codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 5(b) **CX/FH 06/38/5-Add.2**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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The Intercontinental Hotel, Houston, United States of America

ANNEX: MICROBIOCIDAL TREATMENT AND THE APPLICATION OF FOOD SAFETY OBJECTIVES, PERFORMANCE OBJECTIVES AND PERFORMANCE CRITERIA AT STEP 3

In response to CX/FH 06/38/5 –Add. 1, comments were submitted by Australia, Canada, Islamic Republic of Iran, and International Commission on Microbiological Speciation for Foods (ICMSF)

General Comments

AUSTRALIA

This annex, associated with Section 5.2.3 of the Code of Hygienic Practice for Eggs and Egg Products, is intended to provide the risk manager with a practical example of the development and use of food safety metrics. Australia believes that this is an important piece of work that could serve as a reference for concepts, techniques and practical examples of how these new metrics can be determined and are interrelated, and supports the progress of the document subject to appropriate revision. To that end, Australia is pleased to provide some broad suggestions, aimed at simplifying the annex and increasing its usefulness, for consideration by the Committee.

Australia believes that the guidance provided in the proposed annex is applicable to a wide range of food products, even though the specific example being developed relates to liquid whole egg. Because of that wider application, Australia suggests that the Committee should carefully consider where the document should sit within the range of Food Hygiene texts.

Australia notes that similar work is being undertaken elsewhere within CCFH. Particularly, CX/FH 06/38/5-Add.1 seeks comments at Step 3 on a proposed Annex III (Examples of the Use of Food Safety Objectives, Performance Objectives, Process and Product Criteria) to the Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management. Within that proposed draft text, the example is given of the development and application of food safety metrics for *Listeria monocytogenes* in cold smoked salmon. Australia questions whether there is duplication of effort aimed at the same goal – guidance on the development and use of food safety metrics within Codex and member countries' food safety regulatory environments.

In terms of detail, Australia notes that the document is technically complicated, that some of the language could be simplified, and that there are inconsistencies within the text that should be addressed. We hope that the specific comments below assist.

A brief conclusion, a summary of the main steps of the process, would assist in understanding the process described in the paper.

CANADA

Canada would like to thank the United States for its efforts in the development of this document.

At the last CCFH meeting (Alinorm 05/28/13), the Committee agreed to the proposal put forth in CRD 51 on the elaboration of an Annex to the draft Code of Hygienic Practice for Eggs and Egg Products that would "specify the effective microbiocidal treatment including pasteurization as well as the application of the FSO, PO and PC". It is indicated in CRD 51 that the annex "*is intended to provide practical guidance in establishing effective microbiocidal treatments, along with descriptions on how to translate the necessary level of reduction of microorganisms into operational values, including time and temperature in the process*."

Canada questions whether the draft annex meets the original intent, as proposed in CRD 51 and agreed at the 37th CCFH meeting. The document discusses extensively and in a broad manner the concepts of FSO, PC, PO, ALOP, etc. However, we are of the view that the practical guidance provided for establishing effective microbiocidal treatments is insufficient and hence, of limited use to its intended audience.

We believe that the information contained in this document would be of greater use as part of a standalone horizontal document within CCFH and Codex, consolidating microbiological risk management terms and definitions, and providing concrete examples of the application of these terms, such as the example on pasteurized liquid whole eggs.

As mentioned in our comments on CX/FH/06/38/4-Add.1, *Annex III: Examples of the Use of Food Safety Objectives, Performance Objectives, Process and Product Criteria*, Canada recommends that a discussion be held on the use and interpretation of the term "food safety metrics" within the context of microbiological risk management, and that a clear definition be developed for this term to provide an appropriate point of reference for documents being produced by the Committee. Its use in the draft annex should also be clearly aligned with other documents drafted by CCFH, specifically with the document mentioned above.

We are also concerned that CCFH is developing a new interpretation of the definition of Acceptable Level of Protection (ALOP), in which the ALOP becomes the current level of adverse outcomes in a population in question. This is not the initial concept of ALOP, nor should it be the approach that the Committee should take in dealing with ALOP. The current level of adverse outcomes in a population is affected by many factors and hence, may change from day to day (as reflected in different levels of outcomes on annual or other statistics). Canada recommends that the current reference to ALOP be eliminated from the document and suggest that it should be replaced with the following: "The ALOP is the level of protection deemed appropriate by the country. The current level of adverse outcomes in the country (or in populations within the country) may be a reflection of the country's ALOP."

TITLE

ISLAMIC REPUBLIC OF IRAN

Either include some important microorganisms other that *Salmonella*, such as *Coliforms, Campylobacter*, etc. in the text, or else make the title specific to *Salmonella* risk management.

PURPOSE

FIRST PARAGRAPH

CANADA

Footnote 2 presents a different definition of food safety metrics from the one provided in CX/FH 06/38/4 - Add.1, as well as different acronyms for process and product criteria. These documents should be consistent in their presentation of important terms. Canada is of the view that the performance objective (PO) and the performance criteria (PC) are targets which are set by the competent authority to deliver a specified food safety objective (FSO) and/or ALOP, and hence are not relevant measures of the adequacy of individual aspects of a food safety control system. Assessing the adequacy of a system should be relegated to testing or monitoring to establish the extent to which the microbiological criteria (MC), product criteria or process criteria are being met.

We are of the view that the text in the first paragraph of the section on Purpose does not appropriately explain the concept and should be redrafted.

ICMSF

- Footnote 2. An ALOP would not qualify as a metric when this is involved in "assessing the adequacy of individual aspects of a food safety system". The ALOP rather relates to all aspects of all food safety systems operated for products to which a particular food-borne pathogen may be associated. Also FSO, PO and PC would not qualify unambiguously, as they relate to all aspects of the food safety system operated at a certain step, rather than individual aspects. It is suggested to reword to: "A food safety metric is one of several different parameters involved in the microbiological risk management process, including ……. ".
- Footnote 2: some metrics mentioned are not actually defined in Codex or WTO document but rather described (i.e. PdC, PrC, described in ALINORM 05/28/13, Appendix III).
- Footnote 2: The abbreviation for product criterion (PdC) used in the draft is not consistent with that proposed in Annex III to Also, some metrics mentioned are not actually defined in Codex or WTO document but rather described (i.e. PdC, PrC, described in the MRM document, ALINORM 05/28/13, Appendix III, where PoC is used.

BACKGROUND

CANADA

It should be clearly established in this section that the *Illnesses* referred to in bullet point one is the parameter that will be used as the indicator to determine whether or not the public health outcome is achieved by the current program. If the level of illness observed is different from the expected level (i.e., ALOP), then it would be appropriate to examine the other relevant data, e.g., servings consumed, incoming loads, etc., to identify if any changes have occurred in these parameters that may explain the increase in illness.

ISLAMIC REPUBLIC OF IRAN

Add a 6th bullet: *Conformity of HACCP steps during the process with the planned HACCP system*. Also, in the ***Incoming microbiological loads*** add "*Possible post-pasteurization contamination*" (mentioned on page 3, in the *Estimate of illnesses).*

INFORMATION NEEDED TO DEVELOP FOOD SAFETY METRICS

Estimate of illnesses:

FIRST PARAGRAPH

CANADA

The first sentence does not reflect current thinking in risk analysis, i.e., the attribution of foodborne disease from pathogens of public health concern to egg products does not provide a basis for informing the risk manager about the effectiveness of *an established pasteurization process*. It identifies a problem with egg products that could be occurring anywhere in the system. As indicated later in the text, there could be systematic contamination post-pasteurization, changes in microbial heat resistance, inappropriate storage temperatures or reference to shelf life, etc.

SECOND PARAGRAPH

AUSTRALIA

Last sentence, Alternating use of the terms "microbiocidal treatment" and pasteurization", through out the document, limit the scope to pasteurization as the specific microbiocidal treatment being considered.

THIRD PARAGRAPH

ISLAMIC REPUBLIC OF IRAN

First sentence, use "*frequency or concentration of contamination*" instead of "level of contamination".

Servings consumed:

First paragraph

AUSTRALIA

Second sentence, the examples given (particularly with use of the word "homemade") suggest the food safety problem is purely at domestic/consumer level, rather than including the catering/foodservice sector. Australia suggests inclusion of alternative examples, or replace "homemade" with, for example, "freshly prepared", "non-commercial" or other broader term.

SECOND PARAGRAPH

ISLAMIC REPUBLIC OF IRAN

Third and fourth sentences and ***Table 1***: the explanation about reaching from 1.2 to 1.0 is not clear. A more detailed and clear explanation will be very helpful. Also, in the last but one sentence of the second paragraph on ***Servings consumed*** the word *fifteen* should be inserted between *per* and *servings*.

ICMSF

End pf paragraph, current value is 1.2 illnesses per 15M servings. 90% reduction would bring this probably to 0.12 and not to 1.0 as is stated.

Incoming microbiological loads:

First paragraph

ICMSF

Second sentence, it seems an estimated mean value is used of 160 cfu/ml. It might be useful to clarify whether this value was assumed to be the pathogen load in 100% of the cases or whether a certain prevalence was considered and whether this value is higher than previously thought (see statement {under ALOP , paragraph 2, sentence 3}on line 9 of para 3, pg5)

Process lethality:

First paragraph

AUSTRALIA

Use of "D-values" is inadequately explained, if use the "D-value" term here, define it in a footnote. However, the main point here is variability in thermal tolerance of different Salmonella serotypes. Suggested wording:

Process lethality: Lethality is a measure of the effectiveness of a treatment for eliminating the public health pathogen(s) of concern (e.g., Salmonella spp.). In the case of egg products, a goal in establishing an appropriate lethality could be to ensure that there is a sufficiently low likelihood of a cell of Salmonella surviving. By assessing the estimate of Salmonella levels in the raw or unpasteurized product from a baseline study, statistical estimates can be derived that account for the probabilities of surviving Salmonella in the post-pasteurized product at various lethality levels, taking into account the variability in thermal tolerance of different Salmonella serotypes. The risk assessment was used to model the effect of process lethality on the number of predicted illnesses due to surviving cells of Salmonella. In addition to ensuring that there is a sufficiently low likelihood of a cell of Salmonella surviving the microbiocidal treatment for a fixed amount of product consumed (100 ml is the assumed size of a serving, for calculation purposes), the risk manager can also estimate the process lethality required to ensure that there is a sufficiently low likelihood of survival of the pathogen in a high percentage of samples consumed.

last paragraph

ICMSF

First sentence, in the case example, the industry is said to achieve a 4.7 $\log_{10}$ lethality during pasteurization (page 4, paragraphs 5 and 6). On the basis of the risk assessment an increase to 6 $\log_{10}$ is advised. It is not made clear that this higher process lethality is the minimum to be achieved in all cases, like the 4.7 $\log_{10}$ is the minimum generally achieved. Also currently, the target for individual operations may be higher than 4.7 $\log_{10}$ but this may not be consistently achieved in the industry for reasons such as those mention on pg 3, 3rd para). Raising the lethality effectiveness should not only rely on a change to pasteurization conditions, but also other measures (e.g. reducing incoming microbiological load, improved hygiene or product formulations, avoidance of mishandling, assurance of proper control of the pasteurisation process, etc.) that could contribute.

OVERVIEW OF FOOD SAFETY METRIC CALCULATIONS

First paragraph

AUSTRALIA

End of the paragraph, this would require a quantitative risk assessment and, as the annex is dependant on this, this may pose difficulties for countries that do not have access to risk assessment information and expertise. Consideration should be given to the appropriateness of this Annex internationally – i.e. do countries have the data and capacity to perform the calculations?

Appropriate Level of Protection (ALOP) –

CANADA

We believe that the interpretation of ALOP presented in this section may be misleading. The premise presented in the text is that the ALOP is intended to represent the level of public health protection that is actually achieved. However, other Codex texts correctly refer to ALOP as the level of protection deemed to be appropriate by the competent authority. This premise is clearly reflected in the third paragraph of this section which finds itself in a circular argument about the ALOP remaining as currently described until a new PC is implemented and a new ALOP can be articulated. It is the ALOP

that defines the FSO which establishes the PO and, when information is available on the initial load, heat resistance of the pathogen, etc., will eventually allow the calculation of the PC.

Canada recommends a redraft of this section with an appropriate reference to ALOP, as defined in the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (Ref. Footnote 2 of CX/FH 06/38-5-Add.1) and as used in other Codex texts.

AUSTRALIA

The sections on ALOP and FSO are complex, inconsistent with the definitions developed within Codex and elsewhere (ref: Procedural Manual, p46), and incorrectly imply that planned changes to a PC should feed upwards to cause revision of the FSO and ALOP.

Suggested wording:

> ***Appropriate Level of Protection (ALOP)*** – The ALOP is the level of public health protection deemed appropriate to the particular circumstance. In order to articulate a measure of the level of public health protection currently achieved in relation to pasteurized egg product safety, a risk assessment can be used. The risk assessment can provide an estimate of the most likely number of human illnesses associated with pasteurized egg products, using data from food attribution estimates and other public health investigative approaches.
>
> In this example, the contribution of human illness associated with the current pasteurization program for whole egg products is estimated to result in approximately 2,775 illnesses annually, or 1.2 illnesses per 15 million servings (100ml each). Since this level of illness has, up to now, been considered tolerable, it represents the current ALOP.
>
> The competent authority has now determined that the national or regional program must reduce the number of illnesses associated with pasteurized whole egg product by at least 90%. This is the level of public health protection deemed appropriate for pasteurized whole egg products and is consequently a statement defining a new ALOP. Other food safety metrics (eg FSO, PO, PC and others) are affected by the risk management decision to change the ALOP, as described below.
>
> ***Food Safety Objective (FSO)[1]*** – The FSO that contributes to the current ALOP is the level of Salmonella currently present in pasteurized whole egg products at the time of consumption.
>
> However, for this example, since the competent authority has determined that the current level of illness must be reduced by 90% to adequately and appropriately protect public health, a new FSO must be articulated. Using a risk assessment, the maximum frequency and/or concentration in which Salmonella can be present in a serving of pasteurized whole egg products can be estimated.

THIRD PARAGRAPH

ICMSF

In the example, adequate heat treatment during manufacturing is a key factor in assuring product safety. This heat treatment is governed by the process criterion (the description of the time and temperature required). It may not be clear to readers that the process criterion (PrC) is only one of the measures contributing to the overall PC at the manufacturing step, as the PC is the overall, net result of the sum of increases and sum of decreases (to which the PrC contributes) at the step. Where regulatory advice is given about adequate microbiocidal treatment (such as the pasteurization in the example), this most often relates to the PrC and not to the PC (as stated on pg 5, paragraph 3).

[1] The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).

Food Safety Objective (FSO) –

CANADA

The text in this section provides a new interpretation of FSO and suggests that the FSO can be represented by a percent reduction in human illness resulting from a planned change in the PC. We note that this interpretation differs considerably from the current definition of FSO in the Procedural Manual (*Maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)*. We recommend that this section be rewritten to reflect the common understanding of FSO, as defined in the Procedural Manual and other Codex texts

ICMSF

First sentence, replace "frequency" by "level" (level: concentration and/or frequency; e.g. 1cfu/100ml in 100% of cases). Not clear where "value" refers to (FSO?). Here (and in Table 1) the FSO is represented as "the percent reduction", but this is not in line with the Codex definition of FSO. It may be more appropriate to say that "the best representation of the FSO is the maximum hazard level at consumption calculated by the microbiological risk assessment to be resulting from the planned change in PC". Last sentence replace "frequency" by "level".

Performance Objective (PO) –

ICMSF

The PO, like the FSO, is a maximum level. The PO is stated to be less than 1cfu/100ml. This actually is not a specific, maximum level. However, would a PO = 1cfu/100ml be acceptable as PO, maybe with a certain low frequency? It would be a maximum level. Under the section of PC (para 2, pg 6) it seems a 10% chance of *Salmonella* surviving the microbiocidal treatment is indeed considered. However, this is contradicted in the MC section that follows (pg 6, para 3) where it reads that "any sample of pasteurized product is expected to have fewer than 1cfu/100ml).

Microbiological Criteria (MC) –

AUSTRALIA

Fourth sentence, it is unclear as to what is meant by a "substantially large number of samples" – relative to what? Australia suggests the following wording:

> "Any sampling plan designed to detect such a low level of contamination with a high degree of confidence would require a very large number of samples and might not be practical to implement on a routine basis. As an alternative, monitoring and verification…"

Process Criteria (PrC) –

FIRST PARAGRAPH

ICMSF

Second sentence, this mentions a "new PO versus the existing PO". What is the existing PO (not specified in Table 1).

> Determining the PrC:
>
> **Step 2: Identify the D-value and z-value for a given log_{10} reduction at a given temperature, and Step 3: Determine the required log reduction.**

ICMSF

Again, there is a bit of a mix up of the PrC and the PC. The log-reduction needed to be achieved by pasteurization (step 3) is the log reduction established for the PC. As noted, pasteurization is the key

step in the example, but it may need to be clarified that it is assumed in the example that all factors influencing increases or decreases of the pathogen remain unchanged

FOOT NOTES 4 AND 5

AUSTRALIA

No consideration of biological variability and errors in definitions in footnotes (footnotes 4 and 5). Australia suggests the following:

1. It should be made clear the extent to which the D and Z values are chosen to take account of the more thermally tolerant Salmonella serotypes.

2. The calculations are much more difficult to follow in the footnote – consider reinstating into the main body of the text, perhaps in a text box / table.

3. The definition of Z-value in footnote 4 is incorrect. Suggest "The Z value is the temperature change, in degrees Celsius, required to effect a 10-fold (1 log cycle) change in the D value."

4. Provide units for the D values (minutes?) in footnote 5.

ISLAMIC REPUBLIC OF IRAN

Footnote 5, Z value definition: The "formal", commonly used definition is "the degrees of Fahrenheit required for the thermal destruction curve to traverse one log cycle" (Ref.: Jay MJ, *Modern Food Microbiology*, Aspen Publishers, Gaithersburg, 2000, p.350). One may give the formal definition first, followed by the more practical one in the Document, plus an explanation about the relation between the two.

Table 1 – Summary of Food Safety Metric Results

AUSTRALIA

Columns **MC** and **P dC**, a footnote should be included at the end of the table to explain what 'n/p' and 'n/a' mean. The table needs some brief explanatory/summary text.

ICMSF

- Column "ALOP". Delete "less than" before approximately.
- Column "FSO". Not a maximum level and illness/15M serving should be 0.12?
- Column "PO". No "current" PO noted.
- Column "MC". n/p not explained what this means.
- Column "PdC". n/a not explained what this means.

In column "PrC" the time needed for the pasteurisation is kept at 3.5 min. It is stated that the pasteurisation temperature currently should be 61.1°C (142°F) to deliver a PC of 4.8 $\log_{10}$ while it should be 0.5°C higher (61.6°C (143°F) to deliver a PC of 6 $\log_{10}$. Unless the incoming microbial load is significantly lower in the new situation as compared to the current one (while the risk managers actually believed the contrary) or the old PO is significant different higher than the new one (the old one is not quoted), it seems strange that the quite different PC values require an almost identical PrC. Maybe a key consideration in the MRA is missing?