codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item **CX/FFP 03/10-Add.2**

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

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PROPOSED DRAFT STANDARD FOR SMOKED FISH

DOCUMENT ON THE CONTROL OF *CLOSTRIDIUM BOLULINUM*
(Prepared by the United States of America)

Control of *C. botulinum* in smoked fish has been discussed in the Committee for years and the Committee has been unable to develop a consensus position on the issue. The United States has developed the attached paper with a view of developing a consensus on the control of *C. botulinum* in the smoked fish.

A MATRIX OF POSSIBLE *C. BOTULINUM* CONTROL.

The Proposed Standard for Smoked Fish, CX/FFP 00/8, ***Process Definition,*** **second paragraph**, **third sentence,** is relevant to the control of C. botulinum, as follows:

"If the salt content of the product is less than 3% in the water phase and the product is packaged to the exclusion of oxygen (e.g., vacuum packed) the product shall be presented [deep] frozen."

We recommend replacing this sentence with an introductory paragraph followed by a matrix, as provided below. Some countries today require a minimum of 3% water phase salt for non-frozen products while other countries require a minimum of 3.5% and some countries require higher than that. Moreover, there are controls available for non-frozen products that are not based on percentage of salt in the water phase. It is possible that other controls not contemplated within the above sentence will be developed. Under the circumstances, we recommend that the Codex standard provide a matrix that shows control options that are known to exist within the boundaries of the scientific data. Countries where the products are to be consumed should be able to make risk management choices within those boundaries; i.e., should be able to select from the control options in the matrix based on risk management principles. Risk management decisions must be based on good, scientific data, but these decisions will also inherently reflect the values of the society for which the decisions are made, e.g., the amount of risk that a society wants to take relative to the benefits that it perceives. Where risk management options are available within the bounds of good science, the CCFFP should note the science and the choices within the bounds of that science, but should avoid wherever possible appearing to impose a single risk management or choice on all countries. In the case of the above sentence, for example, there are good scientific data by which a country could reasonably make a risk management choice of 3% salt in the water phase based on conditions in that country and level of risk acceptable for that country, while it would be entirely reasonable for other countries to decide that 3% salt in the water phase is not sufficient and a minimum of 3.5% is needed within that country based on their reading of the data, their conditions, and their values regarding risk.

For these reasons, we propose that the standard for smoked fish contain the following language and matrix:

"The formation of *Clostridium botulinum* toxin can be controlled through an application of science-based options involving packaging type, storage temperature, and the use of salt in the water phase. Contries 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 water 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. The following table addresses these control options:

Packaging	**Storage Temp**	**Water Phase Salt**	**Comments**
Air Packaged	4C (40F)	No minimum water phase salt is needed for safety. Nonetheless, where there is a reasonable possibility of severe time/temperature abuse, the country where the product is being consumed might choose a water phase salt barrier of at least 3 -3.5% as a precautionary measure.	Storage temp is 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 water 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.
Reduced Oxygen	Frozen	No minimum water phase salt is needed for safety.	*C. botulinim* toxin cannot form when product is frozen. Because toxin production can occur after thawing, labeling information about the need to keep frozen, to thaw under refrigeration, and to use the product immediately after thawing are important.

Reduced Oxygen	4C (40F)	Water phase salt at minimum level of between 3 -3.5% may be selected by the country where the product is to be consumed.	Water phase salt at a minimum level of between 3-3.5% in combination with smoke will prevent toxin formation in reduced oxygen packaging. As an alternative to water phase salt, time/temperature controls may be used. *C botulinum* cannot grow and produce toxin at or below 3C (38F). Other time/temperature combinations exist that similarly control the formation of toxin (Skinner and Larkin, 1998). 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, may be selected as a control by 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.