codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 6 **CX/FFP 03/7-Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS

Twenty-sixth Session
Ålesund, Norway, 13 - 17 October 2003

PROPOSED DRAFT CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS (SECTIONS 6, 7, 10 TO 15, 17 AND APPENDICES)

GOVERNMENT COMMENTS AT STEP 3
(United Kingdom, United States)

UNITED KINGDOM

SECTION 14 – PROCESSING OF SHRIMPS AND PRAWNS

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.

14.1 FROZEN SHRIMPS AND PRAWNS – GENERAL

- the term shrimp is the internationally recognised generic name for Paneus, Pandalus and Palamindae species.
- shrimps for frozen product originate from a wide variety of sources as varied as deep cold seas to shallow tropical inshore waters and rivers through to aquaculture in tropical and semi tropical regions.
- the methods of catching, or harvesting and processing are as equally varied. Species in northern regions may be caught by modern freezer vessels, cooked, individually quick frozen and packed on board in their final marketing form. More often however, they will be raw IQF on board for further processing at on-shore plants, or even landed chilled on ice. Shrimps of these species are invariably pre-cooked at onshore plants through in-line integrated process lines, followed by mechanical peeling, cooking, freezing, glazing and packing. On the other hand, Paneus species, or warm water shrimps are usually hand peeled before cooking and freezing. More common marketing formats for these shrimps however, are in raw presentations such as head-off shell-on, or as butterfly shrimps, where the head and shell, except for the tail swimmers, are removed and the body is split ventrally and longitudinally to yield an attractive presentation.
- warm water shrimps may also be subject to further added value processes such as marinading and batter and crumb coatings.
- since some raw shrimp products, as well as cooked ones, may be consumed without further processing safety considerations are paramount.

- the processes described above are captured on two flow charts, but it must be appreciated that because of the diverse nature of production methods individual HACCP/DAP plans must be devised for each product.
- Other than the previous description of on-board cooking, there is no reference to processing of shrimps at sea or in farms. It is assumed that product will be correctly handled and processed in line with the relevant sections in the code of practice and that where appropriate some element of pre-preparation, such as de-heading, will have taken place prior to receipt at processing plants.
- Fresh shrimps from estuaries, and shallow coastal waters should be processed as soon as possible after receipt, particularly from artisinal sources with limited facilities.

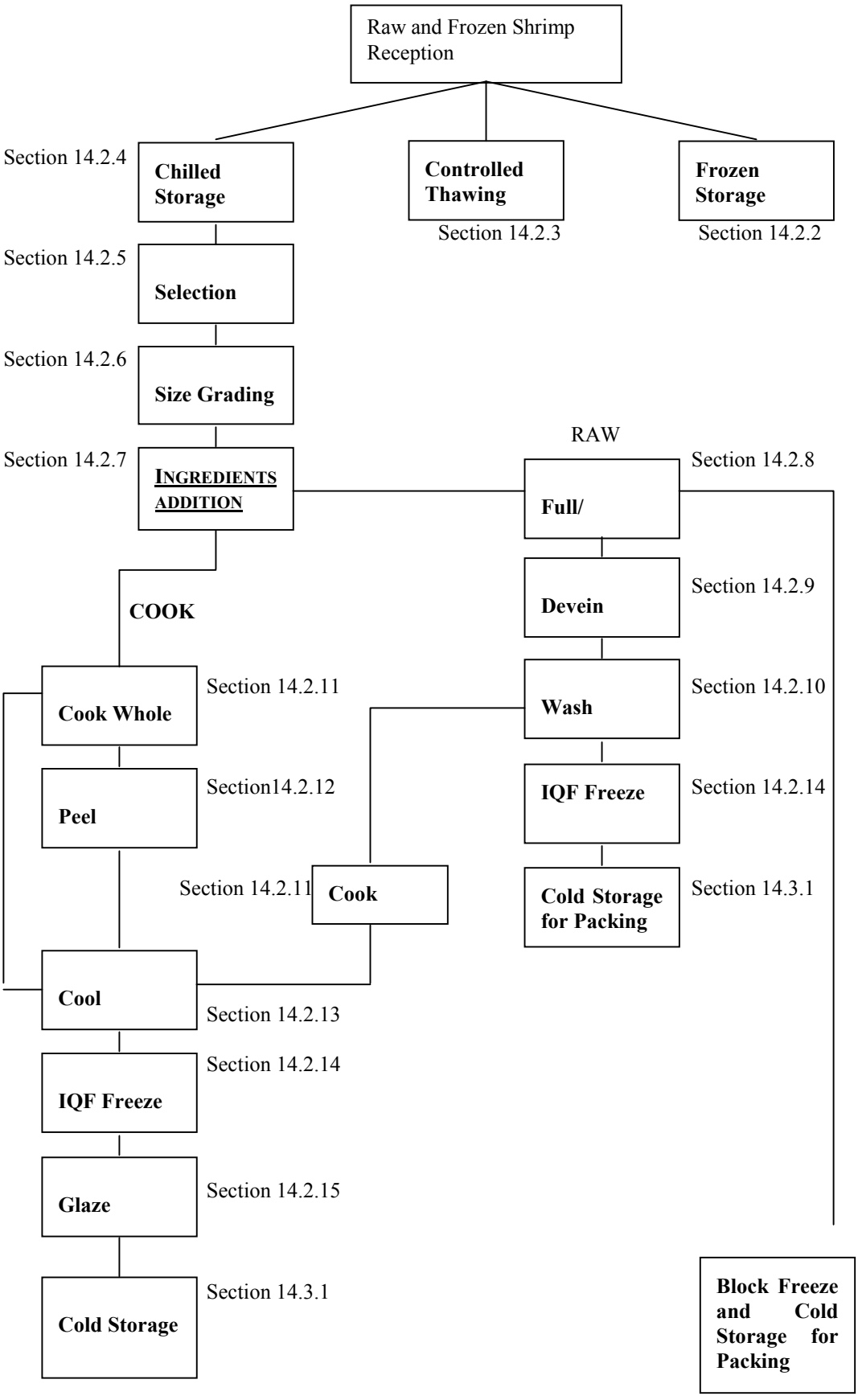


Figure 14.2 Process flow diagram for preparation of frozen shrimps via typical routes for cooked, whole, cooked and peeled and raw prepared and semi prepared products.

SHRIMP PREPARATION [PROCESSING STEPS 14.2.1 TO 14.2.15]

14.2.1 Raw Fresh and Frozen Shrimp Reception (Process Steps)

Potential Hazards: *phyto toxins (e.g. PSP)*
pathogens/Microbiological contamination
antibiotics/Pesticides
Potential Defects: *variable batch quality*
mixed species
taints
Technical Guidance:

- inspection protocols should be devised to cover identified quality , HACCP and DAP plan parameters together with appropriate training for inspectors to undertake these tasks.
- shrimps should be inspected upon receipt to ensure traceability and that they are well iced or deep frozen.
- the origin and previous known history will dictate the level of checking that may be necessary for, for example, phyto toxins in sea caught shrimps for potential antibiotics presence in aquaculture shrimps, particularly if there is no supplier assurance certification. In addition, other chemical indicators for heavy metals, pesticides and indicators of decomposition such as TVBN's may be applied.
- Microbiological checks should be undertaken.
- shrimps should be stored in suitable facilities and allocated use-by times for processing to ensure quality parameters are met in end products.

14.2.2 Frozen Storage

Potential Hazards: *unlikely*
Potential Defects: *protein denuration, dehydration*
Technical Guidance:

- protective packaging should be undamaged, otherwise repacking to exclude possibilities of contamination and dehydration.
- cold storage temperatures to be suitable for storage with minimum fluctuation.
- product to be processed within the best before time on the packaging, or before as dictated at reception.

14.2.3 Controlled Thawing

Potential Hazards: - *microbiological deterioration/contamination*
- *contamination from wrapping*
Potential Defects: *quality deterioration*
Technical Guidance:

- thawing processes may be undertaken from block frozen or IQF shrimps depending on the raw material source. The outer and inner packaging should be removed prior to defrosting to prevent contamination and extra care should be taken on block frozen prawns where inner wax or polyethylene packaging may be entrapped with blocks.
- thawing tanks should be purpose designed and allow for 'counter current' water defrosting where necessary to maintain lowest temperatures possible. However water re-use is discouraged.
- thawing water and ice should either be fresh or sea water of potable quality with a water temperature no higher than 20^{o}C (68^{o}F) by use of additional ice.
- thawing should be achieved as quickly as possible to maintain quality.
- it is desirable for the exit conveyor, leading from the defrost tanks, to be equipped with a series of low velocity sprays to wash the shrimps with chilled clean water.
- immediately after thawing, the shrimps should be re-iced or held in chill to avoid temperature abuse before further processing.

14.2.4 Chilled Storage

Potential Hazards: *unlikely*

Potential Defects: *quality deterioration*

Technical Guidance:

- chilled storage, preferably under ice in chill rooms at less than 4°C after reception.

14.2.4 Selection

Potential Hazards: *unlikely*

Potential Defects: *quality deterioration*

Technical Guidance:

- shrimps may be selected for different quality grades according to specification requirements. This should be undertaken with minimum of delay followed by re-icing of the shrimps

12.2.6 Size Grading

Potential Hazards: *microbiological*

Potential Defects: *quality deterioration*

Technical Guidance:

- size grading of shrimps is typically undertaken through mechanical graders of various degrees of sophistication. There is a possibility of shrimps becoming trapped in the bars of the graders so that regular inspection is required to prevent 'carry over' of old prawns and bacteriological contamination.
- Shrimp should be re-iced and stored in chill prior to further processing.

14.2.7 Addition of Ingredients and Use of Additives

Potential Hazards: *chemical and microbiological contamination*

Potential Defects: *quality deterioration*
ingredient quality
exceeding legislation standards

Technical Guidance:

- according to specification and legislation, certain treatments may be applied to shrimps to improve organoleptic quality, preserve yield or preserve them for further processing.
- examples would including sodium metabisulphite to reduce shell blackening, sodium benzoate to extend shelf-life between processes and sodium polyphosphates to maintain succulence through processing and prevent black spot after peeling, whilst common salt would be added as brine for flavour.
- these ingredients can be added at various stages, for instance common salt and sodium polyphosphates at defrost stages or chilled brine as a flume conveyor between cooking and freezing, or as glaze.
- at whatever stage ingredients are added, it is essential to monitor the process and product to ensure that any legislative standards are not exceeded, quality parameters are met and that where dip baths are used, the contents are changed on a regular basis according to drawn up plans.
- chill conditions to be maintained throughout.

14.2.8 Full and Partial Peeling

Potential Hazards: *microbiological cross contamination*
foreign bodies

Potential Defects: *quality deterioration*
shell fragments

Technical Guidance:

- this process applies mainly to warm water prawns and could be as simple as inspecting and preparing whole large prawns for freezing and down-grading blemished prawns for full peeling.
- other peeling stages could including full peeling or partial peeling leaving tail swimmers intact.

- whatever the process, it is necessary to ensure that the peeling tables are kept clear of contaminated shrimps and shell fragments with water jets and the shrimps are rinsed to ensure no carry over of shell fragments.

14.2.9 Deveining

Potential Hazards: *microbiological cross contamination*
metal contamination
foreign body contamination

Potential Defects: *objectionable matter*
quality deterioration

Technical Guidance:

- the vein is the gut which may appear as a dark line in the upper dorsal region of prawn flesh. In large warm water prawns, this may be unsightly, gritty and a source of bacterial contamination.
- removal of the vein is by razor longitudinally cutting along the dorsal region of the shrimp with a razor slide and removal of the vein by pulling. This may be partially achieved with head-off shell-on shrimps as well.
- this operation is considered to be a mechanical though labour intensive process so that:
- cleaning and maintenance schedules should be place and cover the need for clearing before, after and during processing by trained operatives.
- further, it is essential to ensure that damaged and contaminated shrimps are removed from the line and that no debris build up is allowed.

14.2.10 Washing

Potential Hazards: *microbiological contamination*

Potential Defects: *quality deterioration*
contamination

Technical Guidance:

- washing of peeled and deveined shrimps is essential to ensure that shell and vein fragments are removed.
- shrimps should be drained and chilled without delay prior to further processing.

14.2.11 Cooking Processes

Potential Hazards: *undercooking, microbiological cross contamination*

Potential Quality Defects: *under/over cooking*

Technical Guidance:

- the cooking procedure, in particular time and temperature, should be fully defined according to the specification requirements of the final product, for example whether it is to be consumed without further processing and the nature and origin of the raw shrimp and uniformity of size grading.
- the cooking schedule should be reviewed before each batch and where continuous cookers are in use, constant logging of process parameters should be available.
- only potable water should be used for cooking, whether in water or via steam injection.
- cooking temperatures should be monitored by selecting samples and recording the process in shrimps of the largest size used.
- maintenance and cleaning schedules should be available for cookers and all operations should only be undertaken by fully trained staff.
- adequate separation of cooked shrimps exiting the cooking cycle utilising different equipment is essential to ensure no cross contamination.

14.2.12 Peeling Cooked Prawns

Potential Hazards: *cross contamination*

Potential Defects: *presence of shell*

Technical Guidance:

- this is essentially a process for Pandalus species of cold water prawns and is a highly mechanised process in-line with cooking, cooling and freezing processes.
- cleaning and maintenance schedules should be available, implemented by fully trained staff to ensure efficient and safe processing are essential.

14.2.13 Cooling

Potential Hazards: *microbiological contamination*

Potential Defects: *unlikely*

Technical Guidance:

- cooked shrimps, should be cooled as quickly as possible to bring the temperature of the product to a temperature range limiting bacteria proliferation or toxin production
- cooling schedules should enable the time-temperature requirements to be met and maintenance and cleaning schedules should be in place and complied with by fully trained operatives.
- only cold/iced potable water should be used for cooling and should not be used for further batches, although for continuous operations a top-up procedure and maximum run-length will be defined.
- raw/cooked separation is essential.
- after cooling and draining, the shrimps should be frozen as soon as possible, avoiding any environmental contamination.

14.2.14 Freezing Processes

Potential Hazards: *mcrobiological*

Potential Defects: *slow freezing – textural quality and clumping of shrimps*

Technical Guidance:

- the freezing operation will vary tremendously according to the type of product. At its simplest, raw whole or head-off shrimps may be block or plate frozen in purpose-designed cartons into which potable water is poured to form a solid block with protective ice.
- cooked and peeled Pandalus cold water prawns, at the other extreme, tend to be frozen through fluidised bed systems, whilst many of the warm water shrimp products are IQF frozen either on trays in blast freezers or in continuous belt freezers.
- whichever the freezing process, it is necessary to ensure that the freezing conditions specified are met and that for IQF products, there is no clumping, i.e. pieces frozen together. Putting product into a blast freezer before it is at operating temperature may result in glazed, slow frozen product and contamination.
- freezers are complex machines requiring cleaning and maintenance schedules operated by fully trained staff.

14.2.15 Glazing

Potential Hazards: *microbiological cross-contamination*

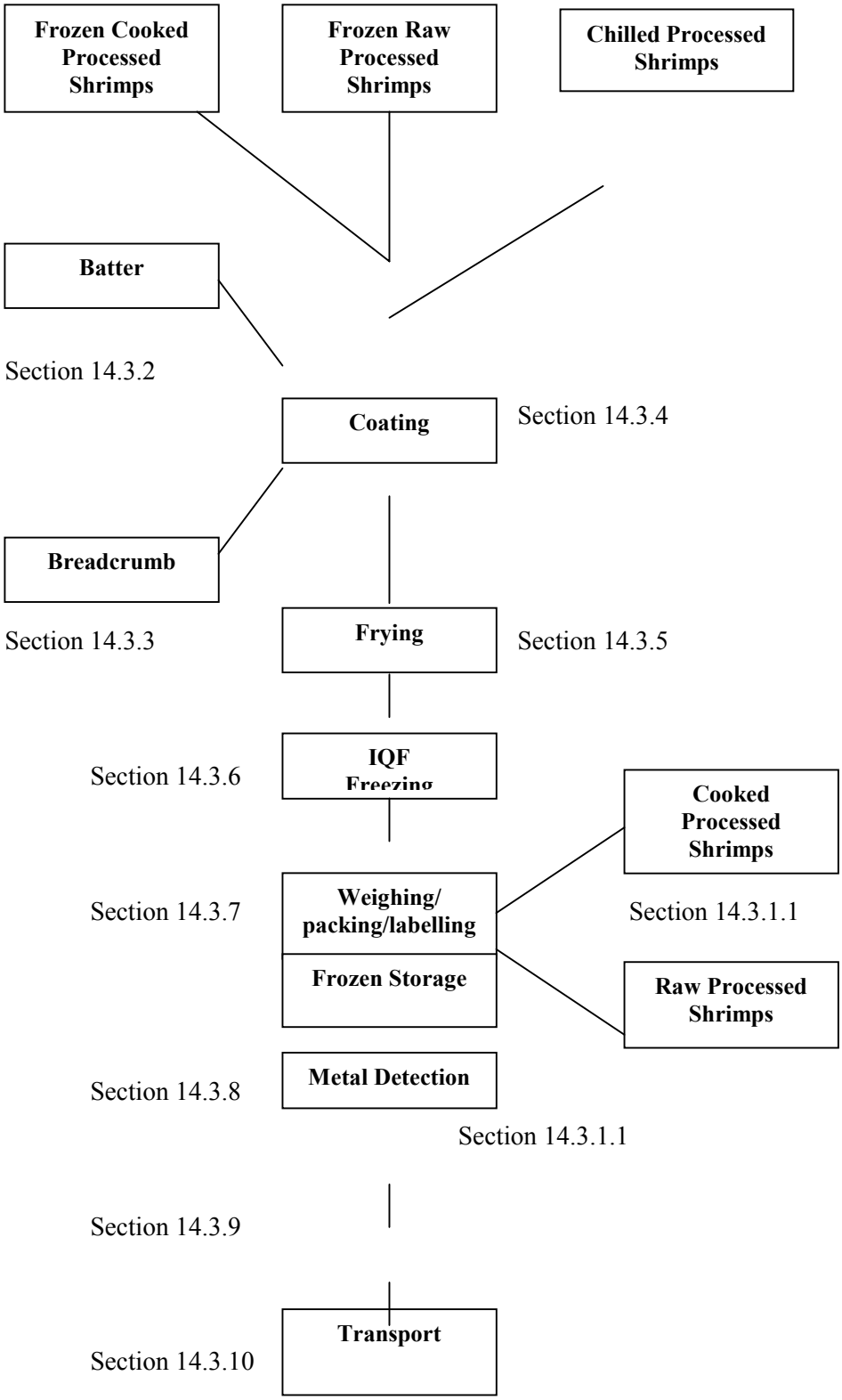
Potential Defects: *inadequate glaze, too much glaze, spot welding, incorrect labelling.*

Technical Guidance:

- glazing is applied to frozen shrimps to protect against dehydration and maintain quality during storage and distribution.
- ice block frozen shrimps is the simplest form of glazing, followed by dipping and draining frozen shrimps in chilled potable water. A more sophisticated process is to pass frozen size graded shrimps under cold-water sprays on vibratory belts such that the shrimps pass at a steady rate to receive an even and calculable glaze cover.

- ideally, glazed shrimps should receive a secondary re-freezing prior to packing, but if not, they should be packaged as quickly as possible and moved to cold storage. If this is not achieved, the shrimps may freeze together and 'spot weld' or clump as the glaze hardens.
- there are Codex methods for the determination of glaze.

14.3 Process flow diagram for further added-value shrimp product preparation and for packing, weighing and labelling of all products.



14.3.1 Further Processing and Packing

Potential Hazards: *microbiological and toxin production*

Potential Defects: *contamination by extraneous material*
poor quality coatings

14.3.4 Coated Product Production

Potential Hazards: *oil fire risks*
microbiological toxins

Potential Defects: *Incorrect coating pick ups and labelling issues*
burnt crumb coating
poor texture

Technical Guidance:

- the essential process flow for further processed added value coated products involves the use of cooked frozen shrimps, raw frozen shrimps or either of these taken chilled immediately from the process lines.
- where chill shrimp materials are used, the issues of quality and continued protein deterioration need to be taken into account.
- where frozen shrimp materials are used, steps should be taken to keep them frozen to preserve quality and texture. Note also that frozen shrimp material should not be glazed otherwise coatings will 'blow-off' on frying or cooking.

14.3.2 Batter

- batter ingredients powders should be checked against buying specification and ideally sieved before use to remove any packaging and extraneous materials.
- water should be potable and chilled
- batter mixing should be to preset recipes and viscosity checked to ensure correct for batter pick up required on product.
- note that bacterial toxin formation is a possibility in batter mixes so that usage times and temperatures should be set and cleaning schedules of equipment defined and maintained.
- tempura style batters may be used, in which case additional crumb coatings will probably not be applied. However, frying temperatures and times will be critical to ensure correct texture.
- where batter is for adherence of a crumb coating, formulation and viscosity will be different to tempura styles.

14.3.3 Breadcrumb

- Breadcrumb formulation and grist, or particle size will need to be checked against buying specification and stored according to supplier instructions to avoid stailing.

14.3.5 Frying

- Whilst frying is necessary for tempura batter coatings, it may not always be used for crumb coating operations, although it does ensure adhesion.
- Fryers should be operated by trained staff. Oil changed on a regular basis to avoid oxidative rancidity.
    - Oil temperatures should be controlled to avoid burning crumb or fire risks.

14.3.6 IQF

- Freezing conditions are typical of those described in 14.2.14

14.3.7 Weighing, Packing and Labelling of Al l Products

Potential Hazards: *unlikely*

Potential Defects: *incorrect labelling*
quality deterioration

Technical Guidance:

- all wrappings for products and packaging including glues and inks should have been specified to be food grade, odourless with no risk of substances likely to be harmful to health being transferred to the packed food.
- all food products should be weighed in packaging with scales appropriately tared to ensure correct weight.
- where products are glazed, coated or otherwise prepared, checks should be carried out to ensure the correct compositional standards to comply with legislation and packaging declarations.
- ingredients lists on packaging should declare presence of ingredients in the food product in descending order by weight, including any additives used and still present in the food.
- all wrapping and packaging should be carried out in a manner to ensure that the frozen products remain frozen and that temperature rises are minimal before transfer back to cold storage.

14.3.8 Metal Detection

Potential Hazard: *residual metal contamination*

Potential Defect:

Technical Guidance:

- products should be metal detected in final pack through machines set to the highest sensitivity possible.
- larger packs will be detected at a lower sensitivity than smaller packs so that consideration should be given to testing product prior to packing. However, unless potential re-contamination prior to packing can be eliminated, it is probably still better to check in-pack.

14.3.9 Storage of End Product

Potential Hazard: *none likely*

Potential Defects: *texture and flavour deviations due to fluctuations in temperature, deep freezer burn, cold store flavour, cardboard flavour*

Technical Guidance:

- all end products should be stored at frozen temperature in a clean, sound and hygienic environment.
- severe fluctuations of storage temperature (greater than $3^{o}C$) has to be avoided.
- too long storage time (depending on fat content of species used and type of coating) should be avoided.
- the facility should be capable of maintaining the temperature of the fish at or colder than $18^{o}C$ with minimal temperature fluctuations.
- the storage area should be equipped with a calibrated indicating thermometer. Fitting of a recording thermometer is strongly recommended.
- a systematic stock rotation plan should be developed and maintained.
- products should be properly protected from dehydration, dirt and other forms of contamination.
- all end products should be stored in the freezer to allow proper air circulation.

14.3.11 Transport of End Product

Potential Hazard: *none likely*

Potential Defects: *quality deterioration*

Technical Guidance:

- during all transportation steps deep-frozen conditions should be maintained $-18^{o}C$ (maximum fluctuation $+/-3^{o}C$) until final destination of product is reached.
- cleanliness and suitability of the transport vehicle to carry frozen food products should be examined.
- use of temperature recording devices with the shipment is recommended.

UNITED STATES

SECTION 6 – AQUACULTURE PRODUCTION

Recommended additional language within sentences highlighted in bold for the convenience of the reader. The United States of America has additional important concerns on some items in Subsections 6.3.1 and 6.3.2.

Figure 6.1 flow chart, insert an additional arrow from the Veterinary drugs box to the Feed box.

Reason: Veterinary drugs are administered directly to the growing fish and through the feed.

6.2 Identification of Hazards and Defects, 1st paragraph, last three sentences, revise to read: "In closed recirculation systems hazards **can be** even further reduced. In those systems, **it is imperative that** the water is constantly purified and reused and **that** water quality is controlled within safe measures. **Where such control exists,** there are hardly any disease outbreaks and mortality rates."

Reason: Outbreaks and high mortality have occurred in recirculation systems where control has not been maintained. As currently drafted, the sentences suggest that hazards are inherently reduced in closed recirculation systems. The suggested revision states that they can be reduced with good control.

6.3.1 Feed Supply, bullet 13 modify this bullet to read: "Farmers should follow manufacturers' instructions on the use of veterinary drugs **or medicated feeds**."

Reason: The instructions referred to may originate from drug as well as feed manufacturers.

6.3.2 Veterinary Drugs, bullet 2, modify this bullet to read: "Veterinary drugs **or medicated feeds** should be used according to drug or feed manufacturers' label instructions, with particular attention to withdrawal periods."

Reason: The manufacturers' can be either the drug manufacturer or the feed manufacturer.

6.3.2 Veterinary Drugs, bullet 8, remove the brackets and modify this bullet by removing the phrase, "so that these substances are not released into the surrounding environment" so that it reads: When using medicinal products and disinfectants at fish farms, special care should be exercised to minimize release of these substances into the surrounding environment.

Reason: too absolute as drafted; it would be impossible to comply with except in a recirculation system.

6.3.3 Growing bullet 10, move this bullet to section 6.3.1 (Feed Supply)

Reason: is more appropriate to section 6.3.1 at step 3 of the Code of Practice for Fish and Fishery Products.

SECTION 7 – BIVALVE MOLLUSCS

Definitions:

2.3 BIVALVE MOLLUSCS

Heat Shocking, add at the end of the first sentence, "**for the purpose of shucking**." Delete the brackets around the second sentence.

Reason: This change is to clarify that product that is heat shocked is not a "cooked" product. Because heat shocking is performed for the purpose of shucking, it will not deactivate targeted microbiological pathogens, as forms of post harvest treatment will do.

Purification: Change the definition to: "**means elimination, reduction, or limitation of target organisms to the satisfaction of the official agency having jurisdiction, without appreciably affecting the sensory characteristics of the product. Purification may include relaying, depuration and/or other forms of post harvest treatment such as low heat, application of hydrostatic pressure, irradiation, and individual quick freezing**."

Reason: Purification can be accomplished by several processes as determined by the competent authority. This definition applies to depuration, but also recognizes that other post harvest treatment processes are now

available in addition to depuration. It is important that Codex allow for, and acknowledge, the progress that is occurring in this area, and not restrict post harvest treatments to just depuration.

Depuration is one of several methods for purifying. We therefore suggest that the definition of **Purification** in the existing draft be used with minor changes to define **Depuration** as follows: "means the reduction of microorganisms from bivalve molluscs by the process of holding live bivalve molluscs, **typically in tanks**, for a period of time under approved, controlled conditions in natural or artificial sea water suitable for the process. **The sea water** may be treated or untreated."

Note: We have removed from the definition the concept that depuration can occur in floats and rafts because we associate floats and rafts with relaying rather than with depuration.

Relaying, suggest rewording "contaminated growing area to an acceptable growing or holding area under the supervision of the agency having jurisdiction…"; change to read "contaminated growing area to a **growing or holding area acceptable for direct consumption** under the supervision……".

Reason: for clarity that relaying can be to an open growing or holding area that the competent authority has deemed acceptable for direct consumption.

GENERAL COMMENTS & SUGGESTIONS

The United States recommends that the scope of Section 7 of the code include only live and raw bivalve molluscs for human consumption and for further processing. The "further processes" such as smoked, canned, marinated, etc. would be addressed in Codes of Practice for the respective processes. Those sections could reference other sections of Section 7 as needed.

The revisions recommended by the United States would result in a general reorganization of Section 7 as follows:

OUTLINE OF SUGGESTED REORGANIZATION OF SECTION 7

7.1 **GENERAL REMARKS, ADDITION TO THE PRE-REQUESITE PROGRAMME**

7.2 **CLASSIFICATION AND MONITORING OF GROWING AREAS**

7.2.1 **Classification of growing areas**

7.2.2 **Monitoring of growing areas**

72.2.1 E. coli/faecal coliforms/total coliforms

72.2.2 Salmonella

72.2.3 Marine biotoxin control

72.2.4 Chemical contaminants

7.3 **HARVESTING AND TRANSPORTATION OF LIVE BIVALVE MOLLUSCS**

7.4 **PURIFICATION OF BIVALVE MOLLUSCS**

7.4.1 **Relaying**

7.4.2 **Depuration in Tanks**

7.4.3 **Other Post Harvest Treatments**

7.5 **PROCESSING OF LIVE BIVALVE MOLLUSCS IN A DISTRIBUTION CENTRE OF AN ESTABLISHMENT**

7.5.1 **Reception**

7.5.2 **Conditioning and storage of bivalve mollusks in sea water tanks, basin, etc.**

7.5.3 **Washing, declumping, debyssing and grading**

7.6 **SHUCKING**

7.6.1 **Hand and Mechanical Shucking and Washing**

7.6.2 **Heat shocking of bivalve mollusks followed by packing**

7.7 PACKING AND LABELING

7.7.1 Live packing and Labeling

7.7.2 Packing and labeling (other than live)

7.8 STORAGE

7.8.1 Live Storage

7.8.2 Storage (other than live)

7.9 DISTRIBUTION

7.9.1 Distribution of live

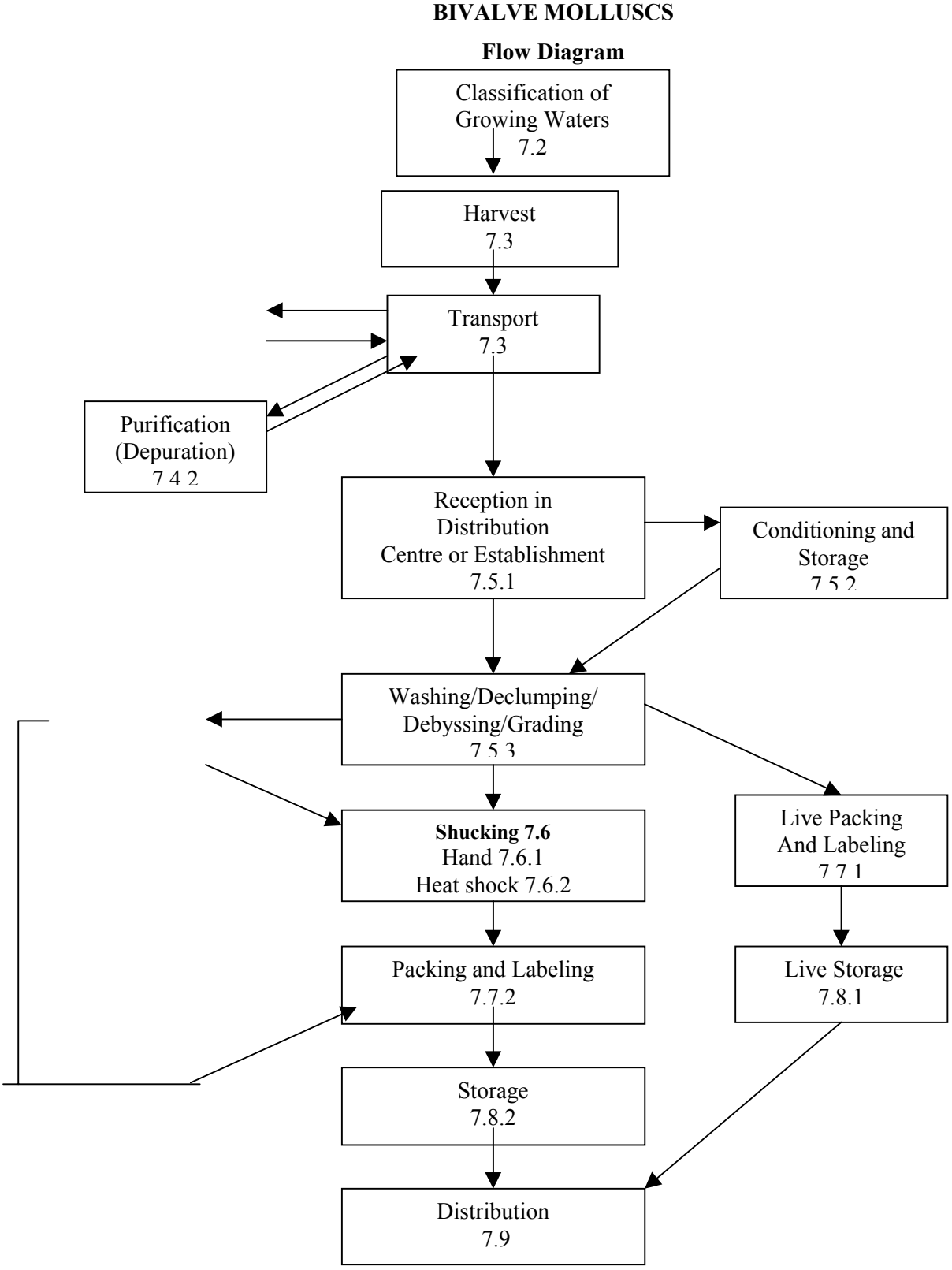
7.9.2 Distribution (other than live)

7.10 DOCUMENTATION

7.11 LOT IDENTIFICATION AND RECALL PROCEDURES

The revisions recommended by the United States would also result in a revised flow diagram as follows:

Figure 7.1 Example of a simplified flow diagram for the production of live bivalve molluscs.



SPECIFIC COMMENTS BY SECTIONS

7.1 GENERAL REMARKS, ADDITION TO THE PRE-REQUISITE PROGRAMME

7.1 para 3, next to last sentence, change all "bivalve molluscs" to "shellfish" when naming DSP, PSP, NSP and ASP because "shellfish" is in the name of the biotoxins.

Also, add "petrochemicals" in the last sentence following organochlorides.

7.1 para 5, suggest that it be revised to read: "Bivalve molluscs from waters subject to contamination **that is not sufficient to result in closure of the area, e.g. low levels of microbiological contamination**……suitable area or **by another** purification process to reduce the level of **target organisms**. **In addition to relaying, purification may involve depuration, heat treatment, hydrostatic pressure, individual quick freezing (IQF), or other forms of post harvest treatments, for the purpose of destroying target organisms. Depuration** is a short term process commonly used to reduce low levels of bacterial contamination ……"

Reason: Some of the recommendations are for clarification and are self-explanatory. With regard to "purification," Codex should recognize the progress being made in new forms of purification processes in addition to depuration and in addition to heat treatment.

7.1 para 6, first and last sentence, replace "purification" with "depuration" wherever it is used.

Reason: This sentence is relevant to depuration, but not to all possible forms of purification.

7.2 CLASSIFICATION AND MONITORING OF GROWING AREAS

7.2.1 Classification of growing areas, 6th para, second bullet, suggest that it be revised to read –" relaying in acceptable water **or another form of** purification in an approved purification centre, **e.g. depuration,** heat treatment**, hydrostatic pressure, IQF,** radiation;"

Reason: To emphasize that relaying is a form of purification, as are the other forms of post harvest treatment that are specifically mentioned—depuration, heat treatment, etc.

7.2.2 Monitoring of growing areas, second para, second sentence, delete everything after "…to monitor growing areas" and replace with: "…..**for species of plankton that can produce toxins and to recognize other environmental signals that a toxic event may be developing.**"

Reason: Clarity and to add that growing areas should be monitored for environmental factors.

7.2.2.1 *E. Coli*/faecal coliforms/total coliforms, second para, last sentence, suggest that it be revised to read "……contamination exceeds a certain threshold-level relaying or **other** purification, **including depuration,** for a time approved……"

7.2.2.1 third para, add a second sentence: "**Because they do not correlate well with the presence of viruses, other controls such as shoreline surveys should always be employed.**"

7.2.2.2 Salmonella, change title to "**Pathogen Monitoring,**" remove bracketed sentence and add text to read:

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, monitoring the shellfish meats may be appropriate as part of the process of 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.

Reason: The principles of harvest water classification, including reliance upon appropriate indicators, has been well established in shellfish safety programs. Studies are being conducted on how to improve monitoring, particularly for the control of virus pathogens for which there are data supporting the need of indicators other than the fecal coliforms as a means to assess the potential virus hazard. For routine harvest water monitoring, analysis for specific enteric bacterial pathogens has not been shown to be effective and, if relied upon as a primary criterion for water classification, could prove to be misleading. An extensive

literature on the strategy of harvest water classification exists. However, there may be situations where a "for cause" monitoring of a specific hazard can help determine the fitness of growing waters for the harvest of molluscs for direct consumption or for some form of purification post harvest treatment. Application of such non-routine monitoring should be done for situation specific occurrences and under established protocols for collection and application of the data to the decision on harvest controls.

7.2.2.3 Marine biotoxin control, para one, add the following sentence after the **first sentence**: "**Growing areas should also be monitored for environmental signals that a toxic event may be occurring, e.g., dead or dying birds, mammals, or fish.**"

7.3 HARVESTING AND TRANSPORTATION OF LIVE BIVALVE MOLLUSCS, second para, delete "relaying" and change the order of listing to "…….purpose of direct human consumption, purification, or further processing."

Reason: Relaying should be considered as one form of purification and not as something separate from purification. "Purification" is listed ahead of "further processing" because it would normally occur in advance of further processing.

7.3 *Potential Hazards*: delete "contamination with biotoxins"

Reason: Presence of biotoxins at hazardous levels would have been detected by monitoring and the authority would have closed the area to harvest under section 7.2.2.3.

7.3 *Technical Guidance,* third bullet, add two additional sentences at the end: "**No overboard discharge of waste, including human faecal material, should occur from harvest vessels in and around shellfish growing areas. No animals should be allowed on harvest vessels.**"

7.3 *Technical Guidance,* eighth bullet, replace "purification" with "depuration" and suggest revising the sentence to read: "……immersion in water for relaying, **depuration**, storage, or conditioning should be kept as short……."

Reason: To clarify that depuration is the form of purification that is being referred to here.

7.4 PURIFICATION OF BIVALVE MOLLUSCS, suggest adding a new section

Reason: Relaying, depuration and other post harvest treatments are forms of purification and will be included as subsections under the general heading of 7.4 Purification of Bivalve Molluscs.

7.4 PURIFICATION OF BIVALVE MOLLUSCS, new section reads as follows:

Each establishment that purifies bivalve molluscs by relaying, depuration and/or other port harvest treatments must develop a schedule acceptable to the official agency having jurisdiction, that addresses such critical factors as the species and size of shellfish, time, type of process used, nature of equipment, measurement devices and their calibration.

Purification centres should maintain the same hygiene standards as section 3.2, 3.3, 3.4, 3.5.

Potential Hazards: Microbiological contamination

Potential Defects: physical damage

Technical Guidance:

- Purification centres must be approved by the official agency having jurisdiction.
- Bivalve molluscs subjected to the purification 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, tanks, floats, rafts used for purification should be acceptable to the official agency having jurisdiction.
- Dead or damaged bivalve molluscs should be removed before the purification 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 or potable water before the purification process.

- After purification the bivalve molluscs should meet the end product specification.
- Appropriate documentation should be maintained for purification. Bivalve molluscs **requiring purification** should not come in contact /be mixed with bivalve molluscs that meet the end product specifications.

Reason: The potential hazards, potential defects and technical guidance bullets are not new language, but are drawn from the original 7.5 "Purification of Bivalve Molluscs in Tanks, Floats and Rafts" because they apply to all types of purification and should be included under general information for the new 7.4 "Purification of Bivalve Molluscs." Changes to the original section include:

(1) The first two paragraphs, highlighted in bold, are written as new language;

(2) The word "polluted" is deleted from the second sentence of the last bullet and is revised to read as written because purification may be necessary due to naturally occurring pathogens in addition to pathogens caused by human pollution.

7.4.1 Relaying, renumbered from 7.4 "Relaying," suggest that it be revised to read:

The requirements for classification and monitoring of growing areas do 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.

Potential hazards: Microbiological contamination

Potential Defects: not likely.

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 to prevent cross contamination and commingling.**
- **Bivalve molluscs undergoing relaying should remain immersed in clean seawater until they satisfy the sanitary requirements of the official agency having jurisdiction.**
- 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.
- Bivalve molluscs should be laid out at a density that will permit them to open and undergo natural purification**.**
- Appropriate documentation should be maintained for relaying operations.

Reason: Relaying is a type of purification that should be included under 7.4 "Purification of Bivalve Molluscs." This section was originally 7.4 "Relaying." Changes to the original section include:

(1) "contamination with biotoxins and chemicals" was deleted under *Potential Hazards*; (2) the first bullet was split to form the second bullet with new language highlighted in bold;

(3) the third bullet consists of new language and is highlighted in bold.

7.4.2 Depuration in Tanks, renumbered and renamed from 7.5 "Purification of Bivalve Molluscs in Tanks, Floats and Rafts," suggest that it be revised to read as follows:

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

Depuration is a **post harvest treatment** intended to reduce the number of pathogenic micro-organisms that may be present in bivalve molluscs 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 heavily contaminated areas or areas subject to contamination by hydro-carbons, heavy metals, pesticides, viruses or biotoxins. Bivalve molluscs harvested for **depuration** should only be harvested from areas that that 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 purification to occur it is essential that the molluscs have not been over-stressed or damaged during harvesting or handling prior to **depuration** and are not in a seasonally weak or spawning condition.

Potential Hazards: *Microbiological contamination*

Potential Defects: *physical damage*

Technical Guidance:

- 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 purification parameters. It should be taken into account that viruses and certain Vibrio spp. are more persistent during **depuration** than the indicator bacteria mostly used for microbiological monitoring (*E. coli* and faecal coliforms).
- 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 seawater until they satisfy the sanitary requirements of the official agency having jurisdiction.
- Bivalve molluscs should be laid out at a density that 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 that 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**, **undepurated** bivalve molluscs should not be placed in the same tank as bivalve molluscs that are already undergoing **depuration**.
- On removal from the **depuration** system, bivalve molluscs should be washed with running potable water or clean seawater, 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.

Reason: Depuration in tanks is a type of purification that should be included under new 7.4 "PURIFICATION OF BIVALVE MOLLUSCS." This new 7.4.2 "Depuration in Tanks" was drawn from old 7.5 "Purification of Bivalve Molluscs in Tanks, Floats and Rafts" and includes the information relevant to depuration. Other information under old 7.5 has already been included as general information under new 7.4. The only changes to the depuration information include:

(1) Adding "post harvest treatment" to the first sentence, highlighted in bold;

(2) Replacing "purification" with "depuration" in the instances highlighted.

7.4.3 Other Post Harvest Treatments, new subsection of **7.4 Purification of Bivalve Molluscs**, suggest to read as follows:

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

Other post harvest treatments of bivalve molluscs are conducted to eliminate, reduce, or limit specified target organisms to levels that are satisfactory to the official agency having jurisdiction. Depending upon the type of treatment, they can be applied to bivalve molluscs that are either whole or shucked. They are intended to retain the sensory qualities of live bivalve molluscs. These treatments include the application of low heat, hydrostatic pressure, (e.g., 60K lb/6 min.) irradiation, and individual quick freezing.

***Potential Hazards*: Failure to eliminate or reduce 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.**
- **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 eliminate pathogens should be approved by the appropriate official having jurisdiction.**

Reason: This section should be added to 7.4 "PURIFICATION OF BIVALVE MOLLUSCS" in order to recognize the other types of treatment currently being used such as low heat, hydrostatic pressure, irradiation, and individual quick freezing.

7.5 PROCESSING OF LIVE BIVALVE MOLLUSCS IN A DISTRIBUTION CENTRE OR AN ESTABLISHMENT, renumbered from 7.6 "PROCESSING OF BIVALVE MOLLUSCS IN A DISTRIBUTION CENTRE OR AN ESTABLISHMENT," suggest the following changes:

(1) Add "**Live**" to the section title to clarify the type of bivalve molluscs addressed in the code;

(2) Add the following general statement under the title, "All steps in the process 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."

Reason: For clarity and proper flow. The added general statement applies to all subsections under 7.5 "PROCESSING OF LIVE BIVALVE MOLLUSCS IN A DISTRIBUTION CENTRE OR AN ESTABLISHMENT," so do not need to repeat in each subsection. "Packing and Labeling," "Storage" and "Distribution" are no longer included under "Processing" and will be renumbered as individual sections 7.7, 7.8 and 7.9 respectively.

7.5.1 Reception, renumbered from 7.6.1 "Reception," ***Technical Guidance*, first bullet, beginning of the sentence,** add, "**Unless the distribution centre engages in post harvest treatment,** bivalve molluscs……"; **second bullet**, change "purification" to "depuration" to read, "…….approved relaying area or after **depuration** in an approved **depuration** centre".

Reason: Clarity and consistency in the use of the terms depuration and purification.

7.5.2 Conditioning and Storage of Bivalve Molluscs in seawater tanks, basins, etc., renumbered from 7.6.2 "Conditioning and Storage of Bivalve Molluscs in seawater tanks, basins, etc.," no changes suggested.

7.5.3 Washing, declumping, debyssing and grading, renumbered from 7.6.3 "Washing, declumping, debyssing and grading," ***Technical Guidance,* first bullet,** delete because is now included under general technical guidance for 7.5 "PROCESSING OF LIVE BIVALVE MOLLUSCS IN A DISTRIBUTION CENTRE OR AN ESTABLISHMENT."

7.6 SHUCKING, add as a new Section and the following as general information for shucked product:

"**Shucking is the processing step that removes the edible portion of the mollusk 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**".

Reason: Shucking is not currently recognized in the code. Old section 7.7 "HEAT TREATMENT/HEAT SHOCKING OF BIVALVE MOLLUSCS IN ESTABLISHMENT" addressed heat treatment for purification purposes and heat shocking followed by packing.

Now heat treatment for purification purposes can be properly included under 7.4 "PURIFICATION OF BIVALVE MOLLUSCS" and heat shocking followed by packing can properly be included under new 7.6 "SHUCKING."

7.6.1 Hand and Mechanical Shucking and Washing, a new subsection reads as follows:

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 product.**

Reason: The Draft Code did not include shucking by hand or by mechanical means, only by shocking by heat/steam.

7.6.2 Heat shocking of Bivalve Molluscs followed by packing, renumbered from 7.7.2 "Heat shocking of Bivalve Molluscs followed by packing," ***Technical Guidance,*** change purification centre to **depuration** centre; **third bullet**, add "…..should be inspected **to determine whether** the bivalve……."

Reason: For consistency in the definition of types of purification; for clarity as to why inspection is conducted.

7.6.2 Heat shocking of Bivalve Molluscs followed by packing, *Technical Guidance,* last bullet, delete

Reason: The original statement addressed use of heat for purification, but this section has isolated heat use for shucking out from the original section 7.7.1.

7.7 PACKING AND LABELING, new section to separately address live and "other than live."

Reason: The U.S. suggests one section for live and one section for "other than live" under 7.7 "PACKING AND LABELING," 7.8 "STORAGE" AND 7.9 "DISTRIBUTION."

7.7 PACKING AND LABELING, add General Guidance, "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."

7.7.1 Live Packing and Labeling, renumbered from 7.6.4 "Packing," ***Potential Hazards,*** add "chemical contamination."

Reason: This section as originally written in 7.6.4 "Packing" addressed live packing and labeling and therefore, only the minor change mentioned above is necessary. Chemical contamination is a potential hazard for live bivalve molluscs because they may be packaged in permeable sacks.

7.7.1 Live Packing and Labeling, fourth bullet, last sentence, change "mention" to "include."

Reason: Labeling for "live" and "other than live" should be consistent and the recommendation is for the date of packaging to be included.

7.7.2 Packing and Labeling (other than live); a new subsection reads as follows:

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

Potential Hazards: **microbial contamination or growth, physical contamination**

Potential Defects: **objectionable matter such as shell pieces; incorrect labeling**

Technical Guidance:

- **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.**
- **Labels should be clearly printed and must comply with the labeling 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. 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 as soon as possible.**
- **Freezing should take place quickly. Slow freezing will damage meat.**
- **Labels on treated raw bivalve molluscs must declare the target hazard that has been eliminated or reduced.**

Reason: There is need for more guidance about packing and labeling "other than live" product. This was not included in the Draft Code.

7.8 STORAGE, now includes subsections for live and "other than live."

7.8.1 Live Storage, renumbered from 7.6.5 "Storage," ***Potential Hazards,*** add "chemical and physical contamination"

Reason: This section as originally written in 7.6.5 "Storage" addressed live storage and therefore, only the minor change mentioned above is necessary.

7.8.2 Storage (other than live), new subsection reads as follows:

Potential Hazards: **microbiological growth**

Potential Defects: **not likely**

Technical Guidance:

- **Storage periods should be kept as short as possible**
- **Avoid damage to packaging of frozen product.**

Reason: Need guidance for storage of other than live, not just live. It was not included in the Draft Code, but is necessary for clarity and to follow the flow.

7.9 DISTRIBUTION, now includes subsections for live and "other than live."

7.9.1 Distribution of live, renumbered from 7.6.6 "Distribution," ***Potential Hazards,*** add "microbiological growth."

Reason: This section as originally written in 7.6.6 "Distribution" addressed live distribution and therefore, only the minor change mentioned above is necessary.

7.9.2 Distribution (other than live), new subsection reads as follows:

Potential Hazards: **microbiological growth**

Potential Defects: **not likely**

Technical Guidance:

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

Reason: Need guidance for distribution of other than live, not just live. It is not included in the Draft Code, but is necessary for clarity and to follow the flow.

7.10 DOCUMENTATION, renumbered from 7.8 "Documentation," no changes suggested.

7.11 LOT IDENTIFICATION AND RECALL PROCEDURES, renumbered from 7.9 "Lot Identification and Recall Procedures," no changes suggested.

REVISED SECTION 7 AS A RESULT OF THE CHANGES PROPOSED

References correspond to relevant Sections of the Code.

SECTION 7 – BIVALVE MOLLUSCS

Definitions:

2.3 BIVALVE MOLLUSCS

Accepted/ means accepted by the official agency having jurisdiction;

Acceptable/

Approved

Conditioning means placing live bivalve molluscs in tanks, floats or natural sites to remove sand, mud or slime and improve product acceptability;

Distribution 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;

Centre

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.

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 for the purpose of shucking. Such treatment is not considered to be a cooking process that would be intended to deactivate microbiological pathogens.

Depuration means the reduction of microorganisms from bivalve molluscs by the process of holding live bivalve molluscs, typically in tanks, for a period of time under approved, controlled conditions in natural or artificial sea water suitable for the process. The sea water may be treated or untreated.

Relaying means the removal of bivalve molluscs from a microbiologically contaminated growing area to a growing or holding area acceptable for direct consumption under the supervision of the agency having jurisdiction and holding them there for the time necessary for the reduction of contaminants to be acceptable level.

Purification means elimination, reduction, or limitation of target organisms to the satisfaction of the official agency having jurisdiction, without appreciably affecting the sensory characteristics of the product. Purification may include relaying, depuration and/or other forms of post harvest treatment such as low heat, application of hydrostatic pressure, irradiation, and individual quick freezing.

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, area 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.

7.1 GENERAL REMARKS, ADDITION TO THE PRE-REQUISITE PROGRAMME

Bivalve molluscan species like oysters, mussels, manila 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 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 molluscan bivalve molluscs is microbiological contamination of waters in which they grow, especially when the bivalve molluscs are intended to be eaten raw. Since molluscs are filter feeders they can concentrate contaminations 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 result from sewage contamination like enteric bacterial and/or viral pathogens (Norwalk-like viruses, viruses causing hepatitis) or from naturally 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) or amnesic shellfish poisoning (ASP). Chemical substances, such as [heavy metals, pesticides, organochlorides, petrochemicals] 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 waters is a responsibility for competent authorities. Until better methods are available, *E.coli*/faecal coliforms or total coliforms may be used as an indicator for the possibility of bacterial and viral pathogens. If biotoxins are found in the bivalve mollusc's flesh in hazardous amounts, the growing area must be closed for harvesting [bivalve molluscs] until toxicological investigation has made clear that the [bivalve molluscs] meat is free from hazardous amount of biotoxins. Harmful chemical substances should not be present in such amounts that the calculated dietary intake exceeds the permissible daily intake.

Bivalve molluscs from waters subject to contamination that is not sufficient to result in closure of the area, e.g., low levels of microbiological contamination, as determined by the authority having jurisdiction, can be made safe by relaying in a suitable area or by another purification process to reduce the level of target organism(s). In addition to relaying, purification may involve depuration, heat treatment, hydrostatic pressure, individual quick freezing (IQF), or other forms of post harvest treatments, for the purpose of destroying 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 risk of viral 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, contamination with biotoxins and chemical contaminations*.

Potential Defects: *not likely.*

Technical Guidcance:

There are 5 different types of important hazards coming from the bivalve mollusc's growing environment:

- enteric bacterial pathogens;
- enteric viral pathogens (e.g. Norwalk like viruses, viruses causing hepatitis);
- naturally occurring bacterial pathogens (e.g. Vibrio spp.);
- biotoxins (e.g. DSP, PSP, NSP, ASP);
- chemical contaminants.

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 reevaluated annually to determine any changes to their impact on the growing area.

When pollution sources have been identified and evaluated, sampling stations for water, 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 purification and distribution centres.

When the limits of any biological or chemical hazard set in the end product specification are exceeded, appropiate 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 suitable for harvesting for either:

- direct human consumption;

- relaying in acceptable water or another form of purification in an approved purification centre e.g. depuration, heat treatment, hydrostatic pressure, IQF, radiation;

- non-suitable for growing or harvesting bivalve molluscs.

The presence of pathogenic Vibrio or viruses do not correlate with the bacterial organisms used as indicators of faecal contamination.

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 it is recommended to have a program present to monitor growing areas for species of plankton that can produce toxins and to recognize other environmental signals that a toxic event may be developing. There should be a programme present for monitoring growing areas for determining the presence and amounts of biotoxins in bivalve mollusc meat.

Harmfull 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 harmfull 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 take the following actions:

- Classification/reclassification of growing areas by frequent monitoring of *E.coli*//faecal coliforms or total coliforms.
- Classification/reclassification of growing areas by frequent monitoring of *Salmonella* ssp. in bivalve mollusc meat.
- Closure/Reopening of growing waters by frequent monitoring of algae in sea water and biotoxins in bivalve molluscs.
- 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;

or

- The bivalve molluscs harvested meet the end product specification.

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 areas should be frequently monitored on the presence of *E. Coli*/faecal coliforms or total coliforms.

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 purification,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 enteric bacterial pathogens. Because they do not correlate well with the presence of viruses, other controls such as shoreline surveys, should always be employed.

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, monitoring the shellfish meats may be appropriate as part of the process of 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

All growing areas should be monitored for the presence of algae with potential for producing marine biotoxins/and or marine biotoxins. Growing areas should also be monitored for environmental signals that a toxic event may be 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.

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 mollusc meat is free from hazardous amounts of biotoxins.

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

7.2.2.4 Chemical contaminants

Growing areas should be monitored on regular basis for chemical contaminants.

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, purification, or further processing.

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

Potential Hazards: Microbiological contamination, and chemical contamination

Potential Defects: Mechanical 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 in and around shellfish growing areas. No animals should be allowed on harvest vessels.
- Wash-down pumps should draw water only from non-contaminated sea water.
- 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 ^{o} C (50^{o} F) or below 2^{o} C(35^{o} F) should be avoided.
- Bivalve molluscs should be freed from excessive mud and weed soon after being harvested by washing it with clean sea water or potable water under suitable pressure. Wash water should not be allowed to flow over bivalve molluscs already cleaned. The water should not be re-circulated.
- The interval between harvesting and immersion in water for relaying, depuration, storage, or conditioning 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 PURIFICATION OF BIVALVE MOLLUSCS

Each establishment that purifies bivalve molluscs by relaying, depuration and/or other post harvest treatment must develop a schedule acceptable to the official agency having jurisdiction, that addresses such critical factors as the species and size of shellfish, time, type of process used, nature of equipment, measurement devices and their calibration.

Purification 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:

- Purification centres must be approved by the official agency having jurisdiction.

- Bivalve molluscs subjected to the purification 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, tanks, floats, rafts used for purification should be acceptable to the official agency having jurisdiction.
- Dead or damaged bivalve molluscs should be removed before the purification 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 or potable water before the purification process.
- After purification the bivalve molluscs should meet the end product specification.
- Appropriate documentation should be maintained for purification. Bivalve molluscs requiring purification should not come in contact /be mixed with bivalve molluscs that meet the end product specifications.

7.4.1 Relaying

The requirements for classification and monitoring of growing areas do 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 .

Potential hazards: Microbiological contamination

Potential Defects: not likely.

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 to prevent cross contamination and commingling.
- Bivalve molluscs undergoing relaying should remain immersed in clean seawater until they satisfy the sanitary requirements of the official agency having jurisdiction.
- 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.
- Bivalve molluscs should be laid out at a density that will permit them to open and undergo natural purification**.**
- Appropriate documentation should be maintained for relaying operations.

7.4.2 Depuration in Tanks

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

Depuration is a post harvest treatment intended to reduce the number of pathogenic micro-organisms that may be present in bivalve molluscs 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 heavily contaminated areas or areas subject to contamination by hydro-carbons, heavy metals, pesticides, viruses or biotoxins. Bivalve molluscs harvested for depuration should only be harvested from areas that that 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 purification to occur it is essential that the molluscs have not been over-stressed or damaged during harvesting or handling prior to depuration and are not in a seasonally weak or spawning condition.

Potential Hazards: *Microbilogical contamination*

Potential Defects: *physical damage*

Technical Guidance:

- 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 purification parameters. It should be taken into account that viruses and certain Vibrio spp. are more persistent during depuration than the indicator bacteria mostly used for microbiological monitoring (*E. coli* and faecal coliforms).
- 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 seawater until they satisfy the sanitary requirements of the official agency having jurisdiction.
- Bivalve molluscs should be laid out at a density that 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 that 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, undepurated bivalve molluscs should not be placed in the same tank as bivalve molluscs that are already undergoing depuration.
- On removal from the depuration system, bivalve molluscs should be washed with running potable water or clean seawater, 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.

7.4.3 Other Post Harvest Treatments

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

Other post harvest treatments of bivalve molluscs are conducted to eliminate, reduce, or limit specified target organisms to levels that are satisfactory to the official agency having jurisdiction. Depending upon the type of treatment, they can be applied to bivalve molluscs that are either whole or shucked. They are intended to retain the sensory qualities of live bivalve molluscs. These treatments include the application of low heat, hydrostatic pressure, (e.g., 60K lb./6 min.) irradiation, and individual quick freezing.

Potential Hazards: *Failure to eliminate or reduce 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.
- 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 eliminate pathogens should be approved by the appropriate official agency having jurisdiction.

7.5 PROCESSING OF LIVE BIVALVE MOLLUSCS IN A DISTIBUTION CENTRE OR AN ESTABLISHMENT

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

All steps in the process 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.

7.5.1 Reception

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

Potential Defects: *Physical damage, physical contamination, dead or dying of bivalve molluscs*

Technical Guidance:

- Unless the distribution centre engages in post harvest treatment, bivalve molluscs dispatched by a distribution centre must leave the distribution centre alive. Therefore stress and excessive shocks of the bivalve molluscs must be avoided.
- Distribution centres 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

7.5.2 Conditioning and storage of bivalve molluscs in sea water tanks, basins etc.

Refer also to Sections 3.2, 3.3, 3.4 and 3.5

Potential Hazards: *Microbiological, chemical, biotoxins and microbiological contamination or growth*

Potential Defects: *Physical damage,physical, contamination,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 seawater tanks, basins, floats, natural sites or rafts can be used if it is acceptable to the official agency having jurisdiction.
- Only clean seawater 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 shellfish species and with the harvesting area. Water condition has to be satisfactory adequate for the process.
- 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**.**

7.5.3 Washing, declumping, debyssing and grading

Refer also to Sections 3.2, 3.3, 3.4 and 3.5

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

Potential Defects: *Mechanical damage*

Technical Guidance:

- Damage to shells and stress will shorten the shelf life of bivalve molluscs and increase the risk of contamination and deterioration. So shellfish 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 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.

7.6.1 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 product.

7.6.2 Heat shocking of bivalve molluscs followed by packing

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

Refer also to Sections 3.2, 3.3, 3.4 and 3.5

Potential Hazards: Physical contamination

Potential Defects: not likely

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 that heat shocks bivalve molluscs should develop a heat shock process schedule, acceptable to the official agency having jurisdiction, that 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 mollusc 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 clean (sea) water and culled for damaged and dead bivalve molluscsprior 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 molluscsshould 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 shucked and packed as soon as possible. Before packing the bivalve molluscs should be examined for objectionable matter such as shell pieces.

7.7 PACKING AND LABELLING

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.

7.7.1 Live Packing and Labelling

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

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

Potential Defects: *Incorrect labelling, presence of damaged or dead bivalve molluscs, presence of physical contamination, like mud*

Technical Guidance:

- Before packing, bivalve molluscs should undergo visual inspection. Bivalve molluscs that are dead, with broken shells, with adhering soil or otherwise unwholesome, should not be passed for human consumption.
- 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.
- 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.

7.7.2 Packing and Labelling (other than live)

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

Potential Hazards: *microbial contamination or growth; physical contamination*

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

Technical Guidance:

- 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.

- 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. Only packaging material required for immediate use should be kept in the packing or filling area.
- Shucked and PHT should be packed and chilled as soon as possible.
- Freezing should take place quickly. Slow freezing will damage meat
- Labels on treated raw bivalve molluscs must declare the target hazard that has been eliminated or reduced.

7.8 STORAGE

7.8.1 Live Storage

Potential Hazards: microbiological growth, chemical and physical contamination

Potential Defects: physical damage

Technical Guidance:

- The end product should be stored under such conditions as will preclude contamination with and/or proliferation of microorganisms. 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 except in the case of retail sale at the distribution centre.

7.8.2 Storage (other than live)\

Potential Hazards: microbiological growth

Potential Defects: not likely

Technical Guidance:

- *Storage periods should be kept as short as possible*
- *Avoid damage to packaging of frozen product.*

7.9 DISTRIBUTION

7.9.1 Distribution of live

Refer also to Section 3.6

Potential Hazards: microbiological growth

Potential Defects: physical damage

Technical Guidance:

- The product should be dispatched in the sequence of the lot numbers.
- Bivalve molluscs intended for human consumption should only leave the distribution centre 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 that might contaminate them.

7.9.2 Distribution (other than live)

Potential Hazards: microbiological growth

Potential defects: not likely

Technical Guidance:

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

7.10 DOCUMENTATION

- The transport of live bivalve molluscs from a growing area to a distribution centre, purification centre, relaying area or establishment must be accompanied by documentation for the identification of batches of live bivalve molluscs.
- Permanent, legible and dated records of relaying and purification should be kept concerning each lot. These records should be retained for a period of minimal one year.
- Purification centres 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. This document should contain the following information:
  - the gatherer's identity and signature;
  - the date of harvesting;
  - name and quantity of bivalve molluscs;
  - the location of the growing area.
- Complete records of harvest area and date of harvest and length of time of relaying or purification of each lot should be maintained by the distribution centre or establishment for a period designated by the official agency having jurisdiction.

7.11 LOT IDENTIFICATION AND RECALL PROCEDURES

Refer also to Section 3.7

- Each product leaving the distribution centre or establishment should have an easily identifiable lot number. This lot number must, encode information on the number of the distribution centre or establishment, the country of origin and day and month of packing, in order to facilitate the traceback of the product. The distribution centres should establish a record-keeping system based on these lot numbers so that individual lots of bivalve molluscs can be traced from the growing area to the end user.
- If a recall must be carried out, its success depends on whether the management of the distribution centre has taken certain preparatory steps in advance.
- Some important aspects are:
  - The affected product must be easily identifiable by lot numbers;
  - Destination and customers of the affected product must be identifiable;
  - Competencies and responsibilities of management and personnel must be clear;
  - Names and telephone numbers of affected personnel, organisations and customers must be present.

SECTION 10 - PROCESSING OF QUICK-FROZEN COATED FISH PRODUCTS

General Comments

As drafted, this code claims to cover finfish and shellfish (see Section 10.2) but this point in the drafting process it only contains material relevant to finfish. Shrimp coating is covered in the draft shrimp code and coated bivalve molluscs are not yet addressed anywhere. The U.S. recommends that additional materials relevant to coated bivalve molluscs be added to this section after the October 2003 session and that consideration be given to moving the material on coated shrimp into this section.

Figure 10.1 Flow Chart, revise box number 9 to read "Coating" in order to be consistent with both the titles of section 10 and section 10.3.6.

10.3 Processing Operations include references to: Section 4 Handling Fresh Fish and Shellfish and Section 8 Processing Fresh, Frozen and Minced fish.

10.3.1 Raw Material Reception, delete "Raw Material"

Reason: The sub sections under 10.3.1 apply to "other ingredients" and "packaging materials", not just too raw material.

10.3.1 Raw Material Reception, delete bracketed sentence.

Reason: this sentence does not appear in other code sections involving reception (see section 8.1.1, for example) and is unnecessary. It could be read as requiring sampling and analysis of all incoming materials for a range of hazards, e.g., chemical, which would not be necessary under many circumstances. Not all examination of incoming materials need involve sampling.

10.3.1.1 Fish, *Potential hazards:* delete "decomposition" and add "histamine"

Reason: The code consistently lists "histamine" as a hazard rather than "decomposition." Where appropriate, "decomposition" is listed as a Potential defect.

Potential defects add "decomposition, dehydration, parasites, bones."

Reason: The defects listed above are likely to occur depending upon the species and form of product received and processing prior to receipt.

10.3.1.3 Packaging Material, *Technical Guidance*, Add a bullet to read:

- Pre-printed labeling should be examined for accuracy.

10.3.2 Storage of Raw Material, Other Ingredients and Packaging, add a new subsection **"10.3.2.2 Fish (Chilled Storage).** For storage and landing of non-frozen fish, refer to Section 8.1.2."

Reason: Most, but not all product is received frozen. This subsection would cover product received chilled.

10.3.2.2 Other Ingredients and Packaging Materials, Change the number to **10.3.2.3,** to accommodate the additional subsection discussed above. **1st bullet**, at the end of the sentence add "away from materials with strong odors."

Reason: Batter, breading and packaging materials are capable of absorbing odors.

10.3.3 Unwrapping, Unpacking, *Potential Hazards* delete "contamination by personnel" and replace it with "microbial contamination"

Reason: For consistency, this material should list hazards, e.g., microbial contamination, rather than state how the hazard can occur.

10.3.5 Separation of Pieces, *potential Hazards*, move "foreign material" to "*Potential Defects."*

Reason: The foreign material likely to be introduced here would not be safety related.

10.3.5 Separation of Pieces, *Technical Guidance,* add a bullet to read:

- "Remove from production line any broken, misshapen or out-of-specification pieces."

10.3.8 Re-Freezing, change the title from "Re-freezing" to "Re-freezing and Final Freezing" and add "Refer 8.3.1."

Reason: This change in the title accommodates those incoming fish that were not frozen when they arrived. Most incoming fish will be frozen, but not always. The referral to 8.3.1 adds the freezing requirements for fresh fish since fresh fish are also battered or breaded.

10.3.9 Packing and labeling, *Potential Hazards,* delete "contamination by personnel" and replace with "microbiological contamination." add "allergens."

Reason: For consistency, this material should list hazards, e.g., "microbiological contamination", rather than state how the hazard could occur.

10.3.9 Packing and labeling, *Technical Guidance,* Add a bullet to read:

Allergens (eggs, wheat, etc.) used as ingredients should be listed on the label.

10.3.11 Transport of End Product, *Potential Defects,* move "**see Section 3.6**" so that it is located above "*Potential Hazards"*. Add "thawing of frozen product" to *Potential Defects.*

Reason: Section 3.6 provides general guidance for transport and should be a reference for all aspects of transporting. Thawing would be a defect if it were to occur and thus should be listed as a *Potential Defect*.

SECTION 11 - PROCESSING OF SALTED FISH

SECTION 2 – DEFINITIONS

Recommended additional language within sentences is highlighted in bold for the convenience of the reader.

2.7 Salted Fish, delete "Heavily Salted", Medium Salted", "Lightly" and "Very Lightly Salted Fish" because they are defined in the Draft Standard for Salted Atlantic Herring and Salted Sprats and are not used in text of this code. "Salt Cured Fish" should also be deleted for the same reason.

2.7 Barrels revise to read: "A cylindrical container made from wood or plastic **or other suitable food contact material** with a lid for watertight closure."

Reason: Barrels can be made of enamel, steel, etc.

SECTION 11 - PROCESSING OF SALTED FISH

Specific Comments

11.1 General, 4th bullet, add at the end: "(See Annex 1)"

Reason: Annex 1 contains procedures for killing living parasites by freezing.

11.1 General, add **6th bullet** to read, "when scombrotoxic fish are being salted, exposure to temperatures that would support toxin function by bacteria should be limited at each step in the process."

11.2.1 Splitting, Washing and Rinsing, *Potential Hazards,* add "histamine."

11.3.1 Handling and 11.3.2 Salt Requirements change "Biological" to "Microbiological" under both *Potential Hazards* and *Potential Defects*.

Reason: Consistency. "Microbiological" is the term that is always used.

11.3.1 Salt Handling, 2nd bullet, change "infection" to "microbial contamination (e.g. *listeria monocytogenes*)."

Reason: Clarity.

11.4 Salting and Maturing, 2nd paragraph, add to the end of the sentence, "and temperature control."

Reason: To prevent scombrotoxin formation or botulinum outgrowth during the slow salting process.

11.4 Salting and Maturing, 3rd paragraph, last sentence, change "infections" to "such microbial contamination."

Reason: Clarity.

11.4.1 Brining and 11.4.2 Brine Injection, *Potential Hazards,* delete "incorrect composition of brine"

Reason: Incorrect composition of brine is not, itself, a hazard. It can, however, be a cause for a microbiological hazard. Microbiological hazards are already included.

11.4.1, 11.4.2, 11.4.3, 11.4.4, 11.4.5, 11.4.6 and 11.6, *Potential Defects,* delete "histamine."

Reason: To use consistent language. "Histamine" is used to refer to the safety hazard associated with scombrotoxin.

11.4.1 Brining, *Technical Guidance,* add a fourth bullet to read:

- "to assure proper salt penetration, fish should be of similar size."

11.4.2 Brine Injection, *Technical Guidance,* add a fourth bullet to read:

- "Conduct metal detection here or later in the process."

Reason: Inspecting daily for broken tips, for blocking and deflections of needles, may not be sufficient to determine if any product was affected by broken needles or when the break occurred.

Sorting, Weighing, Packaging, Wrapping and Labeling, delete references 6.4.4 and 6.5 and change to 8.2.3 (Labeling) and 8.4.4 (Wrapping and Packaging).

SECTION 13 - PROCESSING OF LOBSTERS AND CRABS

Recommended additional language within sentences is highlighted in bold for the convenience of the reader.

13.2.1 Potential Hazards and Defects Associated with Lobsters and Crabs, change reference to "Annex I Potential Hazards Associated with Fresh Fish, Shellfish and Other Aquatic Invertebrates." The 25th Session moved this from Section 4.1 to Annex I.

13.2.1.1 Biological Hazards, last paragraph, Other defects, add the following sentence: "Barnacles and other commensals are common defects in various crab species."

Figure 13.1 Flow Chart, add a box containing the words "Application of Additives" that connects from the box that says "Additives Storage" and points toward the box that says "Tailing".

Reason: Sulfites can be added immediately upon tailing in order to prevent black spots.

13.3.1.1 Live Lobster Reception (Processing Step 1),

Technical Guidance, **2nd bullet,** modify to read "…hazard to human **health** should not…"

Reason: Editorial, to insert missing word.

13.3.1.2 Live Lobster Holding (Processing Step 2), *Potential Hazards,* delete "unlikely" and replace with "drug residue"; *Technical Guidance:* add a bullet to read: "If drugs are used, appropriate withdrawal times must be followed."

Reason: due to use of antibiotics during live lobster holding.

13.3.1.5 Application of Additives to Lobster Tails (Processing Steps 5 & 10)

Add "3" within the parenthetical so the title reads "…..(Processing Steps 3, 5, 10)

Reason: Sulfites can be added immediately upon tailing to prevent black spot.

13.3.1.6 Chilled Storage *Potential Defect,* add "decomposition."

Reason: If temperature rises or storage time is too long.

13.3.1.11 Freezing (Processing Step 12), *Technical Guidance,* 1st bullet, change to read: "air blast, liquid nitrogen, **or other** freezing **methods** should be **rapid** to produce high quality tails."

Reason: There are other potential freezing methods in addition to liquid nitrogen and air blast.

13.3.2.3 Cooling (Processing Step 5), *Potential Hazards,* delete "unlikely" and replace with "microbiological."

Technical Guidance, add a bullet to read: "care should be taken to prevent cross contamination".

Reason: Cross contamination is a common problem moving product from cooking to cooling areas.

13.3.3.6 Sectioning/Meat Extraction (Processing Step 6), *Potential Hazards,* delete "presence of shell fragments"

Reason: the next sub-section is shell fragment removal.

SECTION 14. SHRIMPS AND PRAWNS

General Comments

The U.S. suggests that a "Scope" section be added and the following be included:

Shrimp frozen for further processing may be whole, head-off or beheaded or raw headless, peeled, peeled and de-veined or cooked on board harvest or processing vessels or at on shore processing plants.

Reason: The first step can be on the vessel or at a shore based processing plant. Following catch or receipt, both would chill or freeze or possibly behead and freeze or chill. The hazards would be the same and need the same controls.

Additional hazards need to be listed as *Potential Hazards* at reception such as sulfites, drugs and pesticides because aquacultured shrimp may be used. Sulfites may be controlled at the labeling step rather than at reception or at both steps.

Cross references for Standards and Codes should be included as guidance of continuing processing steps for product types that have hazards specific to the process or are not a final frozen product such as:

- Section 8 Processing of Fresh, Frozen and Minced Fish
- Section 10 Processing of Quick Frozen Coated Fish Products and Codex
- Standard for Quick Frozen Fish Sticks, Fish Portions and Fish Fillets Breaded and Battered (CODEX STAN. 166-1989). This includes more detail necessary to controlling microbial growth (i.e. Staph) during the coating step.
- Reference Section 16 Canned Fish and Shellfish following reception and freezing, possibly following freezing following selection/size grading.

The **CRD 3** from the 25th Session addresses many of our general concerns, revisions and comments. The U.S. supports the adoption of **CRD 3** as the revision for the purposes of discussion at this plenary session.

Specific comments:

The United States has prepared the following comments and suggested revisions to Section 14 Draft proposed by the United Kingdom

[SECTION 14 – PROCESSING OF SHRIMPS AND PRAWNS [TO BE REVISED]

Citation: 14.1 Technical Guidance

Suggested change : first bullet after "Palamindae" add "and other related species in the family Peneidae"

Reason: There are other species of shrimp that may be used commercially other than Peneus, Pandalus or Palamindae

Citation : 14.1 Suggested change: Change the third bullet last sentence after the word "shell-on" by adding "peeled and deveined"

Reason: This is the most common market form

Citation : flow diagram

Suggested change: The raw section should have a step entitled "peel". There should be an arrow from full (could be called "round") to the wash step

Reason: This is the most common market form and it is rare to devein without peeling

Citation 14.2.1 Potential Hazards

Suggested Change: Sulfite should be added as a Potential Hazard and blackspot added as a Potential Defect

Reason: Sulfite used by fishermen and farmers at harvest to protect from blackspot autolysis which occurs in tropical and sub-tropical shrimp species. Since sulfite compounds are potential allergens it should be listed as a hazard reasonably likely to occur

Citation: 14.2.1 Potential Defect, add to read: "softening from head enzymes"

Citation : 14.2.1 Technical Guidance

Suggested change: we suggest adding two bullets to technical guidance

- Incoming lots of shrimp should be monitored for sulfite at harvesting
- A sensoric evaluation should be performed on incoming lots to ensure that the product is of acceptable quality and mot decomposed

Reason: sulfite compounds are regularly used on shrimp at harvest to prevent blackspot. A sensoric evaluation is advisable because shrimp is often mishandled or subject to temperature abuse on the vessel or during transport

Citation: 14.2.1 Potential Defect

Suggested Change: Add to Potential Defect "softening from head enzymes".

Reason: This is a common defect especially for tropical and sub-tropical species.

Citation :14.2.2 Technical Guidance

Suggested change

The United States suggest adding the following bullets to Technical Guidance

The cold storage facility should have a temperature monitoring device preferably a continuous recording unit to properly monitor and record ambient temperature

Reason: Monitoring temperature is important in ensuring the safety and quality of the product in cold storage

Citation 14.2.5

Technical Guidance

Suggested Change: the following bullet point should be added:

- The chilled storage facility should have a temperature monitoring device (preferably a continuous recording unit) to properly monitor and record ambient temperatures.

Reason: Monitoring temperature is important in ensuring the safety and quality of the product in cold storage.

Citation: 14.2.6 Potential Hazards

Suggested Change: Add the word "growth" after microbiological.

Reason: Clarity.

Citation: 14.2.6 Potential Defects

Suggested Change: Add "decomposition" as a potential defect:

Citation: 14.2.6 Technical Guidance

Suggested Change: Add the following bullet;

- The grading process should be carried out promptly to prevent unnecessary microbiological growth and product decomposition.

Citation: 14.2.7 Potential Hazards

Suggested Change: Add sulfites as a potential hazard.

Reason: Adding sulfites during processing is a common practice world-wide.

Citation: 14.2.7 Technical Guidance

Suggested Change: Add the following bullet;

- Sulfites used to prevent blackspot autolysis should be used in accordance with manufacturer's instructions and Good Manufacturing Practices.

Reason: A high level of sulfites in foods may cause a serious allergenic reaction.

Citation: 14.2.8 Potential Hazards

Suggested Change: Move "foreign bodies" from Potential Hazards to Potential Defects.

Reason: This problem is more properly a defect than a health hazards.

Citation: 14.2.12

Suggested Change: Add the word "Mechanical" to the title so reads "Mechanical Peeling Cooked Prawns".

Reason: This distinguishes the process for Pandalid shrimp from Peneid shrimp where hand peeling is most common.

14.3 ?

Comment: There is entry for Cold Storage as indicated in the flow diagram. We suggest the following;

14.2.16 Cold Storage

Potential Hazards: Unlikely

Potential Defects: dehydration, protein denaturation.

Technical Guidance:

See 14.2.2

Citation: Breaded Shrimp Section

Comment: This section may be better if placed in the coated fish chapter of the Code of Practice.

Reason: Clarity.

Citation: Breaded Shrimp Flow Diagram

Suggested Changes: Add reception steps and a thaw step between frozen raw processed shrimp and the coating step. Also, add arrows around the proposed thaw step and from the coating step around the frying step.

Reason: Since breaded shrimp is usually thawed before breaded this step should be acknowledged. An arrow around that step will satisfy the possibility that frozen shrimp are breaded. Since most breaded shrimp are raw breaded there should be an arrow around the frying step.

Citation: 14.3.3 Technical Guidance

Suggested Change: Add the following bullet;

- The outer ply of paper should be removed from the bags of breading before it is dumped in the hopper to prevent contamination from dirt and dust that may be present on the bag.

SECTION 15 - PROCESSING OF CEPHALOPODS

Specific Comments

Figure 15.1, flow chart, revise box #9 to read "Packing/Labelling"

Reason: "labelling" should be added to the title of section 15.6 and this addition should also be reflected in the flow diagram.

15.2.2 Frozen Storage (Processing steps 2 & 10)

Potential Hazards: The U.S. recommends that before cadmium migration from the gut after capture is listed as a potential hazard, data to support this migration should be presented. We have been unable to locate data on this point in the literature. If migration from the gut is shown to occur, this point would appear to fit better at **15.4, Splitting, Gutting, & Washing.**

15.6 Grading/Packing (Processing Steps 8 & 9), revise the title to read "**Grading/Packing/Labelling (Processing Steps 8 & 9);** *Potential Hazards,* add "sulfites." *Technical Guidance:* add a bullet to read: "where sulfites were used in the process, care should be taken to ensure that this additive is properly declared on the label.

Reason: Sulfites are allergens and thus should be listed on the label.

15.7 Freezing (Processing Step 10), *Technical Guidance,* **2nd bullet,** add reference to "Annex I Potential Hazards Associated with Fresh Fish, Shellfish and Other Aquatic Invertebrates"

Reason: This section gives more specific time and temperature for parasite kill.

SECTION 17 – TRANSPORT

General Comments

At the beginning of the section, we recommend the insertion of the following: "Refer to the **Code of Practice General Principles of Food Hygiene**, **SECTION VIII – TRANSPORTATION,** CAC/RCP 1-1969, Rev. 3 (1997), Amended 1999 and the Code of Hygienic Practice for the Transport of Food in Bulk and semi-Packed Food, CAC/RCP 47-2001."

Specific Comments:

17.1 FOR FRESH, REFRIGERATED AND FROZEN PRODUCTS

Add: "Refer to 3.6 Transportation"

Technical Guidance: add as a first bullet "check temperature of chilled product before loading"