

L.N. 255 of 2000

**FOOD, DRUGS AND DRINKING WATER ACT
(CAP. 231)**

Fish Packing and Processing Establishments Regulations, 2000

IN exercise of the powers conferred by articles 4 and 12 of the Food, Drugs and Drinking Water Act, the Minister of Health, on the advice of the Malta Standards Authority, has made the following regulations:—

Citation and
commencement.

1. (1) The title of these regulations is the Fish Packing and Processing Establishments regulations, 2000.

(2) These regulations shall become effective as from the 1st January, 2002.

Interpretation.

2. In these regulation unless the context otherwise requires:

“aproved packing establishment” means a packing establishment where aquaculture and coastal fish products are packed, chilled or stored, insofar as the establishment complies with these regulations and has been inspected and approved by the Director;

“approved processing establishment” means a processing establishment where chilled or frozen fishery products undergo a chemical or physical process such as heating, smoking, salting, dehydration or marinating, or any other process insofar as the establishment complies with these regulations and has been inspected and approved by the Director;

“aquaculture products” means all fishery products born and raised in controlled conditions until placed on the market as foodstuff. Fish caught in their natural environment when juvenile and kept in fattening units until they reach the desired commercial size for human consumption, are also considered aquaculture products. However, they are not considered so if the fish are merely kept alive to be sold at a later date without any attempt being made to increase their size or weight;

“ batch” means the quantity of fishery products obtained under practically identical conditions;

“ chilling” means the process of cooling fishery products to a temperature approaching that of melting ice;

“ clean seawater” means seawater which is free from microbiological contamination, harmful substances or toxic marine plankton in such quantities as may affect the health quality aquaculture products;

“critical point” means any site, procedure, or part of a procedure at which a potential food safety hazard can be prevented or reduced to acceptable levels by appropriate control measures;

“drinking water” means water of such quality as to be fit for human consumption;

“fishery products” means all seawater or freshwater animals, or parts thereof, including their roes but excluding aquatic mammals and amphibians;

“fresh products” means any fishery product, whether whole or prepared, including vacuum-packed products, which have not undergone any treatment to ensure preservation other than chilling;

“frozen products” means any fishery product which has undergone a freezing process to reach a core temperature of -18°C or lower after temperature stabilisation;

“ licensee” means a person who is licensed in terms of regulation 3 of these regulations to keep an aquaculture packing establishment;

“Minister” means the Minister responsible for fishing and aquaculture;

“packing” means the procedure of protecting fishery or aquaculture products by wrapping material, a container or similar object;

“ prepared products” means any fishery or aquaculture product which has undergone an operation affecting its anatomical wholeness, such as gutting, filleting, slicing, heading, and similar operations;

“processed products” means any fishery or aquaculture product, whether chilled or frozen, whether associated or not with other foodstuffs, which has undergone a chemical or physical process such as smoking, salting, heating, marinating and similar processes;

“Superintendent” means the Superintendent of Public Health;

“visible parasite” means a parasite or a group of parasites which has dimension, colour or texture which is clearly distinguishable from fish tissues and which can be seen without optical means of magnifying and under good illumination for human vision;

“visual inspection” means a non-destructive examination of fish or fishery products without optical means of magnifying and under good light conditions for human vision, including, if necessary, candling.

Licence to keep a fish packing or processing establishment.

3. (1) No person shall keep a fish packing or processing establishment unless he holds a licence issued for that purpose by the Minister.

(2) No premises shall be used as a fish packing or processing establishment unless such premises are licensed by the Minister for such use.

(3) The Minister may only grant a licence for the keeping of a fish, packing or processing establishment after considering an application thereof, and after he has ascertained that all the requirements listed in these regulations and any further requirements he may have requested the applicant to perform, have been satisfied.

(4) The Minister may, in granting or renewing any licence, impose any such condition as he may deem fit.

(5) Licences shall be valid for one calendar year and may be renewed from year to year by the Minister after inspection by an authorised officer.

(6) An authorised officer shall have the power of entry to inspect the establishment whenever the Superintendent deems it necessary.

(7) No extensions or alterations in any fish packing or processing establishment may be carried out unless previously authorised by the Superintendent.

(8) The Superintendent shall keep a fish packing or processing establishment register in which there shall be kept the following information:

(a) Service approval number issued by the Superintendent;

(b) Name, address and telephone number of the manager;

(c) Name, address and telephone number of the licensee;

(d) Address and telephone number of establishment;

(e) Site plan, elevation plan, building layout plan and equipment layout plan of the establishment.

(9) The licensee shall be responsible for any premises used in the packing or processing establishment, and such premises shall be either constructed or removed as specified in these regulations.

(10) Persons responsible for the packing or processing establishment shall take all necessary measures so that, at all stages of production, the conditions listed below are met with.

(11) Packing establishments may only be used for their designated purpose of packing fresh fish and no other product may be prepared therein.

(12) Processing establishments shall provide a detailed description of the fish product, and the processing procedures particular to that establishment. This must include all parameters that are being monitored and controlled throughout the process. Records must be available for the Government veterinarian, and must be kept for at least the duration of the shelf-life of the product.

(13) Only scientifically valid treatments may be used in processing establishments to prevent the development of pathogenic micro-organisms or otherwise preserve the product.

5. (1) The fish packing or processing establishment shall be sited at least 200 metres away from inhabited areas, livestock farms and any other industrial or other structures that may emit fumes or other materials that may contaminate the fish and aquaculture products

Packing and processing establishment structure.

(2) Each packing establishment shall be divided into a "contaminated" area where harvested fish are brought in, slaughtered, and first sorted, and a "clean" area where the fish are graded and placed in containers. Work and workers must always proceed from

clean to contaminated area, and never the other way round. Both areas are to be of sufficient size to allow for good hygienic conditions.

(3) Each processing establishment shall be divided into a “contaminated ” area where fresh or frozen fish are first brought in, thawed, cleaned, headed or gutted, and a “clean” area where the fish are filleted, sliced or otherwise processed and placed in containers. Work and workers must always proceed from clean to contaminated area, and never the other way round. Both areas are to be of sufficient size to allow for good hygienic conditions.

(4) The following building requirements shall be complied with within any fish packing or processing establishment:—

(a) floors and walls must be smooth, durable, easy to clean and disinfect, as well as waterproof. A light-coloured, washable coating or paint at a height of at least two metres, with rounded edges and corners must cover the walls. Excess water must drain easily from the flooring;

(b) doors and windows must be easy to clean. These apertures must be constructed in such a way as to prevent entry of animals, birds, flies, and insects. Wood is not to be used if possible, and flush-fitting apertures are preferred. Ceilings and roof-lining must be easy to clean;

(c) adequate illumination either natural or artificial over the work areas is necessary;

(d) equipment, instruments, utensils and working surfaces must be kept clean and disinfected, and must be corrosion-resistant. Working tables and other working surfaces must not be made of wood;

(e) the temperature in the packing areas must be <12°C, and in cold storage 0°C. Adequate ventilation must be set up, if necessary, to ensure temperature maintenance.

Cleaning and
disinfection.

6. (1) There must be an adequate number of facilities for the cleaning of hands, instruments and tools, with hot and cold running water, cleaning and disinfecting products, and single-use hand towels. These must be as near as possible to the work stations, and the taps must not be hand-operable.

(2) There must be an adequate number of facilities for the cleaning and disinfection of the establishment itself as well as its equipment, instruments, and working surfaces.

(3) Disinfectants or detergents used on equipment or instruments which come in contact with the fish must be approved for use in food preparation.

(4) There must be an adequate number of changing rooms and shower rooms with flush lavatories and wash hand basins, foot- or elbow- operated. These rooms must not open directly onto the working area. The wash hand basins shall be near the lavatories and shall have hot and cold running water, materials for cleansing and disinfecting the hands, and disposable hand towels.

7. (1) A watertight, corrosion-resistant container for waste fish must be available at all times during the packing or processing of fish, and its contents removed from the work area frequently. These must be cleansed and disinfected each time they are emptied. Waste removal.

(2) Waste fish must be immediately and hygienically disposed of in appropriate premises outside the establishment at the end of each harvest and, or processing cycle. If waste fish is not removed every day from the establishment, it must be stored in a lockable, temperature-controlled room separate from the work area.

(3) If the destruction of waste fish or the technical treatment of waste fish intended for industrial purposes is carried out on the premises of the establishment, it must take place in lockable rooms separate from the work areas.

(4) Waste water must be collected in an adequate container reservoir or sedimentation tank and disposed of in such a way as to prevent environmental contamination.

8. A pest control programme must be set up for rodents, insects and other pests. Rodenticides, other pesticides and any potentially harmful substances be stored in a lockable cupboard and used with extreme care to prevent the contamination of any product. Pest control.

9. (1) An adequate supply of clean seawater or potable water shall be used for all purposes except for cooling systems. The relevant pipes must be adequately marked to distinguish them from those carrying drinking water or clean seawater. A diagram of the water distribution system and its outlets must be available for inspection by the Government veterinarian. Freshwater and seawater supply.

(2) If a chlorination system is used, the chlorine shall be injected prior to intermediate storage in tanks or reservoirs to allow a contact time of at least 20 minutes between the water and the chlorine

within the tank. Hyperchlorinated water must not come into contact with the aquaculture or fishery products, so the chlorine level must be equivalent to that of potable water for direct human consumption.

(3) For the production and storage of ice, there must be a room of sufficient size, easy to clean and disinfect, and equipped with a refrigeration system of adequate power and a temperature-reading device. Ice may, however, be produced in licensed cold stores outside the packing or processing establishment, and transported in hygienic containers to the establishment when needed.

(4) Ice must be made from clean sea or drinking water and stored in clean receptacles in the cold room.

Personnel.

10. (1) Staff must wear clean, light-coloured working clothes with plastic apron, gloves, and head gear to enclose the hair. Hands must be washed every time work is resumed, and any cuts or skin abrasions covered in a waterproof dressing. No smoking or eating is allowed in the working areas.

(2) Medical certificates must be issued certifying and enabling each member of staff to handle food. These certificates must be renewed annually or whenever requested by the Government veterinarian to whom such certificates will always be available. Persons who may contaminate the food product shall be prohibited from handling it.

(3) The licensee shall ensure that all employees in his establishment shall be educated on the importance of personal hygiene and basic food safety principles. The licensee shall also be responsible for maintaining amongst his employees an awareness of any medical condition that may develop that might effect their employment.

(4) A room for the exclusive use of the Government veterinarian must be available when the volume of work entails his permanent presence.

Self-check system.

11. (1) A self-check system, based on Hazard Analysis Critical Control Point, must be set up by the licensee to identify critical points and monitor them.

(2) Records of results and procedures are to be kept on the premises and be available for inspection.

(3) Critical points are specific to each establishment and must thus be identified for each packing or processing establishment according to its structures, equipment, and work process.

(4) The self-check system must be aimed at monitoring such critical points to ensure that the aquaculture and fishery products satisfy the requirements of these regulations.

(5) This self-check system must include the following:

- (a) description of aquaculture or fishery product;
- (b) identification of critical points all along the packing or processing line;
- (c) identification of the food safety hazards at each critical point;
- (d) control measures to be taken at each critical point to avoid risk;
- (e) personnel especially trained in the field of food safety, hygiene and related subjects, who will undertake the setting up of the self-check system and its running, and keep written records of results obtained for at least two years;
- (f) monitoring procedures and critical limits for the parameters concerned;
- (g) corrective measures to be taken in case of deviation from specified critical limits;
- (h) a sampling programme to be carried out by an approved laboratory in conjunction with the specialised personnel in order to verify and reconfirm the efficacy of the self-check system itself, and revalidate it in case of any change in the work procedures.

12. (1) All equipment necessary for the unloading, harvesting, and landing of fish from the sea cages into the packing establishment must be kept clean and in a good state of repair. Harvest and slaughter in packing establishments.

(2) Handling of fish during harvest, landing and slaughter must be as rapid as possible and the fish transferred to a protected chilled environment as soon as possible. If not packaged immediately, fish must be kept chilled.

(3) The slaughtering of aquaculture products must be carried out hygienically, and the fish must not come into contact with earth, dust or other contaminating substance.

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Post-mortem examination during harvest in packing establishments.

13. A visual inspection on a representative number of samples per batch, must take place during the packing of fresh fish, and any visible parasites or parts of fish which are infested, shall be removed and considered as waste fish, that is, fish unfit for human consumption.

Fish used for processing in processing establishments.

14. Fish, whether fresh or frozen, which are to be used for processing, must satisfy the following conditions:

(a) if chilled fish are to be used for processing, they must be hygienically stored in the cold room under ice made from drinking water or clean seawater until processed;

(b) if frozen fish products are used, they must be stored in rooms equipped with a sufficiently powerful freezing apparatus which enables a rapid lowering of the temperature to ensure that a core temperature of -18°C or lower is reached and maintained. Thawing of these products must be carried out hygienically, with good drainage for melt water and a well controlled temperature increase. After thawing, the products must be processed as soon as possible.

Smoked fishery products in processing establishments.

15. (1) Heading and gutting must be carried out as hygienically as possible in a different section from that of filleting and slicing to avoid contamination.

(2) Guts and other offal must be frequently removed from such section in leakproof containers which are easy to clean and disinfect.

(3) The smoking process itself must be carried out in rooms specially equipped to prevent smoke, heat and other products of combustion to affect other parts of the building where fish is prepared, processed or stored.

(4) Wood or other material used for the smoking process must be stored and handled as much as possible, in the contaminated area away from the clean part of the smoking process.

(5) Wood used for producing smoke must not be painted or glued or treated chemically in any way.

(6) After smoking, the products must be rapidly cooled to their conservation temperature before packing. The appropriate conditions for storage must be clearly marked on the package.

16. (1) Salting must take place in premises which are separated from the rest of the processing plant. Such premises must be kept in a good state of cleanliness and hygiene during and after the salting process.

Salting in processing establishments.

(2) Salt used for salting or brining must be clean and stored hygienically. It may not be reused.

(3) Containers used for salting or brining must be clean, in good state of repair, and must be constructed in such a way as to prevent any contamination during the process.

17. In the case of fishery products which have been subjected to sterilisation in hermetically sealed containers:

Canning processing establishments.

(a) the water used for the preparation must be drinking water;

(b) the process used for the heat treatment must be appropriate, having regard to such major criteria as heating time, temperature, filling, size of containers, and others, and a record of which must be kept. The heat treatment must be capable of destroying or inactivating pathogenic organisms and the spores of pathogenic micro-organisms. The heating equipment must be fitted with devices for verifying whether the containers have in fact undergone appropriate heat treatment. Drinking water must be used to cool containers after heat treatment, without prejudice to the presence of any chemical additives used in accordance with good technological practice to prevent corrosion of the equipment and containers;

(c) further checks must be carried out at random by the manufacturer to ensure that the processed products have undergone appropriate heat treatment, that is:

- incubation tests: incubation must be carried out at 37°C for seven days or at 35°C for ten days, or at any other equivalent combination;

- microbiological examination of contents and containers in the establishment's laboratory or in another approved laboratory;

(d) samples must be taken of production each day at predetermined intervals to ensure the efficacy of sealing or of any other method of hermetic closure. For that purpose, appropriate equipment must be available for the examination of cross-sections of the can-seams;

(e) checks are carried out in order to ensure that containers are not damaged;

(f) all containers which have undergone heat treatment under practically identical conditions must be given a batch identification mark.

Cooked crustaceans
and molluscan
shellfish products.

18. Crustaceans and molluscan shellfish must be cooked as follows:

(a) any cooking must be followed by rapid cooling. Water used for this purpose must be drinking water or clean seawater. If no other method of preservation is used, cooling must continue until the temperature approaching that of melting ice is reached;

(b) shelling or shucking must be carried out under hygienic conditions avoiding the contamination of the product. Where such operations are done by hand, workers must pay particular attention to the washing of their hands and all working surfaces must be cleaned thoroughly. If machines are used, they must be cleaned at frequent intervals and disinfected after each working day. After shelling or shucking, cooked products must immediately be frozen or kept chilled at a temperature which will preclude the growth of pathogens, and be stored in appropriate premises;

(c) every manufacturer must carry out microbiological checks, according to regulation 11, on his production at regular intervals, both during the manufacturing process and before the crustacean and molluscan shellfish products are cooked in the processing plant, in order to comply with the standards set out in Schedule 4 to these regulations;

(d) sampling programmes must be established by the managerial staff of the processing plant in relation to the nature of the products (whole, shelled or shucked), the temperature, the time of cooking and the risk evaluation;

(e) the programmes referred to in paragraph (c) and (d) shall contain, in the event of failure to comply with the standards laid down under headings 1 and 2 of Schedule 4, an undertaking:

- to notify the Superintendent of the findings made and the action taken with regard to unsatisfactory batches, as well as the measures provided for in the second indent below,

- to review the methods of supervising and checking the critical points so as to identify the contamination source, and to carry out analyses more frequently,

- not to market for human consumption batches found to be unsatisfactory on account of the discovery of pathogens or where the M value for *Staphylococcus* provided for under heading 2 of Schedule 4 is exceeded.

The method of analysis used must be recorded with the corresponding results.

19. The mechanical recovery of fish flesh must be carried out under the following conditions: Mechanically recovered fish flesh.

- (a) mechanical recovery of gutted fish must take place without undue delay after filleting, using raw materials free of guts. Where whole fish are used, they must be gutted and washed beforehand;

- (b) the machinery must be cleaned at frequent intervals and at least every two hours;

- (c) after recovery, mechanically recovered flesh must be frozen as quickly as possible or incorporated in a product intended for freezing or stabilizing treatment.

20. (1) During production and before they are released for human consumption, fish and fish products must be subject to a visual inspection as in Schedule 3 for the purpose of detecting and removing any parasites that are visible. The scale and frequency of the inspections, which must be carried out by a qualified person, shall be determined according to the nature of the fishery products, their geographical origin, and their use. Conditions concerning parasites.

(2) During preparation of eviscerated fish the visual inspection must be carried out on the abdominal cavity and livers and roes intended for human consumption in the following manner:

- (a) in the case of manual evisceration, the visual inspection must be carried out in a continuous manner by the operative at the time of evisceration, and

(b) in the case of mechanical evisceration, the visual inspection must be carried out by sampling at least ten fish per batch.

(3) The visual inspection of fish fillets or fish slices must be carried out during trimming after filleting or slicing. Where an individual examination is not possible, because of the size of the fillets or filleting operations, a sampling plan will be drawn up by the Government veterinarian. Where candling of fillets is possible from a technical viewpoint, it will be included in the sampling plan.

(4) Fish or parts of fish which are obviously infested with parasites, and which are removed, must not be placed on the market for human consumption.

(5) The fish and fish products referred to in subregulation (6) which are to be consumed as they are must, in addition, be subjected to freezing at a temperature of not more than -20°C in all parts of the product for not less than 24 hours. Products subjected to this freezing process must be either raw or finished.

(6) The fish and products subject to the conditions in subregulation (5) are:—

(a) fish to be consumed raw or almost raw, such as raw herring, *maatje*;

(b) the following species, if they are to undergo a cold smoking process at which the internal temperature of the fish is less than 60°C :

- herring,
- mackerel,
- sprat,
- (wild) Atlantic and Pacific salmon;

(c) marinated and or salted herring where this process is insufficient to kill the larvae of nematodes.

This list may be amended, in the light of scientific data, and criteria will be laid down to define the processes which are deemed sufficient or insufficient to destroy nematodes.

(7) Manufacturers must ensure that fish and fish products listed in subregulation (3) or the raw materials for use in their manufacture are subjected to the treatment described in subregulation (2) prior to their release for consumption.

(8) The fishery products listed in subregulation (3) must, when they are placed on the market, be accompanied by a document from the manufacturer stating the type of process they have undergone.

21. (1) The packaging material for the dispatch of fresh or processed fish must not alter their organoleptic characteristics or contaminate fish with chemicals or substances harmful to human health. Packaging.

(2) They must be impervious and designed to preserve and protect the fish and have adequate drainage for melt water. Preferably they must not be reusable, unless strong and easy to clean and disinfect.

(3) Unused packaging material is to be stored in a protected, clean environment.

22. (1) Identification of the aquaculture product, in the form of labels, must have the approval number, name and address of farm and packing establishment, and species of fish in a clearly legible, indelible manner affixed onto each container. Identification.

(2) Identification of the fishery product, in the form of labels, must have the approval number, name and address of the processing establishment, species of fish, ingredients, and storage requirements in a clearly legible, indelible manner affixed onto each container.

23. (1) Transport vehicles for fresh or processed fish must transport no other product that might contaminate or otherwise alter the organoleptic characteristics of the fish. Transport.

(2) Such vehicles must be equipped to maintain the temperature at 0°C for fresh fish (or according to the type of product in the case of processed fish) throughout transportation and have a temperature charting device.

(3) Such vehicles must also be easy to clean and disinfect at appropriate facilities provided by the farm itself or by other establishments.

(4) A container for melt water must form part of the vehicle.

24. Packing or processing establishments are to be monitored by the Superintendent according to this programme, which is subdivided into three sections: Monitoring programme for packing or processing establishments.

(a) *Fish health monitoring:*

Random samples of all batches of fish from fish farms are to be taken by the Government Veterinarian for a complete parasitological, bacteriological and anatomopathological examination, to determine the state of health, and any emergent diseases at various stages of the life cycle.

Action will be taken in case of any outbreak of the diseases listed as notifiable.

(b) *Hygiene monitoring:*

Each packing and processing establishment must be inspected regularly by a Government veterinarian to ensure compliance with the above conditions, and swabs, samples of ice, water and fish shall be taken once a month, for bacteriological examination to ensure that the level of hygiene is satisfactory. The tests indicated in Schedule 1 must be carried out.

(c) *Quality control and residue analysis:*

Samples of harvested and processed fish must be taken by an authorised officer to be analysed microbiologically for the presence of bacterial pathogens, organoleptically for freshness and suitability for human consumption in terms of Schedule 2, and chemically for the presence of various residues as indicated in Schedule 3.

Schedule 1

Hygiene Monitoring

	Inspections/ examination	Laboratory method	Limits of tolerance	Frequency
Packing/Processing establishments and personnel	General level of hygiene as listed in these regulations and handling of the product	/	/	Every harvest (Packing Establishment) Monthly (Processing Establishment)
Ice and water samples from each outlet	Total bacterial count;	Colony counts on plate count agar	$<2 \times 10^6 \text{ cfu/ml}$ at 37°C or $<2 \times 10^2 \text{ cfu/ml}$ at 22°C	Monthly
	Total coliforms; Faecal coliforms.	Multiple tube fermentation and MPN count	0	Monthly
	Organoleptic and physicochemical examination	According to regulations as issued under the Food, Drugs and Drinking Water Act, Cap. 231	According to regulations as issued under the Food, Drugs and Drinking Water Act, Cap. 231	Yearly, if supply of water is private

* colony-forming units

Schedule 2

Quality Control: microbiological

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Type of analysis	Tests	Laboratory method	Limits of tolerance	Frequency
Bacteriological	Total bacterial count;	Colony counts on plate count agar	1×10^7 cfu/g	Monthly
	Faecal coliforms;	Multiple tube fermentation at 44° C and MPN count	100 <i>E. coli</i> /g	Monthly
	<i>Salmonella</i> ; <i>S. fecalis</i> ; <i>S. aureus</i> ; <i>V. parahaemolyticus</i>	Innoculation on selective and confirmatory media	0 <100 <i>S. fecalis</i> /g <10 <i>S. aureus</i> /g 0	Monthly
Parasitological	Parasite check	Visual inspection	No visible parasites	Daily (Processing Est.) Each harvest Packing Est.)
Organoleptic	Inspection for freshness	Visual inspection, aided where necessary by Torrymeter readings	Freshly harvested fish should be free from pressure marks, blemishes, injuries or discoloration	Every harvest

Schedule 3

Quality Control: Chemical residues

Chemical group of substances (Aquaculture products only)	Compounds	Laboratory method	Level of action	Number of samples	Frequency
Volatile Nitrogenous Bases	TVB-N	Reference method according to 95/149/EC	To be determined for aquaculture animals		In case of adverse orgonoleptic
Stilbenes	DES; Hexestrol; Dienestrol	HPTLC	1ppb	6	yearly
Steroids	Oestradiol	HPTLC	2.5ppb	6	yearly
Antibacterial substances	Nitrofurans Tetracyclines Sulphonamides Quinolones	HPLC	5ppb	12	yearly
		Four-plate Test	10ppb 100ppb 10ppb	6-8	monthly
Anthelminthics	Ivermectin	HPLC	15ppb	20	yearly
Carbamates	Aldicarb Bufencarb Carbaryl Carbofuran Methiocarb Methomyl	HPLC	10ppb 500ppb 200ppb 100ppb 50ppb 20ppb	10	yearly
Pyrethroids	Cypermethrin Deltamethrin Flumethrin Permethrin Tetramethrin	GC-MS	0.2ppm 0.5ppm 0.5ppm	10	yearly
Organochlorie compounds	DDT BHC Lindane Dieldrin	GC-MS	1.0ppm 0.1ppm 0.1ppm 0.1ppm	10	yearly
Organophosphorus compounds	Malathion Chlorphenvinphos Dichlorvos Coumaphos	GC-MS	10ppm	10	yearly
Chemical elements	Pb Hg As Cd	GF-AAS	500ppb 500ppb 1000ppb 50ppb	30	yearly
Dyes	Malachite green	HPLC	Method still under development		

Schedule 4

Standards for cooked crustacean and molluscan shellfish products

1. Pathogens

Salmonella spp. Absent in 25g
n = 5
c = 0

In addition, pathogens and toxins thereof which are to be sought according to the risk evaluation, must not be present in quantities such as to affect the health of consumers.

2. Organisms indicating poor hygiene (shelled or shucked products)

Staphylococcus aureus

m = 100
M = 1 000
n = 5
c = 2

either: Thermotolerant coliform (44°C on solid medium)

m = 10
M = 100
n = 5
c = 2

or: *Escherichia coli* (on solid medium)

m = 10
M = 100
n = 5
c = 2

Where parameters n, m, M and c are defines as follows>

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 3m or less;
- (b) acceptable where the values observed are between 3m and 10m (= 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.

3. Indicator organisms (Guidelines)

Mesophilic aerobic bacteria (30 °C)

- (a) Whole products

m = 10 000
M = 100 000
n = 5
c = 2

- (b) Shelled or shucked products with the exception of crabmeat

m = 50 000
M = 500 000
n = 5
c = 2

- (c) Crabmeat

m = 100 000
M = 1 000 000
n = 5
c = 2