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.2**
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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

Comments submitted by
Brazil, Colombia[1], European Community and New Zealand

BACKGROUND to Annexes II and III

COLOMBIA

To page 3, add the susceptibility of the host and degree of virulence of the strain among the key factors that indicate a risk of suffering from listeriosis.

Suggest a decision tree to determine whether or not a RTE product requires microbiological testing.

Categorize RTE products according to their chemical and organoleptic characteristics, as not all will allow *Listeria monocytogenes* to reproduce, but rather only serve as carriers when there is cross-contamination.

Paragraph 9, first dash, (Page 3, Spanish), revise Review the following paragraph

una evaluación de riesgos de la venta-al-detalle-a-la-mesa, comparativa de 23 categorías de alimentos LPC, realizada por el Departamento de Alimentos y Medicamentos y el Servicio de Inspección e Inocuidad de los Alimentos de EE.UU. (FDA/FSIS, 2003).

A retail-to-table risk assessment [Translation issue: *una evaluación de riesgos de la "venta-al-detalle-a-la-mesa"*]

(Page 3, English, Page 4, Spanish and French), Bullet 2, change to read " Frequency and amount of food contamination with *L. monocytogenes"* [Translation issue regarding "extent": *Cambiar por frecuencia y cantidad de la contaminación del alimento con L.monocytogenes]*

(Page 4, English, Spanish and French), First Dash, Delete the "S" from pathogens or change to "of the microorganism" (*Quitar la "S" de patogenos o dejar del microorganismo.*)

[1] The Colombian comments in Spanish are included in CX/FH 08/40/5 – Add. 1.

(Page 4, English, Spanish and French), Fourth Dash, delete "key components …control measures" and substitute "The key components of a successful risk management program are based on ensuring that control measures …."

(Page 4, English, Fifth dash; Page 4 Spanish and French, last Dash), in Spanish version change "dosis efectiva" to "dosis infectiva".

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

GENERAL COMMENTS

COLOMBIA

Review all sections of the document, and replace L. Monocytogenes with L. monocytogenes. In the Spanish, remove the article "la" when referring to L. monocytogenes

EUROREAN COMMUNITY

The EC supports the approach proposed by the working group and fully appreciates its achievement to reach a consensus on this challenging task. The present draft has some principal differences compared to the previous draft, such as the inclusion of an alternative approach to the microbiological criteria proposed for ready-to-eat foods in tables 1 and 2, as well as the inclusion of Annex III for environmental monitoring.

The EC would like to emphasise the importance of the approach described in the Chapter 4.3 of the current draft. The proper implementation of this approach must be seen as an equal option, especially to the criterion of absence in 25 g for *Listeria monocytogenes (Chapter 4.2),* in order to provide a high level of consumer protection. The EC also supports the inclusion of Annex III, although this Annex does provide more principles than concrete decision criteria for environmental monitoring. Furthermore, environmental monitoring must first and foremost be seen as a responsibility of Food Business Operators - as an elemental verification activity in their Good Hygiene Practice (GHP) and Hazard Analysis of Critical Control Point (HACCP) programmes. Primarily, environmental monitoring is not the responsibility of the competent authorities and should not be applied in international trade.

As stated in the background to Annexes II and III, the available scientific risk assessments conclude that the vast majority of (nearly all) foodborne human listeriosis cases are caused by a consumption of high numbers of *Listeria monocytogenes*. Furthermore, current epidemiological information from several countries shows that a consumption of *L. monocytogenes* not exceeding 100 cfu/g in food at the time of consumption presents a very low risk to consumers. This information is also expressed in a scientific opinion of The European Food Safety Authority (EFSA)[2].

The EC also fully recognises the fact that there is an observed increase in human listeriosis in some countries, even in countries which are currently implementing the criterion of absence in 25 g of *L. monocytogenes* in ready-to-eat foods. The reasons for this increase need to be further investigated, but it is clear that also the producers of the ready-to-eat foods must take their responsibility in order to control and reduce *L. monocytogenes* in their products, especially in the products where the growth of *L. monocytogenes* can occur. The proper implementation of GHP and HACCP programmes is crucial in this aspect. As recommended in the background text of the draft at hand, any proposed microbiological criteria should primarily be seen as a verification tool for these and other process control approaches.

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[2] Scientific Opinion of the Panel on Biological Hazards on a request from the European Commission on 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. *The EFSA Journal* (2007) 599, 1-42.

NEW ZEALAND

New Zealand supports the advancement of the revised microbiological criteria for *Listeria monocytogenes* in ready-to-eat (RTE) foods to help promote public health and consistency around controls for *L. monocytogenes* in RTE foods in international trade. In establishing microbiological criteria for particular classes of foods, New Zealand is of the view that competent authorities and industry should utilise risk-based metrics approaches where possible and practical. This approach is consistent with the principles of food safety risk management and the guidelines elaborated by Codex in the 'Principles and Guidelines for the Conduct of Microbiological Risk Management' (CAC/GL-63, 2007).

The current proposed guidelines, in describing microbiological criteria for *L. monocytogenes* in RTE foods, largely comprise "hazard-based" criteria and reflect the traditional approach to setting such criteria. Where a risk-based metrics approach to developing microbiological criteria is not possible or practical, New Zealand supports the guidelines for establishing "hazard-based" criteria as presented. However, the basis for such guidelines needs to be clearly identified. Thus the logic and clarity of the document would benefit by making a clearer distinction between the traditional versus risk-based approach and the correct use of terms. In this sense New Zealand recommends that the proposed microbiological criteria for *L. monocytogenes* in RTE foods under sections 4.1 and 4.2 be described as 'hazard-based' approaches and Section 4.3 (currently 'Alternative approach') be described as a 'risk-based' approach.

1. INTRODUCTION

FIRST PARAGRAPH

EUROPEAN COMMUNITY

First sentence, insert '*the*' before '*control*' .

2. SCOPE

FIRST PARAGRAPH

EUROPEAN COMMUNITY

First sentence, amend '*specific*' to '*two broad*' in line one – the reason is that it is not yet clearly established which foods are in which group.

THIRD PARAGRAPH

EUROPEAN COMMUNITY

Amend '*Alternative*' to '*Different*' in line 1.

LAST PARAGRAPH

NEW ZEALAND

New Zealand questions the value of the last paragraph in the Scope. It is unclear as to what "alternative criteria" actually are. Further, New Zealand does not consider that a risk-based approach, as inferred in the last paragraph in the Scope, is an "alternative" approach. Rather, it is the most desirable approach but is obviously limited by availability of data, technical resources etc. Consequently, New Zealand suggests deletion of the last paragraph, with a new second paragraph as follows:

"These guidelines include a "hazard-based" and a "risk-based" approach to development of microbiological criteria, noting that in many circumstances, there are insufficient data or technical resources to develop microbiological criteria according to a risk-based approach as advocated in the Codex in the 'Principles and Guidelines for the Conduct of Microbiological Risk Management' (CAC/GL-63, 2007)."

The current second paragraph would become the last in Scope. It should be noted that performance objectives as an example can only remain if the above paragraph is accepted, as they can only be developed from a full risk-based evaluation of a particular food scenario.

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

NEW ZEALAND

Note suggested title change

As a general comment, all of Section 3 is written in the context of microbiological criteria established according to a traditional (hazard-based) approach. However, CCFH has strongly advocated use of microbiological criteria as a control measure contributing to assurance of a required level of consumer protection, where possible and appropriate. This use needs to be included as an example in this section.

New Zealand suggests that the current paragraph 3 become paragraph 2. This paragraph directly explains what is meant by "acceptability" testing.

Use as a verification tool in HACCP systems is the next example. Therefore, the words "In addition" should be removed.

A third example is the use of a risk-based microbiological criterion to contribute to an assurance that a particular food control system delivers the required level of consumer protection. A new paragraph should be inserted to reflect this i.e."Where possible and practical, microbiological criteria developed according to a risk-based approach (as advocated in the Codex Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC/GL-63, 2007) can be used to assure, or contribute to the assurance, that a particular food control system achieves the required level of consumer protection.

New Zealand does not support the bracketed text in this section, and suggests deletion of the last paragraph (duplicative of what follows).

THIRD PARAGRAPH

EUROPEAN COMMUNITY

Amend first sentence to read '*A microbiological criterion for food defines the acceptability of a product or a food lot, based on the presence or absence, or number of L. monocytogenes in a defined quantity of the product or food.*'

FOURTH PARAGRAPH

NEW ZEALAND

The first sentence in the fourth paragraph should be removed, as this is a generic statement that needs to apply to both "hazard-based" and "risk-based" microbiological criteria. Sampling will not be "risk-based" unless a full risk-based approach to developing the microbiological criterion itself has been undertaken. The second sentence should be modified accordingly i.e. "The competent authority may consider…. "

LAST PARAGRAPH

EUROPEAN COMMUNITY

Amend to '*Different types of food present different risks from L.monocytogenes. In this guidance, foods of broadly similar nature have been grouped, and microbiological criteria established for the following categories*:

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

EUROPEAN COMMUNITY

Change of style throughout the text: "~~*aw*~~ *to* a_w"

NEW ZEALAND

Section 3.1. "Ready-to-eat foods…… . is elaborated "based on scientific justification". In the overall context of this guideline, this is not clear. Science itself is not a justification. The elaboration method is hazard-based and this needs to be stated (as for 3.2). (After all, a risk-based microbiological criterion is also elaborated using science). There are a number of **arbitrary** decisions on input parameters that reinforce the need to make the basis for elaborating this type of criteria very clear.

New Zealand suggests combining of Sections 3.1. and 4.1. under a single title, as follows:

3.1. "A hazard-based approach to establishing microbiological criteria for RTE foods in which growth of L. m. will not occur". The lead sentence would change to "Elaboration of microbiological criteria includes empirical decisions on a number of scientific inputs affecting the level of hazard control, including the…… . All of the text currently in 4.1. would follow.

FIRST PARAGRAPH

EUROPEAN COMMUNITY

First sentence, insert '*and combinations of factors*' after '*factors*' and Inclusion: *Factors such as acidity (pH) and water activity (a_W), are useful…*

Second sentence, modify to read "*Factors such as acidity (pH) and water activity (a_W), are seful…*"

Bullets, Correction:

- a pH ~~below~~ ≤ 4.4,

- an a_w ~~<~~ ≤ 0.92,

Last sentence, parenthesis, Replace '*that*' with '*the*':

SECOND PARAGRAPH

COLOMBIA

Specify what inhibitors are being referred to, because the scientific information is very contradictory on this aspect, and it is not conclusive. Correct all ocurrences of CFU (English acronym) in the Spanish text to UFC (Spanish acronym).

THIRD PARAGRAPH

BRAZIL

Last sentence, modify to read "Such studies ~~would generally~~ should be conducted by food business operators ~~(or by the appropriate product board, sector organizations or contract laboratories)~~ to demonstrate that the food will not have an observable increase in L. monocytogenes levels greater than the proposed criteria during the shelf life and must be appropriately designed to validate that L. monocytogenes will not grow in a food."

Rationale: Considering the different types of foods that could apply to the category RTE foods in which growth of L. monocytogenes will not occur, it is suggested that food business operators should demonstrate

that the food will not have an observable increase in *L. monocytogenes* levels greater than the proposed criteria establish to this category during the shelf life.

EUROPEAN COMMUNITY

We believe the paragraph beginning '*Demonstration…*' has general application and should be transferred into the introductory section of paragraph 3. In the last sentence, change '*must*' to '*should*' – not Codex language.

FOURTH PARAGRAPH

EUROPEAN COMMUNITY

Last sentence, change of word: …*as ~~labelled~~ stipulated by the*…

Last sentence, parenthesis, change to read; …*and use (including a safety margin~~, e.g. 1.3 times the period specified~~).*

Rationale: There seems to be no scientific rationale behind the recommendation of using the factor 1.3 when establishing the expected usage period of a food. If there actually exists science to support this number, it could remain in the text – appropriately referenced.

FIFTH PARAGRAPH

EUROPEAN COMMUNITY

We do not understand the scientific basis for 8°C and question whether it would be universally appropriate. Suggest recasting this paragraph to:

'*For foods intended to be refrigerated, studies to assess whether or not growth of L. monocytogenes will occur should be conducted under reasonably foreseeable conditions of distribution, storage and use.*'

FOOTNOTE 10

EUROPEAN COMMUNITY

Inclusion/removal:

[10]0.5 log is two times ~~of~~ the standard deviation (i.e., 0.25 log) associated ~~to~~ with the experimental enumeration of viable counting / plate counts

3.2 Ready-to-eat foods in which growth of *L. monocytogenes* can occur

EUROPEAN COMMUNITY

Sections 3.1 and 3.2, definition of foods in which growth of *L. monocytogenes* can occur.

The rationale for selecting an average of 0.5 log CFU/g increase to define foods in which growth of *L. monocytogenes* can or cannot occur refers to measurement uncertainty, but does not consider the inherent variation in bacterial levels between and within samples. Standard statistical inference on differences between means (before and after storage) could, preferably, be used.

An alternative definition is suggested as follows: *A ready-to-eat food in which the mean increase in L. monocytogenes for at least the expected shelf life under reasonably foreseeable conditions of distribution, storage and use, with 95% confidence has been shown to not exceed 0.5 log CFU/g is considered a food in which growth of L. monocytogenes will not occur.*

Other confidence or population increase levels could be chosen. Mean is a more precise term than average (which also may refer to the median or the mode).

NEW ZEALAND

New Zealand suggests combining of Sections 3.2. and 4.2. under a single title, as follows:

3.2. "A hazard-based approach to establishing microbiological criteria for RTE foods in which growth of L. m. can occur". All of the text currently in 4.2. would follow.

FOOTNOTE 11

EUROPEAN COMMUNITY

Change to read; *[11]0.5 log is two times ~~of~~ the standard deviation (i.e., 0.25 log) associated ~~to~~ with the experimental enumeration of viable counting / plate counts*

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

SECOND PARAGRAPH

EUROPEAN COMMUNITY

First sentence, after "of" amend to 'evaluation of product formulation, the production environment'

JAPAN

2nd paragraph "Proposed Draft" should be deleted. Because, this annex was approved at the last CAC.

4.1 Microbiological criteria 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

JAPAN

Under the Both **Table 1** and **2**

The following sentences should be inserted.

"WHERE N = NUMBER OF SAMPLES THAT MUST CONFORM TO THE CRITERIA: C = THE MAXIMUM ALLOWABLE NUMBER OF DEFECTIVE SAMPLE UNITS IN A 2-CLASS PLAN. M = A MICROBIOLOGICAL LIMIT WHICH, IN A 2-CLASS PLAN, SEPARATES GOOD QUALITY FROM DEFECTIVE QUALITY."

In addition, since 2 class sampling plan is used for both Table 1 and 2, we should delete the Colum of "M" in these tables.

Rational: This is the phrase to explain what n, c, m in the table means, and the same texts are in the MICROBIOLOGICAL CRITERIA FOR POWDERED INFANT FORMULA, FORMULA FOR SPECIAL MEDICAL PURPOSES AND HUMAN MILK FORTIFIERS, CAC/RCP66-2008.

Footnote a

EUROPEAN COMMUNITY

Insert '*transported*' after '*collected*' in sub-text a. This addition should be repeated at the same location in relation to Table 2.

Footnote b

EUROPEAN COMMUNITY

Inclusion:

…appropriately validated ***using an interlaboratory protocol*** *(e.g. based on ISO 16140).*

Footnote c

EUROPEAN COMMUNITY

After sub-text c insert a new paragraph at the margin

'*The typical action to be taken when there is a failure to meet the above criteria would be to (1) prevent the affected lot from being released for human consumption and (2) recall the product if it has been released for human consumption, and (3) determine and correct the root cause of the failure.*'

NB: this text is lifted directly from the PIF Annex and may be subject to reflection. Issue is that an essential part of a microbiological criterion is a statement of the actions to be taken if the criterion is breached. This text should be repeated at the same location in relation to Table 2.

4.2 Microbiological criteria for ready-to-eat foods in which growth of *L.monocytogenes* can occur

Table 2:

Microbiological criteria for ready-to-eat foods in which growth of *L.monocytogenes* can occur

Footnote b

EUROPEAN COMMUNITY

Inclusion and deletion:

…appropriately validated ***using an interlaboratory protocol*** *(e.g. based on ISO 16140).* ~~*National governments should provide guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.*~~

Footnote c

EUROPEAN COMMUNITY

Insert '*log*' after '*0.25*'

4.3 Alternative approach

JAPAN

Although criteria are not defined clearly, "**4.3 Alternative approach"** can be applied when the application of the 2 microbiological criteria described in section **4.1** and **4.2** are not feasible due to the each country's food culture, variety of traditional foods, eating habit etc. Therefore, Japan would like to support this alternative approach.

FIRST PARAGRAPH

EUROPEAN COMMUNITY

First sentence, amend 'As an alternative approach to……' to 'Further to the approach to…..'

First sentence, "…at the point of consumption" add "**or at other point** that provide"…

SECOND BULLETT

EUROPEAN COMMUNITY

Deletion and inclusion: …*shelf life*[15] *(including a safety margin), and*

Page 12, Bulleted points: this is generic text lifted from elsewhere and references to '*the micro-organisms of concern*' should be replaced by mention of the specific micro-organism of concern in this Annex, which is *L. monocytogenes*.

THIRD BULLETT

EUROPEAN COMMUNITY

Ssuggest this should read '*predictive……. survival factors for L. monocytogenes in the product under reasonably foreseeable conditions of distribution, storage and use.*'

Footnote 15

EUROPEAN COMMUNITY

It is suggested to include the definition of shelf life (coming from the milk code) as follows:

[15] ~~*e.g. 1.3 times the period specified*~~ *.Shelf life: the period during which the product maintains its microbiological safety and suitability at a specified storage temperature and, where appropriate, specified storage and handling conditions.*

The proposal to delete the reference to 1.3 times of the period specified is based on the fact that there seems to be no scientific rationale behind this recommendation of using the factor 1.3 when establishing the expected usage period of a food. If there actually exists science to support this number, it could remain in the text – appropriately referenced.

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.

New Zealand supports the principles and content of this Annex.

a) Environmental Monitoring

LAST PARAGRAPH

EUROPEAN COMMUNITY

Last sentence, change of style: ~~L. monocytogenes~~ *L. monocytogenes*

b) Process Control

JAPAN

(1) We understand "b) Process Control" means the audit of HACCP and SSOP record, and final products tests by the competent authority. If it is correct, the definition of "process control" should be articulated in the first paragraph of "b) Process control".

(2) 1st paragraph, last sentence “actions of production personnel” should be defined to make it easy to understand because it is not clear what this phase means.

(3) 2nd paragraph, the relationship between “process control criteria” and “decision criteria” is not clear. And the definition of “decision criteria” should be articulated. (“Decision criteria” is also used in last paragraph.)

(4) Last paragraph “but are available through standard references” is not reader friendly. We recommend adding some references in this document.