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Agenda Item 4 **CX/FFP 11/31/4**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS
Thirty-First Session
Tromsø, Norway
11 – 16 April 2011

DRAFT STANDARD FOR SMOKED FISH, SMOKE-FLAVOURED FISH AND SMOKE-DRIED FISH
COMMENTS AT STEP 6
(United Status of America)

UNITED STATES OF AMERICA

The United States is pleased to submit the following comments on the Proposed Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish (at Step 6 of the Procedure) in response to CL 2010/26-FFP. Recommended additional language within sentences is highlighted in bold for the convenience of the reader.

2.1.2 Process Definitions, 2nd bullet, "Smoking by regenerated smoke". Revise the last sentence as follows:

"Smoke condensates are products obtained by controlled thermal degradation of wood in a limited supply of oxygen (pyrolysis), subsequent condensation of the resultant smoke vapours, and fractionation of the resulting liquid products **to reduce polycyclic aromatic hydrocarbons (PAHs)**."

Reason: Fractionation should aim to reduce PAHs while retaining other natural antimicrobial components of smoke.

2.1.2 Process definitions, 4th bullet, "Cold smoking". Revise as follows:

"Cold smoking is a process of treating fish with smoke using a time/temperature combination that will not cause significant coagulation of the proteins in the fish flesh **and will not harm naturally occurring spoilage bacteria,** but that will cause some reduction of the water activity."

Reason: Natural spoilage bacteria are necessary so that the product will spoil before Clostridium botulinum toxin production occurs. It is likely that they will also produce acid, which will further inhibit C. botulinum growth and toxin formation.

2.2.1 Product definition. Revise 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, **and may undergo a salting and/or drying process**. The end product must have a smoked taste.

Reason: Salting and drying processes may be used as with smoked fish and smoke-dried fish.

2.2.2 Process definition. Add the following two bullets:

• "Salting" is a process of treating fish with salt of food grade quality to lower water activity in fish flesh and to enhance flavour by any appropriate salting technology (e.g. dry salting, brining, injection salting).

• "Drying" is a process in which the moisture content in the fish flesh is decreased by exposing the fish to circulating air."

Reason: Added the salting and drying definitions to be consistent with the suggested change for Section 2.2.1 (Product definition) above.

2.3.2 Process definition, first bullet. Revise as follows:

"Smoke drying" is a process in which fish is treated by combined smoking and drying steps to such an extent that the final product can be stored and transported without refrigeration and to achieve a water activity of 0.85 or less**, as necessary to control bacterial pathogens and fungal spoilage.**"

Reason: We question if 0.85 is the target water activity generally used for smoke-dried fish, because some fungal spoilage organisms can grow at water activity below 0.85 (0.6 to 0.85). Water activity of 0.85 is necessary to control bacterial pathogens.

3.4 Decomposition. Add an 's' to the word 'unit' as follows:

"The product shall not contain more than 10 mg of histamine per 100g fish flesh based on the average of the sample unit**s** tested."

Reason: The singular implies that a single sample unit will be tested multiple times.

Add new subsection 3.5 as follows (and renumber current subsection 3.5 to 3.6):

> **"3.5 Water activity/water phase salt**
>
> **Shelf stable smoke-dried fish shall have a water activity ≤ 0.85. Other products should be formulated to minimize the likelihood of Clostridium botulinum toxin formation (see Annex 2)."**

Reason: Compositional requirements, including safety requirements, should be listed in the Essential Composition and Quality Factors section per Codex procedure.

4. FOOD ADDITIVES. Comment: The U.S. recommends using the electronic working group's *Proposed Procedure for the Development and Review of Additive Provisions in Fish and Fishery Product Standards* to help elaborate additive provisions.

6.3 Parasites. Revise as follows:

"Products covered by this Standard shall not contain living parasites and particular attention needs to be paid to cold smoked or smoke flavoured products, which should be frozen before or after smoking **to kill any hazardous parasites that may be present** ~~if a parasite hazard is present~~ (see Annex 1). Viability of nematodes, ~~and~~ cestodes and trematodes shall be examined according to Section 8.9 ~~and/or 8.10~~."

Reason: Parasites are a potential hazard in virtually all fin-fish. The U.S. is proposing a revision to Section 8.9 that adds a viability testing method that can be used during determination of visible parasites (Section 8.10).

6.5 *Clostridium botulinum,* 1st paragraph. Revise as follows:

"Toxins of *Clostridium botulinum* are not allowed in smoked fish, smoke-flavoured fish, and smoke-dried fish products. The formation of *Clostridium botulinum* toxin can be controlled through an application of science-based options such as packaging type, **smoking temperature,** storage temperature, and water activity, e.g. by use of salt in the water phase. Examples are shown in the Table in Annex 2, which addresses these control options."

Reason: Processing temperature controls are important to maintain secondary barriers to botulinum toxin formation (heat damage of Clostridium botulinum spores in hot smoked; and low heat to allow survival of natural spoilage bacteria in cold smoked).

6.5 *Clostridium botulinum,* 2st paragraph. We question if any country that requires evisceration would allow evisceration after processing (smoking).

6.6 Histamine. Revise as follows:

"**No sample unit** ~~The product~~ shall ~~not~~ contain histamine that exceeds 20 mg/100g fish flesh. This applies only to susceptible species."

Reason: The draft standard appears to allow averaging for a safety limit. The proposed revision is consistent with wording found in other Codex seafood standards, and a previous draft of this standard (Alinorm 08/31/18 Appendix VII). Averaging histamine measurements over multiple sample units for a

safety limit is inappropriate because a single sample unit over the safety limit presents a human health hazard.

7.3 Storage Instructions. Revise as follows:

"7.3 Storage **and Handling** Instructions

The label shall declare storage **and handling** instructions appropriate for the product. **For example, the label on a frozen reduced oxygen package states 'keep frozen until use, thaw under refrigeration, and use immediately after thawing'**."

Reason: Storage and handling instructions are essential for preventing death from botulinum toxin.

8. Sampling, Examination and Analysis. Add new sections for water phase salt and water activity methodology as follows:

"8.11 Determination of water phase salt

The percentage salt (NaCl) in the aqueous phase can be determined by the following calculation:

$$\text{\% salt aqueous phase} = \frac{\text{\% salt} \times 100}{\text{\% water} + \text{\% salt}}$$

% Moisture: AOAC, 952.08, Sec. 35.1.13, *Solids (Total) in Seafood*

% Salt: AOAC, 937.09, Sec. 35.1.18, *Salt (chlorine as Sodium Chloride) in Seafood*

8.12 Determination of water activity

Water activity measurement is performed with a water activity meter (e.g., Decagon, Novasina) that is properly calibrated with reference standards, and operated and maintained in accordance with the manufacturer's instructions."

Reason: There are provisions for water activity and water phase salt in the standard that require methods.

8.1 Sampling. Delete the last paragraph and revise the first paragraph as follows:

"Sampling of lots for examination of the product ~~for quality~~ shall be in accordance with the General Guidelines on Sampling (CAC/GL 50-2004).

A sample unit is the individually packed product or a 1 kg portion from bulk containers.

~~The sampling of lots for microbial analysis and parasites shall be in accordance with the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997). The number of samples to be taken for the determination of the levels of histamine in a lot, shall be determined by the Competent Authority having jurisdiction."~~

Reason:

- *The General Guidelines on Sampling (CAC/GL 50-2004) are inclusive of microbiological sampling and are more thorough than the Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997). The General Guidelines on Sampling are also applicable to sampling for parasites, hazardous material, % salt, water activity, botulism toxin, net weight, and sensory analysis.*
- *We don't understand the need for a special guideline for histamine because the competent authority decides the number of samples for all examinations. Should the histamine sentence be retained, we suggest moving the words "in a lot" to the position directly after the words "to be taken" because histamine is determined separately for each sample unit for safety purposes.*

8.2 Sensory and Physical Examination. Revise as follows:

"Samples taken for sensory and physical examination shall be assessed by persons trained in such examination and in accordance with procedures elaborated in **this section** ~~Sections 8.4 through 8.7~~ and the 'Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories (CAC/GL 31-1999)'."

Reason: Section numbers are inaccurate, and candling for parasites is excluded.

8.4 Determination of Gelatinous Conditions. Delete this section.

Reason: This is the method for the "Flesh abnormalities" defect listed in Section 9.4, and we suggest deleting section 9.4 and determining texture abnormalities along with flavor during sensory analysis.

8.5 Determination of Net Weight. Revise as follows:

"The net weight is determined as the weight of the product, exclusive of **the dried** packaging material, interleaving material, etc."

Reason: See AOAC method 963.26 used for unglazed frozen seafoods which states "Air-dry empty package at room temperature and weigh." Results may vary substantially if excess packaging moisture is not removed, particularly from interleaving sheets in thinly sliced cold smoked fish.

8.9 Determination of the viability of parasites. Revise as follows:

"Methods used for **extracting and** testing the viability of parasites could include the method set out in Annex I for nematodes in the Standard for Salted Herring and Sprats **(Codex Stan 244-2004)** or other ~~validated~~ methods for parasites acceptable to the competent authority having jurisdiction.

If parasites are found during the "Determination of Visible Parasites" (Section 8.10), they may be carefully removed and put into physiological saline for observation of spontaneous movement that indicates viability. Parasites from salted product may exhibit apparent movement because of water absorption, in which case, three hours of equilibration time in saline should be allowed before observation."

Reason:

- *The salted herring and sprat method is a pepsin digestion method used to isolate worms by dissolving fish flesh, followed by observation of extracted worms for spontaneous movement.*
- *The U.S. is not aware of any validated (collaborative) methods for parasite extraction or viability.*
- *A method to determine viability of parasites found during the "Determination of visible parasites" (Section 8.10) is added.*

9.3 Odour and Flavour: Revise as follows:

> "9.3 Odour, Flavour, and Texture:
>
> A sample unit affected by persistent and distinct objectionable odours, ~~or~~ flavours, or **textures** indicative for decomposition, or rancidity, burning sensation or other sensorial impressions not characteristic of the product, such as fuel oil flavor, or gelatinous and/or pasty texture."

Reason: Objectionable textures (flesh abnormalities) may be more generally covered during sensory analysis. See comment for subsection 9.4.

[9.4 Flesh abnormalities]. Delete this section.

Reason: We do not believe that a moisture analysis (Section 8.4) is necessary to determine gelatinous texture, and it would not necessarily detect pasty or other texture defects. Texture can be more generally covered during flavor and odor analysis.

10. Lot Acceptance, subsection iii: Revise as follows:

"(iii) **The Essential Composition and Quality Factors,** Food Additives, Contaminants, Hygiene and Handling and Labelling requirements of Sections **3,** 4, 5, 6 and 7 are met. For histamine no sample unit shall exceed 20mg/100g of fish flesh as per the sampling plan chosen. (Ref. Section 8.3)."

Reason: The essential composition and quality factors of Section 3 should be met for lot acceptance.

ANNEX 1, Procedures sufficient to kill parasites. Revise as follows:

"~~Any~~ **A** method **that is acceptable to the competent authority having jurisdiction shall be** used to kill parasites ~~shall be acceptable to the competent authority having jurisdiction~~."

Reason: To prevent misinterpretation that the competent authority must accept any method.

ANNEX 2, Examples of combinations of product attributes that minimise the likelihood of *Clostridium botulinum* toxin formation. Revise the introductory text as follows:

"Countries where the products are to be consumed can be expected to make their science-based risk management choices with the assistance of this framework, e.g., 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 applies to smoked fish and smoke flavoured fish where the smoke flavor is provided by smoke condensates. If the smoke flavour is imparted by artificial flavor blends, then 5% aqueous phase salt would be required in order to provide complete protection at ~~any temperature over~~ **temperatures between** 3 °C **and 10 °C**. 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 **or water activity** parameters can minimise the likelihood that *C. botulinum* will grow in the product. *C. botulinum* cannot grow and produce toxin ~~at or~~ below 3 ºC or below a water activity of ~~0.85~~ **0.935**. Other time/temperature combinations exist that similarly control the formation of toxin. **(Skinner, G.E. and Larkin, J.W., 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*, 1998; 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.

Reason:

- *The first paragraph was split into two paragraphs for clarity.*
- *In the second paragraph, an upper temperature of 10 °C was added because proteolytic C. botulinum can grow at temperatures above 10 °C in 5% salt.*
- *In the third paragraph, "time/temperature" was replaced by "temperature or water activity" because these are what are discussed in the next sentence. The limits of temperature and water activity for C. botulinum growth were corrected to be consistent with the International Commission on Microbiological Specifications for Foods (ICMSF).*
- *In the third paragraph, editorial corrections were made to the Skinner and Larkin reference.*

ANNEX 2, Examples of combinations of product attributes that minimise the likelihood of *Clostridium botulinum* toxin formation. Revise the Table as follows:

Product Temperature during Storage	Packaging	Water Activity controlled by Aqueous Phase Salt (NaCl)	Comments
Frozen (≤ minus 18 °C)	Reduced Oxygen*	No maximum water activity needed.	*C. botulinum* 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. The country where the product is consumed may require temperature monitoring for each package to ensure that the time temperature combination does not permit the production of ***Clostridium botulinum*** toxin after thawing.
< 3 °C	Reduced Oxygen*****	No maximum water activity is needed.	*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 **equal or** exceed 3 °C. The country where the product is consumed may require temperature monitoring for each package to ensure that the time-temperature combination does not permit the production of ***Clostridium botulinum*** toxin.
>3 °C to 5 °C	Reduced Oxygen*****	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% (w/w) (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 require 3.5% 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.
>5 °C to 10 °C	Reduced Oxygen*****	5% Aqueous Phase Salt provides complete protection **at this temperature range.**	**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.**
>3 °C to 5 °C	Aerobically Packaged	No maximum water activity 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 *C. botulinum.* 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 *C. botulinum* if there are concerns about the ability of transporters, retailers or consumers to maintain time/temperature control.

***Including vacuum packaging and modified atmosphere Packaging. (As new technologies are developed, e.g. modified atmosphere with high oxygen, new controls may be defined).**

Reason:

- *Rearranged order of rows to sort in sequence of increasing holding temperature and packaging for clarity.*
- *Changed production temperature of "0° C to 3° C" to "< 3° C" and added "equals or exceeds 3° C" to be consistent with ICMSF.*
- *Added "at this temperature range" for clarity.*
- *Italicized Clostridium botulinum species names.*
- *Removed unnecessary brackets and parentheses from temperature ranges in "Product Temperature during Storage" column, and clarified "< or = -18°C".*
- *Moved parenthetical information below "Reduced Oxygen" in the "Packaging column" to the footnote for clarity*
- *Removed a dash in "reason-able"*
- *Grammatical correction for "however" junction in comments for ">5° C to 10° C" row.*