codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 4(b) **CX/FH 06/38/4-Add.2**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Thirty-eighth Session

The Intercontinental Hotel, Houston, United States of America

Comments on the

ANNEX III: EXAMPLES OF THE USE OF FOOD SAFETY OBJECTIVES, PERFORMANCE OBJECTIVES, PROCESS AND PRODUCT CRITERIA AT STEP 3

In response to the FH/CX 06/38/04 – Add.1, comments were received from Canada, International Dairy Federation, and International Commission on Microbiological Criteria for Foods, (ICMSF)

General comments

CANADA

Canada would like to thank the Working Group led by the United States and Australia for the development of this document.

The subject addressed in the document is very complex and Canada is of the view that attempts should be made to make the explanatory text as simple and accessible as possible. It would also be useful to further clarify the purpose of this document and who would be the intended audience.

Both Annexes IIIA and IIIB would benefit from redrafting to ensure that concepts are consistently and clearly explained and all inconsistencies in approach, terminology, etc., are addressed. While the technical information provided in Annex IIIA is more extensive than in Annex IIIB, Canada finds the former more useful since the analyses provided in the example assist the reader in better understanding the text.

ICMSF

Annex IIIB gives adequate guidance on the how microbiological risk assessment (MRA) techniques can be used to derive metrics for risk management. It covers all important aspects in sufficient detail and does show that there is a level of complexity in MRA that needs to be dealt with in MRM. Annex IIIA is more detailed, but is in several parts possibly less accessible for the intended audience.

There is clear focus on the use of the PO, rather than on the other metrics, which is in line with discussions joint FAO/WHO expert meeting in Kiel, Germany, 3-7 April 2006. However, the

guidance and the example essentially take the PO as the starting point for which the (Q)MRA is used to derive FSO/(A)LOP, control measures (e.g. PcC,PoC; the food safety management system) or criteria for verification (i.e. MC). In the MRM document, the starting point is the ALOP. This may be somewhat confusing to the readers.

Associated to the previous point, FSO, PO and PC have been introduced as metrics related to public health (ALOP). It would be most appropriate to use them as metrics only when (1) governmental risk managers are deciding on the values for these metrics to be implemented and (2) they indeed are related to considerations on public health. In the current text, this is not made explicit and at times reference is made to establishing a PO on the basis of what one could call current practice. It may be necessary to be explicit here, for one because as the MRM document states PO and PC can be established by industry. Should they establish PCs or POs without a link to agreed metrics set by government (PO or FSO), then these should not be termed PCs or POs.

Care should be taken not to seem to introduce new terms. Some rephrasing has been suggested to that effect (e.g. risk management criteria; risk management metrics; food safety performance metrics)

IDF

The document covers the subject very well. The focus is on POs which is not surprising, as these will be the operational metrics derived from FSOs. However, the example is based on establishing other metrics from a PO early in the food chain

Although this is not the order specified in the MRM Guidelines, it is a methodology that can be used, as long as all metrics in the end are linked to FSOs (or ALOP). Nevertheless, such (backwards) linking can be demonstrated once the metrics have been established (using a forward approach). We recommend that this be included in the document.

Further, the document could also benefit from the inclusion of an additional example where the methodological starting point is an FSO.

The version in Annex IIIa is more detailed, but benefits from being explicit on the methodology, whereas the simpler version in Annex IIIb is more accessible, but does not include the methodology and therefore may not assist in clarifying the concept.

In order not to loose valuable information, we recommend that the final Annex III be a simple, reader friendly version (similar to the draft annex to the egg code) to which a more technical content (methodology) is appended.

We recommend that a physical working group be established, in which IDF would like to participate.

ANNEX IIIA. EXAMPLES OF APPROACHES FOR UTILIZING QUANTITATIVE MICROBIAL RISK ASSESSMENT TECHNIQUES TO LINK THE STRINGENCY OF CONTROL MEASURES TO HYGIENE OUTCOMES AND METRICS

General comments

CANADA

Canada suggests restructuring the text in the first 5 sections of Annex IIIA in order to clarify the intent of the document. In particular, there appears to be some uncertainty as to whether the microbiological criterion (MC), process criterion and product criterion are linked directly to the level of health protection achieved or whether these measures are derived from the level of health protection desired by the country. Canada is of the view that these parameters should be linked to the intended level of health protection.

Canada recommends that a discussion be held on the use and interpretation of the terms "food safety metrics" and "intermediate metrics" within the context of microbiological risk management, and that clear definitions be developed for these terms to provide an appropriate point of reference for other documents being produced by the Committee. Their use in this text should also be clearly aligned with other documents drafted by CCFH, specifically with the proposed Annex to the Draft Code of Hygienic Practice for Eggs and Egg Products, the *Application of Food Safety Metrics in Risk Management Decision Making – Pasteurized Liquid Whole Eggs* (Agenda Item 5 (b), CX/FH 06/38/4-Add.1). Furthermore, definitions and a clear set of acronyms for the terms Product Criterion and Process Criterion should be developed within CCFH.

3. Relationship between Various Risk Management Metrics

CANADA

- 1st bullet point, last sentence: it is indicated that the product criterion effectively establishes the food safety objective (FSO) for the product. Canada would suggest that, in fact, the product criterion would need to be elaborated from the FSO for the ready-to eat-product, i.e., which water activity (aw) or pH level would be required to ensure that the microbiological load at the point of packaging remains unchanged until the product is consumed in order to ensure that the FSO is not exceeded.
- 2nd bullet point: it is suggested that the Process Criterion relates to how to achieve a desired decrease in microbiological risk. Depending on the type of food under consideration, the treatment, etc., it may be necessary to establish a Process Criterion where the treatment does not result in the growth of pathogens (i.e., no change in levels), or in fact limits the growth of pathogens to a slight increase, where a decrease or no change is not achievable. Neither of these scenarios can be considered a decrease in microbiological risk.
- Last paragraph: key elements such as performance objective (PO) and MC are too casually linked. An MC is clearly established with sampling variability in mind, such that it may be necessary to have an MC lower than a PO in order to obtain the necessary confidence that a negative microbiological result corresponds to a level of pathogens at or below the PO for the product.

5. Direct Use of a QMRA versus Intermediary Metrics

CANADA

First paragraph, third sentence, It is suggested in the text that there is no need to establish intermediary metrics when MC, process criteria and product criteria are entered into the risk assessment model. Canada does not support this suggestion and recommends amending the text to clearly indicate that, in fact, the MC, process criteria, and product criteria are established **because** of the need to verify that a certain PO can be or is obtained by the system in question. Such models inherently consider both the initial load of organisms in the raw materials and the reduction or control delivered by the process or product criteria (and perhaps as reflected by the ability of the product to meet the MC). Either explicitly or implicitly in the risk model, a series of POs will be generated leading to an FSO and through dose response, the level of risk associated with the scenario.

6. Example: *Listeria monocytogenes* in cold smoked salmon

CANADA

The example provided in this section assists the reader to better understand the concepts presented in the earlier part of the document, however, it is not clear how the model addresses the sources of environmental contamination referred to in the first paragraph of section 6.6. Environmental contamination is described as "the primary source" of contamination with *L. monocytogenes* in the model, and it is thus recommended that it be appropriately addressed in this example.

9. Verifying Achievement of Food Safety Performance Metrics through the Establishment of Microbiological Criteria.

CANADA

Canada notes that the confusion regarding which of the parameters, e.g., MC, are actually considered metrics is evident in the title of this section.

The last sentence of the first paragraph as currently written may be misleading since it implies that the MC links the stringency of the PO to a specific level of protection. While the PO is the value from which the MC can be derived, the MC does not link the stringency of the PO to a specific level of protection. As noted in the 2nd sentence of the last paragraph of this section, the PO establishes a decision point between what is considered safe and what is not, whereas the MC establishes the testing scheme to determine if that level is achieved.

Figure 1

CANADA

Canada notes the absence of a "product criterion" in this diagram and recommends its inclusion as appropriate.

ICMSF

Figure 2 was found more helpful that Figure 1. In Figure 1, both in set A and B, there is a typo in "criterion" for process criterion box 1 and 2.

ANNEX IIIB. EXAMPLES OF APPROACHES FOR UTILIZING QUANTITATIVE MICROBIAL RISK ASSESSMENT TECHNIQUES TO LINK THE STRINGENCY OF CONTROL MEASURES TO HYGIENE OUTCOMES AND METRICS

9. Relationship between Various Risk Management Metrics

CANADA

There appears to be a mix-up in the acronyms used for Product Criterion and Process Criterion in the second version of the document. The explanations in the two bullet points following the introductory sentence in section 9, **Relationships between Various Risk Management Metrics**, use the wrong acronyms, i.e., PoC for product criteria and PrC for process criteria. The use of these acronyms should also be clearly aligned between the two annexes.