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported under prescribed regulations within 90 days or there abouts.

Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Traeasury may authorize delivery to the owner or consignee upon the execution by him of a good and sufficient bond event of default. If it appears to the Secretary of HHS that the article can be re-labeled or by other action, be brought into compliance with the Act, final determination as to admission of such article may be deferred. All such re-labeling or other action shall be in accordance with regulations and be under the supervision of an officer of HHS or Customs. All expenses in connection with destruction or the re-labeling or other action shall be paid by the owner or consignee, and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee."

Because most decisions concerning the admissibility of articles are made at the district level, and because procedures vary from district office to district office, a good working relationship with the district office covering the port of entry and a familiarity with its rules should be established prior to importing foods into a particular district. This point should be stressed.

The Importation Process-entry and notice of sampling

The US Customs Service(Customs) in the Department of the Treasury is responsible for overseeing importations. It is the importer's responsibility to arrange for Customs' examination and release of imported foods. Within five days after a shipment arrives at a US port of entry, entry papers must be filed at a location specified by Customs. The entry of imported foods is reported in the FD-700 set of forms. This four-piece snapout set of Forms is required for each entry and provides FDA and Customs with information about the imported merchandise. Upon FDA'S receipt of the forms it will determine whether or not to sample the shipment.

If FDA decides to sample the shipment, a Notice of Sampling FD-712 will be issued to the Importer of Record. Alternatively, if no sampling is made, a May Proceed Notice(part of the FD-700 set, Form FD 702) will be issued instead. Some imported foods are virtually certain to be sampled, such as a new article, or an article placed on Import Alert. An Import Alert deals with a product with a problem or potential problem. Blocklisted foods, which are foods with an unacceptable import history, may be detained without sampling and analysis.

With respect to certain food products which tend to be susceptible to contamination, FDA has entered into Memoranda of Understanding(MOUs) with the health authorities of exporting nations. These memoranda typically recognize the foreign health body as a certifying authority responsible for assuring compliance with FD&C Act.

In instances where a more rigorous examination of the article is necessary to confirm adulteration, FDA will typically run laboratory analyses to determine whether the food should be detained. FDA sampling techniques and results may be obtained by the importer under the Freedom of Information Act.

Notice of Detention

FDA will issue a Notice of Detention and Hearing FD-718 formerly FD-777 if the sample is violative. If the sample complies, a Notice of Release, FD-717, will be issued.

Any food which has not been released by Customs, i.e., is subject to a Notice of Sampling or Detention, may be kept in the possession of the owner or consignee if sufficient bond is posted

to provide for liquidated damages in the event of default. The bond contains a condition, upon the demand of Customs, for the redelivery of the merchandise or any part of the shipment involved, as well as a provision for the performance of, e·g., re-labeling or other conditions so as to comply with the Act. Accordingly, articles held on import status by an importer should be segregated, inventoried, or accounted for so as not to be introduced into commercial distribution.

Notice of Refusal of Admission

Customs must issue a Notice of Refusal of Admission when a shipment is in violation. The shipment must also be exported or destroyed within 90 days of the Notice or what ever time is specified.

Rights of the Importer

Upon Detention an importer may defend the admissibility at a hearing, apply for permission to recondition, re-export the product or ask for a judicial review.

Enforcement Action against Imported Foods

FDA is empowered with three enforcement mechanisms to deal with the importation and distribution of products which fail to meet the requirements of the Act :

(1) Order destruction of the imported goods which have not been reconditioned, denatured or exported.

(2) Revoke bond if a shipment or any portion is distributed prior to FDA May Proceed Notice.

(3) Seizure and condemnation of violative products unlawfully released from the physical custody of Customs.

In addition to what has been said above, a flow-sheet of steps for imported products is at the end of the article.

Automatic Detention

Detention is an administrative action taken by FDA against imported articles which are not incompliance with the law. Detained articles are either released if brought into compliance or refused entry.

Automatic detention. Lists of specific imported products manufactured or shipped by specific foreign firms attached to specific "Import Alerts" which may be detained without examination due to their violative history.

Import Alerts. Notices to the district offices concerning unusual or new problems affection import coverage.

Reasons for an automatic detention at the port of entry may be :

Company or plant not registered
No filed process for acidified or low-acid food
Uncontrolled pH in an acidified food
Underprocessed food item

Failure to comply with Parts 113 & 114 of Title 21 of the US Code of Federal Regulations(CFR)

Apparent container integrity

Lack of mandatory label declaration

Not being registered, having no filed process, uncontrolled pH and a lack of mandatory label declarations were discussed earlier.

Underprocessing is important because of the potential of the presence of *C. botulinum* toxin, the presence of viable *C. botulinum* cells, and having viable spore formers with heat resistance less than *C. botulinum.*

Failure to comply with Parts 113 & 114 may mean process deviations, no control of critical factors, inadequate heat distribution, inadequate process and other factors.

Container integrity may mean seam defects, inadequate double seams, leakage potential demonstrated.

With automatic detention, FDA identifies the potential public health hazard.

Suggestions to Foreign Exporters and U.S. Importers to Expedite Entries

Be certain that packaged foods are fully labeled. Un-labeled or partially labeled goods must necessarily be detained because of lack of the mandatory label information which makes a product misbranded.

Do not export products known to be illegal on the theory that they can be brought into compliance with the law upon arrival. Conditional releases for that purpose are discretionary under the Act and if the privilege is granted, delays and added expense to importers inevitably occur before final release or denial of release. Correct obviously objectionable conditions, that may be responsible for detentions, at the source(before export), such as infestation of foods with insects and other vermin.

Make U.S. Customs entries promptly upon arrival of shipments at the port of entry. The FDA cannot ordinarily act upon an importation until entry is actually filed and the Customs Service has notified the local FDA office. A list follow is at the end of the article. Entry documents should be "flagged" for the attention of the FDA import representative at the appropriate office.

In carrying on business transactions with the importing trade of the U.S., foreign shippers, as well as importing purchasers should remember that they have an obligation to comply fully with U.S. laws affecting these commodities. Continual effort should be made to bring about fundamental correction of any existing conditions which adversely affect purity, strength, or quality of such articles.

Such corrective measures might well be undertaken by individual producers and associations of producers, and possibly by foreign government agencies in the countries of production. By such procedures, elimination of causes of deterioration and contamination in a number of commodities has already been successfully accomplished in various parts of the world. Remember that this is what the Japanese and Taiwanese have done and the Koreans are doing. Individuals, associations, and various foreign government agencies have, in a number of instances, instituted systems of sampling and examination of specific lots intended for shipment to the U.S., for the purpose of predetermining whether they meet the requirements of the US laws.

All imported food products must comply with health and safety standards established under the Food, Drug and Cosmetic Act(FDCA). The FDCA prohibits movement in interstate commerce of adulterated or misbranded foods, drugs, and cosmetics. Food additives and colors must be approved by the U.S. Food and Drug Administration(FDA). Information on the FDCA may be obtained from Washington or District offices :

Case and Advisory Branch, HFS-606
Division of Regulatory Guidance
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
200 C Stret, S. W.
Washington, DC 20204
(202) 205−4726

District Offices

FDA District Offices throughout the United States can help you with your labeling problems. (Ask for a Compliance Branch representative.)

ATLANTA
60 Eighth Street, NE Atlanta, GA 30309
(404) 347−4344

BALTIMORE
900 Madison Avenue
Baltimore, MD 21201
(301) 962−4012

BOSTON
One Montvale Avenue
Stoneham, MA 02108
(617) 279−1476

BUFFALO
599 Delaware Avenue Buffalo,
NY 14202
(716) 846−4478

CHICAGO
1222 Post Office Building
433 West Van Buren Street
Chicago, IL 60607
(312) 353−7379

DENVER
Denver Federal Center, Bldg. 20 P.O. Box 25087
(303) 264−3017

DETROIT
1560 East Jefferson Avenue
Detroit, MI 48207
(313) 226−6260

KANSAS CITY
1009 Cherry Street Kansas City, MO 64106
(816) 374−5521

LOS ANGELES
1521 West Pico Boulevard
Los Angeles, CA 90015−2486
(213) 252−7586

MINNEAPOLIS
240 Hennepin Avenue
Minneapolis, MN 55401
(612) 349−4102

NEW YORK
850 Third Avenue Brooklyn, NY 11232
(718) 965−5301

NEWARK
61 Main Street West Orange, NJ 07052
(201) 645−3023

ORLANDO
7200 Lake Ellenor Drive
Suite 120 Orlando, FL 32809
(305) 855−0900

PHILADELPHIA
900 U.S. Customhouse 2nd & Chestnut Streets
Philadelphia, PA 19106
(215) 597−3708

SAN FRANCISCO
506 Federal Office Building
50 U.N. Plaza San Francisco
CA 94102
(415) 556−0318

CINCINNATI
1141 Central Parkway
Cincinnati, 45202－1097
(513) 684－3501

NASHVILLE
297 Plus Park Boulevard
Nashville, TN 37217
(615) 736－7222

SAN JUAN
P.O. Box 5719
Puerta de Tierra Station
San Juan, PR 00906－5719
(809) 753－4245

DALLAS
3032 Bryan Street Dallas,
TX 75204
(214) 655－5315

NEW ORLEANS
4298 Elysian Fields Avenue
New Orleans, LA 70122
(504) 589－2401

SEATTLE
909 First Street Room 5003
Seattle, WA 98174
(206) 442－5304

USDA

The USDA is specifically charged with the inspection of all commercial shipments of meat, poultry, and raw plant products(horticultural and floricultural) offered for entry into the US.

The importing of fresh produce is of concern to the Animal Plant Health Inspection Service (APHIS) and the Agricultural Marketing Service(AMS) Fruit and Vegetable Division of the USDA. APHIS is concerned with disease, pest, and pesticides on plant material. There is an admissible list of produce that is eligible for import. Products not on the list may be imported providing they are subjected to some lengthy testing and evaluation, called Pest Risk Analysis, which may take nearly a year to complete.

The AMS is responsible for the marketing of produce where there is a marketing order in existence in the US ; this is discussed later under Agricultural Marketing Agreement Act.

The First Step for exporting produce to the U.S. is to identify a broker in the U.S. who is licensed and willing to work with you.

Commission merchants, dealers and brokers buying, selling, negotiating sales, purchasing or handling consignments of fruits and vegetables in interstate or foreign commerce must be licensed under the Perishable Agricultural Commodities Act (PACA). Basically, the law requires that parties fulfill their contractual obligations. Any exporter should be sure that the buyer(US) they are dealing with is licensed.

Trading licenses can be suspended or revoked for violations of the Act. The Act provides a forum where injured parties who suffer damages as a result of breach of trading contracts can recover their losses through informal handling or formal proceedings. Additional information on PACA regulations and requirements may be obtained from :

USDA-AMS-F&V Div.
PACA Branch, Rm 2715-S
P.O. Box 96456
Washington, DC 200090-6456
202-447-2814

An individual grower in any country cannot export at will. An importer in the US has to apply for a Permit regarding Plant Protection and Quarantine.

Plant Quarantine Act

Plant quarantine regulations of the U.S. Department of Agriculture are divided into two classes--prohibitory and restrictive.

Prohibitory orders forbid entirely the entry of designated plants and plant products which are subject to attack by plant pests for which there is no treatment available that would insure complete freedom from such pests. Restrictive orders allow the entry of plants or plant products either under a treatment requirement or inspection requirement ; import permits are required. These permits are issued to resident importers in the United States who are responsible for carrying out the conditions of entry specified in the permit. Questions on entry requirements for plants and plant products should be addressed to :

Permit Unit
PPQ APHIS, USDA
Federal Building Rm 638
6505 Belcrest Rd, Hyattsville, MD
Tel. 301－436－8645, FAX. 301－436－5786

Detailed U.S. regulations on this subject may be found in Title 7 CER 319.

Federal Insecticide, Fungicide and Rodenticide Act

The Federal Insecticide, Fungicide and Rodenticide Act(FIFRA) directs the U.S. Environmental Protection Agency to register all pesticides used in the United States and to establish safe residue tolerances which may be found in domestic or imported food. To obtain information on which pesticide residues are permitted and at what level contact :

Office of Pesticide Programs
U.S. Environmental Protection Agency
Crystal Mall Building 2
1921 Jefferson Davis Highway
Arlington, VA 20460
(703) 557－7090 ; FAX : (703) 557－8244

Agricultural Marketing Agreement Act of 1937

If a person wishes to export a product where there is a US Marketing Order they must comply with the same regulations on quality as the US producer. Section 8e of the Agricultural Marketing Agreement Act requires that whenever the Secretary of Agriculture issues grade, size, quality, or maturity regulations under domestic marketing orders for certain commodities, the same or comparable regulations on imports of those commodities must be issued. Import regulations apply only during those periods when domestic marketing order regulations are in effect. Currently the following imported commodities are subject to import regulations : avocados, dates(other than dates for processing), filberts, graperfruit, table grapes, limes, olives (other than Spanish-style olives), onions, oranges, Irish potatoes, prunes, raisins, tomatoes and walnuts. Import regulations are amended from time to time to conform with changes in domestic marketing order regulations. Additional information regarding requirements for any of the above specified commodities may be obtained from :

Fruit and Vegetable Division, Rm. 2077－S

Agricultural Marketing Service. USDA
P.O. Box 96456
Washington, DC 20090－6456
(202) 447－6393, FAX : (202) 382－0565

SPECIFICATIONS FOR OBTAINING INSPECTION AND CERTIFICATION

United States inspection and certification requirements for imported commodities(avocados, filberts, grapefruit, table grapes, limes, onions, oranges, Irish potatoes, tomatoes, and walnuts) are regulated under section 8e (7 U.S.C. 608e－1) of the Agricultural Marketing Agreement Act (AMAA) of 1937, as amended, are as follows :

(a) The Federal or Federal-State Inspection Service, Fruit and Vegetable Division, Agricultural Marketing Service, United States Department of Agriculture(USDA), is hereby designated as the governmental inspection agency for the purpose of certifying the grade, size, quality, and maturity of the regulated commodities prior to importation into the United States. In addition, the Food Production and Inspection Branch, Agriculture Canada, is authorized to make such inspections and certifications with respect to onions, Irish potatoes, and tomatoes. Inspection by one of these authorized inspection agencies, with evidence thereof in the form of an official inspection certificate issued by such agency, is required for all regulated commodities prior to importation.

(b) USDA inspection and certification services will be available upon application, in accordance with the rules and regulations governing the inspection and certification of fresh fruits, vegetables and other products(7 CFR Part 51). The cost of the inspection and certification shall be borne by the applicant.

(c) The term "importation" means release from custody of the United States Customs Service.

(d) Each inspection certificate issued for commodity to be imported into the United States shall set forth among other things : (3) The name and place of inspection ; (2) The name of the shipper or applicant ; (3) The commodity inspected ; (4) The quantity of the commodity covered by the certificate ; (5) The principal identifying marks on the container ; (6) The railroad car initials and number, the truck and the trailer license number, the name of the vessel, the name of the air carrier, or other identification of the shipment ; and (7) The following statement as facts warrant : Meets or fails to meet U.S. import requirements under section 8e of the Agricultural Marketing Agreement Act of 1937, as amended. Inspection certificates shall cover only the quantity of the commodity that is being imported at a port of entry by an importer.

(e) Importers of such commodities should make arrangements for inspection and certification at the following offices. Such arrangements should be made at least one day prior to entry at Port inspection offices, two days prior to entry at Regional offices, and three days prior to entry at the Washington headquarters office.

WASHINGTON HEADQUARTERS INSPECTION OFFICE :

Chief, Fresh Products Branch, P.O. Box 96456, Rm. 2056-S, Fruit and Vegetable Division, AMS, U.S. Department of Agriculture, Washington, D.C. 20090-6456, PH : 202-447-5870

EASTERN REGIONAL DIRECTOR, Skyline Office Building, 5205 Leesburg Pike, Suite 806, Falls Church, VA 22041, PH : 703-756-6781.

CENTRAL REGIONAL DIRECTOR, Suite 340, 800 Roosevelt Road, Building A, Glen Ellyn, IL 60137, PH : 312-790-6943.

WESTERN REGIONAL DIRECTOR, P.O. Box 214297, Sacramento, CA 95821, PH : 916-978-4254

EASTERN REGION INSPECTION PORTS OF ENTRY OFFICES :

Mobile, AL, PH : 205-690-6154
Miami, FL, PH : 305-592-1375
Everett, MA, PH : 617-389-2480
Newark, NJ, PH : 201-645-2670
Norfolk, VA, PH : 804-441-6218
Santurce, PR, PH : 809-783-2230
Jacksonville, FL, PH : 904-354-5983
Jessup, MD, PH : 301-799-5899
Buffalo, NY, PH : 716-824-1585
Bronx, NY, PH : 212-991-7665
Philadelphia, PA, PH : 215-336-0845
Tampa, FL, PH : 813-272-2470

CENTRAL REGION INSPECTION PORTS OF ENTRY OFFICES :

Detroit, MI, PH : 313-226-6059
St Paul, MN, PH : 612-296-8557
Houston, TX, PH : 713-923-2557
Las Cruces, NM, PH : 505-646-4929
New Orleans, LA, PH : 504-589-6741
El Paso, TX, PH : 915-541-7723
Alamo, TX, PH : 512-787-4091

WESTERN REGION INSPECTION PORTS OF ENTRY OFFICES :

PH : Nogales, AZ, PH : 602-281-0783
Honolulu, HI, PH : 808-548-7138
Salem, OR, PH : 503-378-3775
Los Angeles, CA, PH : 213-894-2489
Burlingame, CA, PH : 415-876-9313 & 9314
Seattle, WA, PH : 206-764-3500

Meat

Export meat products may be a little simpler than that of fruit, vegetables and processed foods. An exporter of meat products unilke an exporter of other processed food products does not have to deal directly with a US government regulatory agency, but instead with your own government food regulatory agency.

The way this service works is that a particular country's government agency, in this case Korea, files a request with the USDA in Washington to export a meat product or products. In filing the request the country has to demonstrate that their regulations are equivalent to the U.S. If so, then, a USDA representative may make an initial visit to the plant(s) in question and then leave the work to the local agency.

Detailed US regulations on meat and meat products should read Title 9 CER Chapter III, Subchapter A, and Subchapter C.

U.S. Customs

The importation of food is also subject to the Tariff Act of 1930 which is administered by the Customs Service under the Department of the Treasury. As stated above in the quote from the FD&C Act, Customs notifies FDA of the arrival of food shipments, and FDA does the inspection and then, in turn, notifies Customs if the shipment may proceed.

While Customs' focus is generally directed at assessing and collecting duties, taxes, and fees, imported foods are not legally entered until a shipment has arrived within the Port of Entry and delivery of the merchandise has been authorized by Customs. Customs is responsible for releasing only those goods which meet all applicable statutory requirements.

Tariff Act of 1930

Rates of duty on imported commodities are published periodically by the U.S. International Trade Commission in the Harmonized Schedules of the United States. Duties on most fruits, vegetables and nuts are included in Chapters 7, 8 and 20. Specific information on import duties may be obtained from :

U.S. Customs Service
Classifications and Value Division
1301 Constitution Avenue, N.W.
Washington, D.C. 20229
(202) 566−8181 ; FAX : (202) 377−9130

Regional Offices U.S. Customs Service

(C : Commissioner ; DC : Deputy Commissioner ; RC : Regional Commissioner ; DD : District Director ; AD : Director)

Regional Headquarters District Offices	Address	Officer
MAIN HEADQARTERS :		
Washington, DC	1301 Constitution Ave., NW., 20229	William Von Raab(C)
New York :		
New York, NY	6 World Trade Center, 10048	Edward F. Kwas(RC)
		Jean F. Maguire(AD)
	Kennedy Airport, 11430	John J. Martuge(AD)
Newark, NJ	Airport International plaza, 07114	Peter J. Baish(AD)
Northeast :		
Baltimore, MD	40 S. Gay St., 21202	A. Robert Beikirch(DD)
Boston, MA	10 Causeway St., 02222	Philip Spayd(RC)
		John Linde(DD)
Buffalo, NY	111 W. Huron St., 14202	Carlton L. Brainarst(DD)
Ogdensburg, NY	127 N. Water St., 13669	William Dietzel(DD)
Philadelphia, PA	2d & Chestnut Sta., 19106	Anthony Piazza(DD)
Portland, ME	312 Fore St., 04112	Emery W. Ingalls(DD)
Providence, RI	24 Weybosset St., 02903	Phillip A. Bernard(DD)

St. Albans. VT Main & Stebbins Sta., 05478	Frank Spendley(DD)
SOUTH CENTRAL :	
Mobile, AL 150 Wall St., 36652	David L. Willette(DD)
New Orleans, LA423 Canal St., 70130	Joel Mish(DD)
SOUTHEAST :	
Charleston, SC 200 E. Bay St., 29401	William Byrd(DD)
Miami, FL 909 SE. First Ave., 33131	George D. Heavey(RC)
77 SE, 5th St., 33131	Thomas J. Mattina(DD)
Norfolk, VA 101 E. Main St., 23510	Dennis H. Murphy(DD)
San Juan, PR U.S. Custom house, P.O.B. 2112, 00903	Mamie Pollock(DD)
Savannah, GA 1E. Bay St., 31401	Robert Richter(DD)
Tampa, FL 4430 E. Adams Dr., 33605	Diane Zwicker(DD)
Washington, DC P.O. Box 17423, 20041	Sidney Reyes(DD)
Wilmington, NC 1 Virginia Ave., 28401	John R. Babb(DD)
SOUTHWEST :	
Dallas/Fort Worth, TX 700 Parkway Plaza, Dallas/Ft. Worth Airport, 75261	David Greenleaf
El Paso, TX Bridge of the Americas(P.O.B. 9516), 79985	Mike Mack(DD)
Houston, TX 5850 San Felipe St., 77057	James Piatt(RC)
Houston/Galveston, TX 701 San Jacinto St., 77052	Patricia McCauley
Laredo, TX Lincoln-Juarez Bridge, 78041	Joseph Castellano
Nogales, AZ International and Terrace Sts., 85621	Frederic Lawrence
Port Arthur, TX4550 75th Ave., 77642	Valerie Hillman.
PACIFIC :	
Anchorage, AK 620 E. 10th Ave., 99501	Duane Oveson(DD)
Honolulu, HI 335 Merchant St., 96806	George Roberts
Los Angeles, CA300 N. Los Angeles St., 90053	Quintin Villanueva,
Los Angeles/Long Beach, CA 300 S. Ferry St., San Pedro	John Heinrich(DD)
Portland, OR 511 NW. Broadway, 97209	Clyde Kellay, Jr.
San Diego, CA 880 Front St., 92188	Allan J. Rappoport
San Francisco, CA555 Battery St., 94126	Paul Andrews(DD)
Seattle, WA 909 lst Ave., 98174	Daniel C. Holland

For further information, contact the Public Affairs Office, U.S. Customs Service, Department of the Treasury, 1301 Constitution Avenue NW., Washington, DC 20229. Phone, 202-566-8195.

Sanitary Inspections

In the US the best method of complying with government regulations is to have an established program for good manufacturing procedures within the regulated company that would include a written manual(s) on "how to". This program would be a quality control/quality assurance program. The program would place high priority on successfully passing an FDA inspection ; the manuals employed should be practical, readily understood, and reliable and should not be cluttered with quotes of legal text or other directives. Manuals should be directed

at an individual who will carry out its directions, i.e. the "how to". Since the FDA does not be inspect foreign plants, the best approach to ensure that food safe for human consumption is produced, is to obtain knowledge and then practice FDA regulations. Types of inspections that take place in the U.S. and an Import inspection are described.

Inspections……There are three types of FDA inspections ; (1) comprehensive inspection, (2) abbreviated inspection, and (3) directed inspection.

A comprehensive inspection, as the name implies, covers everything in the facility subject to FDA jurisdiction. This type of inspection is one that is generally scheduled in the district office on a routine basis.

An abbreviated inspection is one that concentrates on those areas known as critical factors which have a major influence on classifying a firm as being in compliance or not. The critical factors are identified in Chapter 6 of the FDA Inspectors Operation Manual(IOM). If there are no significant objectionable conditions, the inspection is finished and a report is written and discussed with management. If, during the abbreviated inspection, the inspector finds a significant objectionable condition, the inspector is usually directed to conduct a comprehensive inspection.

A directed inspection is one covering specific areas to the extent indicated in the compliance program, the assignment, or specific instructions provided. Most directed inspections are in response to a consumer complaint or some other information indicating a potentially significant food safety problem and not an economic problem, which may call for immediate action : corrective maintenance, process modification, and/or possible a recall for example.

Post-Inspection Activity……The FDA inspector's report is called an Establishment Inspection Report(ETR). This report is a detailed report of the entire inspection and details the inspectors' observations and discussions with company personnel. It includes the results of any testing performed on samples taken from the facility.

It is desirable for a company to develop a set of procedures for following up on the inspections. This is particularly so when an inspection identifies serious problems, and some form of follow-up enforcement action is expected.

Chapter 5 of the IOM covers the broad general facets of Establishment Inspection.

Chapter 6 covers the Inspection Methods relating to 24 specific food areas such as grains, and grain products, egg and egg products, fruit and fruit products, etc. In addition, Chapter 6 details the HACCP inspections of low-acid and acidified canned foods in hermetically sealed containers and inspection instructions for frozen strawberries, pickles and dressings and condiments. Dressings and condiments are also products with an FDA standard of identity.

Chapter 4 of the IOM contains sampling instructions for all types of products of concern to FDA.

Imported foods

In addition Chapter 4 identifies the different types of inspections that may be conducted on imported products. They are :

Records Review……the simplest of inspections since it only involves a review of the Importers paperwork. This operation is performed on every lot of regulated product to determine whether additional action such as sampling is necessary or the product is to be release or a Walk-by inspection is in order.

Walk-by Inspection……represents the next level of review. It is a rapid visual examination of the merchandise for physical damage or for what ever reason.

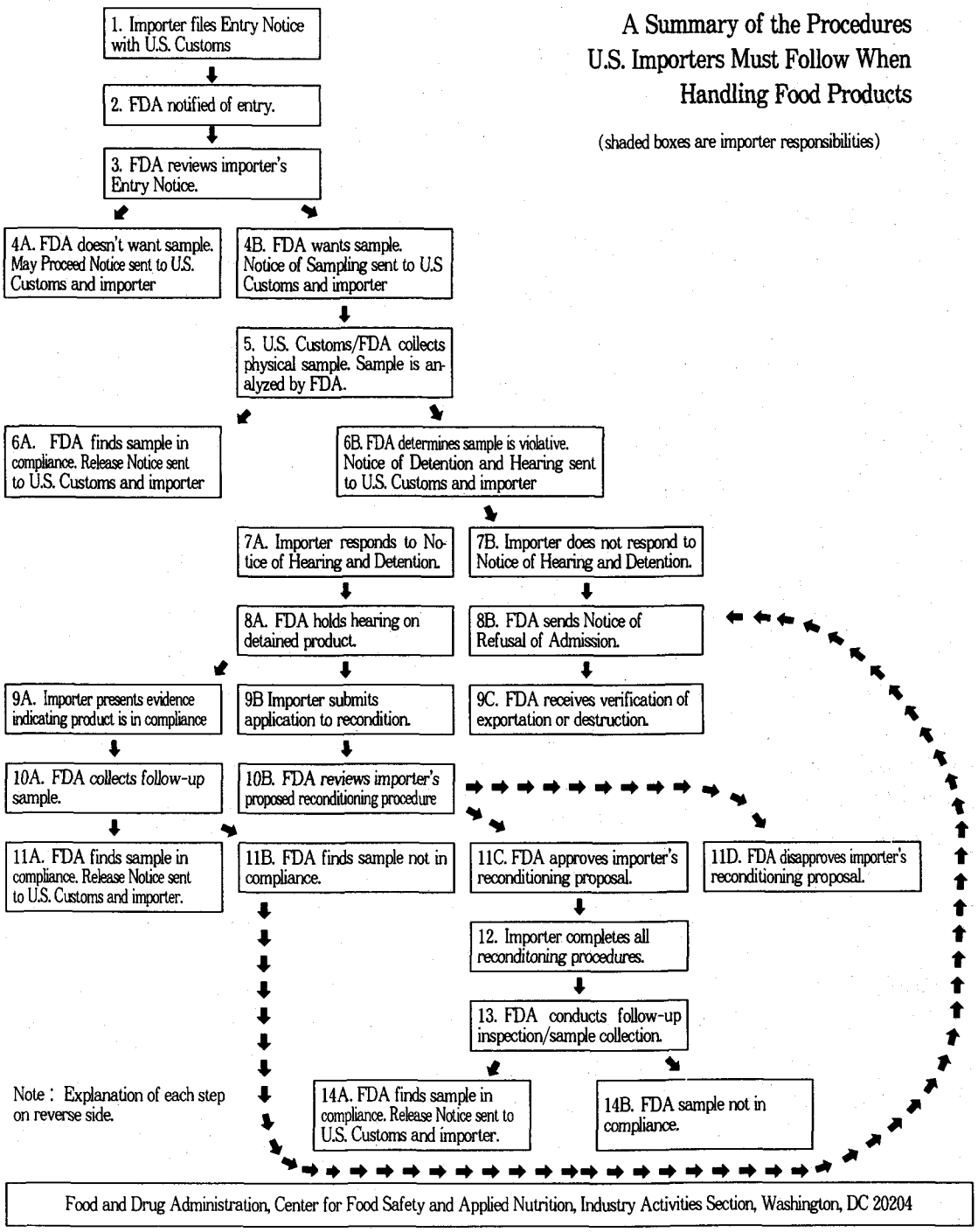
Wharf Examination……is the examination of a product to the extent that it takes to determine that the product appears to be in compliance for the attributes for which the lot was examined.

This type of Examination is a critical non-sampling examination. Canned foods are examined in accordance with a Sample Schedule.

Final Note :

The above is written from the authors perspective of working with the government agencies in carrying out their appointments as university professors working with the food processing industry and should not be interpreted as representatives for the agencies.

IMPORTING FOODS INTO THE UNITED STATES



FDA IMPORT PROCEDURES

1. Importer or agent files entry documents with U.S. Customs Service within five working days of the date of arrival of a shipment at a port of entry.

2. FDA is notified of an entry of regulated foods through :
   - Importers Entry Notice(FDA Form FD 700 set) or Land Port Entry Notice(FDA Form FD 701)
   - Copy of U.S. Custom's Form 7501, "Summary Sheet for Consumption Entry,"
   - Copy of commercial invoice, and
   - Surety to cover potential duties, taxes and penalties.

3. FDA reviews Importer's Entry Notice(FDA Form FD 701) to determine it a physical examination(what examination, sample examination) should be made.

4A. Decision is made not to collect a sample. FDA issues a May Proceed Notice(FDA Form FD 702) to U.S. Customs and the importer of record. The shipment is released as far as FDA is concerned.

4B. Decision is made to collect a sample based on :
   - Nature of the product,
   - FDA priorities, and
   - Past history of the commodity.

FDA issues a Notice of Sampling(FDA Form FD 712) to U.S. Customs and the importer of record. The shipment must be held intact pending further notice. A sample will be collected from the shipment. The importer of record may move the shipment from the dock to another port or warehouse(contact U.S. Customs for details).

5. FDA obtains a physical sample. The sample is sent to an FDA District Laboratory for analysis.

6A. FDA analysis finds the sample to be in compliance with requirements. FDA sends a Release Notice(FDA Form FD 717) to U.S. Customs and the importer of record.

6B. FDA analysis determines that the sample "appears to be in violation of the FD&C Act and other related Acts." FDA sends U.S. Custom and the importer of record a Notice of Detention and Hearing(FDA Form FD 777) which :
   - Specifies the nature of the violation, and
   - Gives the importer of record 10 working days to introduce testimony as to the admissibility of the shipment.

The hearing is the importer's only opportunity to show that the importation meets all legal requirements or to show how the shipment may be made eligible for entry.

7A. Consignee, true owner, importer of record, or a designated representative responds to the Notice of Detention and Hearing. The response permits the introduction of testimony, either orally or written, as to the admissibility of the shipment.

7B. Consignee, true owner, importer of record, or a designated representative neither responds to the Notice of Detention and Hearing nor requests an extension of the hearing period.

8A. FDA conducts a hearing concerning the admissibility of the product. The hearing is an opportunity to present relevant matters and is confined to the submission of pertinent evidence.

8B. FDA issues a Notice of Refusal of Admission(FDA Form FD 772) to the importer of record. This is the same person or firm who was sent a Notice of Sampling. All recipients of the Notice of Sampling and the Notice of Detention and Hearing are sent a copy of FDA Form FD 772.

9A. Importer of record presents evidence indicating that the product is in compliance. Certified analytical results of samples, examined by a reliable laboratory and which are within the published guidelines for levels of contaminants and defects in food for human use, may be presented.

9B. Importer of record submits an Application for Authorization to Recondition or to Perform Other Action(FDA Form FD 766). The form requests permission to try to bring a food that is adulterated or misbranded into compliance by relabeling or other action, or by converting to a non-food use. A detailed method to bring the food into compliance must be given.

9C. FDA receives verification of the exportation or destruction of the shipment from U.S. Customs. The exportation or destruction of the merchandise listed on the Notice of Refusal of Admission is caried out under the direction of U.S. Customs.

10A. FDA collects follow-up sample to determine compliance with guidelines.

10B. FDA evaluates the reconditioning procedure proposed by the importer. A bond is required for payment of liquidated damages.

11A. FDA finds that the sample is "in compliance." A Release Notice(FDA Form FD 717) with the statement "Originally Detained and Now Released" is sent to U.S. Customs and the importer.

11B. FDA finds that the sample is not in compliance. The importer may either submit an Application for Authorization to Recondition or to Perform Other Action(see 9B), or, FDA will issue a Notice of Refusal of Admission(see 8B).

11C. FDA approves importer's reconditioning procedures. The approved application contains the statement "Merchandise Should Be Held Intact Pending the Receipt of FDA's Release Notice."

11D. FDA disapproves applicant's reconditioning procedure if past experinence shows that the proposed method will not succeed. A second and final request will not be considered unless it contains meaningful changes in the reconditioning operation to ensure a reasonable chance of success. The applicant is informed on FDA Form FD 766.

12. Importer completes all reconditioning procedures and advises FDA that the goods are ready for inspection/sample collection.

13. FDA conducts follow-up inspection/sample collection to determine compliance with the terms of the reconditioning authorization.

14A. FDA analysis finds that the sample is in compliance. A Release Notice(FDA Form FD 717) is sent to the importer and to U.S. Customs. The charges for FDA supervision are as-

sessed on FDA Form FD 790. Copies are sent to U.S. Customs which is responsible for obtaining total payment including any expenses incurred by their personnel.

14B. FDA analysis finds that the sample is still not in compliance. Charges for FDA supervision are assessed on FDA Form FD 790. Copies are sent to U.S. Customs which is responsible for obtaining total payment including expenses incurred by their personnel.

IMPORTERS CAN SPEED FOOD ENTRIES !

- Determine before shipment that the product to be imported is legal.
- Have private laboratories examine samples of foods to be imported and certify the analysis of the processsor. While not conclusive, these analyses might serve as an indication of the the processor's ability to produce acceptabe, legal products.
- Become acquainted with FDA's legal requirements, before contracting for a shipment.
- Request assistance from the FDA District Office responsible for your port of entry.
- Know the food importing procedures described on this information sheet.