codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 2 **CX/FH 10/42/2**
October 2010

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-second Session

Kampala, Uganda, 29 November – 3 December 2010

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND/OR OTHER CODEX COMMITTEES TO THE FOOD HYGIENE COMMITTEE

A. DECISIONS OF THE 33rd SESSION OF THE COMMISSION RELATED TO THE WORK OF THE COMMITTEE

Amendments to the Procedural Manual[1]

1. The Commission **adopted** the Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene.

Standards and Related Texts adopted at Steps 5/8[2]

2. The Commission adopted the following standards and related texts:

- Code of Hygienic Practice for Pathogenic *Vibrio* spp. in Seafood; and
- Annex on Control Measures for *Vibrio parahaemolyticus* and *Vibrio vulnificus* in Molluscan Shellfish.

3. The Commission **adopted** the Annex on Fresh Leafy Vegetables (Annex to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003)) and inserted the reference to parasites such as *Giardia lamblia* in the Introduction among the listing of possible of pathogens and noted several Spanish editorial amendments.[3]

[1] ALINORM 10/33/REP, para. 11 , Appendix II

[2] ALINORM 10/33/REP, para. 18 , Appendix III

[3] ALINORM 10/33/REP, paras 25 - 28

B. MATTERS ARISING FROM REPORTS OF THE COMMISSION, CODEX COMMITTEES AND TASK FORCES

CODEX COMMITTEE ON GENERAL PRINCIPLES

Working Principles for Risk Analysis[4]

4. The 26th Session of the CCGP agreed that risk analysis policies developed by Codex committees were generally consistent with the *Working Principles for Risk Analysis*, which complied with the mandate given to the Committee under Activity 2.1 (Codex Strategic Plan). The Committee agreed to forward the review presented in CL 2010/1-GP to the committees concerned for their consideration and review of their risk analysis policies, which would initiate Activity 2.2 of the Strategic Plan. The relevant section of the circular letter relating to the Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene is reproduced as Annex I to this document.

5. The Committee **is invited** to consider the review of its analysis policies in light of the recommendations in CL 2010/1-GP (see Annex I).

Definition of hazard in the Procedural Manual[5]

6. The 26th Session of the CCGP could not reach a conclusion on a proposal to revise the definition of "hazard" in the Procedural Manual by adding the following footnote: "*This definition of hazard as an agent differs from the definition as an effect in many of the authoritative scientific references cited by several Codex committees in their documents on risk analysis. This difference should not be interpreted as producing any conflict in the interpretation or application of the Working Principles of Risk Analysis.*"

7. The Committee **is invited** to consider the above proposal and to provide its views to the next session of the CCGP.

CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS

Endorsement of Hygiene Provisions in Codex Standards

8. In accordance with its Terms of Reference and established practice the Committee on Food Hygiene is invited to endorse the **hygiene provisions** of standards and codes of practice when they have achieved Step 5 status in the Codex Elaboration Procedure.

9. Governments and interested international organizations are invited to consider and take a decision on the suitability for endorsement of the **hygiene provisions** in the following draft texts, which were distributed to Member governments:

- The Proposed Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish (ALINORM 10/33/18, Appendix VI);
- The Proposed Draft Standard for Fish Sauce (ALINORM 10/33/18, Appendix IX).

10. The Committee **is invited** to indicate whether the texts are

- suitable for endorsement;
- suitable for endorsement with amendments; or
- not suitable for endorsement, giving reasons.

11. The texts for the proposed draft standards mentioned above are attached as Annex II to this document.

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[4] ALINORM 10/33/33, paras. 47 - 55

[5] ALINORM 10/33/33, paras. 56 - 58

FAO/WHO COORDINATING COMMITTEE FOR EUROPE (CCEURO)

Proposed draft Guidelines for the Control of *Campylobacter* and *Salmonella* spp. in Chicken Meat[6]

12. The Delegation of the European Union stated that decontaminants cannot be seen as a replacement of GHP at farm level and slaughterhouses, and outlined outstanding concerns on the safety of antimicrobial substances, including those containing chlorine. Although the EU did not allow antimicrobials for decontamination purposes, it wished the work to progress in the Committee on Food Hygiene, due to the importance of the Guidelines in particular for developing countries and proposed to insert a clear requirement that the use of chemical decontaminants is subject to approval/authorisation in the country of retail sale of the final products.

13. Several delegations supported this position as they did not use antimicrobials for decontamination of carcasses due to safety concerns and because food safety should be achieved through good hygienic practice along the food chain. The Committee therefore supported the position of the European Union.

14. The Committee also encouraged all delegations to participate actively in the work of CCFH on the control of *Campylobacter* and *Salmonella* spp. in chicken meat.

[6] REP 11/EURO, paras 107 - 109

Annex I

Risk Analysis Principles and Procedures (excerpt from CL 2010/1-GP)

Food Hygiene

The last session of the Committee on Food Hygiene (2009) completed its risk analysis policies and the *Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene* are submitted to the Committee for endorsement under Agenda Item 2. The Committee may wish to take into account the consistency with the Working Principles while discussing the endorsement of the document. However, as it is not yet adopted in its final form, it will be for the Committee to decide whether it should also be considered in detail in the present review.

Taking into account the specificities of microbiological risk analysis, it appears that the main part of the document clearly describes the various components of risk analysis as applied in the area of food hygiene, including preliminary risk management activities and the establishment of a risk profile, and the steps of risk assessment applied by JEMRA.

As regards the Annex, the Committee may recall that a similar document was considered by the 23rd Session of the Committee (2006) (CX/GP 06/23/2 Part II) where some amendments were proposed and referred back to the CCFH (ALINORM 06/29/33, para. 45-57). One of the recommendations made at the time was that the Committee on Food Hygiene consider the development of a document explaining its policies in the application of risk analysis, as the document proposed included both elements related to decision making and interaction between risk assessors and risk managers.

The Annex includes detailed provisions on the process of work management in the Committee, which are not directly related to the risk analysis process. The Committee may wish to consider as a general issue whether such an Annex should be included in a document on risk analysis policies and whether this is consistent with the *Working Principles*. In other documents on risk analysis policies, there may be a few references to procedure or process issues, as mentioned in the relevant sections above, but in the CCFH document, these issues are discussed in considerable detail.

The section on the *Process for Considering Proposals for New Work* describes how the relevant working group may be convened and operate. The Committee may consider whether this is really necessary as all Committees can always convene working groups according to their needs, provided they follow the *Guidelines on Physical Working Groups*, and the few specificities pertaining to the organisation of each committee may not require specific provisions in the Procedural Manual.

In the *Proposals for New Work* section, it is specified that a risk profile should be developed in addition to the usual requirements for new work. This requirement is already mentioned in paragraph 2 of section II of the main document and may not need to be repeated in the Annex. Paragraph 6 and 7 of the Annex may not be needed as the critical review already specifies that the type of Codex standard or related text proposed, the food safety problem to be addressed, and the relationship with existing Codex standards should be specified in the project documents.

As regards the section on *Obtaining Scientific Advice*, since the main document describes the interaction between risk assessors and risk managers in Section V and VI, it is not clear why there is a need to include another section on the request for scientific advice to JEMRA in an Annex. In order to ensure consistency with the Working Principles, all provisions related to the three components of risk analysis should preferably be included in the same document. The Committee may therefore consider deleting this section and incorporating any relevant provisions therein into the main text. When the CCGP considered a similar document in 2006, as mentioned above, it recommended that such provisions be included in the risk analysis policies document paper to be developed. As this document has been finalised, relations between CCFH and JEMRA may not need to be considered both in the main document and in the Annex.

Annex II

HYGIENE PROVISIONS FOR ENDORSEMENT

PROPOSED DRAFT STANDARD FOR SMOKED FISH, SMOKE-FLAVOURED FISH AND SMOKE-DRIED FISH

6. HYGIENE AND HANDLING

6.1 General Provisions

The products covered by the provisions of this standard shall be prepared and handled in accordance with the appropriate sections of the recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969) and other relevant Codex texts such as codes of practice and codes of hygienic practice, such as the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003).

6.2 Microbiological criteria

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

6.3 Parasites

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 if a parasite hazard is present (see Annex I). Viability of nematodes and cestodes and trematodes shall be examined according to Section 8.9 and/or 8.10.

6.4 *Listeria monocytogenes*

The ready to eat products shall comply with microbiological criteria for *Listeria monocytogenes* in ready to eat foods which was elaborated in the Annex II of the Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready to Eat Foods (CAC/GL 61-2007).

6.5 *Clostridium botulinum*

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, 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.

Countries where the products are to be consumed may allow these products in an uneviscerated state or may require evisceration, either before or after processing, in such a way as to minimize the risk of *Clostridium botulinum*.

6.6 Histamine

The product shall not contain histamine that exceeds 20 mg/100g fish flesh. This applies only to susceptible species.

6.7 Other Substances

The products shall not contain any other substances in amounts, which may present a hazard to health in accordance with standards established by the Codex Alimentarius Commission, and the final product shall be free from any foreign material that poses a threat to human health.

ANNEX 1 (to the Proposed Draft Standard for Smoked Fish, Smoke-flavoured fish and Smoke-dried fish)

PROCEDURES SUFFICIENT TO KILL PARASITES

Any method used to kill parasites shall be acceptable to the competent authority having jurisdiction.

Where freezing is required to kill parasites (i.e. cold smoked fish and smoke flavoured fish), the fish must be frozen either before or after processing to a temperature time combination sufficient to kill the living parasites.

Examples of freezing processes that may be sufficient to kill some or all parasites are:

- Freezing at –20Cº at the thermal centre of the product for 24 hours (for *Anisakis* species and *Pseudoterranova decipiens* only);
- Freezing at –35Cº at the thermal centre of the product for 15 hours (all parasites)[1-4];
- Freezing at –20Cº at the thermal centre of the product for 168 hours (7 days) [1-4] (all parasites).

1 Bier, J. 1976. Experimental Anisakiasis: Cultivation and Temperature Tolerance Determinations. J. Milk Food Technol. 39:132-137.

2 Deardoff, T.L. et al. 1984. Behavior and Viability of Third-Stage Larvae of Terranova sp. (Type HA) and Anisakis simplex (Type I) Under Coolant Conditions. J. of Food Prot. 47:49-52.

3 Health and Welfare Canada (1992) (in consultation with Canadian Restaurant and Food Service Association, Fisheries Council of Canada, and Fisheries and Oceans Canada). Code of practice for the preparation of raw, marinated, and partially cooked fin fish.

4 USFDA - Centre for Food Safety & Applied Nutrition (June 2001), Fish and Fisheries Products Hazards and Controls Guidance, Chapter 5 Parasites, 3rd Edition.

ANNEX 2 (to the Proposed Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish)

Examples of combinations of product attributes that minimise 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 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 flavour is provided by smoke condensates. If the smoke flavour is imparted by artificial flavour blends, then 5% aqueous phase salt would be required in order to provide complete protection at any temperature over 3°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 parameters can minimise the likelihood that *C. botulinum* will grow in the product. *C. botulinum* cannot grow and produce toxin at or below 3ºC or below a water activity of 0.85. 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**	**WATER ACTIVITY CONTROLLED BY AQUEOUS PHASE SALT (NACL)**	**COMMENTS**
[(0°C to 3°C)]	Reduced Oxygen (including vacuum packaging and modified atmosphere Packaging*)	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 exceed 3ºC. 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)]	Aerobically Packaged	No maximum water activity is needed. Nonetheless, where there is a reason-able possibility of severe time/ temperature abuse, the country where the product is being consumed	When these products are packaged aerobically, 5ºC 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

		might choose an aqueous phase salt barrier of at least 3% to 3.5% (w/w) as an additional barrier.	*C. botulinum* 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 maximum water activity is 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 to 5°C)]	Reduced Oxygen (including vacuum packaging + modified atmosphere packaging)	Aqueous phase salt at minimum level of between 3% & 3.5% (w/w) 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 still 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.
[>5°C to 10°C]	Reduced Oxygen	5% (w/w) Aqueous Phase Salt provides complete protection	At these temperatures or higher non-proteolytics (*C. botulinum*) are controlled when aqueous phase salt is 5% (w/w). Proteolytic strains of *C. botulinum* start growing above 10ºC, however. It should be noted that the temperature range of >5ºC to 10ºC 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.

*As new technologies are developed, e.g. modified atmosphere with high oxygen, new controls may be defined.

PROPOSED DRAFT STANDARD FOR FISH SAUCE

6. Hygiene and Handling

6.1 The final product shall be free from any foreign material that poses a threat to human health.

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

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

6.4 The product shall not contain more than 40mg histamine / 100g of fish sauce in any sample unit tested.