

# codex alimentarius commission



FOOD AND AGRICULTURE  
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Agenda Item 9

CX/FFP 08/29/7-Add.2

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

Twenty-ninth Session  
Trondheim, Norway, 18 - 23 February 2008

### PROPOSED DRAFT STANDARD FOR SMOKED FISH, SMOKED-FLAVOURED FISH AND SMOKED-DRIED FISH COMMENTS AT STEP 3 (Brazil, European Community, United States)

#### BRAZIL

- Item 2.1.2 – First bullet

Brazil suggests deleting the text between brackets since it refers to smoke flavoured fish and not to smoked fish which includes fish that has undergone a hot or cold smoking process.

#### EUROPEAN COMMUNITY

The European Community and its Member States (ECMS) wish to commend the Netherlands and the electronic Working Group for having produced this draft Standard for Smoked Fish.

The ECMS generally support the Codex document and would like to propose the following comments:

#### PRELIMINARY COMMENT

It would be useful to have a compilation of the data collected in order to see whether they really justified amending the scope.

#### 1. Scope

01. The expression «*dried-smoked*» should be preferred and, when the differences between the two products are defined subsequently in the document, their conservation and use should be clarified: [smoked fish: is conserved at a controlled temperature and can be consumed as it is or needs to be cooked before consumption][dried-smoked fish: is kept at ambient temperature and requires subsequent preparation to enable it to be consumed]

#### 2. Description

##### 2.1. SMOKED FISH

##### 2.1.1. PRODUCT DEFINITION

##### First paragraph

02. In the first sentence, the expression "without further cooking" implies that cold smoking is a form of cooking. Therefore, it is suggested to delete the last part as follows:

*«Smoked fish is prepared from fish which has undergone a hot or cold smoking process ~~that renders a product that is generally eaten without further cooking~~»*

.In the second sentence: it is proposed to delete the word “**traditional**” as it is usually used in case of smoking process in traditional smoking kilns and the definition covers also smoking process in modern chambers automatically controlled.

*«The smoke must be applied through a ~~traditional~~ smoking process.....».*

03. The definitions must enable a distinction to be made between traditional smoking and smoking using regenerated smoke. Traditional smoking does not involve the use of liquid smoke. However, there is also a treatment with regenerated liquid smoke which can be regarded as equivalent to smoking (exposure of food products to smoke) and therefore described as smoking. The expression "traditional" should therefore be deleted in the second sentence of the first paragraph of 2.1.1:

*«The smoke must be applied through ~~a traditional smoking process~~ one of the smoking processes defined in paragraph 2.1.2 and the end product must have smoked sensory characteristics»*

#### Second paragraph

04. The second part of the sentence in the second paragraph is not easy to understand. It could be reworded as follows:

*«Countries where the products are to be consumed may allow these products in an unviscerated state or may require evisceration, either before or after processing, in such a way as to control the risk of botulinum (cf. Annex 3) ~~since the margin of error in the control of Clostridium botulinum is small even when good practices are followed and the consequences are severe~~».*

#### **Process definitions**

05. The title of this section should be amended:

##### 2.1.2. Process definitions

06. Atomised (regenerated) smoke should be included in the definition of **smoking** and the following wording is suggested:

*«**Smoking** » is the ~~traditional~~ process of treating fish by exposing it to smoke from ~~burning smouldering wood or smouldering plant materials~~ [or smoke concentrates (liquid smoke) derived from burning or smouldering plant materials]. This ~~traditional~~ process is characterised by an ~~integrated~~ combination of one or more salting, drying, heating and smoking steps in a smoking chamber (~~kiln~~).*

*«Traditional smoking» is a process characterised by the use of smoke from wood or other plant matter smouldering at that time.*

*«Smoking by regenerated smoke» is treatment of the product by smoke which is reproduced or regenerated by atomising smoke condensates (liquid smoke) in a smoking chamber under time and temperature conditions similar to those for hot and cold smoking ».*

07. **Hot smoking**: there is an error in the expression used.

*«cause the complete ~~denaturation~~ coagulation of the proteins in the fish flesh ... »*

08. Proposed amendments

*«**Hot smoking**» is a smoking process in which ~~pre-salted and pre-dried~~ fish is smoked at an appropriate combination of temperature and time sufficient to cause the complete ~~denaturation~~ coagulation of the proteins in the fish flesh. ~~«Hot smoking» is generally sufficient to destroy bacteria, kill parasites and destroy non-sporulated pathogens of human concern.~~»*

09. **Cold smoking**

*«**Cold smoking** », treatment by smoke at a temperature lower than that at which the proteins in the fish flesh will be coagulated by the heat, is a smoking process in which fish is treated at an appropriate*

*temperature and time combination to lower ~~water content~~ water activity ( ~~a cold smoking process will not cause considerable coagulation of the fish~~-»*

10. It is incorrect to say that **salting** reduces "water content in fish flesh" in the case of salting by injection. The term "free water content" (aw) should perhaps be used.

11. The definition of salt is given in the Code of Practice for fishery products (Section 2.7, which is currently being drafted) and is broader than here. It would be better to refer to the Code of Practice and to avoid being too restrictive, since there are experiments to reduce the concentration of salt and replace part of the sodium chloride.

The proposed wording is also useful in that it accommodates salts other than NaCl (such as KCl), whilst the draft covers only NaCl.

*«**Salting** » is a process in which fish is salted or pre-salted with salt (~~sodium chloride~~) of food grade quality to lower water content and/or activity ~~water content~~ in fish flesh ~~to facilitate the smoking process~~ and to enhance flavour by any appropriate salting technology. ...*

12. **«Storage»** It is not storage which has to be described here but rather the conditions for conservation during storage.

*«~~During storage is a process in which smoked fish is stored~~ must be kept refrigerated or frozen to assure...»*

## **2.2. SMOKE-FLAVOURED FISH**

### **2.2.1. Product Definition**

13. There is no point in saying that the end product must have smoke sensory characteristics when different products and processes are defined. Smoke-flavoured fish is bound to have different sensory characteristics than smoked fish, which justifies different labelling; the texture, humidity, colour and even the taste can *inter alia* be different.

*«~~the end product must have smoke sensory characteristics.~~ "The end product must have a smoked taste"*

14. **First paragraph:** The third sentence in the first paragraph, which will be included in the definitions, should be deleted in the interests of consistency with the following paragraphs:

*«~~The smoke flavour can be applied to the fish through dipping, spraying, injecting or any other technology.~~*

15. The final wording of this paragraph would be as follows:

*«Smoke-flavoured fish is prepared from fish that has been treated with smoke flavours without undergoing a smoking process as described in 2.1. in a smoking chamber (kiln). The fish can be eaten without further processing. The smoke flavour can be applied to the fish through dipping, spraying, injecting or any other technology. The end product must have a smoked taste.»*

### **2.2.2 Process definitions**

#### **«Smoke flavouring»**

16. It might be useful to mention soaking as one of the techniques for flavouring products (cf. the previous paragraph):

*«**Smoke flavouring** is a process in which fish or fish preparations are treated with smoke flavour. The smoke flavour can be applied by any technology (e.g. dipping, spraying, injection, soaking).»*

#### **«Storage»**

17. It is not storage which has to be described here but rather the conditions for conservation during storage.

*«~~During storage is a process in which~~ smoke-flavoured fish is stored must be kept refrigerated or frozen to assure its safety... ...»*

## 2.3. SMOKE-DRIED FISH

### 2.3.1. Product definition

18. The expression «dried-smoked» should be used in preference to smoke-dried.

19. Proposed amendment

*«~~Smoke dried~~ Dried-smoked fish is prepared from fish .... that renders a product ...that needs further processing—subsequent preparation ... the end product must have dried-smoked sensory characteristics.»*

### 2.3.2. Process definitions

20. It is incorrect to say that **salting** reduces "water content in fish flesh" in the case of salting by injection. The term "free water content" (aw) should perhaps be used.

21. The definition of salt is given in the Code of Practice for fish and fishery products (Section 2.7, which is currently being drafted) and is broader than here. It would be better to refer to the Code of Practice and to avoid being too restrictive, since there are tests for reducing the concentration of salt and replacing part of the sodium chloride.

The proposed wording is also useful in that it accommodates salts other than NaCl (such as KCl), while the draft covers only NaCl.

*«**Salting** » is a process in which fish is salted or pre-salted with salt (~~sodium chloride~~) of food-grade quality to lower water content and/or activity ~~water content~~ in fish flesh ~~to facilitate the smoking process~~ and to enhance flavour by any appropriate salting technology.»*

#### «Storage»

22. It is not storage which has to be described here but rather the conditions for conservation during storage and any wording which suggests that conservation at ambient temperature may guarantee food safety must be avoided.

*«During storage ~~smoke dried~~ dried-smoked fish must be kept typically at ambient temperature, whereby the intensity of the drying-smoking process must be sufficient to assure the safety and quality of the product in conformity with sections 3 and 5 when it is kept»*

## 3. Essential composition and quality factors

### 3.3. WOOD OR OTHER PLANT MATERIAL FOR GENERATION OF SMOKE

23. *The relevant provisions outlined in the Proposed draft Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes (N07-2006) (under developments) should be considered.*

24. Last sentence Proposal for change: "In addition, wood or other plant material must **be handled in a way to avoid** contamination and microbiological or fungal growth."

### 3.5. DECOMPOSITION

25. In the English version « 10 m » should be replaced by « 10 mg ».

26. Reference should be made to fish which are likely to contain histamines and not to all fish, for which such analysis is not necessary:

*« For species belonging to families of fish likely to accumulate histamine, the product shall not contain more than 10 mg of histamine per 100 g of fish flesh based on the average of the sample unit tested.»*

#### 4. Food additives

27. The brackets are to be kept at this stage.

#### 5. Hygiene and handling

##### 5.3. PAH

28. Reference should be made to the Proposed draft Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes (N07-2006) (under development). Thought might be given to having different concentration limits depending on the process and on the category of products (smoked, smoke-flavoured, dried-smoked)

*«Benzo(a)pyrene is widely accepted as an indicator for the level of polycyclic aromatic hydrocarbons. No sample unit of smoked fish ~~smoke flavoured fish~~ shall contain a level of benzo(a)pyrene that exceeds 5µg/kg of fish muscle in the end product. This level may be even lower for smoke-flavoured fish. For smoke-dried fish this level applies only to the final ready to eat product.»*

##### 5.4. PARASITES

29. It would be useful to make a distinction between wild and farmed fish, since farmed fish can be contaminated only if their feed is not properly controlled (unprocessed or lightly processed feed). As in the case of histamine, the paragraph on parasites should apply only to fish liable to have them.

*«Smoked fish and smoke flavoured products shall not contain living parasites. (e.g. larvae of nematodes) and particular attention needs to be paid to cold-smoked products. For fish likely to have parasites, viability of nematodes, cestodes and trematodes shall be examined according to Annex 1. If living parasites may be present are confirmed, the products must not be placed on the market for human consumption before they are treated in conformity with the methods laid down in Annex 2.»*

##### 5.5. LISTERIA MONOCYTOGENES

30. CCFFP should consider the ongoing work on this issue in the CCFH to further elaborate this section

The concentrations of *Listeria monocytogenes* in smoked products must be lower than those likely to present a risk for consumers (General Principles of Food Hygiene CAC/RCP 1-1969, Rev. 4-2003)

##### 5.7. HISTAMINE

31. The term «*muscle*» should be replaced by «*flesh*». Moreover, reference should be made to fish likely to contain histamine and not to all fish, for which this analysis is not necessary.

*"for species belonging to families of fish susceptible to accumulating histamine, no sample unit shall contain histamine that exceeds 20mg/100 g of fish flesh muscle»*

#### 6. Labelling

##### 6.1. NAME OF THE FOOD

*~~«The name of the food declared on the label shall only contain the word "smoked" if processed according to 2.1, contain the word "smoke flavoured" if processed according to 2.2, or "smoke-dried" if processed according to 2.3.~~*

*~~In addition to the specified labelling designation, common, usual or trade names of the fish species shall be used in accordance with the law and custom of the country in which the food is sold in a manner not to mislead the consumer. Any reference to the origin of the fish, as opposed to the place of processing, shall not mislead the consumer»~~*

32. Proposed wording to avoid any ambiguity:

*«The name of the food must be "smoked X" if treated by the processes described in paragraph 2.1, "smoke-flavoured X" if treated by the processes described in paragraph 2.2, "dried-smoked X" if treated by the processes described in paragraph 2.3, X being the common or commercial name of the species of fish used in accordance with the law or the customs of the country in which the food is*

sold, so as not to mislead the consumer. Where smoke condensate has been used this must be clearly indicated on the label»

### 6.3. LABELLING OF NON-RETAIL CONTAINERS

33. In the second paragraph, an identification mark is not sufficient to identify a lot, as the lot number and hence the manufacturing date are not contained in the identification marks.

## 7. Sampling, examination and analysis

### 7.1, SAMPLING

34. It is surprising to see the size of the sample unit specified in a Codex standard.

## 8. Definition of defectives

### 8.4 FLESH ABNORMALITIES

35. The criterion of 85% moisture does not appear relevant (this is a very high concentration which may encourage fraud in connection with products immersed in liquid).

## 9. Lot Acceptance

36. "*(ii) the average net weigh of all sample units is not less than the declared weigh, provided there is no unreasonable shortage in any container and no individual container is less than 95% of the declared weigh; and*"

## UNITED STATES

In response to CX/FFP 08/29/7, the United States respectfully submits the following comments on the Proposed Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish (at step 3 of the Procedure). Recommended additional language within sentences is highlighted in bold for the convenience of the reader.

### 2.1.2 Process Definitions

Comment: The definitions listed under this subsection would more appropriately be described in the Code of Practice. Regardless of where the Committee decides to place the definitions, the U.S. has the following suggestions:

#### 2.1.2 Process definitions, first bullet "Smoking"

- Delete the word "traditional" where it appears

Reason: "Traditional" does not include the use of liquid smoke so the term is inappropriately used in this definition.

- **First sentence**, delete the brackets.

- **Last sentence**, Revise (to read as follows) and move to the end of the first paragraph under 2.1.1 Product definition:

"The process is characterized by an integrated combination of salting, drying, heating (**where used**) and smoking steps in a smoking chamber (kiln)."

Reason: The sentence is more appropriately placed under 2.1.1 Product definition because it is a general definition that describes all smoked products, including cold smoked products.

#### 2.1.2 Process definitions, second bullet "Hot smoking," revise to read as follows:

" "Hot smoking" is a smoking process in which pre-salted and pre-dried fish is smoked at an appropriate combination of temperature and time sufficient to cause the complete denaturation of the fish flesh, to kill parasites, to **destroy** non-spore forming pathogens, **and to injure spore formers** of human concern."

Reason: The cook required in hot smoking is at a level to injure non-proteolytic spores of *Clostridium botulinum*.

#### 2.1.2 Process definitions, third bullet "Cold smoking," revise to read as follows:

“ “Cold smoking” is a smoking process in which **pre-salted and pre-dried fish is smoked at an appropriate combination of temperature and time that will not** cause considerable coagulation of the fish flesh.”

Reason: To be consistent with what the U.S. is proposing for the definition of ‘hot smoking.’

**2.1.2 Process definitions, fourth bullet “Salting,”** revise to read as follows:

“ “Salting” is a process in which fish is **treated** with salt of food grade quality (e.g. dry salting, brining, injection salting) to lower water **activity** in fish flesh and to enhance flavour.”

Reason: Clarification.

**2.1.2 Process definitions, last bullet “Storage,”** revise to read as follows:

“ “Storage” is a process in which smoked fish is stored refrigerated or frozen **as described in Annex 3** to assure their safety and quality in conformance with Sections 3 and 5.”

Reason: A reference to Annex 3 should be made here because that is where the storage temperatures are actually described.

**2.2.2 Process definition, first bullet “Smoke flavours,”** revise to read as follows:

“Smoke flavours are smoke condensates **in aqueous or oil solution or dry.**”

Comment: The U.S. is unaware of any science that would support the use of artificial flavour blends as having the same safety characteristics as smoke condensate where *C. botulinum* is a hazard (refrigerated vacuum packaged fish). There are also food additive implications for what those ingredients might be.

### **2.3 Smoke-Dried Fish**

Comment: The U.S. does not believe that this product should be included because it is fundamentally different and is not ready to eat, resulting in significantly different hazards that are relevant. We would welcome the countries that produce these products to further explain the processes and consider whether their inclusion is appropriate. If the Committee decides to include it, we offer the following comments:

**2.3.2 Process definition, second bullet “Drying,”** revise to read as follows:

“ “Drying” is a process in which the moisture content in the fish flesh is decreased **to water activity of 0.85 or less in a time frame that prevents the toxin formation or growth of pathogens of public health concern. This could be accomplished** by exposing the fish to circulating air, mechanical dryers or natural conditions using sun and wind energy.”

**2.3.2 Process definition, fourth bullet “Packaging,”** revise to read as follows:

“ “Packaging” Smoke-dried fish should be packed in a way to avoid contamination **and to prevent rehydration.**”

Reason: If rehydration occurs pathogens can grow during storage.

## **4. FOOD ADDITIVES**

Comment: We recommend inserting the following language:

**“Flavors**

**Smoked flavors as defined by Codex Alimentarius.**

**Colours, preservatives, flavor enhancers and antioxidants used in accordance with Tables 1 and 2 of the Codex General Standard of Food Additives in food category 9.2.5 (Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms) are acceptable for use in foods conforming to this standard.”**

We also recommend that the CCFPP forward the following provisions to the Codex Committee on Food Additives (CCFA) with a recommendation that CCFA endorse them for adoption at Step 8 in the General Standard for Food Additives food category 9.2.5:

<b>Additive</b>	<b>ML</b>	<b>Comment</b>
<b><u>Preservatives</u></b>		
251 Sodium Nitrate	500 mg/kg	For use in smoked fish products only
250 Sodium Nitrite	200 mg/kg	For use in smoked fish products only
<b><u>Colours</u></b>		
129 Allura Red AC (FD&C Red No. 40)	500 mg/kg	For use in smoked fish products only
110 Sunset Yellow 6 (FD&C Yellow No. 6)	500 mg/kg	For use in smoked fish products only

**5.3 Polycyclic Aromatic Hydrocarbons (PAH), delete this subsection**

Reason: The science does not support this level as posing a health risk at the level of U.S. consumption.

**ANNEX 3, Title**, change to read as follows:

**“ANNEX 3 Combinations of Product Attributes that Minimize the Likelihood of *Clostridium botulinum* Toxin Formation”**

Reason: The language that we propose replacing refers to “control and prevention” of *Clostridium botulinum* toxin. This language has generated some confusion because “control and prevention” sound like matters that should be addressed in a code of practice, rather than in a standard. In fact, this Annex refers to product attributes, some of which are initially addressed in the Process Definition section (2.2). The choice presented to the CCFFP in our view, is to select a single attribute to control *Clostridium botulinum*, such as 3.5% water phase salt, or to acknowledge that the science allows for alternative attributes depending upon conditions within the country of sale. This Annex is an attempt to do the latter. It may be appropriate for the code of practice for smoked fish products to address how to achieve these attributes, but we feel that it is essential that they be provided within the standard.

**ANNEX 3, Introductory paragraph, last sentence**, revise to read as follows:

**“This table does not apply to smoke-dried fish because **the required water activity of 0.85 or below inhibits the growth of all foodborne pathogens so that refrigeration is not required.**”**

**ANNEX 3, Table, Column 1, Title**, revise to read as follows: **“Product Temperature during Storage”**

Reason: To emphasize that Annex 1 provides options for product attributes, consistent with a Codex standard.

**ANNEX 3, Table, Column 2, Row 1**, delete “Any” and replace with **“Reduced Oxygen (including vacuum packaging and modified atmosphere packaging\*)”**.

Reason: Correction. To refer to the appropriate type of packaging.

**ANNEX 3, Table, Column 2, Row 3**, replace the double asterisk with a single asterisk

Reason: This is a technical revision to accommodate other comments.

**ANNEX 3, Table, Column 3, Title**, delete asterisk

Reason: We are recommending that the paragraphs to which the asterisk applies be moved into the introductory paragraphs before the table itself. An asterisk would no longer be needed.

**ANNEX 3, Table, Column 3, Row 2, second sentence**, revise end of sentence to read as follows:

**“...might choose an aqueous phase salt barrier of at least 3% to 3.5% as **an additional barrier.**”**

Reason: To avoid the use of the term “precaution.” That term has potential meaning that would be unintended in this context.



ANNEX 3, Table, Column 4, Row 1, change to read as follows:

**“*C. botulinum* toxin cannot form below 3°C. Temperature monitoring is needed for each package, e.g. time temperature integrators, to ensure that the temperature does not exceed 3°C.”**

Reason: Clarification

ANNEX 3, Table, Column 4, Row 2, first sentence, revise to read as follows:

**“When these products are packaged aerobically, 5°C is the maximum recommended storage temperature for the control of pathogens generally and for quality.”**

Reason: Clarification

ANNEX 3, Table, Column 4, Row 3, change to read as follows:

**“*C. botulinum* toxin cannot form when product is frozen. In the absence of adequate aqueous phase salt, toxin production can occur after thawing so, labeling information about the need for the consumer to keep the product frozen, to thaw it under refrigeration, and to use it immediately after thawing, is important.”**

Reason: Clarification

ANNEX 3, Table, Column 4, Row 4, add a sentence to read as follows:

**“For that reason, the country where the product is consumed may require the higher aqueous phase salt as a barrier to growth of non-proteolytic strains of *C. botulinum* if there are concerns about the ability of transporters, retailers or consumers to maintain time/temperature control.”**

ANNEX 3, Table, Column 4, Row 5, revise to read as follows:

**“At these temperatures or higher non-proteolytics (*C. botulinum*) are controlled when aqueous phase salt is 5%. Proteolytic strains of *C. botulinum* start growing above 10°C, however.**

**It should be noted that the temperature range of >5°C to 10°C is not recommended for smoked fish products because of the possibility of growth of other microorganisms. It is included in this Annex solely to provide information about attributes affecting *C. botulinum* toxin formation when packaging is reduced oxygen.”**

Reason: Clarification

ANNEX 3, first asterisk, first sentence, revise to read as follows:

**“As an alternative to aqueous phase salt, certain time/temperature parameters can minimize the likelihood that *C. botulinum* will grow in the product.”**

Reason: To clarify that this Annex refers to product attributes. The proposed revision would replace language that refers to “controls.”

ANNEX 3, first asterisk, second paragraph, first sentence, revise to read as follows:

**“However, in countries where consumer acceptance and regulatory enforcement of shelf life are not norms, continuous monitoring such as that provided by time/temperature integrators on consumer packages can be an important adjunct to shelf-life monitoring in the country where the product will be consumed.”**

Reason: To clarify that time/temperature integrators are a monitor of temperature and not a part of labeling.

ANNEX 3, first asterisk, both paragraphs, delete the asterisk and move both paragraphs to the introductory material before the table. They would be the second and third paragraphs of the introduction.

Reason: To emphasize the importance of shelf life considerations as described in these paragraphs. Shelf life is an important factor in some countries. The table itself does not address shelf life because the original workgroup that convened in Denmark concluded that the various possibilities for shelf life would be too difficult to capture within the table.

ANNEX 3, second asterisk, replace the double asterisk with a single asterisk

Reason: We have suggested moving the paragraphs contained under the first asterisk to the introductory paragraphs before the table so, the second asterisk would then be single rather than double.

### ANNEX 3

Comment: If all the U.S. suggestions on the Annex are incorporated into the standard, a revised version of the Annex would read as follows (with the table on second page):

#### ANNEX 3 Combinations of Product Attributes that Minimize the Likelihood of *Clostridium botulinum* Toxin Formation

Countries where the products are to be consumed can be expected to make their science-based risk management choices within this framework, i.e., select some options and exclude others, based on conditions within the country (e.g., nature and enforcement of refrigeration and shelf life controls; transportation times and conditions; variability in amount of salt in the aqueous phase that could occur despite best efforts to achieve a required percentage, etc.), and the level of protection that the country chooses for itself for this particular risk. This table does not apply to smoke-dried fish because **the required water activity of 0.85 or below inhibits the growth of all foodborne pathogens so that refrigeration is not required.**

As an alternative to aqueous phase salt, certain time/temperature parameters can minimize the likelihood that *C. botulinum* will grow in the product. *C. botulinum* cannot grow and produce toxin at or below 3°C. Other time/temperature combinations exist that similarly control the formation of toxin (Skinner,G.E. and Larkin,J.W. (1998) Conservative prediction of time to *Clostridium botulinum* toxin formation for use with time-temperature indicators to ensure the safety of foods. *Journal of Food Protection* **61**, 1154-1160). Where enforcement of shelf life as well as consumer acceptance of shelf life are norms, the country may select a system that relies on the combination of existing storage temperature conditions (i.e. during transport, retail storage, and consumer storage) and shelf life limitations.

However, in countries where consumer acceptance and regulatory enforcement of shelf life are not norms, continuous monitoring, such as that provided by time/temperature integrators on consumer packages can be an important adjunct to shelf-life monitoring in the country where the product will be consumed. The necessity for time/temperature integrators exists because, unlike freezing, temperature control through refrigeration is not a visual condition and cannot be determined without an additional monitoring control.

Product Temperature During Storage	Packaging	Aqueous Phase Salt	Comments
[(0°C to 3°C)]	Reduced Oxygen (including vacuum packaging and modified atmosphere Packaging*)	No minimum aqueous phase salt is needed.	<i>C. botulinum</i> toxin cannot form below 3° C. Temperature monitoring is needed for each package, e.g. time temperature integrators, to ensure that the temperature does not exceed 3°C.
[(>3°C to 5°C)]	Aerobically Packaged	No minimum aqueous phase salt is needed.  Nonetheless, where there is a reasonable possibility of severe time/temperature abuse, the country where the product is being consumed might choose an aqueous phase salt barrier of at least 3% to 3.5% as an additional barrier.	When these products are packaged aerobically, 5°C is the maximum recommended storage temperature for the control of pathogens generally and for quality. In air-packaged products, aerobic spoilage organisms provide sensory signs of spoilage before the formation of toxin by <i>C. botulinum</i> . However, even in air packaging it is possible for anaerobic micro-environments to exist and toxin may form if the product is subject to severe time/temperature abuse. For that reason, the country where the product is consumed may still require aqueous phase salt as a barrier to growth of non-proteolytic strains of <i>C. botulinum</i> if there are concerns about the ability of transporters, retailers or consumers to maintain time/temperature control.
Frozen (< or = -18°C)	Reduced Oxygen (including vacuum packaging and modified atmosphere Packaging*)	No minimum aqueous phase salt is needed for safety.	<i>C. botulinum</i> toxin cannot form when product is frozen. In the absence of adequate aqueous phase salt, toxin production can occur after thawing so, labelling information about the need for the consumer to keep the product frozen, to thaw it under refrigeration, and to use it immediately after thawing, is important.
[(>3°C to 5°C)]	Reduced Oxygen (including vacuum packaging and modified atmosphere packaging)	Aqueous phase salt at minimum level of between 3% & 3.5% may be selected by the country where the product is to be consumed.	Aqueous phase salt at a minimum level of between 3 and 3.5% (aqueous phase salt) in combination with chilling will significantly delay (or prevent) toxin formation. For that reason, the country where the product is consumed may still require the higher aqueous phase salt as a barrier to growth of non-proteolytic strains of <i>C. botulinum</i> if there are concerns about the ability of transporters, retailers or consumers to maintain time/temperature control.
[>5°C to 10°C]	Reduced Oxygen	5% Aqueous Phase Salt provides complete protection	At these temperatures or higher non-proteolytics ( <i>C. botulinum</i> ) are controlled when aqueous phase salt is 5%. Proteolytic strains of <i>C. botulinum</i> start growing above 10°C, however.  It should be noted that the temperature range of >5°C to 10°C is not recommended for smoked fish products because of the possibility of growth of

			other microorganisms. It is included in this Annex solely to provide information about attributes affecting <i>C. botulinum</i> toxin formation when packaging is reduced oxygen.
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\*As new technologies are developed, e.g. modified atmosphere with high oxygen, new controls may be defined.