

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
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ORGANIZATION



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Agenda Item 5

CX/FFP 06/28/5-Add.1

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

Twenty-eighth Session
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PROPOSED DRAFT CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS GOVERNMENT COMMENTS AT STEP 3

UNITED STATES

Section 11. Processing of Salted Fish

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

SECTION 2 – DEFINITIONS

2.7 Salted Fish, delete “**Heavily Salted Fish**”, “**Medium Salted Fish**”, “**Lightly Salted Fish**”, “**Very Lightly Salted Fish**,” and “**Salt Cured Fish**”

Reason: These terms are defined in the Draft Standard for Salted Atlantic Herring and Salted Sprats and are not used in text of this code.

2.7 Salted Fish, revise the definition of “**Barrel**” 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, add **6th bullet** to read, “**when scombrototoxic fish are being salted, exposure to temperatures that would support toxin formation by bacteria should be limited at each step in the process.**”

11.1 GENERAL, Flow Chart

- Delete the box for “Salt and Salt Storage” and move the reference to “*Section 11.3*” to the “Ingredients Reception” and “Ingredients Storage” steps so that the references would read “*Sections 8.5.1 and 11.3*” and “*Sections 8.5.2 and 11.3*”
- Extend the line from “Ingredients Storage” down so that it does not cross over the lines from “Splitting” and “Filleting”

Reason: For clarity and because the information in Section 11.3 for Salt and Salt Storage would be considered part of the Ingredient Reception and Ingredient Storage steps.

11.2.1 Splitting, Washing and Rinsing, add “**histamine**” to *Potential Hazards* and revise **1st bullet** to read, “the design of the splitting line should be continuous and sequential to permit the uniform flow without stops or slow-downs **in order to prevent histamine formation;**”

Reason: Histamine should be included as a potential hazard at this step and the first technical guidance bullet addresses the control.

11.3.1 Handling and 11.3.2 Salt Requirements, change “*Biological*” to “*Microbiological*” under *Potential Hazards* and change “*Biological*” to “*Decomposition*” under *Potential Defects*.

Reason: Consistency. “Microbiological” is the term that is used for the potential hazard and “decomposition” is the potential defect.

11.3.1 Salt Handling, 2nd bullet, change “infections” to “**microbial contamination (e.g. *listeria monocytogenes*).**”

Reason: Clarity.

11.4 SALTING AND MATURING, 1st paragraph, delete second sentence and replace with the following, “**The salting process, including the temperature, should be sufficiently controlled to prevent the development of *Clostridium botulinum*, or the fish should be eviscerated.**”

Reason: The flow diagram allows for uneviscerated fish so, the code of practice should be consistent with the intent as described by the flow diagram. This code of practice should be consistent with the standard to which it applies (Salted Atlantic Herring and Sprat), which allows for eviscerated and uneviscerated fish according to the country where the product will be consumed.

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.

11.5 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 12 - PROCESSING OF SMOKED FISH

Section 12 - introductory paragraphs, 2nd, 3rd, 4th and 6th paragraphs, combine into one paragraph and maintain as the second paragraph.

Reason: Editorial.

Section 12 - introductory paragraphs, bracketed 5th paragraph, delete

Reason: The question raised in the bracketed sentence is whether the use of liquid smoke should be a “process” under this code of practice or whether it should be regarded as a “flavoring substance.” U.S. believes that liquid smoke can legitimately be within the scope of this document as either of these things, depending on how it is used. Liquid smoke can be used as an alternative to wood as a smoke generator and can result in a product that is indistinguishable from wood-smoked fish. For that reason, it is a “process” that could be incorporated into the “smoke generation” step. We also do not rule out the possibility that liquid

smoke could be injected or applied on the surface of the fish for flavor enhancement or to prevent microbiological growth.

Section 12 – introductory paragraphs, 9th paragraph, delete

Reason: The draft Codex standard that this paragraph refers to is being expanded to include all smoked fish, not just cold smoked. Thus, the paragraph’s reference to a standard solely for cold smoked fish is neither accurate nor necessary.

Section 12 – introductory paragraphs, 10th paragraph, delete or clarify

Reason: We do not understand the meaning of this sentence. .

Section 12 – introductory paragraphs, 11th paragraph, delete

Reason: All HACCP controls should be validated, not just controls not specifically covered in this section of the code of practice. Also, this provision is novel and not found in other sections of the code of practice.

Figure 12.1, the four boxes at the top of the flow diagram should all relate to “reception,” in keeping with standard practice for flow diagrams within the Code of Practice. Currently there is nothing in the flow diagram for “fish reception” or “packaging reception.” Therefore, the text box reading “Fish Preparation *Section 12.1*” should be replaced with “**Fish Reception *Section 12.1***; ” the text box reading “Packaging *Section 12.5*” should read “**Packaging Reception *Section 12.1***;” the text box reading “Firewood Reception *Section 12.2*” should read “**Firewood Reception *Section 12.1***;” and the text box reading “Ingredients Reception” should read “**Ingredients Reception *Section 12.1***.” (We are proposing similar modifications within the body of the code.) A revised flow diagram is included in these comments.

Figure 12.1 to accommodate the reception step change, above, revise all remaining section numbers and processing step numbers to read as follows:

- Firewood Storage *Section 12.1* (1)**
- Salting (currently “pre-salting”) *Section 12.2* (2)**
- Smoke Generation *Section 12.3* (3)**
- Hot Smoking *Section 12.3* (3)**
- Cold Smoking *Section 12.3* (3)**
- Cooling *Section 12.4* (4)**
- Freezing *Section 12.4* (5)**
- Slicing *Section 12.5* (6)**
- Packing *Section 12.6* (7)**
- Labeling *Section 12.7* (8)**
- Chilling (currently “cooling”) or Freezing *Section 12.8* (9)**
- Storage *Section 12.9* (10)**
- Thawing *Section 12.10* (11,13)**
- Distribution/Transport *Section 12.9* (12)**
- Retail *Section 12.9* (14)**

Figure 12.1, add a diagonal arrow from “Cooling” to “Slicing”.

Reason: The product does not have to go through the freezing step before slicing.

Figure 12.1 change “Pre-Salting” to “**Salting**”

Reason: Pre-salting should be changed to “salting” because the text at current section 12.1 addresses salting. (We are also recommending that section 12.1 be renamed “Salting.”) The process definition of “salting” given in the Standard for Salted Atlantic Herring and Salted Sprat reads as follows: “Salting is the process of mixing fish with the appropriate amount of food grade salt, sugar, spices and all optional ingredients and/or of adding the appropriate amount of salt-solution of the appropriate concentration.” This process appears to be what is being referred to in the text at current subsection 12.1.

12.1, We suggest revising section 12.1 to read as follows:

“12.1 RECEPTION (PROCESSING STEP 1)

12.1.1. Fish Reception

See Section 8.1.1 for finfish

Molluscan shellfish shall be obtained from approved growing waters and from firms approved by the official agency having jurisdiction over shellfish safety (see Section 7).”

12.1.2 Packaging Reception

See section 8.5.1

12.1.3 Ingredients Reception

See section 8.5.1

Ingredients used for brining should be examined at reception to ensure that the products are adequately packaged and have been held under hygienic conditions.

12.1.4 Firewood Reception and Storage

Potential Hazards: Chemical contamination

Potential Defects: Off-flavors and odors

Technical Guidance:

- Only wood that has not been treated with any chemicals such as paint or impregnating remedies should be used for smoke generation.
- Wood containing mold or fungus may impart off-flavors and odors and should be rejected.
- Store wood in a dry place separated from the production rooms.

Reason: The text was missing a reception step.

Current Section 12.1 “PRE-SALTING (PROCESSING STEP 1)” revise to read:

“12.2 SALTING (PROCESSING STEP 2)”

Reason: We are proposing that reception be processing step 1 at section 12.1. We are proposing that “pre-salting” be changed to “salting” for the reasons stated previously.

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

References correspond to relevant Sections of the Code.

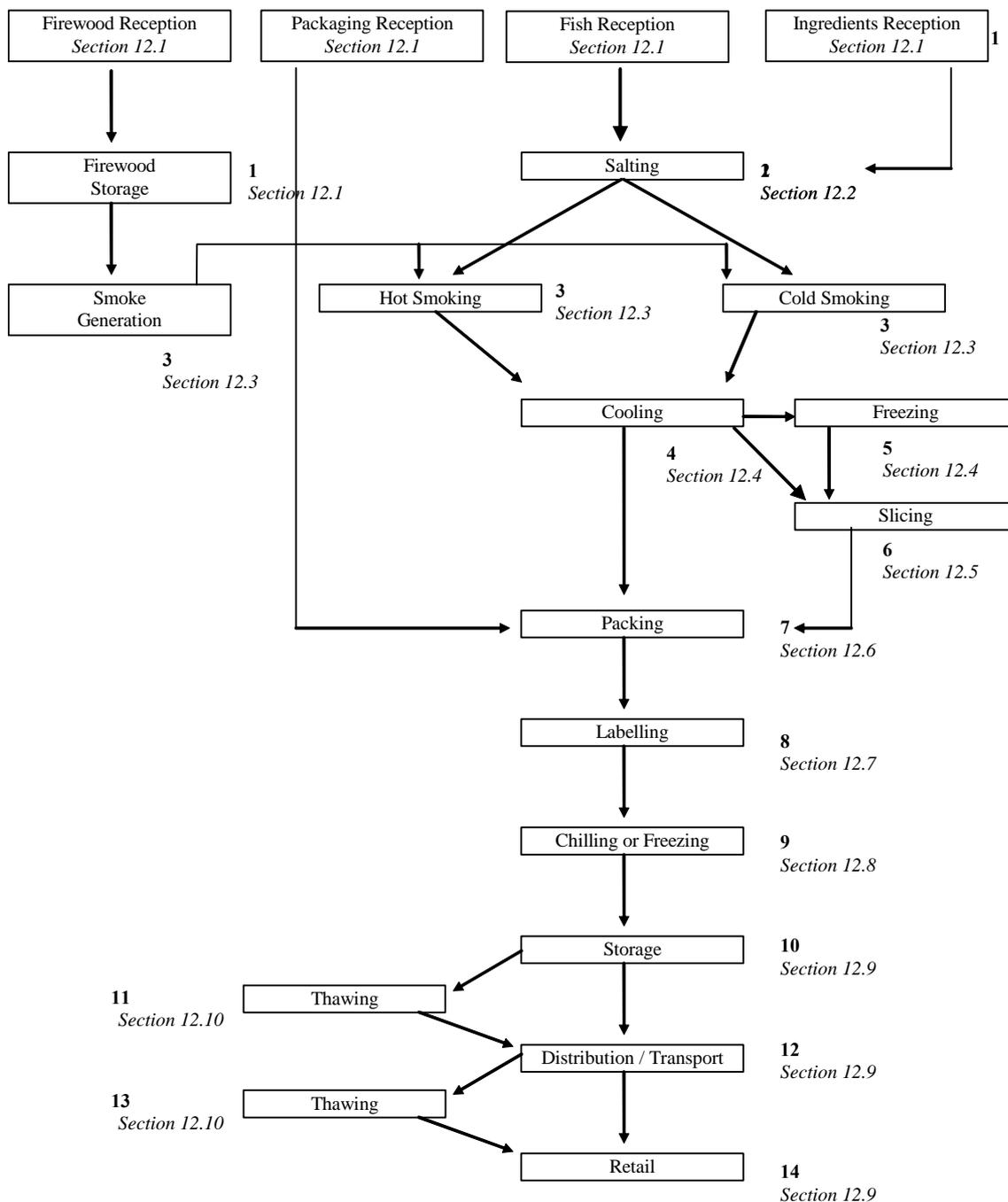


Figure 12.1 Example of a flow chart of a Hot Smoking and Cold Smoking preparation Line, including possible slicing operation at the Cold Smoking line.

12.1, 12.2, 12.3, 12.4, 12.5, 12.6, 12.7, 12.8, Technical Guidance, change the paragraphs to bullets

Reason: These paragraphs should be written as technical guidance bullet points to be consistent with standard formatting.

12.2 SALTING (currently 12.1 PRE-SALTING), Technical Guidance, revise the 1st paragraph to read as follows: “Fish for hot smoking are **usually** salted only a short time to gain taste, e.g. 0-2 hours, by floating in medium strength salt brine.”

Reason: The “i.e.” is changed to “e.g.” because time should be adequate to achieve appropriate water phase salt for safety and may exceed 2 hours.

12.2 SALTING (currently 12.1 PRE-SALTING), Technical Guidance, 2nd paragraph, revise to read, “Fish for cold smoking are **usually** dry salted or salted by pickle injection of a medium strength salt brine to gain taste. The salted fish is left for about 24 hours under refrigeration **to allow the salt to diffuse equally throughout the fish.**”

Reason: Clarity.

12.2 SALTING (currently 12.1 PRE-SALTING), Technical Guidance, 3rd paragraph, delete and replace with a new bullet to read:

- “**Where product is brined at temperatures above those specified in Section 8.1.2, care should be taken to ensure that the processing is carried out rapidly to avoid possible spoilage or, in scombrototoxin species, histamine formation.**”

Reason: This suggested modification provides information about temperatures and also addresses decomposition in species that are not subject to histamine formation.

12.2 SALTING (currently 12.1 PRE-SALTING), Technical Guidance, 3rd bullet, change to read:

- “**for product that will be packaged in reduced oxygen and that will rely on salt as the primary barrier to the growth of *Clostridium botulinum*, the salt content in the fish should be in accordance with Annex 1 of the Standard for Ready To Eat Smoked Fish (under elaboration).**”

Reason:

(a) A barrier of salt in the water phase for *Clostridium botulinum* is essential only where the product is to be packaged in modified atmosphere.

(b) Annex 1 provides that countries where the product is to be consumed should be free to require either 3% or 3.5% salt in the water phase based on conditions in the country and the level of protection they wish to have for their consumers. There are scientific data that can support a level of protection reflected by 3% and data that could lead a country to conclude that a minimum of 3.5% in the water phase is needed to protect its consumers. The process is the same regardless of whether the product is hot smoked or cold smoked.

12.2 THE SMOKING, change the title to “12.3 SMOKE GENERATION AND SMOKING (PROCESSING STEP 3)”

Reasons: (a) For consistency with the flow diagram, which refers to “Smoke Generation.” Smoke generation and smoking would occur simultaneously and could therefore be considered the same processing step; and (b) “Smoke Generation” is germane to technical guidance that addresses liquid smoke as a smoke generator in addition to wood.

12.3 SMOKE GENERATION AND SMOKING (currently 12.2 THE SMOKING), Potential Hazards, change “biochemical development” to “histamine”

Reason: If “biochemical development” refers to histamine, then “histamine” is the term that should be used. Otherwise, the U.S. would like clarification on the meaning of “biochemical development.”

12.3 SMOKE GENERATION AND SMOKING (currently 12.2 THE SMOKING), Technical Guidance, add a new 1st paragraph (will be the first bullet) to read as follows:

- “**Smoking may be accomplished by the controlled direct combustion of wood or by vaporization of liquid smoke in the smoking chamber.**”

Reason: A technical guidance bullet is needed to address smoke generation and liquid smoke. Smoking can occur through the burning of wood or by vaporization of liquid smoke.

12.3 SMOKE GENERATION AND SMOKING (currently **12.2 THE SMOKING**), Technical Guidance, **1st paragraph**, add a sentence at the end to read as follows: **“It should also be kept short to prevent pellicle (skinlike layer) formation that would inhibit subsequent smoke penetration.”**

Reason: There will be no penetration of the smoke during smoking if pellicle formation occurs.

12.3 SMOKE GENERATION AND SMOKING (currently **12.2 THE SMOKING**), Technical Guidance, **2nd paragraph**, remove the brackets and revise the first sentence to read: **“In the hot smoking process the temperature in the centre of the product should reach 63°C or higher for at least 30 minutes.”**

Reason: Clarity. We think this is what the sentence meant to say. Also, we believe that 63°C is the correct temperature for the point being made.

12.3 SMOKE GENERATION AND SMOKING (currently **12.2 THE SMOKING**), Technical Guidance, **4th paragraph**, delete the second sentence.

Reason: This is addressed in the 3rd bullet.

12.3 SMOKE GENERATION AND SMOKING (currently **12.2 THE SMOKING**),

Technical Guidance, **5th paragraph**, delete here and include under the new 12.1.4 “Firewood Reception and Storage” that we have proposed.

Reason: Examination of wood to be used for smoke generation to ensure that it is free of chemicals or paint ought to be performed at the reception step. We have proposed that 12.1 be devoted to reception of all materials including firewood.

12.3 SMOKE GENERATION AND SMOKING (currently **12.2 THE SMOKING**), Technical Guidance, **1st bullet**, delete

Reason: This point has already been addressed in the 5th paragraph. Also, we are proposing to move the fifth paragraph to a new 12.1.4 “Firewood Reception and Storage.” See previous comment.

12.3 SMOKE GENERATION AND SMOKING (currently **12.2 THE SMOKING**), Technical Guidance, **2nd bullet**, delete

Reason: We are proposing to include this information in a new 12.1.4 “Firewood Reception and Storage.”

12.3 SMOKE GENERATION AND SMOKING (currently **12.2 THE SMOKING**), Technical Guidance, **4th bullet**, delete

Reason: This point has already been addressed in the 1st paragraph.

12.3 SMOKE GENERATION AND SMOKING (currently **12.2 THE SMOKING**), Technical Guidance, **5th bullet**, add a sentence to read as follows: **“Continuous monitoring devices are recommended to ensure that both time and temperature conditions are met.”**

Reason: It is difficult to monitor both time and temperature without continuous monitoring.

(currently **12.3**) **SLICING OF COLD SMOKED PRODUCTS** should come after **12.4 COOLING AND/OR FREEZING** and be renumbered to 12.5. The processing step associated with this subsection should be Processing Step 6 .

Reason: These sections should be switched and renumbered to reflect the processing steps and the proposed flow diagram.

(currently **12.3**) **12.5 SLICING OF COLD SMOKED PRODUCTS**, Potential Defects, replace “Unlikely” with **“Uneven slicing and torn slices”**

(currently **12.3**) **12.5 SLICING OF COLD SMOKED PRODUCTS**, Technical Guidance, **2nd and 3rd paragraphs** should be deleted, and **last bullet** should be modified to read:

- **“keep the slicer and the conveyor belts clean by frequent and planned cleaning during the process in order to prevent accumulation and growth of *Listeria monocytogenes* and other pathogens.”**

Reason: The second and third paragraphs are recommended for deletion because they would be redundant with the last bullet as modified.

12.4 COOLING AND/OR FREEZING, Technical Guidance, delete 2nd paragraph and revise 1st paragraph to read as follows:

- “cooling after smoking (process step 4) is important and should be carried out **promptly to avoid microbiological growth;**”

Reason: To clarify the purpose for prompt cooling. We are also suggesting the addition of a new subsection that would differentiate cooling in process step 4 from cooling, or preferably chilling, in process step 9. If this suggestion is accepted, the second paragraph would not be needed in subsection 12.4 and the processing steps referred to should be Processing Steps 4 & 5.

12.4 COOLING AND/OR FREEZING, Technical Guidance, delete 2nd bullet; remove brackets in the 1st bullet; modify 1st bullet by deleting the word “hot.”

Reason: The temperatures to which all smoked products are cooled after smoking should be the same and are described in the first bullet, making the second bullet unnecessary. The second bullet also contains temperature requirements that are colder than necessary.

12.4 COOLING AND/OR FREEZING, Technical Guidance, add a new bullet to read as follows:

- “**The freezing process should be carried out rapidly in order to minimize crystallization of the flesh.**”

12.6 (currently 12.5) PACKING OF HOT AND COLD SMOKED PRODUCTS, clarify Potential Hazards, 3rd Technical Guidance paragraph and 1st Technical Guidance bullet

Comment: Reference is made in these three instances to “dilution of preservatives from smoke by condensing water.” The U.S. would like clarification on how this would occur. Also, we think that this concern probably relates to the hazard of microbiological growth because dilution of preservatives could allow for such growth. If this is what was intended, then we suggest that “dilution of preservatives from smoke by condensing water” be redrafted into a technical guidance bullet.

12.6 (currently 12.5) PACKING OF HOT AND COLD SMOKED PRODUCTS, after title add “Refer to Section 8.2 Processing of Vacuum or Modified Atmosphere Packed Fish”

12.6 (currently 12.5) PACKING OF HOT AND COLD SMOKED PRODUCTS, Technical Guidance, add a new bullet to read as follows:

- “**If modified atmosphere packaged (MAP), barriers such as temperature (freezing or refrigeration with adequate monitoring, e.g. the use of time-temperature integrators on each package) or salt must be used to prevent growth of *C. botulinum*.**”

12.7 (currently 12.6) LABELLING, after “Refer to Section 8.2.3 “Labeling” add “and Section 8.5 “Packaging, Labels & Ingredients”

Reason: Both of these sections include information on labels and should be referenced.

12.7 (currently 12.6) LABELLING, Technical Guidance, delete 3rd paragraph and 1st bullet

Reason: This information, if deemed necessary, should be included in the standard rather than the code of practice. In fact, it is currently included in brackets in the draft standard. On the merits, we have problems with it in the standard, as well as here in the code of practice, because it is not clear why consumers need to be told that a refrigerated product was previously frozen. For products that contain adequate water phase salt, or are packaged aerobically, the fact that a product was previously frozen is not an important consideration and informing the consumer serves no clear purpose. However, for products where water phase salt is not used, freezing is the only control where the product is packaged in reduced oxygen. If those products were thawed prior to sale, they would be potentially more hazardous. We would not recommend thawing frozen smoked fish products prior to sale under those conditions and are concerned that this labeling provision would have the inadvertent effect of encouraging thawing of product where freezing is the principle control of *Clostridium botulinum*.

(proposed new) **12.8 CHILLING OR FREEZING (PROCESSING STEP 9) to read as follows:**

“12.8 CHILLING OR FREEZING (PROCESSING STEP 9)

Potential Hazards: Microbiological contamination, microbiological growth

Potential Defects: Decomposition

Technical Guidance:

- **Chilling after packing and labeling is important and should be carried out promptly to avoid microbiological growth;**
- **Air packaged product should be chilled to 4°C in two hours or less;**
- **Modified atmosphere packaged product should be reduced and maintained to $\leq 3^{\circ}\text{C}$ in two hours or less;**
- **The freezing process should be carried out rapidly in order to minimize crystallization of the flesh;**
- **Frozen product should be adequately protected from dehydration in storage.**

Reason: The primary purpose of this comment is to change “cooling” to “chilling.” Chilling should be a distinct step from cooling. The primary difference in these steps is that the product should be brought to temperature within a shorter amount of time at the chilling step. The amount of time is shorter because the product is already cool from the cooling step and extending the allowance of time beyond two hours for chilling could lead to temperature abuse with potential microbiological growth. If these changes are accepted, the subsequent subsections would need to be renumbered as follows: “**12.9 STORAGE, DISTRIBUTION AND RETAIL (PROCESSING STEPS 10, 12 & 14)**” and “**12.10 THAWING (PROCESSING STEPS 11 & 13).**”

12.9 (currently 12.7) STORAGE, DISTRIBUTION AND RETAIL, Technical Guidance, revise paragraph (bullet) to read as follows:

- “Definition of storage temperature and shelf life for both cold and hot smoked products should take into account the risk of microbiological growth during chilled storage, in particular growth of *Clostridium botulinum* and *Listeria monocytogenes* in cold smoked products but also in hot smoked filets in evacuated plastic bags.”

Reason: Both *C. botulinum* and *L. monocytogenes* need to be considered when determining temperatures for storage and during transportation.

SECTION 13 – PROCESSING OF LOBSTERS AND CRABS

The United States recommends that the draft section of the Code of Practice for Lobster and Crabs be divided into a separate section for lobsters and a separate section for crabs. The primary reason for this recommendation is length. If the document were to remain as a single section covering both lobsters and crabs, we predict that the final version would be at least 35 pages long once all needed technical modifications are made to it.

If the CCFFP is receptive to the idea of a separate section for lobsters and a separate section for crabs, the United States has prepared a draft section for each for the Committee’s consideration as substitutes for the current draft. We are hereby submitting them as part of our comments, as an attachment to this letter.

On the other hand, if the CCFFP would prefer to retain lobster and crab as a single section, we have also prepared extensive comments on it, which we are also submitting (below, in this letter). Among other things, these comments include a new sub-section describing the processing of cooked fresh and frozen crab that is missing from the current draft. These product forms cover the majority of processed crabs. This subsection would add another 4 pages to the text. In our view, this additional material supports the desirability of dividing the document into separate sections. Recommended additional language within sentences is highlighted in bold in the comments below for the convenience of the reader. We also recognize that significant renumbering will need to be done with revisions to this draft and those changes may not all be accurately reflected in our comments or in the separate draft sections for lobsters and for crabs.

SECTION 7 – LIVE AND [RAW] BIVALVE MOLLUSCS, delete brackets.

Reason: The United States recommends that the brackets be removed from the title and that the scope of Section 7 of the code include live and raw bivalve molluscs that are suitable for direct human consumption. Raw bivalve molluscs would retain the sensory characteristics of live bivalve molluscs. Both live and raw bivalve molluscs may be subject to further processing, such as such as smoking, canning, marinating, etc.,

but these would be addressed in sections of the Code of Practice for the respective processes. Those sections could reference Section 7 as needed.

Definitions:

2.3 BIVALVE MOLLUSCS

“Distribution Centre:” at the end of the definition delete the period and add: **“from which the bivalve molluscs are dispatched alive.”**

Reason: The Distribution Centre as defined in the current draft describes a facility where bivalve mollusks are taken for cleaning, conditioning, grading, etc. and from which they must leave alive. Consequently, shucking, freezing, and processing to reduce or limit target organisms must occur elsewhere. This kind of arrangement, e.g. where freezing, shucking, etc. must take place in a different facility, reflects one practice in some countries, but is not universal. Much of the world permits functions beyond preparation for live consumption in facilities that receive, condition, wash, declump and grade bivalve mollusks. These products may be treated or further processed in the same facility in which the products are initially received. The United States is unaware of public health problems that would require geographical separation of these functions. Consequently, to accommodate all international practices that are scientifically defensible, we propose retaining the definition of “distribution centre” but modifying it slightly in a way that allows for other establishments that perform “distribution centre”-type functions but also perform functions such as shucking, freezing, or processing to reduce or limit target organisms.

“Post Harvest Treated Bivalve Molluscs:” Delete this definition.

Reason: The term is sufficiently explained with Section 7 of the Code of Practice that it does not have to be defined here.

Figure 7.1: The United States is refraining from offering comments on the flow chart at this time. We are going to propose that Section 7 be divided into two parts, a part for “live” and a part for “raw” bivalve molluscs. Our proposal will contain a flow diagram consistent with that concept.

SPECIFIC COMMENTS BY SECTIONS

7.1 GENERAL REMARKS, ADDITION TO THE PRE-REQUISITE PROGRAMME

7.1, para 5, revise to read:

“Bivalve molluscs from waters subject to ~~low levels of microbiological~~ contamination, as determined by the authority having jurisdiction, can be made safe by relaying in a suitable area or **by a purification (depuration) process to reduce the level of bacteria and the level of viruses if the process is continued long enough, or by a heat treatment to destroy the pathogens processing to reduce or limit target organisms.** Purification (**depuration**) is a short term process commonly used to reduce low levels of bacterial contamination, but long ter

Reason: The Code of Practice should take into account the progress that has been made in processing to reduce or limit target organisms while retaining the sensory characteristics of live bivalve molluscs. For example, processing to reduce or limit target organisms may be capable of destroying high levels of *Vibrio vulnificus* and *Vibrio parahaemolyticus* even though the water may contain low levels of microbiological contamination associated with human activity, e.g. sewage, that shellfish safety programs have traditionally targeted. Because processing to reduce or limit target organisms could destroy high levels of target organisms, we are recommending deletion of the phrase “low levels of microbiological contamination” from the first sentence. We are also recommending deletion of the phrase “heat treatment” from the first sentence and replacement with “processing to reduce or limit target organisms.” There is a form of heat treatment that is actually used as a process to reduce or limit target organisms. However, “heat treatment” could also be a form of processing that would be outside the scope of this section of the Code of Practice if the scope were limited to live and raw.

7.2 CLASSIFICATION AND MONITORING OF GROWING AREAS

7.2.1 Classification of growing areas, 6th paragraph, second bullet, revise to read:

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

– Suitable for harvesting for direct human consumption, relaying in acceptable water or purification in an approved purification centre or ~~other forms of approved~~ **processing to reduce or limit target organisms** e.g. heat treatment, radiation, **hydrostatic pressure, IQF; or**

– Non-suitable for growing or harvesting Bivalve Molluscs.”

Reason: Clarity and to emphasize that bivalve molluscs that will be processed to reduce or limit target organisms must also come from classified growing areas.

7.2.2 Monitoring of growing areas, sixth paragraph, second bullet, add a new sentence (shown here in bold):

“The bivalve molluscs harvested meet the end product specification. **This can be determined directly or through adequate monitoring of the water.**”

Reason: Adequate water monitoring can provide an accurate picture of whether end product specifications are being met.

7.2.2.1, third paragraph, add a second sentence:

“**Because these indicators do not correlate well with the presence of viruses, other controls such as shoreline surveys should always be employed.**”

7.2.2.1, fourth paragraph, remove the brackets and retain the sentence.

Reason: The sentence accurately represents the direction of current efforts to improve this aspect of safety programs for bivalve molluscs.

7.2.2.3 Marine biotoxin control, paragraph 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 paragraph, revise to read, “This section applies to the transportation of bivalve molluscs for the purpose of direct human consumption, ~~further processing~~—relaying, purification, **processing to reduce or limit target organisms, or further processing.**”

Reason: To include processing to reduce or limit target organisms and to move “further processing” to the last item in the sentence because it would be the last of the activities to occur in time.

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 Relaying, add two sentences at the end of the introductory material (provided here in bold):

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

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

Reason: To properly distinguish relaying from purification (depuration). Section 7.5 as currently drafted is entitled “Purification...in tanks, floats and rafts.” We associate “floats” and “rafts” with relaying but not with purification.

7.4 Relaying, add the following sentence at the end of the first technical guidance bullet:

“**These areas should be adequately separated from the bivalve molluscs in adjacent waters to prevent cross contamination and commingling.**”

7.4 Relaying, add the following technical guidance bullet after the second technical guidance bullet:

- “**Relaying sites could become biotoxic from a bloom, or could become an unexpected a source of environmental pathogens such as *vibrio* bacteria, and should therefore be monitored as appropriate while they are being used for relaying.**”

7.5 PURIFICATION OF BIVALVE MOLLUSCS IN TANKS, FLOATS AND RAFTS; change title to “PURIFICATION (DEPURATION)”

Reason: Purification is also known as depuration and that fact should be made clear here. To be consistent with 7.4 “RELAYING,” the type of system does not need to be specified in the title. We are unaware of purification that occurs in a system without tanks and the text within the section refers to tanks only. We associate floats and rafts with relaying rather than with purification (depuration).

7.5, second paragraph, last sentence, replace the second “that” with “are.”

Reason: Editorial correction.

7.5, Technical Guidance, third bullet, revise to read:

“The process and the equipment, e.g. tanks, ~~float, rafts~~ used for purification purposes should be acceptable to the official agency having jurisdiction.”

Reason: To be consistent with the notion that purification (depuration) occurs in tanks only. Again, floats and rafts are used for relaying but we are not aware of their use in purification (depuration).

7.6 [PROCESSING OF BIVALVE MOLLUSCS IN A DISTRIBUTION CENTRE OR AN ESTABLISHMENT], delete brackets.

Reason: See the reasons for our suggested revision to the definition of “distribution centre” in section 2.3.

7.6 insert new first paragraph to read as follows:

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

7.6, first paragraph (proposed to be the second paragraph), revise to read as follows:

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

Reason: To accommodate both “distribution centres” in those countries that require them and other types of establishments in those countries that allow them.

7.6.1 Reception, Technical Guidance, revise bullets to read:

- ~~“Bivalve Molluscs dispatched by a distribution centre must leave the distribution centre alive. Therefore Stress and excessive shocks to bivalve molluscs that will be dispatched live from a distribution centre or other establishment must be avoided.~~
- **“Distribution centres and other establishments that prepare live bivalve molluscs should only accept bivalve molluscs which meet the end product specifications and which originate directly from approved growing areas or after relaying in an approved relaying area or after purification in an approved purification centre or tank.”**

Reason: To accommodate both “distribution centres” and other establishments.

7.6.4 Packing, rename and renumber to **“7.9 PACKING AND LABELING,”** include the bulleted information under a new section titled **“7.9.1 LIVE PACKING AND LABELING”** and revise entire subsection to read:

“7.9 PACKING AND LABELING

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

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

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

7.9.1 Live Packing and Labeling

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

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

Technical Guidance:

- Before packing bivalve molluscs should undergo visual inspection. Bivalve molluscs which are dead, with broken shells, with adhering soil or otherwise unwholesome, should 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 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 ~~mention~~ **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.”

Reason: The U.S. suggests that there should be one subsection for “live” packing and labeling (proposed 7.9.1) and another for “raw” packing and labeling (proposed 7.9.2, below) because the time temperature controls differ for live and raw products. There is increased risk for packing and labeling of raw products. This section as originally written in 7.6.4 “Packing” addressed live packing and labeling and therefore, only the minor changes written above are necessary. Chemical contamination is a potential hazard for live bivalve molluscs because they may be packaged in permeable sacks. Labeling for “live” and “raw” should be consistent and the recommendation is for the date of packaging to be included. Add a **new subsection “7.9.2 Raw Packing and Labeling”** to read as follows:

“7.9.2 Raw Packing and Labeling

Potential Hazards: Microbiological pathogens, physical contamination

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

Technical Guidance:

- 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.
- If labels on post harvest treated raw bivalve molluscs make safety claims relating to the post harvest treatment, the claims should be specific to the target hazard that has been eliminated or reduced.”

Reason: There is need for more guidance about packing and labeling “raw” product.

7.6.5 STORAGE, renumber to **7.10 “STORAGE,”** include the bulleted information now in “7.6.5 Storage” under a new subsection titled “**7.10.1 Live Storage.**” Under ***Potential Hazards,*** add “**chemical and physical contamination.**”

(proposed) **7.10 STORAGE**, expand to include a new subsection “**7.10.2 Raw Storage**” to read as follows:

“7.10.2 Raw Storage

Potential Hazards: microbiological pathogens

Potential Defects: unlikely

Technical Guidance:

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

Reason: The U.S. suggests that guidance is needed for “Raw Storage.” The original “7.6.5 Storage” addressed only live storage and therefore, may remain as live storage guidance with the addition of guidance for raw storage. Moving this whole section to 7.10 coincides with the new flow diagram.

7.6.6 Distribution, renumber to “**7.11 DISTRIBUTION**,” include the bulleted information now in “7.6.6 Distribution” under a new subsection titled “**7.11.1 Distribution of Live**,” and ***Potential Hazards***, change “*unlikely*” to “***Microbiological pathogens***.”

(proposed) **7.11.1 Distribution of Live**, 2nd bullet, revise to read:

- “Bivalve molluscs intended for human consumption should only **be distributed** in closed packaging.”

(proposed) **7.11 DISTRIBUTION**, expand to include a new subsection “**7.11.2 Distribution of Raw**” to read as follows:

“7.11.2 Distribution of Raw

Potential Hazards: *Microbiological pathogens*

Potential Defects: *unlikely*

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: The U.S. suggests that guidance is needed for “Distribution of Raw.” The original “7.6.6. Distribution” addressed distribution only of live and therefore, may remain as is with the addition of guidance for distribution of raw. Moving this whole section to 7.11 coincides with the new flow diagram.

7.7 POST HARVEST TREATMENT, rename to read **PROCESSING TO REDUCE OR LIMIT TARGET ORGANISMS** and remove brackets.

Reason: This section should be included in this code in order to incorporate processes such as low heat, hydrostatic pressure, irradiation, and individual quick freezing that reduce or limit target organisms while maintaining the sensory qualities of a live raw product.

7.7 POST HARVEST TREATMENT (changed to PROCESSING TO REDUCE OR LIMIT TARGET ORGANISMS), ***Potential Hazards***, revise to read, “~~*Failure to eliminate or reduce microbiological contamination by target organisms*~~”

Reason: The description of potential hazards should be consistent throughout the text and with other sections of the Code of Practice.

7.7 POST HARVEST TREATMENT (changed to PROCESSING TO REDUCE OR LIMIT TARGET ORGANISM), ***Technical Guidance***, **third bullet**, revise to read, “The treatment parameters established to reduce or eliminate pathogens should be approved by the ~~appropriate~~ official **agency** having jurisdiction.”

Reason: Editorial change for consistency throughout the text.

(changed to PROCESSING TO REDUCE OR LIMIT TARGET ORGANISMS), last three paras, delete.

Reason: The information in these paragraphs is unnecessary here because it is generally included in other sections.

7.7.1 Heat treatment for purification purposes, delete entire subsection.

Reason: This section of the Code of Practice currently limits the definition of purification to mean depuration and therefore, it would be confusing to link heat treatment to “purification.” We are aware of only two types of heat treatment in current use that are within the scope of this section of the code of

practice. Those include low heat as a type of processing to reduce or limit target organisms, mentioned in 7.7, and heat shocking as described in 7.7.2.

7.7.2 Heat shocking of bivalve molluscs followed by packing, renumber to “7.8.2,” delete last bullet and revise third bullet to read as follows:

- “Before heat shocking the bivalve molluscs should be inspected ~~if~~ **to determine whether** the bivalve molluscs are alive and not badly damaged.”

Reason: Heat shocking is a method to remove shells from the bivalve molluscs. This method is a type of shucking process and should be included under a separate section that describes shucking processes (see new section 7.8 SHUCKING below). The third bullet should be revised as above for clarity as to why the inspection is conducted. The last bullet may be deleted because this section refers to heat use for shucking only.

(proposed) **7.8.2 Heat shocking of bivalve molluscs followed by packing**, the term “heat shocking” should be used consistently in this section rather than be used interchangeably with “heat shucking.”

7.8 DOCUMENTATION, renumber to “7.12,” and 7.8 becomes a new section (see below).

“**7.8 SHUCKING**,” add as a new subsection to read as follows and expand to include a new subsection “**7.8.1 Hand and Mechanical Shucking and Washing**”:

“7.8 SHUCKING

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.

7.8.1 Hand and Mechanical Shucking and Washing

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

Potential Hazards: Physical contamination, microbiological contamination

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

Technical Guidance:

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

Reason: The Draft Code did not include shucking by hand or by mechanical means, only by shocking by heat/steam. Both of these shucking processes should be included here. Shucking is often the last step before “further processing” and therefore should be included in this section of the code rather than be included in sections of the code devoted to “further processing” (i.e. canning, marinating, breading, etc.).

7.9 LOT IDENTIFICATION AND RECALL PROCEDURES, renumber to “7.13” and revise first two bullets to read as follows:

- “Each product should have an easy identifiable lot number. This lot number must include an identification code, the number of the establishment **that distributes the product**, the country of origin and day and month of packing, in order to facilitate the trace-back of the product. A record keeping system **should be** based on these lot numbers so that individual lots of bivalve molluscs can be traced from the growing area to the end user.
- If a recall must be carried out, its success depends on **having certain recall procedures prepared** in advance.

Reason: These suggested changes remove the need to refer to a “distribution center”.