codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 2 **CX/FH 09/41/2**
October 2009

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-first Session

Loews Coronado Bay Hotel, California, United States of America, 16 - 20 November 2009

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

A. GENERAL DECISIONS OF THE 32ND SESSION OF THE CODEX ALIMENTARIUS COMMISSION (Rome, Italy, 29 June – 4 July 2009)

1. The Commission **adopted** several amendments to the Procedural Manual, including amendments to the Format of Codex Standards which contains a revised section on Hygiene. These amendments will be included in the 19th Edition of the Procedural Manual. The Commission also **adopted** 28 new or revised Codex standards or related texts elaborated by the Codex Committees and Task Forces; it **approved** a number of new work proposals and proposals for discontinuation of work. The Commission also took various decisions which are important for the work of the Commission and its subsidiary bodies. Among them the Commission:

- Considered several matters referred by its subsidiary bodies or pending from earlier sessions; agreed to postpone the decision on possible new work on animal feeding until its 33rd Session;
- Noted the status of implementation of the Strategic Plan 2008-2013; considered the Evaluation of the Capacity of the Codex Secretariat; did not support the recommendation to return to biennial sessions of the Commission; and agreed to refer all other recommendations to the 63rd Session of the Executive Committee and the 33rd Session of the Commission;
- Agreed on several recommendations intended to improve the participation of developing countries, especially as regards capacity building and the Codex Trust Fund.
- Elected by general consent the following officers for the Commission:
  - **Chairperson**: Ms Karen HULEBAK (USA)
  - **Vice-Chairpersons**: Mr Sanjay DAVE (India), Mr Ben MANYINDO (Uganda), and Mr Knud ØSTERGAARD (Denmark).

2. Details on all these and other matters can be found in ALINORM 09/32/REP which is available from: http://www.codexalimentarius.net

B. DECISIONS OF THE 32nd SESSION OF THE COMMISSION RELATED TO THE WORK OF THE COMMITTEE

3. The following texts considered and adopted by the Commission have direct relation to the work of the Codex Committee on Food Hygiene (CCFH).

DRAFT STANDARDS AND RELATED TEXTS ADOPTED AT STEP 8 OR STEP 5/8

Proposed Draft Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods (Annex II to 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) (ALINORM 09/32/REP, paras 40-45)[1]

4. The Commission **adopted** the Proposed Draft Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods (Annex II to 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) at Step 5/8, with the omission of Steps 6 and 7, with small editorial amendments in the third bullet point of Section 3.1 Ready-to-Eat foods in which growth of *L. monocytogenes* will not occur, in order to separate freezing from other combinations that could prevent the growth of *L. monocytogenes* and in footnote 8 to make the wording more easily readable.

Proposed Draft Microbiological Criteria for Powdered Follow-up Formulae and Formulae for Special Medical Purposes for Young Children (Annex II to the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008))[2]

5. The Commission corrected the title of the publication in footnote 20 and **adopted** the Proposed Draft Microbiological Criteria for Powdered Follow-up Formulae and Formulae for Special Medical Purposes for Young Children (Annex II to the Code of Hygienic Practice for Powdered Formulae for Infants and Young Children (CAC/RCP 66-2008)) as proposed.

ELABORATION OF NEW STANDARDS AND RELATED TEXTS

6. The Commission **approved** the elaboration of a Code of Hygienic Practice for Control of Viruses in Food, job code N07-2009. This document will be considered by the 41st Session of the CCFH at Step 4.

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

The Use of the Lactoperoxidase System (LPS) for Milk and Milk Products in International Trade[3]

7. The Commission recalled, that while adopting the *Guidelines for the Preservation of Raw Milk by the Lactoperoxidase System* by the 19th Session of the Commission in 1991, it was emphasized that the LPS should not be used for products intended for international trade[4] and that this statement was reconfirmed at its 27th Session in 1999[5].

8. The 27th Session of the Commission in 2004, while adopting the draft Code of Hygienic Practice for Milk and Milk Products (CAC/RCP 57-2004), added at the end of footnote 9 of Appendix A that *the use of lactoperoxidase system for milk in international trade will be re-examined by the CCFH after completion of an expert review by FAO/WHO of available data and considering the FAO Lactoperoxidase Expert Group report about potential risks and benefits of lactoperoxidase system*.

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1 ALINORM 09/32/13, Appendix II

2 ALINORM 09/32/13, Appendix III.

3 ALINORM 09/32/9C paras 6-17, ALINORM 08/31/13, paras 173-180, ALINORM 09/31/REP, paras 179-189

4 ALINORM 91/40, para. 234

5 ALINORM 99/37, para. 216

9. A joint FAO/WHO technical meeting on benefits and potential risks of the lactoperoxidase system of raw milk preservation (Rome, Italy, 28 November - 2 December 2005)[6] had been convened upon request of the Committee on Food Hygiene and data as well as the safety evaluation by the 35th meeting of JECFA had indicated that there were no safety concerns relating to the components or metabolites of the LPS when used in accordance with the Guidelines.

10. The Commission also recalled that consensus could not be reached at its 30th Session on the proposal to lift the restriction on the use of the LPS for products in international trade and that this matter had been sent to the 39th Session of the Committee on Food Hygiene (2007) in order to identify additional information regarding the risks in respect of the LPS. The 39th Session of the Committee on Food Hygiene considered this matter and there was no agreement on the lifting of the restriction and therefore the Committee referred the issue back to the Commission.

11. At the 31st session of the Commission, it was proposed to lift this restriction and to amend footnote 9 in Appendix A: Microbiostatic Control Measures of the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RCP 57-2004) by an addition of the following: *"Any trade in milk treated by the lactoperoxidase system should only be on the basis of mutual agreement between countries concerned, and without prejudice to trade with other countries"*. In view of the lack of time to resolve the issue, the Commission agreed to postpone further discussion on this matter until its 32nd Session.

12. The Dominican Republic, speaking as Chair of the Group of 77 countries pointed out that the use of the LPS was safe and that the final conclusion on its use should be taken by the Commission. The Secretariat clarified that the G 77 had no special status or recognition within Codex. Tunisia noted that it did not delegate authority to any other country to speak on its behalf in the Commission.

13. The Delegation of Cuba, supported by several delegations, drew the attention of the Commission to the fact that data and scientific analysis by FAO/WHO showed that the use of the LPS was safe, therefore proposed to lift the restriction without adding a footnote, however other delegations were of the view that an addition to the footnote was necessary. One delegation indicated that the proposed addition was superfluous as all trade between countries took place on the basis of mutual agreements.

14. Other delegations were against allowing the use of the LPS for milk in international trade and stressed that refrigeration should be the preferred method for milk preservation.

15. After some discussion the Commission **agreed** to lift the restriction that the LPS could not be used for milk products intended for international trade and to amend footnote 9 in Appendix A: Microbiostatic Control Measures of the *Code of Hygienic Practice for Milk and Milk Products* (CAC/RC 57-2004) by adding: *"Any trade in milk treated by the lactoperoxidase system should only be on the basis of mutual agreement between countries concerned, and without prejudice to trade with other countries"*.

16. The delegations of Chile Cote d'Ivoire, Cuba, Ecuador, Guinea, Mali, Nigeria, Paraguay, Sudan, Togo, Uruguay and Venezuela expressed their reservation to the decision to add an additional sentence to footnote 9.

C. MATTERS ARISING FROM OTHER CODEX COMMITTEES AND TASK FORCES

CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS

Endorsement of Hygiene Provisions in the Codex Standards and Codes of Practice

17. 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.

18. 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 Draft Code of Practice for Fish and Fishery Products (sections on Lobsters and Crabs) at Step 8 (ALINORM 10/33/18, Appendix II);

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[6] Report available at http://www.fao.org/ag/agn/agns/chemicals_lactoperoxidase_en.asp

- The Draft Standard for Sturgeon Caviar at Step 8 (ALINORM 10/33/18, Appendix V).
- The Proposed Draft Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish at Step 5 (ALINORM 10/33/18, Appendix VI);
- The Proposed Draft Standard for Fish Sauce at Step 5 (ALINORM 10/33/18, Appendix IX).

19. 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.

20. The texts for the draft and proposed draft standards mentioned above are attached to this document. However, hygiene provisions for the Code of Practice for Fish and Fishery Products, sections on lobsters and crabs, can be found throughout the texts and are not included in this document. The text for the section on lobsters and crabs in Appendix II of ALINORM 10/33/18 and complete descriptions on the consideration of elaboration of all the hygiene provisions for all the abovementioned are available for downloading from the following website: http://www.codexalimentarius.net.

HYGIENE PROVISIONS FOR ENDORSEMENT

DRAFT STANDARD FOR STURGEON CAVIAR (at Step 8)

6. HYGIENE

6.1 It is recommended that the product covered by the 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) and other relevant Codex Codes of Practice.

6.2 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).

6.3 The product 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.

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

PROPOSED DRAFT STANDARD FOR SMOKED FISH, SMOKE-FLAVOURED FISH AND SMOKE-DRIED FISH (at Step 5)

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

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

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 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 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 might choose an	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 *C. botulinum* if there are concerns about the ability of transporters,

		aqueous phase salt barrier of at least 3% to 3.5% (w/w) as an additional barrier.	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 (at Step 5)

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.