

DRAFT CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS**(At Step 8 of the Procedure)****SECTION 2. DEFINITIONS FOR THE PURPOSE OF THIS CODE****2.3 LIVE AND RAW BIVALVE MOLLUSCS**

Accepted / Acceptable / Approved	means accepted by the official agency having jurisdiction;
Conditioning	means placing live bivalve molluscs in tanks, floats or natural sites to remove sand, mud or slime and improve product acceptability;
Distribution Centre	means any approved on-shore or off-shore installation or establishment for the reception, conditioning, washing, cleaning, grading and packaging of live bivalve molluscs fit for human consumption from which the bivalve molluscs are dispatched alive;
Growing Areas	means all brackish and marine areas approved for the production or harvesting of bivalve molluscs either by natural growth or by aquaculture destined for human consumption. The growing areas may be approved as production or harvesting areas for bivalve molluscs for direct consumption, or they may be approved as production or harvesting areas for bivalve molluscs for either depuration or relaying
Heat Shocking	means the process of subjecting bivalve molluscs in the shell to any form of heat treatment, such as steam, hot water, or dry heat for a short period of time, to facilitate rapid removal of meat from the shell for the purpose of shucking.
Depuration	means the reduction of microorganisms to a level acceptable for direct consumption by the process of holding live bivalve molluscs for a period of time under approved, controlled conditions in natural or artificial sea water suitable for the process, which may be treated or untreated.,
Depuration centre	means any approved establishment for the depuration of live bivalve molluscs.
Relaying	means the removal of bivalve molluscs from microbiologically contaminated growing area to an acceptable growing or holding area under the supervision of the agency having jurisdiction and holding them there for the time necessary for the reduction of contamination to an acceptable level for human consumption.

2.9 LOBSTERS

Autolysis	is the breakdown or deterioration of lobster meat or viscera by means of indigenous enzymes
Black spot	is the appearance of dark pigments at the joints and injured parts of lobster segments, caused by oxidative enzyme reaction;
Butt end of the tail	is that part of the tail muscle of lobsters which extends into the cephalothorax;
Cephalothorax	is the body region of lobsters which is formed anatomically by the fusion of head and thorax;

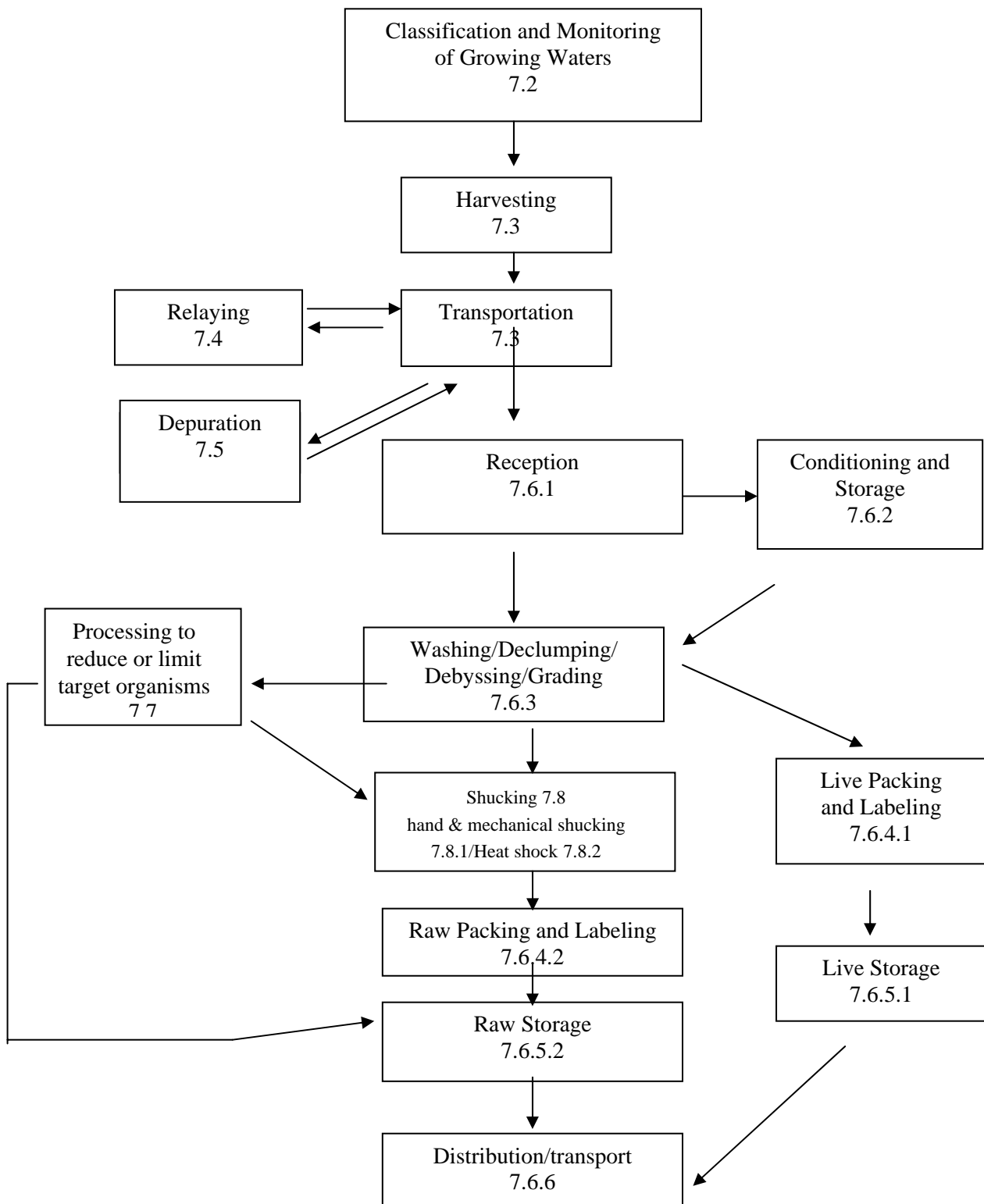
Claw	means the pincer appendage at the end of the lobster arm;
Cooking	means boiling of lobsters in potable water, clean sea water or brine or heating in steam for a period of time sufficient for the thermal centre to reach a temperature adequate to coagulate the protein;
Deterioration	means those natural processes of quality reduction that occur after harvesting and that are quite independent of man's deliberate intervention;
De-vein	is to remove the intestine/vein from the lobster tail;
Enzymatic activity	is the catalytic action of enzymes on biochemical reactions;
Insensible	is the state of unresponsiveness as a result of thermal, electrical, or physical process imposed on lobsters prior to cooking;
Intestine/Vein	is used in this code to mean the posterior portion of the lobster alimentary tract;
Lobster	means commercially important species in the order Decapoda, and families Nephropidae, Palinuridae or Scyllaridae or other important economic taxonomic families;
Pasteurisation	means subjecting lobster meat to heat at times and temperatures, which inactivates spoilage and pathogenic micro-organisms without noticeable changes in appearance, texture and flavour of the product;
Pounding	refers to the holding of live lobsters in water tanks or floating crates for extended periods of time;
Shell	is the hard outer covering of lobsters;
Shucking	is the process of removing the meat from the shell and appendages of the lobsters;
Tail	is the abdomen or posterior part of the body;
Tailing	is the process of separating the tail from the cephalothorax;
Trimming	is the process of removing any signs of blood, membrane or remnants of the gut which may be attached to the shell or meat of lobsters;
Waste	means those lobster parts which remain after the meat removal operation is completed.

SECTION – 7 – LIVE AND RAW BIVALVE MOLLUSCS

In the context of recognising controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop control measures and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

This flow chart is for illustrative purposes only. For implementation of HACCP principles, a complete and comprehensive flow chart has to be drawn up for each product.

References correspond to relevant Sections of the Code.



7.1 GENERAL REMARKS, ADDITION TO THE PRE-REQUISITE PROGRAMME

Bivalve molluscs species like oysters, mussels, manilla and hard shell clams can survive for extended periods out of water and can be traded for human consumption as live animals. Other species like cockles can be traded live if carefully handled, but are normally processed. Species not adapted to dry conditions soon die out of water and are best handled as chilled products or processed.

When spawning (following “gonad ripening”) occurs, it becomes undesirable and in many instances impracticable to trade them as live animals. Stress can induce spawning.

The main hazard known for the production of bivalve molluscs is microbiological contamination of waters in which they grow, especially when the bivalve molluscs are intended to be eaten live or raw. Since molluscs are filter feeders they concentrate contaminants to a much higher concentration than the surrounding sea water. The contamination with bacteria and viruses in the growing area is therefore critical for the end product specification and determines the process requirements for further processing. Gastro-enteritis and other serious diseases such as hepatitis can occur as a result from agricultural run-off and/or sewage contamination like enteric bacterial and/or viral pathogens (Norovirus, viruses causing hepatitis) or from natural occurring bacterial pathogens (*Vibrio* spp.). Another hazard is formed by biotoxins. Biotoxins produced by some algae can cause various forms of serious poisoning like diarrhetic shellfish poisoning (DSP), paralytic shellfish poisoning (PSP), neurotoxic shellfish poisoning (NSP), amnesic shellfish poisoning (ASP) or poisoning caused by Azaspiracid (AZP). Chemical substances, such as heavy metals, pesticides, organochlorides, petro-chemical substances may also form a hazard in certain areas.

To control the hazards, identification and monitoring of growing areas is very important for bivalve molluscs safety. The identification, classification and monitoring of these areas is a responsibility for competent authorities in cooperation with fishermen and primary producers. *E. coli*/faecal coliforms or total coliforms may be used as an indicator for the possibility of faecal contamination. If biotoxins are found in the bivalve molluscs flesh in hazardous amounts the growing area must be closed for harvesting bivalve molluscs until toxicological investigation has made clear that the bivalve mollusc meat is free from hazardous amount of biotoxins. Harmful chemical substances should not be present in the edible part in such amounts that the calculated dietary intake exceeds the permissible daily intake.

Bivalve molluscs from waters subject to microbiological contamination, as determined by the authority having jurisdiction, can be made safe by relaying in a suitable area or a depuration process to reduce the level of bacteria and the level of viruses if the process is continued long enough, or by processing to reduce or limit target organisms. Depuration is a short-term process commonly used to reduce low levels of bacterial contamination, but long term relaying is required if there is a greater risk of contamination.

Especially when the bivalve molluscs need to undergo relaying or depuration to be eaten raw, stress and excessive shocks of the bivalve molluscs must be avoided. This is important because these bivalve molluscs should be able to function again during depuration, relaying or conditioning.

7.2 CLASSIFICATION AND MONITORING OF GROWING AREAS

Potential Hazards: *Microbiological contamination, biotoxins, chemical contamination*

Potential Defects: *unlikely*

Technical Guidance:

There are 5 different types of important hazards coming from the bivalve molluscs growing environment:

- enteric bacterial pathogens (e.g. *Salmonella* spp.);
- enteric viral pathogens (e.g. Norovirus, viruses causing hepatitis);
- naturally occurring bacterial pathogens (e.g. *Vibrio* spp.);
- biotoxins (e.g. okadaic acid group (DSP), saxitoxin group (PSP), brevetoxin group (NSP), domoic acid group (ASP), azaspiracid group (AZP);
- chemical contaminants (e.g. heavy metals such as lead, cadmium and mercury).

7.2.1 Classification of growing areas

Surveys of the growing area, shoreline and land catchment should be conducted to determine sources of both domestic and industrial pollution which may affect the quality of the growing area water and bivalve molluscs. Sources may include municipal sewage outputs, industrial outputs, mine wastes, geophysical contaminants, domestic animal holding pens, nuclear power plants, refineries or other sources. The need to reschedule hygiene surveys will be determined by population shifts and changes in agricultural and industrial activities in the coastal area. Resurveys should be conducted at an acceptable frequency and known pollution sources should be re-evaluated on a regular basis to determine any changes to their impact on the growing area.

When pollution sources have been identified and evaluated, sampling stations for water and/or bivalve molluscs and/or sediments should be established and studies conducted to determine the effects of the pollutants on water and bivalve molluscs quality. The data should be evaluated by the official agency having jurisdiction and growing areas should be classified according to official standards and criteria.

When interpreting growing area data, the official agency having jurisdiction should take into account variations which may affect the level of pollution during the most unfavourable hydrographic and climatic conditions as influenced by rainfall, tides, winds, methods of sewage treatment, population variations and other local factors, since bivalve molluscs respond rapidly to an increase in the number of bacteria or viruses in their environment by accumulating these agents. The agency should also consider that bivalve molluscs have the ability to accumulate toxic chemicals in their tissue in concentrations greater than the levels found in the surrounding water. FAO, WHO, or other international or national food standards may be used as a guide to acceptable levels.

The official agency having jurisdiction should immediately announce decisions concerning the classification of growing areas to the affected producers and depuration and distribution centres.

When sampling shellfish meats for classification purposes, if the limits of any biological or chemical hazard set in the end product specification are exceeded, appropriate measures must be taken under the responsibility of the official agency having jurisdiction.

Classified growing areas should be clearly defined by the official agency having jurisdiction as either:

- suitable for harvesting for direct human consumption, relying in acceptable water or depuration in an approved depuration centre or approved processing to reduce or limit target organisms; or
- non-suitable for growing or harvesting bivalve molluscs.

7.2.2 Monitoring of growing areas

Growing areas should be routinely monitored for changes in water quality and/or bivalve molluscs quality, and sub-standard areas patrolled to prevent harvesting for purposes other than that established by the official agency.

Biotoxins in bivalve molluscs can be caused by plankton containing toxins. For early warning purposes, where appropriate, it is recommended to have a programme present to monitor growing areas for the species of plankton that can produce toxins and to recognize other environmental signals that a toxic event may be developing.

Harmful chemical substances within bivalve molluscs should not be present in amounts so that the calculated dietary intake exceeds the permissible daily intake. A monitoring system should be present for harmful chemical substances.

When routine monitoring programmes or resurveys show that the growing area no longer meets the classification criteria, the area should be reclassified or closed for harvesting immediately by the official agency having jurisdiction.

In determining the public health suitability of bivalve molluscs classified growing areas the official agency having jurisdiction should consider the following actions:

- Classification/reclassification of growing areas by sanitary survey, monitoring of *E.coli*/faecal coliforms or total coliforms at an appropriate frequency based on the risk of contamination, and other sanitary control measures as applicable.
- Classification/reclassification of growing areas by monitoring of pathogens at an appropriate frequency based on the probability of contamination in bivalve mollusc meat (see 7.2.2.2).
- Closure/Reopening of growing areas by the monitoring of biotoxins in bivalve molluscs alone or in combination with the monitoring of phytoplankton in seawater at an appropriate frequency based on the probability of contamination (see 7.2.2.3).
- Control of chemical contaminants.

Under the responsibility of the official agency having jurisdiction the growing areas providing bivalve molluscs for direct human consumption meet the following requirements at time of harvest:

- The area is not subject to contamination that may present an actual or potential hazard to human health;
- The bivalve molluscs harvested meet the end product specification. This can be determined by examination of mollusc's flesh or through adequate monitoring of the water, as appropriate.

Growing areas providing bivalve molluscs for indirect human consumption should be defined in relation to the further procedure of the lot.

7.2.2.1 *E. Coli*/faecal coliforms/total coliforms

All growing water and/or molluscan flesh should be monitored for the presence of *E. coli*/faecal coliforms or total coliforms at an appropriate frequency based on the probability and degree of faecal contamination.

Tests for suitable indicator bacteria such as faecal coliforms or *Escherichia coli* or total coliforms should be used to determine the degree of faecal contamination. The effectiveness of indicator bacteria used should be kept under constant review for their reliability as measures for the degree of faecal contamination. If faecal contamination exceeds a certain threshold-levels relaying or depuration for a time approved by the official agency having jurisdiction may be allowed.

E. coli/faecal coliforms or total coliforms may be used as an indicator for the presence of faecal contamination. Because these indicators do not correlate well with the presence of viruses, other controls such as shoreline surveys should always be employed.

Other methods such as bacteriophage and viral detection could also be used as indicators when validated analytical methods become available in the future.

7.2.2.2 Pathogen Monitoring

Shellfish sanitation programs rely upon the use of indicator organisms for the presence of contamination rather than upon attempts to monitor for specific pathogens. However, where there has been a shellfish borne outbreak caused by an identified pathogen such as *Salmonella* and others (*Vibrio* and viruses), monitoring the bivalve molluscs may be appropriate as part of the process of closure/reopening the affected harvest area. The species, and typically the actual strain, should be known to ensure that monitoring is addressing the source of the pathogen. Predetermined acceptance/rejection levels for the pathogen should have been established in order to use such monitoring results for decision making. Other conditions including the sanitary survey requirements should also have been satisfied as a condition of reopening this area.

7.2.2.3 Marine biotoxin control

Phytoplankton monitoring is a valuable complementary tool that can be used, in combination with the required monitoring of marine biotoxins in shellfish tissue, to optimize program management and resources. Growing areas should also be monitored for environmental signals that a toxin event maybe occurring, e.g. dead or dying birds, mammals, or fish. The risk of blooms of toxic algae may show seasonal variability and areas may also be affected by toxic algae previously unknown in the surrounding sea or coastal waters. These risks should be recognised when drawing up monitoring schedules.

It is important to note that in using indicator shellfish species, the absence of toxicity in indicated species is assumed to imply the absence of toxicity in other species in the growing area. This implication must be verified for each shellfish species and for each group of toxins before defining a particular shellfish species as an indicator for that growing area.

The official agency having jurisdiction should close immediately and effectively patrol affected areas when acceptable levels are exceeded in edible portions of bivalve molluscs meats. These areas should not be opened before toxicological investigation has made clear that the bivalve molluscs meat is free from hazardous amounts of biotoxins.

The official agency having jurisdiction should immediately announce these decisions to the affected producers and depuration and distribution centres.

In establishing sampling programme over space and time, consideration should be given to assuring adequate location and number of sampling sites. Testing for a particular biotoxin may not be appropriate when it has been demonstrated that this biotoxin has not been associated with bivalve molluscs in the growing and harvesting areas. Sampling frequency must be sufficient to address spatial-temporal changes in micro-algae, toxins in shellfish and to cover the risks of rapid rises in shellfish toxicity.

Spatial Representational Sampling

The selection of sampling stations for both benthic and suspended culture should be based on sites which have historically presented toxicity in the early stages of a toxic event. It is recognised that sampling, generally, cannot be carried out in a statistically valid way without excessive cost. In order to protect public health, the selection of sampling stations should give appropriate coverage of the extent of a toxic event or the likely “worst case scenario” in a growing area. This should be based on expert judgment using the following factors:

- Hydrography, known upwellings, fronts, current patterns and tidal effects.
- Access to sampling stations in all weather conditions during harvesting.
- Desirability of toxin and micro-algal sampling at the same sampling station.
- In addition to primary (routine) stations, the need for secondary (complementary) and offshore stations.
- Existence of *in-situ* growth (for example, toxic micro-algae from cyst beds).
- The advection of offshore toxic micro-algal blooms into growing areas.

Routine sampling for micro-algae will generally mean taking an integrated sample from the water column. When a toxic event is in progress or developing, targeted, depth-specific sampling should be considered.

Sampling for shellfish grown in suspension, should at least involve an integrated sample composed of shellfish taken from the top, middle and bottom of the lines.

Temporal Representational Sampling

Minimum weekly sampling frequencies are adopted by most monitoring programmes in areas where toxicity is prevalent and where harvesting is taking place or about to take place. Decisions on the frequency of sampling should be based on risk evaluation. Inputs into the decision may include factors such as seasonality (toxicity and / or harvesting), accessibility, historical baseline information, including toxin and micro-algal data, and the effects of environmental factors such as wind, tide and currents.

Sampling frequency and the factors that may lead to it being changed should be described in a “Marine Biotoxin Action Plan” for the growing area.

Shellfish Sample Size

There is no internationally agreed sample size for different shellfish species. There may be high variability of toxicity among individual shellfish. The number of shellfish sampled should be sufficient to address this variability. For this reason, the number of shellfish in the sample, rather than the mass of the shellfish flesh should be the determining factor for the sample size. Additionally, the size of the sample should be sufficient to allow the test or tests for which the sample is being taken to be carried out, and the shellfish sampled should be of the size marketed.

7.2.2.4 Marine biotoxin test methods

Methods suitable for the determination of marine biotoxins are listed in the draft Standard for Live and Raw Bivalve Molluscs. Any methods may be deemed suitable for screening purposes provided they are approved by a country’s competent authority.

7.2.2.5 Chemical contaminants

Growing areas should be monitored for chemical contaminants on a sufficiently frequent basis to provide confidence that any identified sources of chemical contamination are not contaminating the shellfish. Shellfish growing areas where there are no known point sources of likely chemical contamination should only require occasional checks every few years. However, where there are known point sources of specific contamination shellfish may need to be checked more frequently on a routine basis. There should also be the capacity to sample shellfish reactively if a defined event occurs – for example a spillage of anti-fouling paint.

7.3 HARVESTING AND TRANSPORTATION OF LIVE BIVALVE MOLLUSCS

Refer also to Sections 3.1, 3.3, 3.4 and 3.5

This section applies to the transportation of bivalve molluscs for the purpose of direct human consumption, relaying, depuration, processing to reduce or limit target organisms, or further processing.

Appropriate handling procedures depend on different species, growing area and season.

Potential Hazards: Microbiological contamination, biotoxins, chemical contamination

Potential Defects: Physical damage

Technical Guidance:

- Dredges and other harvesting equipment, decks, holds and containers, which are contaminated from use in a polluted area, should be cleaned and if applicable disinfected (sanitised) before being used for bivalve molluscs from an unpolluted area.
- Holds in which bivalve molluscs are held or containers should be so constructed that the bivalve molluscs are held above the floor level and drained so that the bivalve molluscs is not in contact with wash-down or bilge water, or shell fluid. Where necessary a bilge pumping system must be provided.
- Suitable precautions should be taken to protect bivalve molluscs from being contaminated by polluted water, droppings from sea birds, footwear which may have been in contact with faecal matter or by other polluted material. No overboard discharge of waste, including human faecal material, should occur from harvest vessels around shellfish growing areas. No animals should be allowed on harvest vessels.

- Wash-down pumps should draw water only from non-contaminated seawater.
- Bivalve molluscs should be harvested from and stored in a growing area or relaying area acceptable to the official agency having jurisdiction.
- On removal from water or during handling and transportation, bivalve molluscs should not be subjected to extremes of heat or cold or sudden variations in temperature. Temperature control is critical in handling live bivalve molluscs. Special equipment, such as insulated containers and refrigeration equipment should be used if prevailing temperatures and the time involved so require. Bivalve molluscs should not be exposed to full sun or surfaces heated by the sun or come into direct contact with ice and other freezing surfaces, nor should it be held in closed containers with solid carbon dioxide. In most cases storage above 10°C (50°F) or below 2°C (35°F) should be avoided.
- Bivalve molluscs should be freed from excessive mud and weed soon after being harvested by washing it with clean seawater or potable water under suitable pressure. Wash water should not be allowed to flow over bivalve molluscs already cleaned. The water could be re-circulated if it meets the definition for clean water.
- The interval between harvesting and immersion in water for relaying, storage, conditioning or depuration should be kept as short as possible. This also applies to the interval between final harvesting and handling in a distribution centre.
- If bivalve molluscs are to be re-immersed after harvest they should be re-immersed in clean seawater.
- Appropriate documentation should be maintained for harvesting and transportation activities.

7.4 RELAYING

The requirements for classification and monitoring of growing areas also apply to Relaying areas.

Relaying is intended to reduce the level of biological contaminants that may be present in bivalve molluscs which have been harvested from contaminated areas to such levels that the bivalve molluscs will be acceptable for human consumption without further processing. Bivalve molluscs harvested for relaying should only be harvested from areas that are so designated/classified by the official agency having jurisdiction. Relaying methods vary worldwide. Bivalve molluscs may be placed in floats, rafts or directly on the bottom.

Potential Hazards: *Microbiological contamination, biotoxins, chemical contamination*

Potential Defects: *unlikely.*

Technical Guidance:

- Relaying operations should be strictly supervised by the official agency having jurisdiction to prevent contaminated bivalve molluscs from being diverted directly to the consumer market or from cross contamination of other bivalve molluscs. Boundaries of relaying areas should be clearly identified by buoys, poles or other fixed means. These areas should be adequately separated from the bivalve molluscs in adjacent waters and suitable control systems should be in place to prevent cross contamination and commingling.
- Holding time and minimum temperature in the accepted area prior to harvest will be determined by the official agency having jurisdiction according to the degree of contamination before relaying, the temperature of the water, the bivalve molluscs species involved and local geographic or hydrographic conditions to ensure that contamination levels have been adequately reduced.
- Relaying sites could become biotoxic from a bloom, or could become an unexpected a source of environmental pathogens such as *Vibrio* bacteria, and should therefore be monitored as appropriate while they are being used for relaying.
- Bivalve molluscs should be laid out at a density which will permit them to open and undergo natural depuration.

- Appropriate documentation should be maintained for relaying operations.

7.5 DEPURATION

Refer also to Sections: 3.2, 3.3, 3.4 and 3.5

Depuration is intended to reduce the number of pathogenic micro-organisms that may be present in bivalve molluscs which have been harvested from moderately polluted areas to such levels that the bivalve molluscs will be acceptable for human consumption without further processing. Depuration alone is not suitable for cleansing bivalve molluscs from more heavily contaminated areas or areas subject to contamination by hydro-carbons, heavy metals, pesticides, viruses, vibrios or biotoxins. Bivalve molluscs harvested for depuration should only be harvested from areas that are so designated/classified by the official agency having jurisdiction.

The required conditions vary according to the species of molluscs and the design of the depuration system.

For natural functioning and therefore depuration to occur it is essential that the molluscs have not been overstressed or damaged during harvesting or handling prior to depuration and should not be in a seasonally weak or spawning condition.

Depuration centres should maintain the same hygiene standards as sections 3.2, 3.3, 3.4, 3.5.

Potential Hazards: *Microbiological contamination*

Potential Defects: *physical damage*

Technical Guidance:

Depuration centres and tanks should be approved by the official agency having jurisdiction.

- Bivalve molluscs subjected to the depuration process should not contain metallic ions, pesticides, industrial wastes or marine biotoxins in such quantities that it presents a health hazard to the consumer.
- Use only shellstock designated as acceptable by the official agency having jurisdiction.
- The process and the equipment, e.g. tanks, used for depuration should be acceptable to the official agency having jurisdiction.
- Dead or damaged bivalve molluscs should be removed before the depuration process, when practicable. Surfaces of shells should be free from mud and soft commensal organisms. If necessary the bivalve molluscs should be washed with clean sea water before the depuration process.
- The length of the period of depuration should be adapted to the water temperature and physical water quality parameters (clean sea water, salinity, dissolved oxygen and pH levels suitable to permit the bivalve molluscs to function normally), the degree of contamination before depuration and the bivalve molluscs species. Microbiological investigation of process water and of bivalve molluscs meat should be used to assess depuration parameters. It should be taken into account that viruses and *Vibrio* spp. are more persistent during depuration than the indicator bacteria mostly used for microbiological monitoring and that the reducing of the number of indicator bacteria does not always reflect the real situation as regards contamination by viruses and *Vibrio*.
- Water used in depuration tanks should be changed continuously or at suitable intervals or if recirculated be treated properly. The flow of water per hour should be sufficient to the amount of bivalve molluscs treated and should depend on the degree of contamination of the bivalve molluscs.
- Bivalve molluscs undergoing depuration should remain immersed in clean sea water until it satisfies the sanitary requirements of the official agency having jurisdiction.
- Bivalve molluscs should be laid out at a density which will permit them to open and undergo natural depuration.

- During the process of depuration, the water temperature should not be allowed to fall below the minimum at which bivalve molluscs remain physiologically active; high water temperatures which adversely affect the pumping rate and the depuration process should be avoided; tanks should be protected from the direct rays of the sun when necessary.
- Equipment in contact with water, i.e. tanks, pumps, pipes or piping, and other equipment should be constructed of non-porous, non-toxic materials. Copper, zinc, lead and their alloys should preferably not be used in tanks, pumps or piping systems used in depuration processing.
- To avoid recontamination of bivalve molluscs undergoing depuration, unpurified bivalve molluscs should not be placed in the same tank as bivalve molluscs which are already undergoing depuration.
- On removal from the depuration system, bivalve molluscs should be washed with running potable water or clean sea water, and handled in the same manner as living bivalve molluscs taken directly from a non-polluted area. Dead, with broken shells or otherwise unwholesome bivalve molluscs should be removed.
- Before removing the bivalve molluscs from the tanks drain the water from the system to avoid resuspension and reingestion. The tanks should be cleaned after each use and disinfected at suitable intervals.
- After depuration the bivalve molluscs should meet the end product specification.
- Appropriate documentation should be maintained for depuration.

7.6 PROCESSING OF BIVALVE MOLLUSCS IN A DISTRIBUTION CENTRE OR AN ESTABLISHMENT

Some countries require that bivalve molluscs that are to be frozen and/or shucked, and/or processed to reduce or limit target organisms must first pass through a “distribution centre” from which they exit alive. Other countries allow freezing, shucking, and processing to reduce or limit target organisms to occur in establishments that perform the functions of a “distribution centre.” Both practices are legitimate and the products from each one should be equally permitted in international trade. Where “distribution centre” activities and processing activities occur under the same roof, care must be taken to ensure adequate separation of activities to prevent cross-contamination or commingling products.

Distribution centres that prepare live bivalve molluscs suitable for direct consumption and establishments that prepare live and raw bivalve molluscs suitable for direct consumption should maintain the same hygiene standards as sections 3.2, 3.3, 3.4, 3.5.

7.6.1 Reception

Potential Hazards: Microbiological, chemical and physical contamination

Potential Defects: Viable parasites, physical damage, foreign matter, dead or dying of bivalve molluscs

Technical Guidance:

- Stress and excessive shocks to bivalve molluscs that will be dispatched live from a distribution centre or other establishment must be avoided.
- Distribution centres and other establishments that prepare live bivalve molluscs should only accept bivalve molluscs which meet the end product specification and which originate directly from approved growing areas or after relaying in an approved relaying area or after depuration in an approved depuration centre or tank.

7.6.2 Conditioning and storage of bivalve molluscs

Refer also to Sections 3.2, 3.3, 3.4 and 3.5

Potential Hazards: Microbiological contamination, chemical contamination, biotoxins

Potential Defects: Physical damage, foreign matter, dead or dying of bivalve molluscs

Technical Guidance:

Conditioning means storage of bivalve molluscs in sea water tanks, basins, floats, rafts or natural sites with the intention to remove mud, sand and slime.

- The process of storing bivalve molluscs in sea water tanks, basins, floats, natural sites or rafts can be used if it is acceptable to the official agency having jurisdiction.
- Only clean sea water should be used in the tanks, floats, natural sites or rafts and should be of an adequate salinity and adequate physical water quality parameters to permit the bivalve molluscs to function normally. Optimum salinity will vary with bivalve molluscs species and with the harvesting area. Water condition has to be satisfactory adequate for the process. Where natural sites are used for conditioning these should be classified by the official agency having jurisdiction.
- Before conditioning or storage bivalve molluscs should be washed to remove mud and soft commensal organisms and dead or damaged bivalve molluscs should be removed when practicable.
- During storage bivalve molluscs should be laid out at a density and under such conditions that will permit them to open and function normally.
- The oxygen content in the seawater should be maintained at an adequate level at all times.
- The temperature of the water in storage tanks should not be allowed to rise to such levels as to cause weakness of the bivalve molluscs. If ambient temperatures are excessively high, tanks should be placed in a well-ventilated building or away from the direct rays of the sun. The length of the period of conditioning should be adapted to the water temperature.
- Bivalve molluscs should be stored in clean sea water only for such time as they remain sound and active.
- Tanks should be drained, cleaned and disinfected at suitable intervals.
- Recirculating wet storage systems must contain approved water treatment systems.

7.6.3 Washing, declumping, debyssing and grading

Refer also to Sections 3.2, 3.3, 3.4 and 3.5

Potential Hazards: Microbiological contamination, chemical and physical contamination

Potential Defects: Mechanical damage

Technical Guidance:

- All steps in the process, including packaging, should be performed without unnecessary delay and under conditions which will prevent the possibility of contamination, deterioration and the growth of pathogenic and spoilage micro-organisms.
- Damage to shells and stress will shorten the shelf life of bivalve molluscs and increase the risk of contamination and deterioration. So bivalve molluscs have to be handled carefully:
 - The number of handlings with bivalve molluscs should be minimised;
 - Excessive shocks should be avoided.
- The different process steps should be supervised by technically competent personnel.
- The outsides of the shells should be washed free of mud, and all soft adhering organisms should be removed. Hard adhering organisms should also be removed when possible, care being taken not to chip lips of shells by vigorous washing. Washing should be carried out using pressurised clean (sea) water.
- Bivalve molluscs having formed clumps should be declumped and debyssed as appropriate. The equipment used should be designed and adjusted to minimise the risk of damage to the shells.

7.6.4 Packing and Labelling

Refer also to Sections: 3.2, 3.3, 3.4 and 3.5

All steps in the process of packaging should be performed without unnecessary delay and under conditions that will prevent the possibility of contamination, deterioration and the growth of pathogenic and spoilage micro-organisms.

The packaging material should be appropriate for the product to be packed and for the expected conditions of storage and should not transmit to the product harmful or other objectionable substances or odours and tastes. The packaging material should be sound and should provide appropriate protection from damage and contamination.

7.6.4.1 Packing and Labelling of Live Bivalve Molluscs

Potential Hazards: Microbiological contamination, physical contamination, chemical contamination

Potential Defects: Incorrect labelling, presence of damaged or dead bivalve molluscs, foreign matter

Technical Guidance:

- Before packing bivalve molluscs should undergo visual inspection. Bivalve molluscs which are dead, with broken shells, with adhering soil or otherwise unwholesome, should be rejected for human consumption.
- The packaging material should avoid contamination and should be drained.
- Labels should be clearly printed and must comply with the labelling laws of the country where the product is marketed. The packaging material may be used to bear an indication as to how the bivalve molluscs should be kept from the time they were bought at the retailer. It is recommended to include the date of packaging.
- All packaging material should be stored in a clean and sanitary manner. Product containers should not have been used for any purpose, which may lead to contamination of the product. Packaging material should be inspected immediately before use to ensure that they are in a satisfactory condition and where necessary disposed of or cleaned and/or disinfected; when washed they should be well drained before filling. Only packaging material required for immediate use should be kept in the packing or filling area.”

7.6.4.2 Packing and Labelling of Raw Bivalve Molluscs

Potential Hazards: Microbiological and physical contamination

Potential Defects: objectionable matter such as shell pieces; incorrect labelling

Technical Guidance:

- Labels should be clearly printed and must comply with the labelling laws of the country where the product is marketed. The packaging material or label may be used as a means to convey appropriate storage instructions to the consumer after retail purchase. It is recommended to include the date of packaging
- All packaging material should be stored in a clean and sanitary manner. Only packaging material required for immediate use should be kept in the packing or filling area.
- Shucked and post harvest treated product should be packed and chilled or frozen as soon as possible.
- Freezing should take place quickly (see section 8.3). Slow freezing will damage meat.
- If labels on post harvest treated raw bivalve molluscs make safety claims relating to the post harvest treatment, the claims should be specific to the target hazard that has been eliminated or reduced.”

7.6.5 Storage

7.6.5.1 Storage of Live Bivalve Molluscs

Potential Hazards: Microbiological contamination, chemical and physical contamination

Potential Defects: physical damage

Technical Guidance:

- The end product should be stored under such conditions as will preclude the contamination with and/or proliferation of micro-organisms. The packaging material of the end product should not have direct contact with the floor but should be placed on a clean, raised surface.
- Storage periods should be kept as short as possible.

- Reimmersion in or spraying with water of live bivalve molluscs must not take place after they have been packed and have left the distribution centre or establishment except in the case of retail sale at the distribution centre.

7.6.5.2 Storage of Raw Bivalve Molluscs

Potential Hazards: *Microbiological contamination, chemical and physical contamination*

Potential Defects: *physical damage*

Technical Guidance:

- Storage periods should be kept as short as possible
- Damage to packaging of frozen product should be avoided.

7.6.6 Distribution / Transport

7.6.6.1 Distribution of Live Bivalve Molluscs

Refer also to Sections 3.6 and 17

Potential Hazards: *Microbiological contamination*

Potential Defects: *Physical damage*

Technical Guidance:

- The product should be dispatched in the sequence of the lot numbers.
- Temperature should be maintained during distribution to control microbial growth.
- Bivalve molluscs intended for human consumption should only be distributed in closed packaging.
- The means of transport should provide sufficient protection of the bivalve molluscs against damage to the shells from shocks. The bivalve molluscs should not be transported with other products which might contaminate them.

7.6.6.2 Distribution of Raw Bivalve Molluscs

Potential Hazards: *Microbiological contamination*

Potential Defects: *unlikely*

Technical Guidance:

- Temperature should be maintained during distribution to control microbial growth.
- The product should be dispatched in the sequence of the lot numbers.
- Transportation should be able to maintain chilled or frozen product for safety and quality.

7.7. PROCESSING TO REDUCE OR LIMIT TARGET ORGANISMS

Refer also to Sections 3.2, 3.3, 3.4, and 3.5.

Bivalve molluscs processed to reduce or limit target organisms are products prepared from live or raw bivalve molluscs that have been processed after harvest to reduce or limit specified target organisms within the product to levels that are satisfactory to the official agency having jurisdiction. Processing to reduce or limit target microorganisms is intended to retain the sensory qualities of a live bivalve mollusc. As with all live and raw bivalve molluscs, these bivalve molluscs must meet all microbiological criteria associated with traditional harvest water controls designed to prevent faecal contamination and resulting introduction of enteric pathogens as well as toxins and other contaminants. However, these growing area controls are not designed for control of pathogens that are independent from faecal contamination.

Potential Hazards: *Microbiological contamination*

Potential Defects: *Coagulation of meat, defective meat texture, hydrostatic medium forced into the flesh.*

Technical Guidance:

- Any treatment developed to eliminate or reduce pathogens should be thoroughly validated scientifically to ensure that the process is effective (see the Draft Guidelines for the Validation of Food Safety Control Measures).
- The control treatments (heat, pressure, etc.) should be closely monitored to ensure that the product does not undergo textural changes in the flesh that are unacceptable to the consumer.
- The treatment parameters established to reduce or limit pathogens should be approved by the official agency having jurisdiction.
- Each establishment which purifies bivalve molluscs with a heat treatment must develop a heat treatment process schedule, acceptable to the official agency having jurisdiction, which addresses such critical factors as the species and size of bivalve molluscs, time of exposure to heat, internal bivalve molluscs temperature, type of heat process used, water/steam to bivalve molluscs ratios, nature of heat equipment, measurement devices and their calibration, post heating chilling operations, cleaning and sanitising of heat process equipment.

7.8 SHUCKING

Shucking is the processing step that removes the edible portion of the mollusc from the shell. It is usually done by hand, mechanically or through heat shock with steam or hot water. This step may expose the product to microbiological or physical contamination.

7.8.1 Hand and Mechanical Shucking and Washing,

Physical removal of shellfish meat from the shell will often expose the product to dirt, mud and detritus that should be removed before further processing through washing or other means.

Potential Hazards: Physical contamination, microbiological contamination

Potential Defects: Cuts and tears of the flesh, presence of sand and mud

Technical Guidance:

- Care should be taken to eliminate excess mud, detritus and sand from the shucking tables.
- The product should be examined to ensure that cuts and tears are minimized.
- Shucked molluscs should be rinsed or washed to further eliminate mud, sand, detritus and reduce the microbiological level of the products.

7.8.2 Heat shocking of bivalve molluscs followed by packing

Heat shocking is a method to remove shells from the bivalve molluscs.

Refer also to Sections 3.2, 3.3, 3.4 and 3.5

Potential Hazards: Physical contamination

Potential Defects: unlikely

Technical Guidance:

- The bivalve molluscs must come from approved growing areas and/or after relaying in an approved relaying area or depuration in an approved depuration centre or tank. Each establishment which heat shucks bivalve molluscs should develop a heat shuck process schedule, acceptable to the official agency having jurisdiction, which addresses such critical factors as the species and size of bivalve molluscs, time of exposure to heat, internal bivalve molluscs temperature, type of heat process used, water/steam to bivalve molluscs ratios, nature of heat equipment, measurement devices and their calibration, post heating chilling operations, cleaning and sanitising of heat process equipment.
- All bivalve molluscs should be washed with pressurised potable water or clean sea water and culled for damaged and dead bivalve molluscs prior to heat treatment.
- Before heat shocking the bivalve molluscs should be inspected to determine whether the bivalve molluscs are alive and not badly damaged

- Heat shocked bivalve molluscs should be cooled to 7°C or less within two hours of being heat treated (this time includes the shucking process). This temperature should be maintained during transport, storage and distribution.
- The heat shocked bivalve molluscs should be packed as soon as possible. Before packing the bivalve molluscs should be examined for objectionable matter such as shell pieces.

7.9 DOCUMENTATION

- The transport of live bivalve molluscs from a growing area to a distribution centre, depuration centre, relaying area or establishment should be accompanied by documentation for the identification of batches of live bivalve molluscs.
- Storage and transport temperatures should be indicated.
- Permanent, legible and dated records of relaying and depuration should be kept concerning each lot. These records should be retained for a period of minimal one year.
- Depuration centres or tanks and distribution centres and establishments should only accept lots of live bivalve molluscs with documentation issued by or accepted by the official agency having jurisdiction. Where appropriate, this document should contain the following information
 - the gatherer's identity and signature;
 - the date of harvesting;
 - common and/or scientific name and quantity of bivalve molluscs;
 - the location of the growing area and the status of this area (suitable for harvesting for direct human consumption, suitable for relaying, suitable for depuration, suitable for approved processing to reduce or limit target organisms).
 - for distribution centres and establishments, if appropriate, the date and duration of depuration and the responsible's identity and signature.
 - for distribution centres and establishments, if appropriate, the date and duration of relaying, the location of the relaying area and the responsible's identity and signature
- Complete records of harvest area and date of harvest and length of time of relaying or depuration of each lot should be maintained by the distribution centre or establishment for a period designated by the official agency having jurisdiction.

7.10 LOT IDENTIFICATION AND RECALL PROCEDURES

Refer also to Section 3.7

- "Each product should have an easy identifiable lot number. This lot number must include an identification code, the number of the establishment that distributes the product, the country of origin and day and month of packing, in order to facilitate the traceability/product tracing of the product. A record keeping system should be based on these lot numbers so that individual lots of bivalve molluscs can be traced from the growing area to the end user.
- .

SECTION 13 - PROCESSING OF LOBSTERS

In the context of recognising controls at individual processing steps, this section provides examples of potential hazards and defects and describes technological guidelines, which can be used to develop control measures and corrective action. At a particular step only the hazards and defects, which are likely to be introduced or controlled at that step, are listed. It should be recognised that in preparing a HACCP and/or DAP plan it is essential to consult Section 5 which provides guidance for the application of the principles of HACCP and DAP analysis. However, within the scope of this Code of Practice it is not possible to give details of critical limits, monitoring, record keeping and verification for each of the steps since these are specific to particular hazards and defects.

This section applies to lobsters in the genus *Homarus*, and to rock lobsters, spiny lobsters, and slipper lobsters in the genera *Palinurida*, and *Scyllaridea*, and to squat lobsters in the genera *Cervimundia* and *Pleuronocodes*, and the Norwegian lobster, *Nephrops norvegicus*.

13.1 GENERAL – ADDITION TO PRE-REQUISITE PROGRAMME

In addition to the pre-requisite programme outlined in Section 3 of this document, the processing facility operators are encouraged to evaluate the design and construction of their facility and the maintenance and sanitation of their operation, specific to the processing of lobsters. Consideration should be given to the following:

13.1.1 Design and Construction of Equipment and Utensils

- in batch systems the inactivation tank, cooker and cooling tank should be located adjacent to each other and may be provided with an overhead hoist or gantry provided to transfer baskets from one to the other;
- cookers should be designed to provide constant and adequate supply of heat so that all lobsters could be given the same time/temperature exposure during the cooking operation;
- a chamber of adequate length, through which an open link conveyor passes and which is equipped with spray nozzles so that the lobsters are sprayed from all sides, may be used for the purpose.

13.1.2 Hygiene Control Programme

- When an establishment has its own supply of fresh water or seawater or other water sources, and chlorine is used for water treatment, the residual content of chlorine should not exceed that of potable water.
- water, which has been in contact with lobsters, should not be re-used unless reconditioned to avoid taint problems;
- it is undesirable for the same workers to handle the raw as well as the cooked product. If this is unavoidable, stringent precautions should be taken to prevent cross contamination of the cooked product by micro-organisms from raw material;

13.2 General Considerations for the Handling of Lobsters

Refer to Section 4 – General Considerations for the Handling of Fresh Fish and Shellfish.

13.2.1. Potential Hazards and Defects Associated with Lobsters

Refer also to Section 4.1 Potential Hazards Associated with Fresh Fish and Shellfish and Section 5.3.3.1 Identification of Hazards and Defects

13.2.1.1 Potential Hazards

Bacteria

Staphylococcus aureus is an aerobic or facultatively anaerobic gram positive spherical micro-organism. It is coagulase-positive and ferments glucose. Some strains can produce enterotoxins.

Staphylococcus is not found in the normal microflora on fish. The natural habitat for this organism is the skin and mucous membranes of animal and man. The presence of *Staphylococcus* on fish is an indication of post-harvest contamination due to poor personal hygiene. The organism is a poor competitor and will not

multiply in fish. However, in fish or shellfish products, where the normal flora is reduced or eliminated (i.e. cooked peeled shrimp or crab meat), the presence of staphylococci indicates a potential for food poisoning.

Listeria monocytogenes is widely dispersed in the environment and foods. The organism is not exceedingly heat resistant and is killed by proper cooking. *L. monocytogenes* can grow in the presence or absence of oxygen and can survive in salt concentrations up to 10% NaCl. It can also endure frozen storage. An important factor in foodborne listeriosis is that the pathogen can grow to significant numbers at refrigeration temperatures when given sufficient time.

Despite the fact that a wide variety of foods may be contaminated with *L. monocytogenes*, outbreaks and sporadic cases of listeriosis are predominately associated with ready to eat (RTE) foods. Although the data is limited, surveys suggest that RTE seafood such as cooked lobster, cooked crab and smoked fish have been found to contain this bacterium.

Chemical Hazards

Veterinary Drugs

Medicated feeds or drugs may be used to control the spread of aquatic animal diseases where lobsters and/or crabs are maintained and fed in holding pounds. Residues of veterinary drugs in excess of recommended guidelines should be considered as a potential hazard.

Biotoxins

PSP toxins (saxitoxins) have been identified in the hepato-pancreas of lobsters.

13.2.1.2 Potential Defects

Black discoloration. Black discoloration is caused by melanin formation most commonly in the ventral tail segment joints and muscle surrounding the pericardium. It develops in the integumentary tissues and muscle surfaces, but does not occur in the muscle meat tissue. The use of sulfating agents to prevent this discoloration is a common practice and may result in unacceptable residues. The potential for residues of sulfating agents leads to labelling requirements because these chemicals are common allergens.

13.2.2 Minimise the Deterioration of Lobsters - Handling

Refer also to Section 4.3 – Minimise the Deterioration of Fish – Handling

- it is generally known that under similar conditions, the quality of lobsters deteriorate more rapidly than fish and therefore care in maintaining the lobsters live prior to processing is strongly recommended;
- since lobster legs and other appendages can be easily broken and the damage can cause the risk of infection and weakening of the lobster, care should be taken to handle live lobsters at all times;
- tanks and wells for pounding live lobsters should be so placed and constructed as to ensure survival of the lobsters;
- live lobsters should be carefully packed in clean tanks, wells, crates, open-weave bag, or in boxes covered with wet sacking and held at as low a temperature as practicable, as required of varying species;
- holding tanks are regarded as a better method of storage for long-term handling than well storage;
- the use of clean Hessian or jute bags, for transport, is preferred. Bags made of woven synthetic material should not be used;
- where bags open weave are used for transport, precautions should be taken to avoid suffocation of lobsters due to slime or mud;
- care also should be taken to maintain the necessary humidity in holding the lobsters live in bags for transport;
- species, which mutilate each other, should have the claws banded as soon as possible after catching;
- if it is not possible to keep lobsters alive until the time of processing, lobsters should be killed. Tails should be carefully separated and cleaned before freezing or cooling down to the temperature of melting ice, which should be done as rapidly as possible.

13.3 Processing Operations – Lobsters

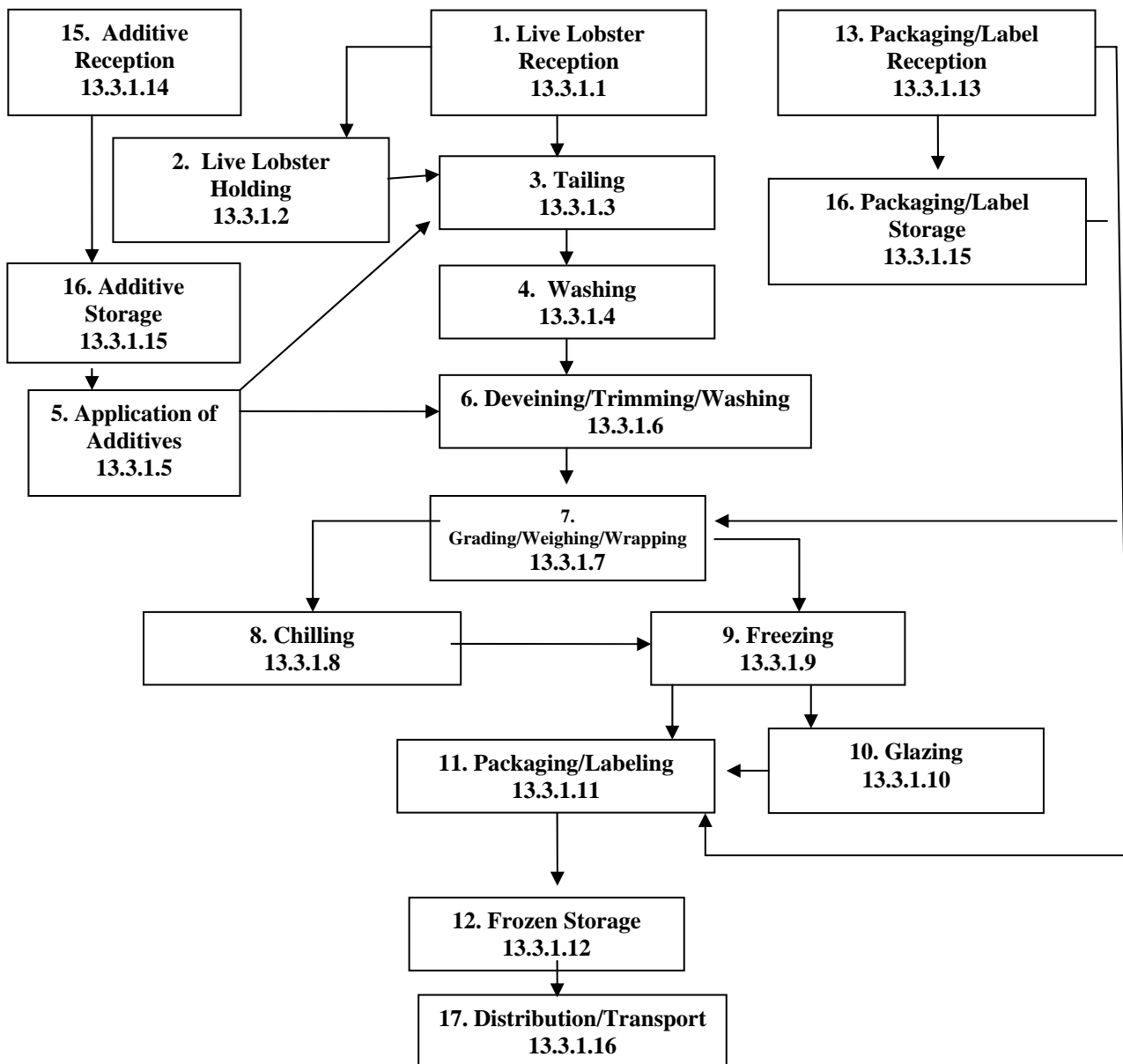
Once a processing facility has established a pre-requisite programme (Section 3) the principles of HACCP (Section 5) can be applied to each individual process within that facility.

This section provides two examples of products derived from lobsters. Special consideration was given to elaborate on products which involve heat treatment because of their potential impact on food safety (such as post processing handling). The products and their respective flow diagrams are as follows: Frozen Raw Lobster Tails (Fig. 13.1), Chilled Cooked Whole Lobster/Chilled Cooked Lobster Meat (Fig. 13.2). To provide an appreciation for other products of lobsters, a reference has been included in Appendix A and B.

This flow chart is for illustrative purposes only. For in-factory HACCP implementation a complete and comprehensive flow chart has to be drawn up for each process

This flow chart is for illustrative purposes only. For in-factory HACCP implementation a complete and comprehensive flow chart has to be drawn up for each process

Figure 13.1 Example of flow chart for frozen raw lobster processing



13.3.1 Frozen Raw Lobster Tail

13.3.1.1 Live Lobster Reception (Processing Step 1)

Potential Hazards:

Potential Defects: Reception of weak or injured lobsters, lobster decomposition

Technical Guidance:

- live lobsters should be inspected upon receipt to ensure that they are alive, which can be demonstrated by active leg movement and the tail of lobsters being curled lightly underneath the body when the lobster is picked up. Dead lobsters have a high probability of decomposition due to a high autolysis rate and should not be processed
- weak lobsters should be processed immediately;

- since lobster legs and other appendages can be easily broken and the damage can cause to risk of infection and weakening of the lobsters, care in handling should be applied to live lobsters at all times. The necessary skills should be acquired by lobster handlers;
- lobsters should be rejected if they are known to contain harmful or extraneous substances and/or defects which will not be eliminated or reduced to an acceptable level by normal procedures of sorting or preparation. An appropriate assessment should be carried out to determine the reason(s) for loss of control and the HACCP or DAP plan should be modified where necessary.

13.3.1.2 Live Lobster Holding (Processing Step 2)

Refer also to Section 13.2.2 – Minimise the Deterioration of lobsters – Handling, of this document. Refer also to “Section 6.1.2 – Growing Water Quality” and Section 6.3.2 Veterinary Drugs.

Potential Hazards: *Veterinary Drug Residues*

Potential Defects: *Lobster decomposition*

Technical Guidance:

- all live lobsters should be processed as soon as possible;
- storage time should be monitored where appropriate and should be as short as practical;
- to minimise damage, black discoloration (melanosis) and mortality losses during captivity, especially for the moulting stage of lobsters, over-crowding should be avoided and this can be achieved by controlling the stocking density;
- for short-term storage, live lobsters should be held in suitable containers and in land-based tanks and wells that should be supplied with running sea water, or in dry crates;
- dead whole lobsters should not be processed and should be rejected and disposed in a proper manner. An appropriate assessment should be carried out to determine the reason(s) for loss of control and the DAP plan should be modified where necessary.
- If drugs are used, appropriate withdrawal times must be followed.

13.3.1.3 Tailing (Processing Step 3)

Potential Hazards: *Microbiological contamination*

Potential Defects: *Improper tailing, decomposition*

Technical Guidance:

- when lobsters are not landed alive, the tail and cephalothorax should be separated immediately after catching. This practice is strongly recommended as they are brought on board. Tails should be carefully separated and cleaned before freezing or cooling down to the temperature of melting ice, which should be done as rapidly as possible;
- tailing should be carried out as rapidly as possible;

13.3.1.4 Washing (Processing Step 4)

Refer also to section 8.1.5 – Washing and Gutting.

Potential Hazards: *Unlikely*

Potential Defects: *Poor cleaning*

Technical Guidance:

- lobster tails should be washed in plenty of running potable water, or clean sea water, or water as outlined in 13.1.2, to remove all impurities;

13.3.1.5 Application of Additives to Lobster Tails (Processing Step 5)

Potential Hazards: *The use of non-approved additives; incorrect application of Sulphites¹.*

¹ List of additive names for “sulphites” and “phosphates” can be found in the Codex Standard for Quick Frozen Lobsters (Codex Stan. 95-1981.)

Potential Defects: *Physical contamination, black spots due to inadequate application of Sulphites⁷, incorrect application of Phosphates⁷.*

Technical Guidance:

- Mixing and application of appropriate additives should be carried out by trained operators;
- Regular checks of the additive levels should be carried out.
- Tails with black spots should be discarded.
- Non-approved additives should not be allowed in the processing facility.
- sulphites should be used in accordance with manufacturer's instructions and Good Manufacturing Practice.

13.3.1.6 De-veining/Trimming/Washing (Processing Step 6)

Refer to Section 8.1.5 – Washing and Gutting

Potential Hazards: *Microbiological contamination*

Potential Defects: *Incomplete de-veining, decomposition, dark membrane attached to the shell, physical contamination*

Technical Guidance:

- the intestine should be removed immediately and consideration should be given to use methods such as ejection by water pressure, vacuum, or physical removal by appropriate utensils (such as scissors, knives or extractors);
- skills should be acquired by lobster handlers with particular attention being given to the removal of membrane and blood from the front end of the tail where the meat is exposed;
- an adequate supply of clean water or potable water should be available for the washing of de-veined and trimmed lobster tails to ensure that no remnants of the gut or its contents remain;
- the de-veined or trimmed lobster tails should be washed and well iced or appropriately chilled in clean containers and stored in specially designated and appropriate areas within the processing facility;
- the de-veining process should be carried out quickly to prevent product spoilage. Tails waiting for de-veining should be kept on ice or refrigerated at 4°C or less.

13.3.1.7 Grading/Weighing /Wrapping (Processing Step 7)

Potential Hazards: *Microbiological contamination*

Potential Defects: *Incorrect net weight, inadequate wrapping, inappropriate packaging material, incorrect grading*

Technical Guidance:

- lobster tails should be graded into species, sizes and weights for the relevant market, to assure the economic integrity of the final product;
- calibrated balances should be provided for accurate grading;
- balances should be calibrated periodically with a standardized weight to ensure accuracy;
- packaging material should be clean, sound, durable, sufficient for its intended use and of food grade material;
- the wrapping and packaging operation should be conducted in a sanitary manner to avoid contamination of the product;
- care should be taken to ensure that the front end of tail where the meat is exposed is completely wrapped to protect against dehydration;
- weights of finished packages should be monitored at regular intervals to assure that they are the proper net weight.

13.3.1.8 Chilling (Processing Step 8)

Refer to sections 4.2 – Time and Temperature Control.

Potential Hazards: Microbiological contamination

Potential Defects: Decomposition

Technical Guidance:

- for lobster tails, chilling in refrigerated sea water is not recommended because excessive salt penetration into the muscle will take place rapidly. However, refrigerated clean water systems can be used for rapid pre-cooling before freezing or storage in ice;
- chilling should take place as rapidly as possible to prevent microbiological growth and deterioration.

13.3.1.9 Freezing (Processing Step 9)

Refer to section 8.3.1 – Freezing Process

Potential Hazards: Unlikely

Potential Defects: Poor texture

Technical Guidance:

- air blast, liquid nitrogen, or other freezing methods should be rapid to produce high quality tails and to ensure that the textural qualities of the product are retained;

13.3.1.10 Glazing (Processing Step 10)

Refer to Section 8.3.2 – Glazing

Potential Hazards: Microbiological contamination

Potential Defects: Incomplete glaze, foreign matter

Technical Guidance:

- glaze water should be replaced regularly to ensure that a high bacterial load does not occur and to prevent build-up of foreign material;
- chilling of glaze water will result in a more uniform application of glaze that will better protect the product;

13.3.1.11 Final Packaging/Labelling (Processing Step 11)

Refer to Section 8.2.3 – Labelling.

Potential Hazards: Absence of labelling of allergenic additives

Potential Defects: Subsequent dehydration, incorrect labelling.

Technical Guidance:

- packaging material should be clean, sound, durable, sufficient for its intended use and of food grade material;
- care should be taken to ensure that the front end of tail where the meat is exposed is completely wrapped to protect against dehydration.
- where sulphites were used in the process, care should be taken to ensure that this additive is properly declared on the label.

13.3.1.12 Frozen Storage (Processing Step 12)

Refer to Section 8.1.3 – Frozen Storage

Potential Hazards: Unlikely

Potential Defects: Freezer burn, dehydration.

Technical Guidance:

- products should be properly packaged to protect against freezer burn and dehydration;
- glaze is recommended as a further measure to ensure against dehydration;

13.3.1.13 Packaging and Label Reception (Processing Step 13)

Refer to section 8.5.1 – Reception – Packaging, Labels & Ingredients

Potential Hazards: Unlikely

Potential Defects: Contaminated packaging, incorrect labels.

Technical Guidance:

- packaging materials should be examined for signs of contamination;
- labels should be examined for accuracy and to adherence to applicable regulations;

13.3.1.14 Additives Reception (Processing Step 15)

Refer to section 8.5.1 – Reception – Packaging, Labels & Ingredients

Potential Hazards: Biological, chemical and physical contamination

Potential Defects: Contamination, mislabelling

Technical Guidance:

- Additive shipments should be examined to ensure that they are not contaminated and that the container integrity is sufficient;
- Additive shipments should be examined to ensure that they are the correct chemical and meet purchase specifications;

13.3.1.15 Additives, Packaging and Label Storage (Processing Steps 14 and 16)

Refer to Section 8.5.2 – Storage – Packaging, Labels & Ingredients.

Potential Hazards: Unlikely

Potential Defects: Contaminated additives or packaging material.

Technical Guidance:

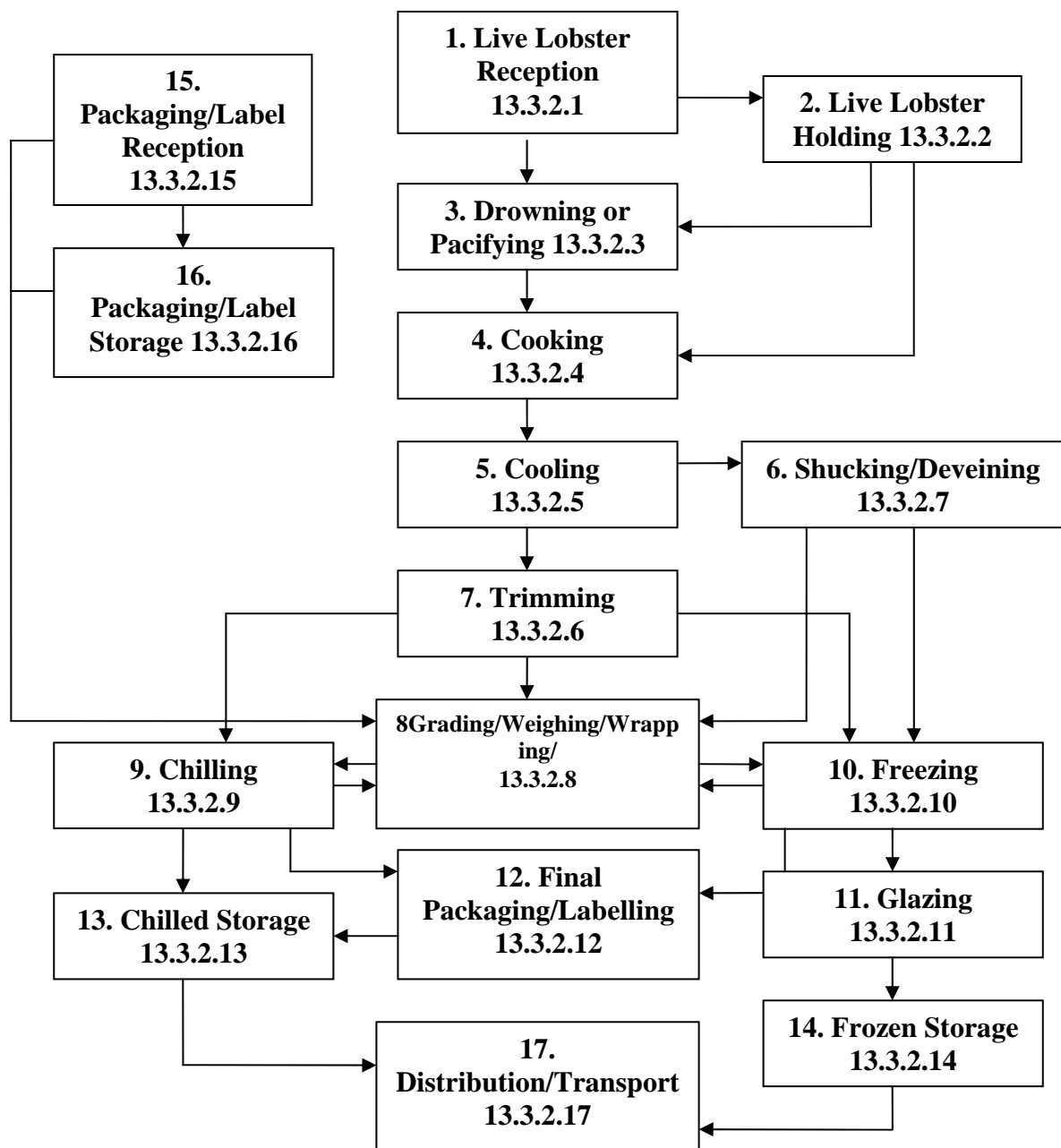
- food additives and packaging material should be protected from dust, dirt and other sources of contaminants;
- pests and insects should be excluded from the packaging storage area;

13.3.1.16 Distribution and Transport (Process Step 17)

Refer to Section 17 – Transport

This flow chart is for illustrative purposes only. For in-factory HACCP implementation a complete and comprehensive flow chart has to be drawn up for each process

Figure 13.2 Example of Flow Chart for Processing of Cooked Lobsters



13.3.2 Chilled and Frozen Cooked Whole Lobster and Cooked Lobster Meat

This section is designed with additional operation steps pertaining specifically to Cooked Whole Lobster and Cooked Lobster Meat.

13.3.2.1 Live Lobster Reception (Processing Step 1)

Refer to Subsection 13.3.1.1 of this document.

13.3.2.2 Live Lobster Holding (Processing Step 2)

Refer to subsection 13.3.1.4 of this document

13.3.2.3 Drowning or Pacifying (Processing Step 3)

Potential Hazards: Unlikely

Potential Defects: Unlikely

Technical Guidance:

- some species (not *Homarus*) are prepared for cooking by drowning suffocation in clean water with a low oxygen content or by immersing in chilled clean water;
- another possible process is an electric shock (pulse) in potable water, clean water or brine.

13.3.2.4 Cooking (Processing Step 4)

Potential Hazards: Microbiological contamination

Potential Defects: Over / undercooking

Technical Guidance:

- a cooking schedule for boiling or steaming should be designed which takes into consideration the appropriate parameters which can affect the cook such as time/temperature and size of the lobster;
- cooking should be carried out by appropriately trained personnel who have acquired the necessary skills to monitor and ensure that all lobsters are given the same time/temperature exposure and adequate heat penetration during the operation ;
- each cooker should be equipped with a suitable thermometer to show the cooking operation temperature. Fitting of a recording thermometer is strongly recommended. A simple device to indicate time of cooking should be supplied.
- lobsters should be cooked according to size until the shell is uniformly orange-red in colour, and depending on the product, until the meat can be easily removed from the shell. Overcooking causes the meat to shrink excessively, lower yields and undercooking makes it difficult to remove the meat from the shell;

13.3.2.5 Cooling (Processing Step 5)

Potential Hazards: Microbiological contamination

Potential Defects: Unlikely

Technical Guidance:

- cooling times should be kept as short as possible and every effort should be made to avoid contamination of the product during this period;
- cooling should be done in a proper manner, immediately after cooking, to end it uniformly throughout the batch and to avoid holding at temperatures which would encourage the growth of bacteria;
- cooling should be done in cold circulated air, running potable water or clean sea water;
- where lobsters are cooked on a continuous basis, cooling is also best done on a continuous basis;
- the same water should not be used for cooling more than one batch;

- shell removal should not be performed until the product has adequately cooled;
- care should be taken to ensure that cross contamination of cooked lobsters does not occur;
- cooked lobsters should be handled as a ready-to-eat product that has its normal microflora destroyed which can allow pathogens to proliferate.

13.3.2.6 Trimming (Processing Step 7)

Potential Hazards: Microbiological contamination

Potential Defects: Unlikely

Technical Guidance:

- an adequate supply of clean sea water, potable water or water as outlined in section 13.1.2 should be available to remove adhering coagulate protein. Spray washing on a conveyor is sometimes sufficient but it may be necessary to brush by hand. These methods can be combined;
- all surfaces and brushes should be frequently cleaned during operation in order to minimise the microbial activity of contact surface and utensils;

13.3.2.7 Shucking, De-veining and Washing (Processing Step 6)

Potential Hazards: Microbiological contamination

Potential Defects: Presence of shell fragments

Technical Guidance:

- the shucking and de-veining of cooked lobsters should be done quickly and carefully, in order to provide an attractive product;
- care should be taken to prevent cross-contamination of cooked product with raw lobster or any questionable material;
- depending on the vessel or processing facility product flow pattern and where a prescribed critical limit for staging time and temperature regime has been established for the control of hazards, the shucked or de-veined cooked lobster should be washed and appropriately chilled in clean containers and stored in specially designated and appropriate areas within the processing facility;
- lobster meat should be thoroughly washed on all surfaces in cold potable water, clean sea water or water as outlined in section 13.1.2;

13.3.2.8 Grading/Weighing/Wrapping (Processing Step 8)

Potential Hazards: Microbiological contamination

Potential Defects: Incorrect grading, inadequate wrapping, inappropriate packaging material, incorrect net weight

Technical Guidance:

- lobster should be graded into species, sizes and weights for the relevant market, to assure the economic integrity of the final product;
- lobster meats should be uniform in size;
- calibrated balances should be provided for accurate grading;
- balances should be calibrated periodically with a standardized weight to ensure accuracy;
- wrapping material should be clean, sound, durable, sufficient for its intended use and of food grade material;

13.3.2.9 Chilling (Processing Step 9)

Refer to sections 4.2 – Time and Temperature Control.

Potential Hazards: Microbiological contamination

Potential Defects: Deterioration

Technical Guidance:

- chilling lobsters in refrigerated sea water is not recommended because excessive salt penetration into the muscle will take place rapidly. However, refrigerated clean water systems can be used for rapid pre-cooling before freezing or storage in ice;
- chilling should take place as rapidly as possible to prevent microbiological growth and deterioration.

13.3.2.10 Freezing (Processing Step 10)

Refer to section 8.3.1 – Freezing Process

Potential Hazards: Unlikely

Potential Defects: Unlikely

Technical Guidance:

- air blast, liquid nitrogen, or other freezing methods should be rapid to produce high quality whole lobsters and lobster meats to ensure that the textural qualities of the product are retained;

13.3.2.11 Glazing (Processing Step 11)

Refer to Section 13.3.1.10 of this document

13.3.2.12 Final Packaging/Labelling (Processing Step 12)

Refer to Section 8.2.3 – Labelling.

Potential Hazards: Absence of labelling of allergenic additives

Potential Defects: Subsequent dehydration, incorrect labelling.

Technical Guidance:

- packaging material should be clean, sound, durable, sufficient for its intended use and of food grade material;
- care should be taken to ensure that exposed lobster meats are completely wrapped to protect against dehydration.

13.3.2.13 Chilled Storage (Processing Step 13)

Refer to Section 8.1.2 – Chilled Storage

Potential Hazards: Microbiological contamination

Potential Defects: Decomposition, foreign matter

Technical Guidance:

- temperatures in chilled storage should be 4° C or less;
- product should be properly protected to avoid contamination by condensates and splashing water;

13.3.2.14 Frozen Storage (Processing Step 14)

Refer to Section 13.3.1.12 of this document.

13.3.2.15 Packaging/Label Reception (Processing Step 15)

Refer to Section 13.3.1.13 of this document.

13.3.2.16 Packaging/Label Storage (Processing Step 16)

Refer to Section 8.5.2 – Storage – Packaging, Labels & Ingredients.

Potential Hazards: Unlikely

Potential Defects: Contaminated Packaging Material.

Technical Guidance:

- packaging material should be protected from dust, dirt and other sources of contaminants;
- Pests and insects should be excluded from the packaging storage area;

13.3.2.17 Distribution and Transport (Process Step 17)

Refer to Section 17 –Transport

APPENDIX III**DRAFT STANDARD FOR LIVE AND RAW BIVALVE MOLLUSCS****(At Step 8 of the Procedure)****1. SCOPE**

This standard applies to live bivalve molluscs and to raw bivalve molluscs that have been shucked and/or frozen, and/or processed to reduce or limit target organisms while essentially retaining the sensory characteristics of live bivalve molluscs. Raw bivalve molluscs are marketed either in a frozen or chilled state. Both live and raw bivalve molluscs may be intended for direct consumption or further processing. The standard does not apply to scallops when the final product is the adductor muscle only.

Part I below applies to live bivalve molluscs while Part II applies to raw bivalve molluscs.

PART I – LIVE BIVALVE MOLLUSCS**I-2. DESCRIPTION****I-2.1 Product Definition**

Live bivalve molluscs are products that are alive immediately prior to consumption. Presentation includes the shell.

I-2.2 Process Definition

Live bivalve molluscs are harvested alive from a harvesting area either approved for direct human consumption or classified to permit harvesting for an approved method of purification, e.g. relaying or depuration, prior to human consumption. Both relaying and depuration must be subject to appropriate controls implemented by the official agency having jurisdiction.

I-2.3 PRESENTATION

Any presentation of the product shall be permitted provided that it:

- meets all requirements of this standard; and
- is adequately described on the label to avoid confusing or misleading the consumer.

The bivalve molluscs may be packed by weight, count, count per unit of weight, volume or per package.

I-3. ESSENTIAL COMPOSITION AND QUALITY FACTORS**I-3.1 Bivalve Molluscs**

Live bivalve molluscs should possess organoleptic characteristics associated with freshness, as well as an adequate response to percussion (i.e. the shellfish will close by themselves when tapped) and freedom from extraneous matter, as determined by specialists familiar with the species concerned.

I-3.2 Final Product

Live bivalve molluscs shall meet the requirements of this standard when lots examined in accordance with Section I-10 comply with the provisions set out in Section I-9. Live bivalve molluscs shall be examined by the methods given in Section I-8.

I-4. FOOD ADDITIVES

Food additives are not permitted in live bivalve molluscs.

I-5. CONTAMINANTS

I-5.1 The products covered by this Standard shall comply with the Maximum Levels of the Codex General Standard for Contamination and Toxins in Foods (CODEX/STAN 193-1995) and the maximum residue limits for pesticides and veterinary drugs established by the CAC.

I-5.2 The following provisions apply to the edible parts of live bivalve mollusc (the whole part or any part intended to be eaten separately)

Name of biotoxin groups	Maximum level /kg of mollusc flesh
Saxitoxin (STX) group	≤0.8 milligrams (2HCL) of saxitoxin equivalent
Okadaic acid (OA) group	≤0.16 milligrams of okadaic equivalent
Domoic acid (DA) group	≤20 milligrams domoic acid
Brevetoxin (BTX) group	≤200 mouse units or equivalent
Azaspiracid (AZP) group	≤0.16 milligrams

I-6. HYGIENE AND HANDLING

I-6.1 It is recommended that the products covered by provisions of this standard be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1 – 1969), the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003) and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

I-6.2 The products should comply with any microbiological criteria established in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

I-6.3 Growing area monitoring programs, irrespective of the type of indicator bacteria used, must ensure that live bivalve molluscs destined for direct human consumption meet the *E.coli* limit as identified below when tested in accordance with an MPN method specified in ISO 16649-3 or equivalent.

I-6.4 In analysis involving five (5) 100g samples of the edible parts (the whole part or any part intended to be eaten separately), none may contain more than 700 *E. coli* and not more than one (1) of five (5) samples may contain between 230 and 700 *E.coli*, or equivalent as decided by the competent authority having jurisdiction

Microorganism = *Escherichia coli* n=5 c=1 m=230 M=700 3 Class Plan

where ‘n’= the number of sample units, ‘c’= the number of sample units that may exceed the limit ‘m’, and ‘M’ is the limit which no sample unit may exceed.

I-6.5 In analysis involving five (5) 25g samples of the edible parts (the whole part or any part intended to be eaten separately), no sample may indicate the presence of *Salmonella* when tested using a method validated against the reference method ISO 6579.

Microorganism = *Salmonella* n=5 c=0 m=0/25g 2 Class Plan

where n = number of samples that must conform to the criteria; c = the maximum allowable number of defective sample units; m = a microbiological limit which separates good quality from defective quality.

I-6.6 Where the microbiological criteria are not met, actions should be taken as deemed appropriate by the competent authority. In following up, consideration should be given to detention, recall and further processing in a manner to eliminate the hazard from implicated lots. In addition, assessment of the status of harvesting areas and/or establishment controls should be undertaken.

I-7. LABELLING

In addition to the provisions of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) the following specific provisions apply:

I-7.1 The Name of the Food

The name of the food to be declared on the label shall be the common or usual name of the species of bivalve molluscs in accordance with the law and custom of the country in which the food is sold and in a manner not

to mislead the consumer.

I-7.1.1 There shall appear on the label, reference to the presentation provided for in Section I-2.3- Presentation in close proximity to the name of the product in such descriptive terms that will adequately and fully describe the nature of the presentation of the product to avoid misleading or confusing the consumer.

I-7.1.2 In addition to the specified labelling designations above, the usual or common trade names of the variety may be added so long as it is not misleading to the consumer in the country in which the product will be distributed.

I-7.2 Content Declaration

Live bivalve molluscs shall be labelled by weight, count, count per unit weight, or volume as appropriate to the product.

I-7.3 Storage Instructions

The label shall specify the conditions for storage and/or temperature that will maintain the product safety/viability during transportation, storage and distribution.

I-7.4 Labelling of Non-retail Containers

Labelling for live bivalve molluscs shall contain the following information::

- (i) Identification of the product by common and/or scientific names as determined by the competent authority. The country where the product is sold can determine if the scientific name must be indicated on the label.
- (ii) Information that might be needed in the event of a food safety problem, including lot identification which could be lot code or date and location of harvest, information about harvest area, date of harvesting, purification or relaying as appropriate, as well as identification of the despatch centre or other establishment from which they were shipped.
- (iii) Durability or shelf life.

Date of minimum durability may be replaced by the statement "Bivalves must be alive when sold".

I-8. SAMPLING, EXAMINATION AND ANALYSES

I-8.1 Sampling

- (i) Each sample shall contain a sufficient number of bivalve molluscs to ensure that the sample is representative.
- (ii) The portion of the bivalve mollusc analysed should be the edible part. This is generally the whole tissue. Where whole-tissue analysis is not possible or practical, the most contaminated tissue (e.g. the digestive gland) may be dissected and analysed and the results converted to an edible tissue basis. The conversion factor should be supported by adequate data.

I-8.2 Sensory and Physical Examination

Samples taken for sensory and physical examination shall be assessed by persons trained in such examination and in accordance with procedures elaborated in Sections I-7.3 through I-7.5, and Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories" (CAC/GL 31-1999).

I-8.3 Determination of Count per Unit Weight or Volume

When declared on the label, the count of bivalve molluscs shall be determined by counting the numbers of bivalve molluscs in the container or a representative sample thereof and dividing the count of bivalve molluscs by the actual weight/volume to determine the count per unit weight or volume.

I-8.4 Method of Analysis of *Escherichia coli* in bivalve molluscs

The ISO/TS 16649-3 – Horizontal method for the enumeration of beta-glucuronidase-positive *Escherichia coli* – Part 3: Most probable number technique using 5-bromo-4-chloro-3-indolyl-beta-D-glucuronide or other validated methods in accordance with the protocol set out in the ISO 16140 or other internationally accepted similar protocol.

I-8.5 Method of Analysis of *Salmonella* in bivalve molluscs

The methods to be employed for *Salmonella* should be ISO 6579, or other validated methods that provide

equivalent sensitivity, reproducibility and reliability.

I-8.6 Determination of Biotoxins

Provision	Methodology	Principle	Type
Saxitoxin group	AOAC Official Method 2005.06 (Paralytic Shellfish Poisoning Toxins in Shellfish) four matrices and 12 toxins	LC-FL	II

I-9 DEFINITION OF DEFECTIVES

A sample unit shall be considered as defective when it exhibits any of the properties defined below.

I-9.1 Foreign Matter

The presence in the sample unit of any matter which has not been derived from bivalve molluscs, does not pose a threat to human health and is readily recognized without magnification or is present at a level determined by any method including magnification, that indicates non-compliance with good manufacturing and sanitation practices.

I-9.2 Dead or Damaged Product

The presence of dead or damaged product. Dead product is characterised by no response to percussion (i.e. shellfish will close by themselves when tapped). Damaged product includes product that is damaged to the extent that it can no longer function biologically. A Sample unit shall be considered defective if dead or damaged bivalve molluscs exceed 5% by count.

I-10 LOT ACCEPTANCE

A lot shall be considered as meeting the requirements of this standard when:

- (i) the total number of defectives as classified according to section I-8 does not exceed the acceptance number (c) of the appropriate sampling plan in the General Guidelines on Sampling (CAC/GL 50-2004);
- (ii) the total number of sample units not meeting the count designation as defined in section I-7.3 does not exceed the acceptance number (c) of the appropriate sampling plan in the General Guidelines on Sampling (CAC/GL 50-2004);
- (iii) the average net weight of all sample units is not less than the declared weight, provided there is no unreasonable shortage in any individual container;
- (iv) the Food Additives, Contaminants, Hygiene and Labelling requirements of Sections I-4, I-5, I-6 and I-7 are met.

PART II – RAW BIVALVE MOLLUSCS

II-2 DESCRIPTION

II-2.1 Product Definition

Raw bivalve molluscs processed for direct consumption or for further processing are products that were alive immediately prior to the commencement of processing and comply with Section I-2.2 relating to harvesting, purification and relaying. They have been shucked and/or frozen and/or processed to reduce or limit target organisms while essentially retaining the sensory characteristics of live bivalve molluscs. Raw bivalve molluscs are marketed in a frozen or chilled state.

II-2.2 Process Definition

Raw bivalve molluscs must meet the process definition in I-2.2 before they can be processed for direct consumption or further processing.

Bivalve molluscs that have been processed to reduce or limit target organisms while essentially retaining the sensory characteristics of live bivalve molluscs are ones that have been processed to assure reduction or

limitation of the target organisms to the satisfaction of the official agency having jurisdiction.

II-2.3 Presentation

Any presentation of the product shall be permitted provided that it:

- meets all requirements of this standard; and
- is adequately described on the label to avoid confusing or misleading the consumer.

The bivalve molluscs may be packed by weight, count, count per unit of weight, volume or per package.

II-3 ESSENTIAL COMPOSITION AND QUALITY FACTORS

II-3.1 Raw Bivalve Molluscs

Raw bivalve molluscs shall be of a quality fit for human consumption.

II-3.2 Ingredients

The packing medium and all other ingredients used shall be of food grade quality and conform to all applicable Codex standards.

II-3.3 Final Product

Raw bivalve molluscs shall meet the requirements of this standard when lots examined in accordance with Section II-9 comply with the provisions set out in Section II-8. Raw bivalve molluscs shall be examined by the methods given in Section II-7.

II-4 FOOD ADDITIVES

Only the use of the following additives is permitted in raw bivalve molluscs.

Antioxidants

For chilled shucked molluscs any antioxidant listed in food category 09.1.2 (Fresh Molluscs, crustaceans and echinoderms) of the General Standard for Food Additives (CODEX STAN 192-1995).

For raw frozen molluscs any antioxidant listed in food category 09.2.1 (Frozen fish, fish fillets, and fish products, including molluscs, crustaceans, and echinoderms) of the General Standard for Food Additives (CODEX STAN 192-1995).

II-5 CONTAMINANTS

Raw bivalve molluscs should meet the requirements of I-5

II-6 HYGIENE AND HANDLING

Raw bivalve molluscs should meet the requirements of I-6

II-7 LABELLING

In addition to the provisions of the Codex General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985) the following specific provisions apply:

II-7.1 The Name of the Food

The name of the food to be declared on the label shall be the common or usual name of the species of bivalve molluscs in accordance with the law and custom of the country in which the food is sold and in a manner not to mislead the consumer.

II-7.1.1 There shall appear on the label, reference to the presentation provided for in Section II-2.3- Presentation in close proximity to the name of the product in such descriptive terms that will adequately and fully describe the nature of the presentation of the product to avoid misleading or confusing the consumer.

II-7.1.2 In addition to the specified labelling designations above, the usual or common trade names of the variety may be added so long as it is not misleading to the consumer in the country in which the product will be distributed.

II-7.2 Content Declaration

Raw bivalve molluscs shall be labelled by weight, count, count per unit weight, or volume as appropriate to the product.

II-7.3 Storage Instructions

The label shall specify the conditions for storage and/or temperature that will maintain the food safety and characteristics of the product during transportation, storage and distribution including date of minimum durability and for date of shucking.

II-7.4 Labelling of Non-retail Containers

Refer to I-6.4 Labelling of Non-retail Containers.

II-7.4.1 Every package containing bivalve molluscs that have been processed to reduce or limit target organisms must be provided with a label certifying that all molluscs have been processed to reduce the target organism to levels acceptable to the official agency having jurisdiction.

II-7.4.2 Safety claims for bivalve molluscs processed to reduce or limit target organisms should be specific to the target organisms that have been reduced or limited as described in the Code of Practice. **II-8. SAMPLING, EXAMINATION AND ANALYSES**

II-8.1 Sampling

Sampling of lots for examination of net weight shall be carried out in accordance with an appropriate sampling plan meeting the criteria established by the CAC.

II-8.2 Sensory and Physical Examination

Samples taken for sensory and physical examination shall be assessed by persons trained in such examination and in accordance with procedures elaborated in Sections II-7.3 through II-7.7, and Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories" (CAC/GL 31-1999).

II-8.3 Determination of Net Weight and Drained Weight

The net weight and drained weight of all sample units shall be determined by the procedures described or mentioned in sections II-7.3.1 through II-7.3.5.

II-8.3.1 Determination of Net Weight

- (i) Weigh the unopened container;
- (ii) Open the container and remove the contents;
- (iii) Weigh the empty container, (including the end) after removing excess liquid and adhering meat;
- (iv) Subtract the weight of the empty container from the weight of the unopened container.
- (v) The resultant figure will be the total net content.

II-8.3.2 Determination of Net Weight of Frozen Products not Covered by Glaze

The net weight (exclusive of packaging material) of each sample unit representing a lot shall be determined in the frozen state.

II-8.3.3 Determination of Net Weight of Products Covered by Glaze

AOAC official method 963.18, Net Contents of Frozen Seafoods

II-8.3.4 The AOAC official method 963.26 should be used to determine the net weight of products with water added that is inside a "block-frozen" product.

II-8.3.5 Determination of Drained Weight

In the case of shucked bivalve molluscs, the drained weight shall be determined according to AOAC official method 953.11.

II-8.4 Determination of Count per Unit Weight or Volume

When declared on the label, the count of bivalve molluscs shall be determined by counting the numbers of bivalve molluscs in the container or a representative sample thereof and dividing the count of bivalve molluscs by the actual weight/volume to determine the count per unit weight or volume.

II-8.5 Sample Preparation

II-8.5.1 Procedures for Thawing

For frozen product, the sample unit is thawed by enclosing it in a film type bag and immersing in water at room temperature (not greater than 35 °C). The complete thawing of the product is determined by gently squeezing the bag occasionally so as not to damage the texture of the bivalve molluscs, until no hard core or ice crystals are left.

II-8.6 Methods of Analysis of *Escherichia coli*

Refer to I-8.4 Methods of Analysis of *Escherichia coli*

II-8.7 Method of Analysis of *Salmonella*

Refer to I-8.5 Method of Analysis of *Salmonella*

II-8.8 Determination of Biotoxins

Refer to I-7.5 Determination of Biotoxins

II-9 DEFINITION OF DEFECTIVES

The sample unit shall be considered as defective when it exhibits any of the properties defined below.

II-9.1 Deep Dehydration (Frozen Products)

Greater than 10% of the weight of the bivalve molluscs in the sample unit or greater than 10% of the surface area of the block exhibits excessive loss of moisture clearly shown as white or abnormal colour on the surface which masks the colour of the flesh and penetrates below the surface, and cannot be easily removed by scraping with a knife or other sharp instrument without unduly affecting the appearance of the bivalve molluscs.

II-9.2 Foreign Matter

The presence in the sample unit of any matter which has not been derived from bivalve molluscs, does not pose a threat to human health and is readily recognized without magnification or is present at a level determined by any method including magnification, that indicates non-compliance with good manufacturing and sanitation practices.

II-9.3 Odour/Flavour

Persistent and distinct objectionable odours or flavours indicative of decomposition or rancidity.

II-9.4 Texture

Textural breakdown of the flesh, indicative of decomposition, characterized by muscle structure that is mushy or paste-like.

II-10 LOT ACCEPTANCE

A lot shall be considered as meeting the requirements of this standard when:

- (i) the total number of defectives as classified according to section II-8 does not exceed the acceptance number (c) of the appropriate sampling plan in the General Guidelines on Sampling (CAC/GL 50-2004);
- (ii) the total number of sample units not meeting the count designation as defined in section II-2.3 does not exceed the acceptance number (c) of the appropriate sampling plan in the General Guidelines on Sampling (CAC/GL 50-2004);
- (iii) the average net weight of all sample units is not less than the declared weight, provided there is no unreasonable shortage in any individual container;
- (iv) the Food Additives, Contaminants, Hygiene and Labelling requirements of Sections II-4, II-5, II-6 and II-7 are met.