codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 5 **CX/FH 08/40/5 - Add.1**
November 2008

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Fortieth Session
The Marriot Hotel, Guatemala City, Guatemala

PROPOSED DRAFT MICROBIOLOGICAL CRITERIA FOR *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS at Step 3

Comments Submitted by:

Australia, Kenya, Philippines, the United States of America, Confederation of the food and drink industries of the EU (CIAA), International Association of Consumer Food Organizations (IACFO)[1]

GENERAL COMMENTS

AUSTRALIA

Australia supports the progression of Annexes II and III through the Codex Process.

UNITED STATES

The U.S. supports the advancement of both documents (Annexes II and III) going forward together for adoption by the Commission at Step 5/8.

ANNEX II: MICROBIOLOGICAL CRITERIA FOR *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS

GENERAL COMMENTS
KENYA

Kenya would like to request the working Group to clarify the definition of Ready-To-Eat Foods, it can vary from country to country.

Kenya also proposes that the Ready-To-Eat Foods should be categorized to ease the commenting on the document for there can be other ready- to- eat food which can not be contaminated by L. monocytogenes.

[1] Comments submitted in Spanish and French are being translated and would be distributed at a later stage.

3. USE OF MICROBIOLOGICAL CRITERIA FOR *L. MONOCYTOGENES* IN READY-TO-EAT FOODS

Second Paragraph

PHILIPPINES

First sentence: After "…Analysis" Delete "...and..."

3.1 Ready-To-Eat foods in which growth of *L. monocytogenes* will not occur

Fourth Paragraph

PHILIPPINES

First Sentence: At the end the sentence Add "…for *Listeria monocytogenes such as that found in the* Codex General Guidelines on Sampling." (CAC/GL 50-2004, Section 3.2.1)

Rationale: Whenever relevant Codex documents exist, we recommend that these be used.

UNITED STATES

Second sentence: The U.S. feels the practical implications of the "(on average) 0.5 log CFU/g" language may need clarification.

CIAA

Last sentence: inside the parenthesis after "specified"… Add "for moderate or long shelf-life foods"

Rationale: 1.3 times the period specified may be difficult for short shelf-life foods.

IACFO

IACFO requests clarification on whether changes to the text in the fourth paragraph under section 3.1 and the first paragraph under section 3.2 are intended to signal differing interpretations of the two passages. Section 3.1 uses a parenthetical "(on average)" in referring to the observable increase in *L. monocytogenes* in foods where growth will not occur. However, the first paragraph under section 3.2 uses "an average" in referring to increased levels in foods where growth can occur. In Draft 31-07-2008, the sentences used identical language (the word "mean") with a parenthetical note that "(exact wording will be provided)". The change in the proposed text suggests a difference in usages is intended. Common law canons of statutory interpretation presume a change in language implies a change in meaning. For example, the parenthetical "(on average)" may be interpreted to mean averaged across multiple instances of product testing. Meanwhile, deleting the parenthetical and using "an average" may appear to mean within a single sampling, multiple tests yield an average result of 0.5 log cfu/g increase. The first meaning would allow in variability, while the second would require specific, repeatable results. The Committee should clarify whether a difference is intended and how that difference may affect foods that would be allowed to apply the relaxed standard of 100 cfu/g.

IACFO rejects the rationale proffered by the EU member countries that a relaxed standard will lead to more testing (and therefore greater safety). The 100 cfu/g standard has already been in place in some EU member countries, but the region's *Listeria* rates are rising rather than falling. IACFO is not aware of any country that has come forward with demonstrated experience linking a relaxed standard to improved health outcomes. Rather, given the liability issues involved, companies are no more likely to increase product testing under a 100 cfu/g standard, as they could then be found to sell food they knew had a potential to cause death or miscarriage.

Fifth Paragraph

CIAA

First sentence: CIAA would suggest stronger wording of the caveat that other conditions could be used whenever there is knowledge of the supply chain.

Seventh Paragraph

CIAA

First sentence: reads "If information is lacking" appears to duplicate the third paragraph under Section 4.1, beginning with: "If the factors that prevent growth cannot be demonstrated…"

4. MICROBIOLOGICAL CRITERIA FOR *L. MONOCYTOGENES* IN READY-TO-EAT FOODS

4.1 Microbiological criterion for ready-to-eat foods in which growth of *L. monocytogenes* will not occur

Table 1: Microbiological criterion for ready-to-eat foods in which growth of *L. monocytogenes* will not occur

Footnote a

CIAA

After "…provide" Add the phrase "…or support the provision of…"

Rationale: to recognize that such guidance could be provided by other professional bodies (e.g. national and sector guides, etc).

Footnote b

UNITED STATES

In Annex II, footnote "b" after tables 1 and 2 need consistency. In particular, starting at the sentence beginning with "Other…" the remainder of the footnote in both tables should be consistent. We suggest that the footnote on Table 2 is appropriately worded. The last sentence of footnote "b" in Table 2 is a repeat of footnote "a" and should be deleted

Footnote c

UNITED STATES

In Annex II, the U.S. is re-examining the phrasing of footnote "c" after Table 1.

Rationale: This footnote may need clarification to make its meaning more transparent.

4.3 Alternative approach

First paragraph

AUSTRALIA

First sentence: Australia seeks clarification of how 'competent authorities would choose to establish and implement other validated limits for the *L. monocytogenes* concentration at the point of consumption'?

Third paragraph

UNITED STATES

First sentence: after "…operators" add "…to validate that the hazard is controlled and…" Alternatively before the period at the end of first sentence add "…and validate the effectiveness of the alternative approach (e.g., by using historic national public health data and market basket sampling)."

Rationale: We believe validation is also critically important for business operators.

IACFO

First sentence: before the period add "and validate the effectiveness of the alternative approach (e.g. by using historic national public health data and market basket sampling)."

Rationale: IACFO proposes the additions below to section 4.3 to establish a requirement that countries validate an alternative approach provides equivalent consumer protection, using national experience, including epidemiological and market basket sampling. Countries using alternative approaches should be required to validate their approach both through national historic experience and for conditions where the product may be shipped. The validation would ensure that domestic controls work to limit *Listeria* concentrations all the way to the point of consumption.

Fourth Paragraph

UNITED STATES & IACFO

Add an additional bullet at the end of section 4.3:

- Review of national public health experience validating the effectiveness of the alternative approach.

IACFO

IACFO reiterates its opposition to the recommendation for a tolerance of 100 cfu/g for *L. monocytogenes* in ready-to-eat foods, even those where growth will not occur. Global consumers cannot afford weakened protections from *Listeria* that will result from this relaxed tolerance. The committee should consider four factors in assessing the recommended tolerance.

1. Expert bodies recommended against relaxed standard.

In Europe, in 1999 the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) recommended that *L. monocytogenes* should be kept at a concentration below 100 cfu/g in ready- to-eat food at the point of consumption[2] In 2000, the Scientific Committee on Food (SCF) made the same recommendation.[3]

2. Countries applying 100 cfu/g are seeing increased rates of infection.

In the years following adoption of a 100 cfu/g standard, some countries in the European Union noticed statistically significant increases in listeriosis cases between 1999-2006. These countries include: Germany (0 to .6/100,000), the Netherlands (.1 to .6/100,000), the United Kingdom (.2 to .4/100,000), Ireland (0 to .2/100,000), Spain (.1 to .2/100,000), and Lithuania (0 to .1/100,000).[4]

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[2] *EFSA Request for updating the former SCVPH opinion on* Listeria monocytogenes *risk related to ready-to-eat foods and scientific advice on different levels of* Listeria monocytogenes *in ready-to-eat foods and the related risk for human illness*, Dec. 6, 2007, p. 4.

[3] *European Commission Health & Consumer Protection Directorate-General. Opinion of the Scientific Committee on Food in respect of* Listeria monocytogenes, June 22, 2000, http://ec.europa.eu/food/fs/sc/scf/out63_en.pdf.

[4] *Human* Listeria monocytogenes *infections in Europe- an opportunity for improved European Surveillance*, Euro Surveillance, 2008;13(13).

3. The relaxed standard increases risk of cross contamination.

The standard allows more *Listeria*-contaminated products on national and international markets resulting in conditions that support the spread of the pathogen. Studies show that *L. moncytogenes* can establish itself in areas where food is processed, forming a biofilm on stainless steel surfaces and surviving on equipment, in cold storage and on floors.[5] Contamination can easily spread in a retail environment where meat on a slicer can contaminate other meat placed on the same cutting surface. This is true for products that support and do not support the growth of *Listeria*.

4. Relaxed standard has significant impact on health in developing countries.

The experience of developed countries in addressing *Listeria* raises significant concerns about trade of these products to developing countries where food products may be handled under significantly different conditions. For example, in countries where refrigerators are less common and food is kept at ambient temperatures, *Listeria* may grow quite rapidly. Developing countries may also have larger populations of immunocompromised consumers, due to poor nutrition and non-food-related-illness.

ANNEX III: RECOMMENDATIONS FOR THE USE OF MICROBIOLOGICAL TESTING FOR ENVIRONMENTAL MONITORING AND PROCESS CONTROL VERIFICATION BY COMPETENT AUTHORITIES AS A MEANS OF VERIFYING THE EFFECTIVENESS OF HACCP AND PREREQUISITE PROGRAMS FOR CONTROL OF LISTERIA *MONOCYTOGENES* IN READY-TO-EAT FOODS.

IACFO

IACFO supports Annex III, which provides guidance for environmental testing and process controls designed to verify a program is effective for controlling *L. monocytogenes*. This is an essential step for reducing contamination and the potential for recurring contamination from undetected harborage sites within a manufacturing facility. The addition of guidance on environmental testing and process controls improves protection of public health.

b) Process Control

Third Paragraph

UNITED STATES

At the end of the paragraph add a sentence to read "The presence of Listeria monocytogenes in finished product can also indicate the lack of control of Listeria monocytogenes in the processing environment."

Rationale: After the working group meeting, there was an additional sentence present at the end of paragraph three. It was removed during the post-working group comment period because it may have been a little unclear. The U.S. suggests adding the sentence back and modified to make it clearer.

CIAA

The term "process control" has many meanings in food processing which are not associated with microbiological criteria or analysis. It is not clear until the third paragraph that we are discussing microbiological analysis and not other types of process control (e.g. Control of time and temperature).

It should be clear that the way in which such a program is managed will depend upon the status of the finished product. For example, an "occasional 'in control' positive sample" for *L. monocytogenes* in the finished product as indicated in paragraph three would represent a non-compliant product if covered by Annex II, 4.2, but could be used as an indicator of emerging loss of control for some products which are covered by Annex II, 4.1 For all such products, it would be more useful to incorporate hygienic indicators,

[5] *Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on* Listeria Monocytogenes*, European Commission*, Sept. 23, 1999.

such as *Listeria* spp. , which could indicate the presence of problems before they lead to a non-compliant product.

Due to statistical limitations of sampling, in most cases it is more effective to use trending of environmental sample data than to rely upon finished product sampling to indicate adverse trends.

CIAA would like to propose the reinforcement of reference to HACCP principles throughout both Annexes, emphasizing that end-testing of products is not the only way to ensure safe products.