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Annexes

Relevant regulations, procedures, guidance or standards used by the European Union

A.1 DIRECTIVE 97/78 ANNEX II – BORDER INSPECTION POSTS (EUROPEAN UNION)

Approved requirements for border inspection posts

In order to obtain Community approval, border inspection posts must have:

- the staff necessary to check the documents (public health and animal health certificates or any other document laid down by Community legislation) accompanying the products,
- sufficient numbers, in relation to the quantity of products dealt with by the border inspection post, of veterinary and auxiliary staff specially trained to carry out checks that products correspond to the accompanying documents and systematic physical checks of each product consignment,
- sufficient staff to take and process random samples of product consignments presented at a given border inspection post,
- sufficiently large premises available to the staff responsible for carrying out veterinary checks,
- appropriate hygienic premises and facilities for carrying out routine analyses and taking samples in accordance with this Directive,
- appropriate hygienic premises and facilities for taking and processing the samples for the routine checks laid down in Community rules (microbiological standards),
- the services of a specialized laboratory able to carry out special analyses on the samples taken at that post,
- premises and cold stores for the storage of part-consignments taken for analysis and products whose release for free circulation has not been authorized by the veterinary officer responsible for the border inspection post,
- appropriate equipment for the rapid exchange of information, in particular with other border inspection posts (through the computerized system provided for in Article 20 of Directive 90/425/EEC or the Shift project),
- the services of an establishment qualified to carry out the treatment provided for in Directive 90/667/EEC.

A.2 LEVELS OF PHYSICAL CHECKS ON PRODUCTS OF ANIMAL ORIGIN (EUROPEAN UNION)

<table>
<tr>
<td>Category I - 20 percent of consignments of:

Fresh meat including offal, and products, of bovine, ovine, caprine, porcine and equine species
Fish products in hermetically sealed containers (stable at ambient temperature), fresh/frozen fish, dried/salted fishery products
Whole eggs, hatching eggs
Lard and rendered fats
Animal casings</td>
<td rowspan="2">All products from the Czech Republic:

10 percent of all category I products
25 percent of all category II products
Apiculture products
Hunting trophies
Processed pet food, raw material for the manufacture of pet food
Minimum of 1 percent, maximum of 5 percent of all category III products
100 percent sampling for the first 6 consignments, then 25 percent of all processed animal protein

All products from New Zealand:

2 percent of all animal product consignments for human consumption
1 percent of all other animal products
20 percent of consignments of processed animal protein not for human consumption

All products from Canada:

10 percent of all products of animal origin except:
Bulk processed animal protein – 100 percent for the first six consignments, then 20 percent
Fish, fishery products and bivalve molluscs
15 percent</td>
</tr>
<tr>
<td>Category II - 50 percent of consignments of:

Poultry, rabbit, game (farmed or wild) meat and products
Milk and milk products for human consumption
Egg products
Processed animal protein for human consumption
Other fishery products other than those in Category I and bivalve molluscs
Honey</td>
</tr>
<tr>
<td colspan="2">Category III - minimum 1 percent, maximum 10 percent of all consignments of:

Semen, embryos, manure
Milk and milk products not for human consumption
Gelatine
Frogs legs and snails
Bones and bone products
Hides and skins
Bristles, wool, hair and feathers
Horns and horn products, hooves and hoof products
Raw material, blood, blood products, glands and organs for pharmaceutical use
Blood products for technical use
Pathogens
Hay and straw</td>
</tr>
</table>

A.3 DOCUMENTARY REQUIREMENTS (UNITED KINGDOM/EUROPEAN UNION)

This excerpt details the requirements for importers of products of animal origin (with some specific text for fish and fish products) into the UK. Though it is UK law, it is based on, and refers to, EC legislation.

Text from: http://www.hillingdon.gov.uk/environment/food_safety/imported_food_advice.php.

Pre-notification

It is a legal requirement under The Products of Animal Origin (Third Country Imports) (England) Regulations 2002, that at least 6 hours advance notice of arrival must be given for consignments arriving by air that contain Products of Animal Origin.

When the consignment arrives, it must be moved without delay by an authorized transport operator to one of the inspection facilities. The documents for the consignment must also be presented without delay to the Imported Food Office. Checks will only be carried out at the inspection facility when the documents are presented.

Certificate of Veterinary Checks (CVC)

These are standard forms based on European Union requirements. The agent/importer must complete the left half of the certificate and present it to this office along with specific documents. A CVC must be completed for each part of the consignment that has a public health certificate. Once the consignment and documents have been inspected the certificate is completed, signed and stamped by an Authorized Officer of the London Borough of Hillingdon or Official Veterinary Surgeon, and 3 copies are returned to the agent/ importer. The white copy must remain with the consignment until its arrival at the premises of destination stated in the health certification or documentation, the yellow copy I submitted to Customs with the entry and the blue copy is retained by the agent.

The following documents must be submitted with the CVC:

1) Health Certificates

Health Certificates are obtained from the competent authority of the country of origin. They must contain specific information as detailed in European Union Decisions and Directives. The general requirements for all health certificates are that it must:

- Be the original copy
- Have a unique reference number
- Be fully completed
- Not have unauthorized alterations or be defaced in any way, i.e. no tippex, crossings out etc.
- Be drawn up in English (i.e. in the official language of the Member State where the checks are carried out. If necessary more than one language can be used.)
- Be made out to a single recipient
- Consist of a single sheet of paper (for fish & fishery products)
- Be signed by the Official Veterinary Surgeon or equivalent official representative of the Competent Authority of the country of origin and have an official health stamp of the country of origin in a different colour to that of the printing ink.
- Be dated in relation to the date of loading of the products for dispatch towards the community. Health certificates issued retrospectively will not be accepted.
- Detail the address(s) and approval number(s) of the processing plant of origin. This must correspond to that detailed on the packaging.

Where Health certificates fail to comply with any of these requirements, the consignment will be refused entry.

2) Invoices/Packing list
Invoices must relate to the consignment, be dated in relation to the date of despatch, and preferably be in their original format. It is advisable that the following information is included: Air Waybill number, consignee and consignor, details of species of fish/ types of product, net weight.

3) Airway Bill (AWB)
An AWB is also required. This must relate to the consignment and preferably be the original copy.

4) CVC Charges
We are required by European Union legislation to make a charge for Veterinary Checks. At Heathrow, this is usually based upon the gross weight of the consignment. Further to these charges, your consignment will be subject to charges for the transportation of the consignment to the inspection facility (by authorized transport operator), Border Inspection Post handling charges and transit shed handling fees. You will need to contact the individual bodies for their scale of charges. Payment for the veterinary checks must be received before the CVC is issued and the consignment released.

Specific requirements for fish and fishery products

- Packaging and markings
- Packaging of consignments of fish and fishery products must comply with the requirements laid down in Council Directive91/493/EEC (as amended).

The country and establishment of origin must be marked on the packaging in indelible letters. All letters must be fully legible and grouped together on the packaging in place where they are visible from the outside without any need to open the packaging. All layers of sealed packaging must be marked. (Please note that there are additional requirements for the labelling of consignments of live bivalve molluscs under Council Directive 91/492/EEC.)

Materials used in the packaging of fishery products must:

a) Protect the product from substances that are harmful to health

b) Be strong enough to protect the fish.

c) Not affect the taste or smell of the fish.

Packaging materials may not be re-used unless made of materials which are easy to clean and have previously been cleaned and disinfected.

Transport
Fish and fishery products may not be stored or transported with other products which may contaminate or affect their hygiene, unless they are packaged in such a way as to provide satisfactory protection.

Fresh or thawed fishery products and cooked and chilled crustacean and molluscan shellfish products must be stored and transported at a temperature approaching that of melting ice (up to 4 °C). Frozen fishery products must be stored and transported at –18 °C or less. Products must be transported in such a way that these temperatures are maintained throughout transportation.

General Points to Note
Imports of fishery products from certain third countries are not permitted and therefore it is important to check with this office or the Food Standards Agency before importing fish into the European Union.

Live fish or shellfish e.g. lobsters, eels, mussels, clams etc. can only be imported into the UK if the importer has a current licence issued by the Centre for Environment, Fisheries and Aquaculture Science.

Consignments of fish and fishery products destined for testing or quality/visual assessment, are subject to the complete checks and must be issued with a Certificate of Veterinary Checks.

Consignments that fail the veterinary checks

Where a consignment of Products of Animal Origin fails any stage of the veterinary check because it does not meet import requirements or there is some irregularity, a notice is served on the importer or his/her agent under Regulation 21 of the Products of Animal Origin (Third Country Imports) (England) Regulations 2002. The Notice will normally specify that the consignment should be re-dispatched away from the European Union (and Iceland, Norway & Faeroe Islands) by a given date or be destroyed. However, the option for re-export will not be given where it is unacceptable on animal or public health grounds.

There is the right of appeal against the notice within one day by way of complaint for an order to a Magistrates Court. There is information about this at the bottom of the Notice.

A.4 MICROBIOLOGICAL STANDARDS (EUROPEAN UNION) - EXISTING AND UPCOMING STANDARDS

Existing standards

			Sampling plan				
Food Category	**Micro-organism**	**Limit**	**N**	**c**	**m**	**M**	**Additional information**
Live bivalve molluscs (Directive 91/492/EEC)	*Salmonella*	Absence in 25 g					
	Faecal coliforms	<300 / 100 g					Production area A
		< 6 000 / 100 g					Production area B
		< 60 000/ 100 g					Production area C
	E. coli	<230 / 100 g					Production area A
		<4 600 / 100 g					Production area B
Cooked crustaceans and molluscan shellfish (Decision 93/51/EEC)	*Salmonella*	Absence in 25 g	5	0			
	S. aureus		5	2	100 cfu/g	1000 cfu/g	
	Any pathogen	Quantities to affect human health					
	Thermotolerant coliforms		5	2	10 cfu/g	100 cfu/g	
	E. coli, guideline*		5	1	10 cfu/g	100 cfu/g	
	Mesophilic aerobic bacteria, guideline*		5	2	10^4 cfu/g	10^5 cfu/g	Whole products
			5	2	$5x10^4$ cfu/g	$5x10^5$ cfu/g	Shelled and shucked
			5	2	10^5 cfu/g	10^6 cfu/g	Crabmeat

Production area A: bivalve molluscs can be collected for direct human consumption

Production area B: bivalve molluscs can be collected but only placed on the market for human consumption after treatment in a purification centre, after relaying

Production area C: bivalve molluscs can be collected but placed on the market only after relaying over a long period (at least two months), whether or not combined with purification, or after intensive purification for a period to be fixed in accordance with the procedure provided for in Article 12 of Directive 91/492.

n = number of units comprising the sample,
m = limit below which all results are considered satisfactory,
M = acceptability limit beyond which the results are considered unsatisfactory,
c = number of sampling units giving bacterial counts of between m and M.

The quality of a batch is considered to be:
(a) satisfactory where all the values observed are 3 m or less;
(b) acceptable where the values observed are between 3 m and 10 m (= M) and where c/n is 2/5 or less.
The quality of a batch is considered to be unsatisfactory:
– in all cases where the values are above M,
– where c/n is greater than 2/5.

* These guidelines are to help manufacturers decide whether their plants are operating satisfactorily and to assist them in implementing the production monitoring procedures.

Draft standards under consideration by the European Union (These are presented here for information only. Still being discussed at EC and are likely to change meanwhile.)

1. Microbiological criteria defining the safety of fish and fishery products

Food category	Micro-organisms / Metabolites	Sampling plan[1]		Limits		Analytical reference method[2]	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
1.2 Ready-to-eat foods able to support the growth of *L. monocytogenes* other than those intended for infants and young children and ready-to eat-foods for special medical purposes[3]	*Listeria monocytogenes*	5	0	Absence in 25 g[5]		EN/ISO 11290-1	End of the manufacturing process	The batch shall not be placed on the market[4]
		5	0	100 cfu/g[6]		EN/ISO 11290-2[7]	Products during the shelf-life	The batch shall not be placed on the market or it shall be withdrawn from the market[4]
1.3 Ready-to-eat foods unable to support the growth of *L. monocytogenes* other than those intended for infants and young children and ready-to eat-foods for special medical purposes[3, 8]	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2[7]	Products during the shelf-life	The batch shall not be placed on the market or it shall be withdrawn from the market[4]
1.16 Cooked crustaceans and molluscan shellfish	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	End of the manufacturing process and products on the market	The batch shall not be placed on the market or it shall be withdrawn from the market[4]
1.17 Shelled and shucked products of cooked crustaceans and molluscan shellfish	Coagulase-positive staphylococci	5	2	100 cfu/g	1000 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process and products on the market	The batch shall not be placed on the market or it shall be withdrawn from the market[4]
1.19 Live bivalve molluscs and live echinoderms, tunicates and gastropods	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products ready to be placed on the market and products on the market	The batch shall not be placed on the market or it shall be withdrawn from the market[4]
1.20 Live bivalve molluscs and live echinoderms, tunicates and gastropods	*E. coli*[9]	1 [10]	0	<230 / 100 g of flesh and intra-valvular liquid		Draft ISO 16649-3	Products ready to be placed on the market and products on the market	The batch shall not be placed on the market or it shall be withdrawn from the market[4]
1.21 Fishery products, other than those below, from fish species of the families: *Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae* and *Scombraesosidae*	histamine	9	2	100 ppm	200 ppm		Products ready to be placed on the market and products on the market	The batch shall not be placed on the market or it shall be withdrawn from the market[4]
1.22 Fishery products, which have undergone enzyme maturation treatment in brine, manufactured from fish species of the families: *Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae* and *Scombraesosidae*	histamine	9	2	200 ppm	400 ppm		Products ready to be placed on the market and products on the market	The batch shall not be placed on the market or it shall be withdrawn from the market[4]

[1] n= number of units comprising the sample; c= number of samples units giving values over m or between m and M
[2] The most recent edition of the standard shall be used.
[3] Regular testing against the criterion is not useful in normal circumstances for foodstuffs such as ready-to-eat foods, which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (e.g. products heat treated in their final package and UHT milk); fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds; bread, biscuits and similar products; bottled or packed waters, soft drinks, beer, cider, wine, spirit drinks and similar products; sugar, honey and confectionery; including cocoa and chocolate products; and live bivalve molluscs.
[4] The batch is regarded as unsafe. The batch shall not be placed on the market, and if already on the market, it shall be withdrawn from the market. In addition, corrective actions, such as improvements in production hygiene and selection of raw materials, shall take place. If authorized by the competent authority, reprocessing of the unsafe batch with a treatment efficient to eliminate the hazard is possible.
[5] This criterion applies, if the manufacturer is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life.
[6] This criterion applies, if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that should be low enough to guarantee that the limit 100 cfu/g is not exceeded at the end of the shelf-life.
[7] A 1 ml of inoculum is plated on a Petri dish of 140 mm diameter or on 3 Petri dishes of 90 mm diameter
[8] Products with pH < 4.4 or a_w < 0.92, products with shelf-life less than 5 days and live bivalve molluscs are automatically considered to belong to this category. Other categories of products can also belong to this category following scientific justification.
[9] *E. coli* is used here as an indicator of faecal contamination
[10] A pooled sample comprising a minimum of 10 individual animals
[11] This criterion applies to mechanically separated meat (MSM) referred to in Chapter III, paragraph 3, in section V of Annex III of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.
[12] Preliminary testing of the batch of seeds before starting the sprouting process or the sampling to be carried out at the stage where the highest probability to find *Salmonella* is expected.

Interpretation of the test results (European Union draft microbiological standards)

L. monocytogenes in ready-to-eat foods intended for infants and for special medical purposes and salmonella in foodstuffs:

The microbiological quality of the batch tested shall be considered:
- satisfactory, if all the values observed indicate the absence of the bacterium,
- unsatisfactory, if the presence of the bacterium is detected in any one sample unit.

L. monocytogenes in other ready-to-eat foods and *E.coli* in live bivalve molluscs:

The microbiological quality of the batch tested shall be considered:
- satisfactory, if all the values observed are ≤ m,
- unsatisfactory, if any of the values are >m.

Staphylococcal enterotoxins:

The microbiological quality of the batch tested shall be considered:
- satisfactory, if in all the sample units the enterotoxins are not detected,
- unsatisfactory, if the enterotoxins are detected in any of the sample units.

Coagulase-positive staphylococci in cooked crustaceans and molluscan shellfish:

The microbiological quality of the batch tested shall be considered:
- satisfactory, if all the values observed are ≤ m,
- acceptable, if maximum of c/n values are between m and M, and the rest of the values observed are ≤m,
- unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M

Histamine in fishery products from fish species of the families *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryfenidae*, *Pomatomidae* and *Scombraesosidae:*

The microbiological quality of the batch tested shall be considered:
- satisfactory, if the mean value observed is ≤ m and maximum of c/n values are between m and M,
- unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M or if the mean value is >m

2. Criteria indicating the acceptability of the process for fishery products

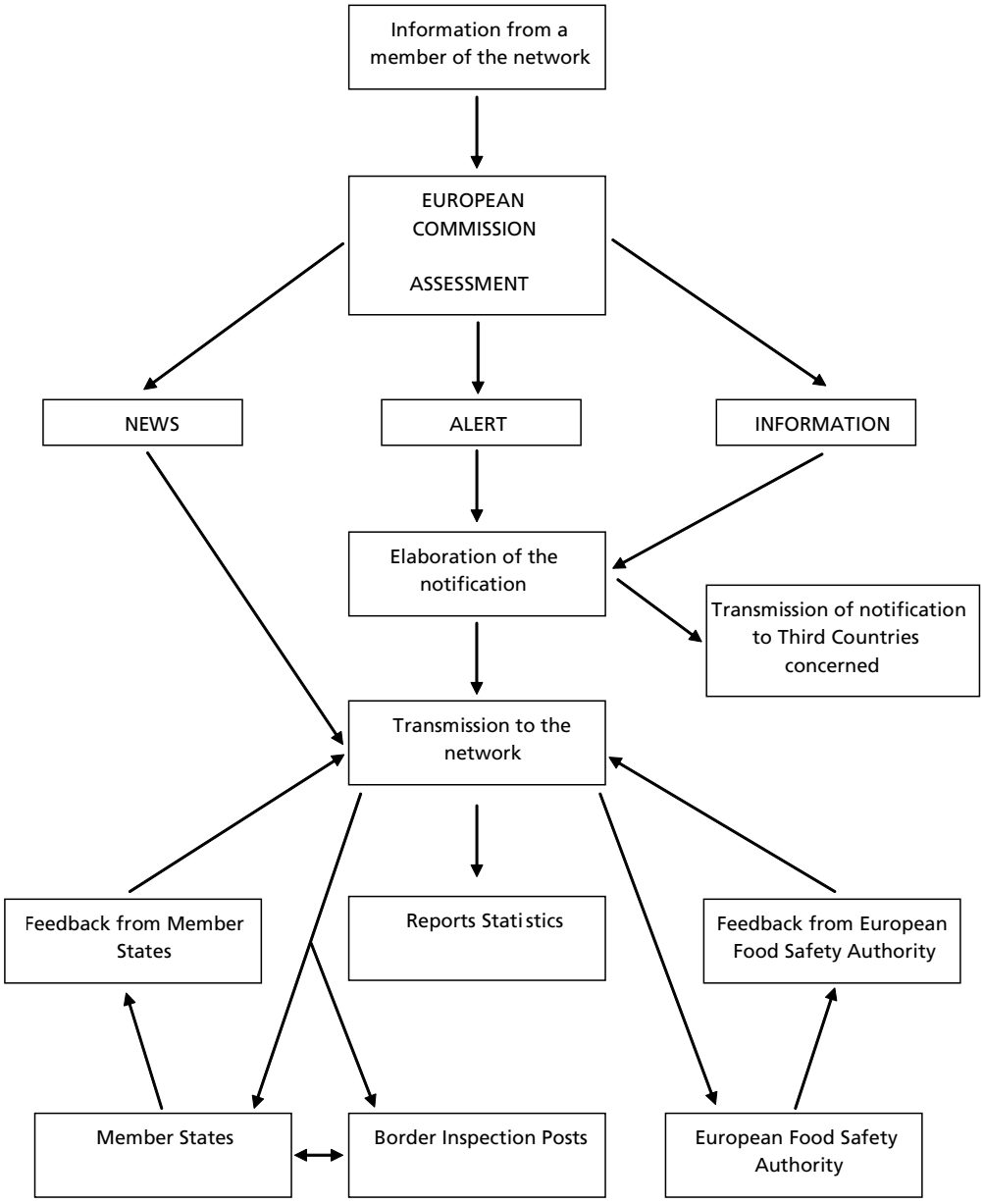
Food category	Micro-organisms	Sampling plan[1]		Limit		Analytical reference method[2]	Stage where the criterion apply	Action in case of unsatisfactory results
		n	c	m	M			
Cooked crustaceans and molluscan shellfish	total *Vibrio parahaemolyticus* count	5	2	10 cfu/g	100 cfu/g	ISO 8914 with MPN technique	End of the manu-facturing process	Improvements in production hygiene
Shelled and shucked products of cooked crustaceans and molluscan shellfish	*E. coli*	5	2	1 cfu/g	10 cfu/g	ISO 16649-draft 3	End of the manu-facturing process	Improvements in production hygiene

[1] n= number of units comprising the sample; c= number of samples units giving values between m and M
[2] The most recent edition of the standard shall be used.

Interpretation of the test results

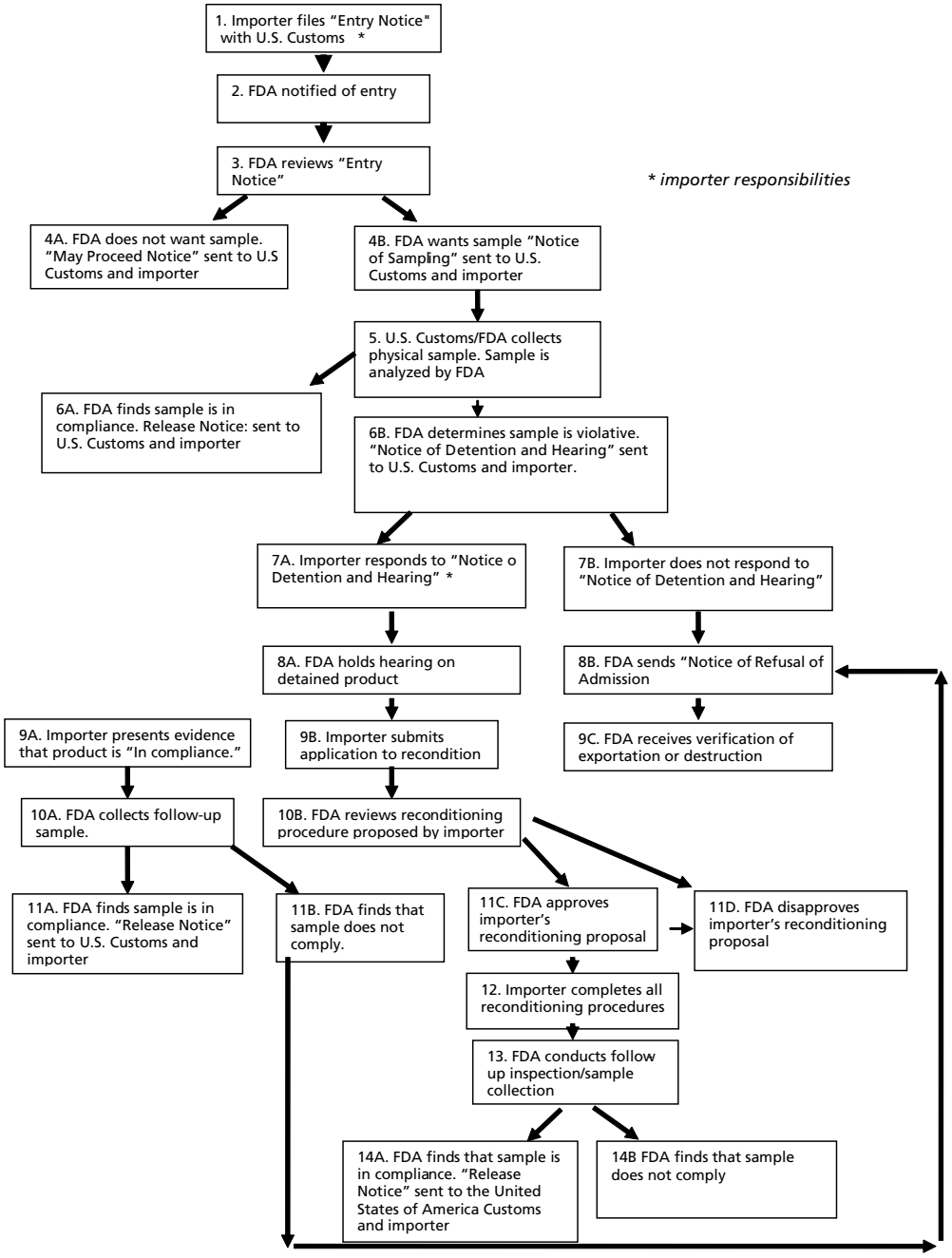
The microbiological quality of the process tested shall be considered:
- satisfactory, if all the values observed are ≤ m,
- acceptable, if maximum of c/n values are between m and M, and the rest of the values observed are ≤m,
- unsatisfactory, if one or more of the values observed are >M or more than c/n values are between m and M.

A.5 FLOW CHART FOR TRANSMISSION OF INFORMATION IN RAPID ALERT NETWORK (EUROPEAN UNION)



Relevant regulations, procedures, guidance or standards used by the US FDA

A.6 A SUMMARY OF PROCEDURES THAT UNITED STATES IMPORTERS MUST FOLLOW WHEN HANDLING FOOD PRODUCTS



FDA import procedures notes to diagram

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

2. FDA is notified of an entry of a regulated food through:
- Importer's Entry Notice (FDA Form FD 700 set) or Land Port Entry",
- Copy of United States of America 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 if a physical examination (wharf examination, sample examination) should be made.

4A. Decision is made not to collect a sample. FDA sends a "May Proceed Notice"(FDA Form FD 702) to the United States of America 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 sends a "Notice of Sampling" (FDA Form FD 712) to United States of America 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 of warehouse (contact the United States of America 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 the requirements. FDA sends a Release Notice (FDA Form FD 717) to the United States of America. 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 the United States of America. Customs 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 present a defense of the importation and/or to present evidence as to 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 relabelling or other action, or by converting to anon-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 the United States of America Customs. The exportation or destruction of the merchandise listed on the Notice of Refusal of Admission is carried out under the direction of the United States of America Customs.

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

10B. FDA evaluates the reconditioning procedures 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 the United States of America. 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 experience knows 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 From 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 the United States of America Customs. The charges for FDA supervision are assessed on FDA Form FD 790. Copies are sent to the United States of America 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 the United States of America Customs which is responsible for obtaining total payment including expenses incurred by their personnel.

A.7 FDA/EPA GUIDANCE LEVELS IN SEAFOODS

Product	Guideline/Tolerance	Reference
Ready to eat fishery products (minimal cooking by consumer)	Enterotoxigenic *Escherichia coli* (ETEC): 1x 10^3 ETEC/g, LT or ST positive	Compliance Programme 7303.842
Ready to eat fishery products (minimal cooking by consumer)	*Listeria monocytogenes*: presence of organism	Compliance Programme 7303.842
All fish	*Salmonella* species: presence of organism	Compliance Policy Guide Section 555.300
All fish	1. *Staphylococcus aureus*: positive for staphylococcal enterotoxin, or	
	2. *S. aureus* level $\geq 10^4$/g (MPN)	
Ready to eat fishery products (minimal cooking by consumer)	*Vibrio cholearae*: presence of toxigenic 01 or non-01	Compliance Programme 7303.842
Ready to eat fishery products (minimal cooking by consumer)	*Vibrio parahaemolyticus*: level ≥ 1 x 10^4/g (Kanagawa positive or negative)	Compliance Programme 7303.842
Ready to eat fishery products (minimal cooking by consumer)	*Vibrio vulnificus*: presence of pathogenic organism	Compliance Programme 7303.842
All fish	*Clostridium botulinum*:	Compliance Programme 7303.842
	1. Presence of viable spores or vegetative cells in products that will support their growth; or,	
	2. Presence of toxin	
Clams and oysters, fresh or frozen, imports	Microbiological:	Compliance Policy Guide Section
	1.*E. coli*: MPN of 230/100 g (average of subs or 3 or more of 5 subs)	
	2. APC: 500 000/g (average of subs or 3 or more of 5 subs)	
Clams, oysters, and mussels, fresh or frozen, domestic	Microbiological:	Compliance Programme 7303.842
	1. *E. coli* or faecal coliform: 1 or more of 5 subs exceeding MPN of 330/100 g or 2 or more exceeding 230/100 g	
	2. APC: 1 or more of 5 subs exceeding 1 500 000/g or 2 or more exceeding 500 000/g	
Salt-cured, air-dried uneviscerated fish	Not permitted in commerce (small fish exemption)	Compliance Policy Guide Section 540.650
Tuna, mahi mahi, and related fish	Histamine: 500 ppm set based on toxicity; 50 ppm set as defect action level, because histamine is generally not uniformly distributed in a decomposed fish; therefore, if 50 ppm is found in one section, there is the possibility that other units may exceed 500 ppm	Compliance Policy Guide Section 540.525
All fish	Polychlorinated biphenyls: 2.0 ppm (edible portion)*	
Fin fish and shellfish	Aldrin and dieldrin: 0.3 ppm (edible portion)	Compliance Policy Guide Section 575.100
Frog legs	Benzene hexachloride: 0.3 ppm (edible portion)	Compliance Policy Guide Section 575.100
All fish	Chlordane: 0.3 ppm (edible portion)	Compliance Policy Guide Section 575.100
All fish	Chlordecone: 0.4 ppm crabmeat and 0.3 ppm in other fish (edible portion)	Compliance Policy Guide Section 575.100
All fish	DDT, TDE and DDE: 5.0 ppm (edible portion)	Compliance Policy Guide Section 575.100
All fish	Heptachlor and heptachlor epoxide: 0.3 ppm (edible portion)	Compliance Policy Guide Section 575.100
All fish	Mirex: 0.1 ppm (edible portion)	Compliance Policy Guide Section 575.100
All fish	Diquat: 0.1 ppm[a]	40 CFR 180.226
Fin fish and crayfish	Fluridone: 0.5 ppm[a]	40 CFR 180.420
Fin fish	Glyphosate: 0.25 ppm[a]	40 CFR 180.364
Shellfish	Glyphosate: 3.0 ppm[a]	40 CFR 180.364

* These values are tolerances.

Fin fish	Simazine: 12 ppm[a]	40 CFR 180.213a
All fish	2,4-D: 1.0 ppm[a]	40 CFR 180.142
Salmonids, catfish and lobster	Oxytetracycline: 2.0 ppm	21 CFR 556.500
All fish	Sulfamerazine: no residue permitted	21 CFR 556.660
Salmonids and catfish	Sulfadimethoxine/ormetoprim combination: 0.1 ppm	21 CFR 556.640
All fish	Unsanctioned drugs*: no residue permitted	Compliance Policy Guide Section 615.200
Crustacea	Toxic elements: 76 ppm arsenic, 3 ppm cadmium, 12 ppm chromium, 1.5 ppm lead, 70 ppm nickel	Food and Drug Administration Guidance Documents
Clams, oysters, and mussels	Toxic elements: 86 ppm arsenic, 4 ppm cadmium, 13 ppm chromium, 1.7 ppm lead, 80 ppm nickel	FDA Guidance Documents
All fish	Methyl mercury: 1.0 ppm	Compliance Policy Guide Section 540.600
All fish	Paralytic shellfish poison: 0.8 ppm (80μg/100 g)saxitoxin equivalent	Compliance Policy Guide Section 540.250 and Compliance Programme 7303.842
Clams, mussels and oysters, fresh, frozen or canned	Neurotoxic shellfish poison: 0.8 ppm (20 mouse units/100 g) brevetoxin-2 equivalent	National Shellfish Sanitation Programme Manual of Operations
All fish	Amnesic shellfish poison: 20 ppm domoic acid, except in the viscera of Dungeness crab, where 30 ppm is permitted	Compliance Programme 7303.842

* Sanctioned drugs are approved drugs, low regulatory priority drugs and drugs used under an INAD, Source: FDA, 2001.

A.8 IMPORT REFUSAL REPORT (UNITED STATES OF AMERICA)

Taken from *http://www.fda.gov/ora/oasis/ora_oasis_ref_intro.html*

The Import Refusal Report replaces the FDA Import Detention Report (IDR).

The Food, Drug, and Cosmetic Act (the Act) authorizes FDA to detain a regulated product that appears to be out of compliance with the Act. The FDA district office will then issue a "Notice of FDA Action" specifying the nature of the violation to the owner or consignee. The owner or consignee is entitled to an informal hearing in order to provide testimony regarding the admissibility of the product. If the owner fails to submit evidence that the product is in compliance or fails to submit a plan to bring the product into compliance, FDA will issue another "Notice of FDA Action" Refusing admission to the product. The product then has to be exported or destroyed within 90 days.

The IDR gives an incomplete picture in that it only reflects the initial action by the Agency and not the ultimate determination of the compliance status of the product. The IRR reports on those products for which the determination was to refuse admission to the product.

The IRR is generated from data collected by FDA's Operational and Administrative System for Import Support (OASIS) and is updated monthly. Each month, the IRR is available sorted by country and by product based on the industry code which is the first two characters of FDA's product code (e.g., all fishery/seafood products will be coded 16...).

FDA has prepared this information in an effort to provide the importing community with information on products that have been found to appear in violation of the Act.

The Import Refusal Report provides the following information:

COUNTRY	The country of origin of the FDA manufacturer. This may be different than the country of origin for the United States of America Customs purposes. Note: This field is only provided for the IDR sorted by product.
MANUFACTURER NAME/ CITY	Identifies the name and city of the foreign establishment responsible for the product refused.
DISTRICT	Identifies FDA District Offices that have jurisdiction over the refused product.
ENTRY NO.	A unique identifier assigned to each entry.
DOCUMENT/LINE/ SUFFIX	A unique identifier for the product within an entry. An entry may have one or more of these number/letter identifiers.
PRODUCT CODE	A unique identifier assigned to products regulated by FDA.
PRODUCT DESCRIPTION	Identifies or describes the product offered for entry.
DATE	Identifies the date when the action was taken.
REASON	Identifies the reason for the agency actions. The specific reason for the detention can be accessed by double clicking the reason given in the IRR or by searching under the file titled "Violation Code Translations."

Partial Refusal - If this is present on a listing, it means that there was a reconditioning action which resulted is a portion of the shipment being refused.

Relevant regulations, procedures, guidance or standards in use in Japan

A.9 FISH DESIGNATED BY THE CONVENTION ON INTERNATIONAL TRADE IN ENDANGERED SPECIES OF WILD FAUNA AND FLORA (CITES) OR WASHINGTON CONVENTION (JAPAN)

Fish designated by the Washington Convention or CITES.

a. Fish classified in Appendix I of the Convention.
   Endangered species of flora and fauna. Generally, no commercial trade is permitted. Eight species, including coelacanths, etc.

b. Animals classified in Appendix II of the Convention.
   Flora and fauna endangered unless international trade is severely restricted. Commercial trade is possible. An export license issued by the controlling agency of the exporting country with the consent of scientific authorities is required. Six species of sturgeons, etc.

c. Animals classified in Appendix III of the Convention.
   An export license from the exporting country is required. (Import of the specific species from the specific country) In addition, a certificate of origin is required.

d. When importing species included in Appendices II and III from designated countries, an export license from such countries or a certificate of origin from other countries shall be submitted to the customs house. Moreover, Advance Confirmation of METI is required.

(Note) See the Ministry of Economy, Trade and Industry's Gazette (March 31, 1998) for animals designated by the Washington Convention.

A.10 FOOD SANITATION LAW AND QUARANTINE LAW (JAPAN)

Purpose of Law
This law is intended to protect the public from possible health hazards of food or drink and to contribute to the improvement and promotion of public health.

Outline of Law
Neither food additives nor preparations or food products containing such food additives may be sold unless the Ministry of Health, Labour and Welfare determines them to be harmless to human health (Article 6).

When the Ministry of Health, Labour and Welfare establishes standards for the manufacture, labelling and specifications for foods and additives for sale, and for food utensils or containers/packages for sale or for use in business, any items contrary to these standards shall not be sold (Article 7, 10 and 11).

Anyone who imports foods, food additives, food utensils or containers/packages intended for sale or use in business shall notify the Ministry of Health, Labour and Welfare of that intent (Article 16).

The Ministry of Health, Labour and Welfare, the Prefecture Governor, the Mayor of the city or the Headman of the Special Ward may, when necessary, have the officers and employees concerned carry out on-site inspections of food, additives, food utensils and containers/packages for sale or for use in business (Article 17).

Subject Items
- Foods (medicines and quasi-drugs stipulated by the Pharmaceutical Affairs Law are excluded).
- Food additives (used in the process of manufacturing foods or added, mixed, permeated or otherwise used for the processing or preservation of food).
- Food utensils and containers/packages.
- Toys with which babies come in contact.
- Cleansers (for cleaning vegetables, fruit or tableware).

Expected Revisions to Food Sanitation law

The food sanitation law is under following review, which will be promulgated and enforced in a few years.

Purposes of law and obligation of country or authority

(a) Review of purposes and regulations of law
To provide for "attempting to the protection of public health by securing the safety of foods"

(b) Obligation of country and municipal corporation
To provide for endeavouring of giving information concerning food sanitation, promotion of research, listening to the opinion from the people and reflecting it to policy, and mutual co-operation between the country and municipal corporations etc.

(c) Obligation of distributors
To provide for distributors' responsibility to prevent the occurrence of the hazard originating form foods by voluntary safety securing for foods and by cooperation to measures enforced by the country and/or municipal corporations.

Specifications and standards

(a) Introduction of a positive list system for residual pesticides (provisions for the effect for prohibiting the distribution food etc. including

pesticides etc to which the residual standard is not stipulated as a rule) Note: Additionally, study for the revision of the laws involved concerning the introduction of mechanism that the residual standard is stipulated upon registering pesticides etc.
(b) Introduction of measures allowing the prohibition of the use of existing additives that are proved to have a safety problem
(c) Enhancement of safety assurance of a newly developed food
(d) Introduction of tentative prohibition measures for uptake foods by a specific method
(e) Introduction of banning a false and exaggerated advertisement concerning health enhancement in foods

Monitoring and inspection system
(a) Maintenance of monitoring and inspection system
(b) Shift from a specified system to a registration system for an inspection organization to implement the ordinance and inspection
(c) Delegation of monitoring inspection to registered inspection organizations
(d) Preparation and announcement of the guideline of monitoring instruction and implementation plan of monitoring inspection on imported foods stipulated by the Minister of Health, Labor and Welfare (tentative name)
(e) Preparation and announcement of the implementation plan for food sanitation by the administrative divisions (tentative name)
(f) Promotion of addressing of safety assurance of foods by business entities
(g) Introduction of describing a necessary opinion to business entities by food sanitation supervisors and of respecting obligation to such opinion by business entities

Strengthening of measures for responding to an accident caused by foods poisoning
(a) Introduction of an instructive authorization by the Minister of Health, Labor and Welfare when a large scale and wide area of food poisoning etc. are generated
(b) Maintenance of survey and report regulations by the head of public health centre when no report is given from doctors
(c) Establishment of obligation for paying effort and maintaining records of purchasing sources by distributors

Reinforced penalty
(Including the increasing of the amount of penalty for the breach of labelling obligation and that for breaching corporations)

Authorities concerned
Standards Division, Department of Food Safety, Pharmaceutical and Medical Safety Bureau. The Ministry of Health, Labour and Welfare.

Purpose of Law
This Law aims to prevent the causative agents of infectious diseases which do not ordinarily exist within the territory of this country from entering by way of ships or aircraft, and also to take necessary measures to prevent other infectious diseases carried by ships and aircraft.

Outline of Law
This law intends to ascertain whether any crew members or passengers of ships or aircraft coming into Japan from foreign countries require quarantine for infectious

diseases, and to take measures to isolate, detain or disinfect any such individuals found. Also, animals and cargo are subject to inspection and measures for epidemic prevention are enacted if necessary.

Epidemics Subject to Quarantine
Infectious disease quarantine (Ebola virus, haemorrhagic fever, Crimean-Congolese haemorrhagic fever, plague (Black Death), Marburg disease, Lassa fever, cholera, and yellow fever)

Quarantine Procedures
When infectious diseases subject to quarantine are found by inspection or by prior notification, the chief of the quarantine station issues a quarantine certificate.

Even if the quarantine certificate is not issued, a provisional certificate may be issued for a certain period until no possibility of the intrusion of causative agents of the infectious disease is found.

Authorities concerned
Office of Quarantine Station Administration, Department of Food Sanitation, Pharmaceutical and Medical Safety Bureau, The Ministry of Health, Labour and Welfare.[1]

Regulation on Additives

a. Fresh fish including tuna, yellowtail, etc., may not have carbon dioxide added under the Food Sanitation Law.
b. Cultivated marine products are sometimes allowed to contain antibiotic or antimicrobial substances used to increase production, which use shall be confirmed as meeting the specification standard in Japan. For instance, only 0.10 ppm of the antibiotic oxytetracycline is allowed to remain.
c. Among marine products, globefish must have an attached health certificate issued by the government agency of the exporting country, which must include the species and area of collection as part of the import notification.
d. Moreover, if after examination it is found that an inspection is necessary, an inspector will conduct an on-site inspection. On the successful completion of inspection, the food import notification will be stamped "Passed"; if rejected, the importers will be instructed to take measures to either destroy or reship.
e. The specification for frozen foods shall be applied for frozen fillets of fish and stripped shellfish for sashimi, which stipulates the number of *Bacillus* per specimen of 1 gram as 100 ,000 or less and colon *Bacillus* as negative.
f. Moreover, processed marine products frozen after heat processing (frozen foods processed after heating) shall have 3 000 000 or fewer bacilli per 1 (one) gram of specimen and *Escherichia coli* must be negative.
g. Other dried, salted, processed marine products must comply with additive standards, including preservation materials, etc.

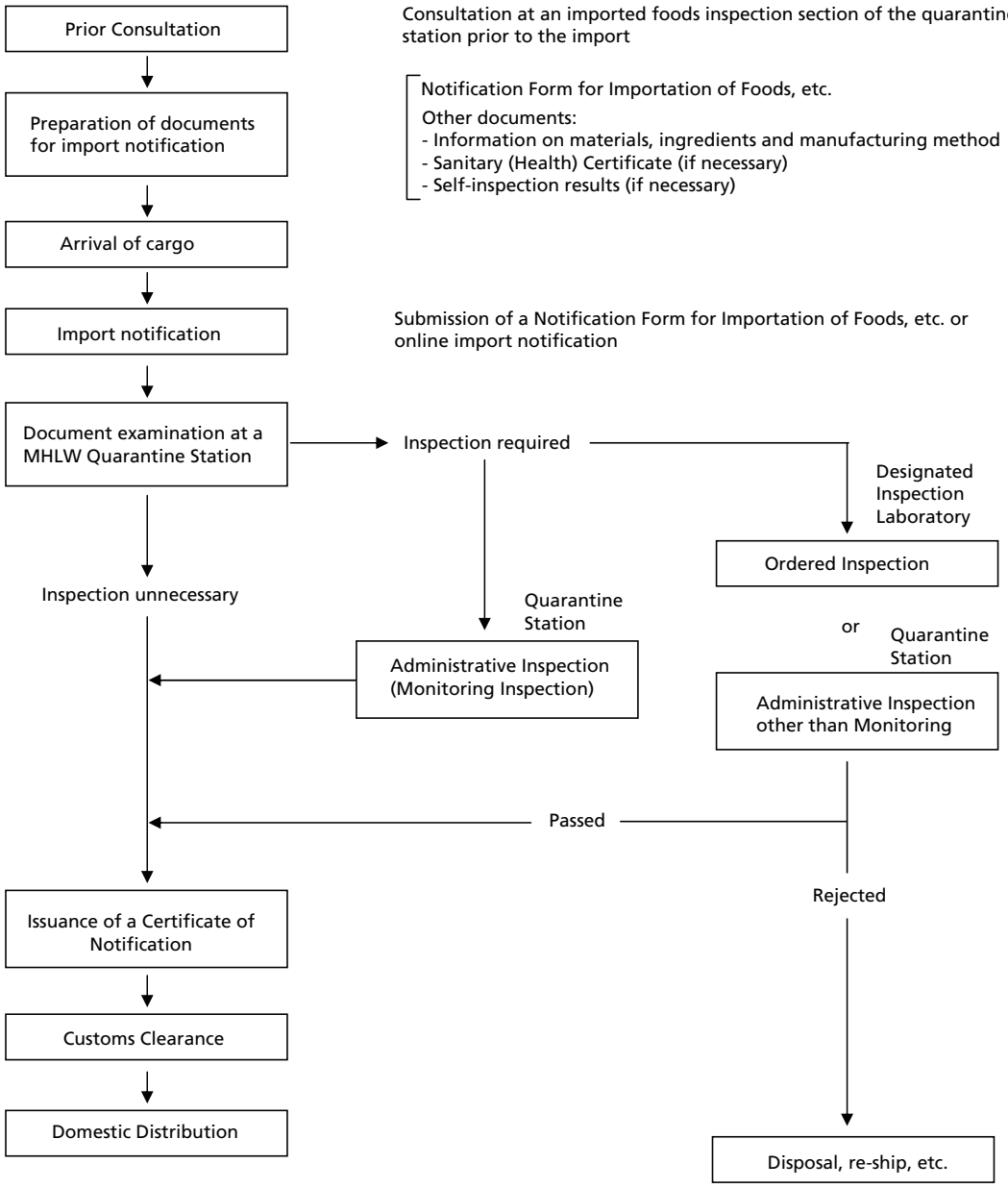
Bacteriological and chemical guidelines for fish and seafood in Japan

1) Fish fillets, shucked shellfish, frozen foods (frozen fish or shellfish) intended to be consumed raw
   – microbial count: <100 000 /g product
   – Coliform: negative
   – *Vibrio parahaemolyticus* : < 100 MPN count /g

[1] http://www.mhlw.go.jp/english/index.html

2) Oyster intended to be consumed raw
   – *Vibrio parahaemolyticus*: < 100 MPN/g
   – *E. coli* : <230/100 g product
   – microbial count: < 50 000/g product
3)Globefish poison (tetrodotoxin)
   a. Only types of globefish which can be consumed, and edible parts from sea areas where fishing is permitted
4)Shellfish poison
   a. paralytic shellfish poison < 4 Mouse Units MU/g
   b. diarrheal shellfish poison < 0.5 MU/g
5)Ciguatera poison
   a. certain fish species are prohibited for import and domestic distribution
6)Veterinary drugs residues
   • Food shall not include unauthorized antibiotic residues. Fish and shellfish shall not include residues of synthetic antimicrobials.
   • Foods may contain residues of these drugs only when the drugs comply with standards established by the law (MRLs where applicable).
   • Use of licensed drug. Proper use of drug. Respect scrupulously the defined withdrawal period. Prevention of human error
7)Withdrawal periods for:
   a. Shrimp: Oxytetracycline (25 days), Oxolinic acid (30 days)
   b. Japanese flounder: Oxytetracycline (40 days), Sodium nifurstyenate (2 days)
   c. Eel:Oxytetracycline (30 days), Oxolinic acid (25 days), Sulphamonomethoxine (30 days),Sulphamonomethoxine with ormetoprim (30 days), Florfenicol (7 days), Miloxacin (20 days)
8)Environmental Contaminants should not accumulate in edible parts of the fish beyond unsafe levels:
   a. PCB (polychlorinated biphenyls). Pelagic or offshore: 0.5 ppm. Coastal or freshwater: 3 ppm
   b. Mercury: Total mercury: 0.4 ppm. Methyl mercury: 0.3 ppm

A.11 PROCEDURE OF IMPORT NOTIFICATION OF FOODS AND RELATED PRODUCTS (JAPAN)



A.12 INSPECTION SYSTEMS (JAPAN)

Inspection Order System
When the examination of the document and information on the sanitary situation of the exporting country, the nature of the food and related items, or the record of non-compliance of the similar items in the past, indicate that the concerned food, etc. is suspected to violate with the Food Sanitation Law, the inspection order will be issued by the Minister of Health, Labour and Welfare and the import procedure will be suspended until the compliance of the concerned food, etc. is proved. This system is called "Inspection Order System" and the importer is responsible for the cost of the inspection.

The items that are subject for this system are designated in the Cabinet Order, and details of each item is specified every year.

Monitoring Inspection System
"Monitoring inspections" are carried out at the Ministry of Health, Labour and Welfare Quarantine Station for foods that are unlikely to be non-compliant with the Food Sanitation Law. Every year, the monitoring inspection system designates the items subject to monitoring inspections based on the annual import volumes and the record of non-compliance in the past for each item.

The purpose of the monitoring inspection system is to collect information data on the safety of the diverse food items that are brought to Japan as well as to promote the smooth distribution of these items. While MHLW food sanitation supervisors carry out sample inspections, the import procedures can be forwarded without waiting for the inspection results.

Other Inspection Systems
In addition to monitoring inspections, MHLW food sanitation inspectors conduct other inspections. These include inspections for foods that are imported for the first time into Japan, inspections of foods that are non-compliant with the Food Sanitation Law, and inspections of foods that have experienced an accident during transportation.

Also, occasionally, the MHLW quarantine station requires the importers to conduct an inspection of the cargo based on the premise that importers also have an obligation to ensure food safety.

A.13 ALLERGIC LABELLING (JAPAN)

Foods that include allergens are classified into those that require labelling under the Food Sanitation Law and those that are advised by notification. The two categories are based on the actual number of allergic cases and the severity (see table below).

Food allergen classification (Japan)

Category	Basis for selection	Foodstuffs that include an allergen
Foods that require labelling under the Food Sanitation Law	Foods causing serious illness and with significant numbers of cases	Wheat, buckwheat, egg, milk and peanuts
Foods where a warning should be displayed	Foods posing less risks or with a smaller numbers of cases. Also where scientific evidence is not well established	Abalone, squid, salmon, roe, lobster, orange, crab, kiwi fruit, beef, walnut, salmon, mackerel, soybean, chicken, pork, mushroom, peach, yam, apple and gelatine.

Foods to be subjected to allergic labelling

All processed foods packed in bags, boxes or containers. Foods or food additives for business use and not for direct sale to consumers shall also be labelled.

However, exceptions to labelling requirements include individually weighed items sold in a retail outlet, bread sold loose, box lunches made to order and foods with a packaging area under 30 cm^2.

Contents that require a warning

Even where small amounts of protein are included in a foodstuff, this should be displayed, except where the protein content is less than one mg per kg of processed foods.

Labelling restrictions

The following labelling are not permitted.

- Labelling such as "Foods may contain…" or "Food sometimes contain…"
- Labelling that implies the foodstuff contains valuable ingredients as a major component - such as abalone, salmon roe, or mushroom.

Relevant regulations, procedures, guidance or standards in use in Canada

A.14 BACTERIOLOGICAL AND CHEMICAL GUIDELINES FOR FISH AND FISH PRODUCTS

Bacteriological Guidelines

Escherichia coli	Cooked or ready-to-eat products n=5,c=1 m/g=4 M/g=40 Reject if c=2 or more, or if any one sample exceeds M All other types n=5,c=2 m/g=4 M/g=40 Reject if c=3 or more, or if any one sample exceeds M
Coagulase-positive *Staphylococci*	All types n=5,c=1 m/g=1 000 M/g=10,000 Reject if c=2 or more, or if any one sample exceeds M
Salmonella	All types n=5, Absent in each 25 g sample or in pooled samples of 125 g. Reject if Salmonella is detected.
Vibrio cholerae	Cooked or ready-to-eat products n=5, Absent in each 25 g sample or in pooled samples of 125 g. Reject if Vibrio cholerae is detected.
Listeria monocytogenes	Cooked or ready-to-eat products supporting growth of Listeria monocytogenes with refrigerated shelf life>10 days. n=5, Absent in each 5 g sample or in pooled samples of 25 g. Reject if Listeria monocytogenes is detected. Cooked or ready-to-eat products supporting growth of Listeria monocytogenes with refrigerated shelf life <=10 days and the products not supporting growth.*** n=5, <=100 cfu/g in each 10 g sample analysed separately (direct plating method)**** Reject if >100 cfu/g of Listeria monocytogenes is detected in any sample. or absent in each 5 g sample or in pooled samples of 25 g (enrichment method)**** Reject if Listeria monocytogenes is detected. *** Foods not supporting growth of L. monocytogenes include the following: (a) pH 5.0-5.5 and Aw <0.95 (b) pH <5.0 regardless of Aw (c) Aw <=0.92 regardless of pH (d) frozen foods The pH and Aw determination should be done on 3 of 5 analytical units. None of the analysed units can fall into the range of pH and Aw supporting the growth of L. monocytogenes. The designated analytical unit is taken from each sample unit. Processed products which require cooking and which are clearly labelled with adequate cooking instructions are excluded from testing for L. monocytogenes. **** The method used for detecting Listeria depends on GMP status of a plant and the type of food.

NOTE:
m - no. of bacteria per gram separating acceptable from marginally acceptable samples.
c - no. of samples that may exceed this number of bacteria per gram.
M - no sample can exceed this number of bacteria per gram.

Note:
The analysis of all fish or fishery products shall be conducted in accordance with approved methods.
Raw shucked or in the shell oysters, clams, mussels or other molluscs and whole scallops which comply with Section 6(1)(b) of the Fish Inspection Regulations are considered satisfactory when Escherichia coli MPN per 100 g of shellfish meat does not exceed a MPN of 230 or if one of the five samples exceeds a MPN of 230 but is less than or equal to a MPN of 330, based on a 5-tube decimal dilution test.

Chemical Contaminants

Mercury	All fish products (except swordfish, shark, tuna (fresh and frozen) - 0.5 ppm
Arsenic	fish protein concentrate - 3.5 ppm
Lead	fish protein concentrate - 0.5 ppm
Fluoride	fish protein concentrate - 150 ppm
2,3,7,8 TCDD (Dioxin)	All fish products - 20 ppt
DDT and Metabolites (DDD and DDE)	All fish products - 5.0 ppm
PCB	All fish products - 2.0 ppm
Piperonyl butoxide	Dried Cod - 1.0 ppm
Other agricultural chemicals or their derivatives	All fish products - 0.1 ppm

Note:
Samples to consist of a minimum of 5 units representative of the lot. Analysis may be carried out on a composite of all sample units.
A lot of fish will be considered reject if the sample value exceeds the action level. Fish or fish products exceeding these guidelines may be permitted for export if they do not violate regulations of the exporting country.
Action level is based on contaminants level of edible weight.

Histamine	Enzyme ripened products (e.g. anchovies, anchovy paste, fish sauce) - 20 mg/100 g All other scombroid fish products (e.g. canned or fresh or frozen tuna, mackerel, mahi-mahi) - Samples are collected according to sampling plan 1 (AQL 6.5) for re-inspection. - Any sample exceeding 50 mg/100 mg will result in the lot being rejected with no right to re-inspection. The acceptance number is that corresponding to the number for decomposition.
Shellfish Toxins - Molluscan Shellfish	PSP 80 ug/100 g ASP 20 ug/g DSP 1ug/g - PSP toxin levels equal to or greater than 80 ug/100 g and/or ASP levels equal to or greater than 20 ug/g will result in closure of the shellfish area. - Where shellfish samples collected from a plant are equal to or greater than the above levels, the production lot is detained. If the lot has already been distributed, possible recall will be considered. - The minimum acceptable sample is that which when shucked will produce 100 g of drained meats from 5 pooled sub-samples. Depending on the size of animals, the total number of shellfish required varies from 1 (geoduck) to 25 (pink scallops). - DSP testing will be conducted only in suspect harvesting areas or as a result of consumer complaints. Okadaic acid and/or DTX-1 levels in digestive tissue exceeding 1ug/g, singly or in combination, will result in closure of the shellfish area.
Therapeutants	Florfenicol 0.8 ppm in salmonid muscle Sulfadiazine & suifadimethoxine 0.1 ppm in salmonid muscle Teflubenzuron 0.3 & 3.2 in salmonid muscle & skin respectively Trimethoprim 0.1 ppm in salmonid muscle Previously, the Administrative MRL for each of these drugs was 0.1 ppm. It should be noted, from CFIA data up until October, 1999 there were no detectable levels of florfenicol in domestic farmed salmon.

A.15 SUMMARY OF REQUIRED TESTING FREQUENCIES (CANADA)

Product Type	Product Description	15 percent Monitoring	5 percent Monitoring (except 2 percent where noted)
Canned	All	Standard Tests (Container Integrity, Sensory, Net Content, Label)	
	All Fish oils/organs	Pesticides	
	All Aquacultured Species		Drug residues
	All Crustaceans		Sulphites
	Molluscan bivalve shellfish from agreement countries		2 percent for Marine toxins
	Molluscan bivalve shellfish from non-agreement countries	Marine toxins	
	All Scrombroids		Histamine
	Albacore Tuna		Mercury/Histamine
Fresh/Live	All fresh or live fish		2 percent monitoring for standard tests (Sensory, Net Content, Label)
	All Aquacultured Species		Drug Residues
	All Carnivores		Mercury
Fresh	All Crustaceans		Sulphites
	Scallops		Moisture
	All Scrombroids		Histamine
Raw Molluscan Bivalve Shellfish	Raw uncooked molluscan bivalve shellfish from agreement countries		2 percent monitoring for Marine toxins, *E. coli* and label
	**not permitted from non-agreement countries		
Frozen/Salted/ Other	All	Standard Tests (Sensory, Label, Net Content)	
	All Aquacultured species		Drug residues
	All Crustaceans		Sulphites
	All Fish oils/organs	Pesticides	
	Large Carnivorous		Mercury
	Molluscan bivalves from non-agreement countries cooked in a manner to coagulate all the protein	Marine toxins	
	Scallops	Moisture	
	Smoked and Dried Fish		Nitrites
	Scrombroids	Histamine	
Ready-To-Eat	All	Standard Tests (Sensory, Net Content, Label)	
	All Aquacultured species		Drug residues
	Anchovies and anchovy paste	Histamine	
		Applicable Safety Parameters (salt, pH, water activity)	
	All Fish Oils/Organs		
	Caviar	Borates	
		Applicable Safety Parameters (salt, pH, water activity)	
	All Crustaceans	*L. monocytogenes* *E. coli* *Salmonella* *S. aureus*	Sulphites
	Fish roe	Applicable Safety Parameters (salt, pH, water activity)	
	Fish sauces	Histamine	
		Applicable Safety parameters (salt, pH, water activity)	

Kamaboko	*L. monocytogenes* *E. coli* *Salmonella* *S. aureus*	
Molluscan bivalve shellfish from agreement countries (must be cooked sufficiently to be coagulated)		Marine toxins *L. monocytogenes* *E. coli* *Salmonella* *S. aureus*
Molluscan bivalve shellfish from non-agreement countries (must be cooked sufficiently to be coagulated)	Marine toxins *L. monocytogenes* *E. coli* *Salmonella* *S. aureus*	
All Scrombroids	Histamine	
Smoked fish (including frozen and unfrozen ready-to-eat products made from smoked fish, ex. mousses)	*L. monocytogenes* *E. coli* *Salmonella* *S. aureus*	Nitrates/nitrites
All other frozen ready-to-eat products.	*L. monocytogenes* *E. coli* *Salmonella* *S. aureus*	
All other non-frozen ready-to-eat products	*L. monocytogenes* *E. coli* *Salmonella* *S. aureus* Applicable Safety Parameters (salt content, pH, water activity)	

This table is for products from processors not on the following: "A" List, IAL, MOU Preferred Status List and MRA Plant List.

A.16 EXAMPLE ALERT NOTIFICATIONS (EUROPEAN UNION)

http://europa.eu.int/comm/food/food/rapidalert/index_en.htm

ALERT NOTIFICATIONS

DATE:	NOTIFIED BY:	REF.:	REASON FOR NOTIFYING:	COUNTRY OF ORIGIN:
23-02-2004	ITALY	2004.090	Listeria monocytogenes in smoked salmon	DENMARK
23-02-2004	FRANCE	2004.091	Salmonella enteritidis in eggs	FRANCE
24-02-2004	NETHERLANDS	2004.092	fumonisins in maize meal	ITALY
24-02-2004	FRANCE	2004.093	Listeria monocytogenes in Saint Nectaire cheese	FRANCE
26-02-2004	ITALY	2004.094	Listeria monocytogenes in smoked salmon	DENMARK
27-02-2004	FRANCE	2004.095	ochratoxin A in spices/curry	INDIA
27-02-2004	FRANCE	2004.096	unauthorized additive (annato/bixin/ norbixin - E-160b) and colour Sudan 1 in sweet pepper	SPAIN
27-02-2004	ITALY	2004.097	Salmonella typhimurium in frozen pork cheeks	BELGIUM
27-02-2004	PORTUGAL	2004.098	Vibrio parahaemolyticus in crab claws and crab clusters	NIGERIA
27-02-2004	DENMARK	2004.099	Salmonella typhimurium DT 104 in fresh tenderloin	DENMARK
27-02-2004	DENMARK	2004.100	Salmonella typhimurium DT 104 in fresh ham	DENMARK
27-02-2004	GERMANY	2004.101	sulphites in dried apricots	TURKEY; FRANCE
27-02-2004	SWEDEN	2004.102	Salmonella enteritidis in frozen marinated chicken breasts	DENMARK

INFORMATION NOTIFICATIONS

DATE:	NOTIFIED BY:	REF.:	REASON FOR NOTIFYING:	COUNTRY OF ORIGIN:
23-02-2004	ITALY	2004.ALM	histamine in chilled yellowfish tuna loin	INDONESIA; NETHERLANDS
24-02-2004	ITALY	2004.ALN	damaged by water of fresh mackerel (Scomber scombrus)	SPAIN
24-02-2004	ITALY	2004.ALO	insufficient labelling of spices	TUNISIA
24-02-2004	GREECE	2004.ALP	histamine in dry salted sardines	GREECE
25-02-2004	ITALY	2004.ALQ	aflatoxins in sesame paste with dried fruits	TUNISIA
25-02-2004	ITALY	2004.ALR	aflatoxins in pistachios in shell	IRAN
25-02-2004	GERMANY	2004.ALS	aflatoxins in hazelnut kernels	TURKEY
25-02-2004	GERMANY	2004.ALT	aflatoxins in groundnut kernels	ARGENTINA
25-02-2004	GERMANY	2004.ALU	aflatoxins in groundnut kernels	ARGENTINA
25-02-2004	GERMANY	2004.ALV	aflatoxins in pistachios in shell	SLOVAKIA
25-02-2004	GERMANY	2004.ALW	aflatoxins in pistachio kernels	IRAN

A.17 OASIS EXAMPLE REPORT (UNITED STATES OF AMERICA)

http://www.fda.gov/ora/oasis/ora_oasis_ref.html

Country of Origin **Manufactuerer's name** **City/ISO Country Code** **Product Code**	**Product Description** **Date**	**Entry # Doc**	**Line**	**Suffix** **District** **Reason**
Philippines Sampaguita Foods Inc Quezon City , PH 16ACT99	FERMENTED SILVER FISH (MONAMON) 12-JAN-2004	561-0072478-2	2	2 FLA-DO FILTHY
Spain Angulas Aguinaga, S.A. Irura–Guipuzcoa, ES 16AEE15	CANNED BABY EELS 12–JAN-2004	512-0616123-7	1	1 SWI–DO NO PROCESS
Chile African Food North York ON, CA M3N1H4 16AEE22	MACKEREL IN TOMATO SAUCE 15-JAN-2004	551-2708178-9	5	1 C NYK-DO NUTRIT LBL NEEDS FCE NO PROCESS
Canada Maliban Foods Co. North York Ontario, CA M4A1W3 16AEE22	MACKEREL IN TOMATO SAUCE HOT CHILLI 15-JAN-2004	551-2708178-9	5	1 B NYK-DO NUTRIT LBL NEEDS FCE NO PROCESS
Canada Geesha Foods North York ON, CA M3L1A2 16AEE22	MACKEREL IN TOMATO SAUCE 15-JAN-2004	551-2708178-9	5	1 A NYK-DO NUTRIT LBL NEEDS FCE NO PROCESS
Morocco Unimer Etamar (Plant #2) Safi , MA 1234 16AEE33	SEASON S/B SARDINES IN SOY OIL 12-JAN-2004	J21-0033970-9	1	1 NYK-DO MFRHACCP
Morocco Unimer Etamar (Plant #2) Safi , MA 1234 16AEE33	SEASON S/B SARDINES IN SOY OIL 12-JAN-2004	J21-0033970-9	1	2 NYK-DO MFRHACCP

A.18 EXAMPLE OF IMPORT ALERT LIST (CANADA)

Note: This is an extract from the first entries in a long alphabetical list by country.

Country	Product Type	Processor	Product	Analysis	Alert Type	Date on IAL	Last Reject	Pass Count	Container Design
Argentina	Frozen/salted/ other	Antonio Barillari S.A.	Frozen shrimps and prawns, shell-on, headed, raw	Net weight determination	Alm	21/01/04	21/01/04	0	---
Argentina	Frozen/salted/ other	Antonio Barillari S.A.	Frozen shrimps and prawns, peeled and deveined, raw	Net weight determination	Alm	21/01/04	21/01/04	0	---
Argentina	Frozen/salted/ other	Atlantic Surf II	Scallops - frozen meat, raw	Sensory evaluation	Ala	17/05/00	17/05/00	0	---
Argentina	Frozen/salted/ other	Conarpesca S.A. (approval no. 2267)	Frozen shrimps and prawns, peeled, raw	Sulphites	Ali	26/11/02	26/11/02	0	---
Argentina	Frozen/salted/ other	Glaciar pesquera	Scallops - frozen meat, raw	Sensory evaluation	Alm	17/03/03	17/03/03	0	---
Argentina	Frozen/salted/ other	Glaciar Pesquera	Scallops - frozen meat, raw	Sensory evaluation	Alm	10/07/03	10/07/03	0	---
Argentina	Frozen/salted/ other	Vieira Argentina S.A.	Frozen crabs - other, other	Net weight determination	Alm	12/02/03	12/02/03	0	---
Argentina	Frozen/salted/ other	Wanchese Fish	All products	Phosphates	Alm	12/09/02	12/09/02	3	---
Australia	Frozen/salted/ other	Orient Seafood Processors Ptv (reg. Est. 3883)	Abalone - dried	Net weight determination	Alm	25/08/03	25/08/03	0	---
Bahamas	Frozen/salted/ other	G&l Seafood Company Ltd	Lobsters - other, other	Net weight determination	Ali	02/04/03	31/03/03	3	---
Bahamas	Frozen/salted/ other	Marsh Harbour Exporting & Importing Ltd	Conch - meat, other (frozen)	Sensory evaluation	Ali	26/09/01	26/09/01	0	---
Bahamas	Frozen/salted/ other	Marsh Harbour Exporting & Importing Ltd	Conch - meat, dried (frozen)	Sensory evaluation	Ali	26/09/01	26/09/01	0	---
Bahamas	Frozen/salted/ other	Performance Fisheries Ltd.	Conch - meat, other (frozen)	Sensory evaluation	Ali	17/09/01	17/09/01	0	---
Bangladesh	Frozen/salted/ other	Coastal Seafoods Limited	Batashi - other (frozen)	Sensory evaluation	Alm	20/10/00	20/10/00	0	---
Bangladesh	Frozen/salted/ other	Coastal Seafoods Limited	Ayre - other (frozen)	Net weight determination	Alm	20/10/00	07/01/04	0	---
Bangladesh	Frozen/salted/ other	Coastal Seafoods Limited	Batashi - other (frozen)	Net weight determination	Alm	20/10/00	20/10/00	0	---
Bangladesh	Frozen/salted/ other	Coastal Seafoods Limited	Shoil gozar - other (frozen)	Net weight determination	Alm	20/10/00	07/01/04	0	---
Bangladesh	Frozen/salted/ other	Coastal Seafoods Limited	Bailla - other (frozen)	Net weight determination	Alm	20/10/00	20/10/00	1	---
Bangladesh	Frozen/salted/ other	Frozen Food Ltd	Boal - headed and dressed (frozen)	Net weight determination	Alm	25/10/00	25/10/00	0	---

A.19 DEFINITIONS OF PRODUCT TYPES (EUROPEAN UNION)

Definitions extracted from Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products.

"fresh products" means any fishery product whether whole or prepared, including products packaged under vacuum or in a modified atmosphere, which have not undergone any treatment to ensure preservation other than chilling;

"prepared products" means any fishery product which has undergone an operation affecting its anatomical wholeness, such as gutting, heading, slicing, filleting, chopping, etc.;

"processed products" means any fishery product which has undergone a chemical or physical process such as the heating, smoking, salting, dehydration or marinating, etc., of chilled or frozen products, whether or not associated with other foodstuffs, or a combination of these various processes;

"preserve" means the process whereby products are packaged in hermetically sealed containers and subjected to heat treatment to the extent that any micro-organisms that might proliferate are destroyed or inactivated, irrespective of the temperature at which the product is to be stored;

"frozen products" means any fishery product which has undergone a freezing process to reach a core temperature of –18°C or lower after temperature stabilization;

A.20 FDA GUIDELINE ON INSECTS AS FILTH

On August 16, 1994 FDA issued a revision of import alert 16-21 "Filth in Fresh or Frozen Raw Shrimp" dated March 20, 1980. At that instance (August 1994) this new guidance (i) defines and sets forth defect action levels for flies and other insects, insect fragments and hair. The broader definition of insect or insects is used to group flies and cockroaches in the previous alert, (2) Changes defect levels for "incidental flies" from 10 in a sample to 3 in a sample for "incidental insects", (3) Changes defect action levels for "filth fly fragments" from 3 in a sample to 5 for "filth insect fragments", (4) Sets forth a new action level of 15 in a sample for "unidentified fragments", (5) Reduces action levels for rat or mouse hairs from 3 in a sample to 2 in a sample and for other striated, but not rat or mouse hairs from 4 to 3 in sample, and (6)Defines filth and incidental insects.

In the above guidance "filthy insects" are: Ants, Cockroaches, Rove Beetles, House Flies (Muscidae), Humpbacked Flies (Phoridae), Moth Flies (Psychodidae), Black Scavenger Flies (Sepsidae), Small Dung Flies (Sphaeroceridae), Vinegar Flies (Drosophilidae), Chloropid Flies (Chloropidae), Anthomyiid Flies (Anthomyiidae), Blow Flies (Calliphoridae), and Flower Flies (Syrphidae). The guidance indicates that this is not necessarily a complete list of filth insects which might be found in shrimp. "Incidental insects" are the following: Dance Flies (Empididae), Beach Flies (Canecidae), Tachinid Flies (Tachinidae). Once more the guidance indicates that this is not necessarily a complete list of incidental insects which might be found in shrimp.