codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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

Comments in response to CX/FH 07/39/6 submitted by: Brazil, Canada, Islamic Republic of Iran, Malayasia, Mexico, Peru, Philippine, the United States of America, EuroCommerce and International Dairy Federation (IDF)

GENERAL COMMENTS

CANADA

Canada wishes to congratulate Germany and the members of the Working Group for the development of the document CX/FH 07/39/6, **Microbiological criteria for *Listeria monocytogenes* in ready-to-eat foods.**

BRAZIL

Brazil congratulates the drafting group led by Germany for the advances obtained to the document. Continuing the revision of the document, the alterations in the items described below are suggested.

EUROCOMMERCE

EuroCommerce welcomes the draft document drafted by Codex on Microbiological criteria for *Listeria Monocytogenes* in ready-to-eat foods at Step 3, which we understand is intended to be completed over two sessions of the Committee (by 2008) for adoption by CODEX in 2009.

We would like to take the opportunity to provide you with some comments on this document.

We are pleased that the background mentions the following as considerations to be taken into account when setting micro criteria for specific RTE foods:

Working documents will be uploaded onto the Codex website:
www.codexalimentarius.net/web/index_en.jsp
Delegates are kindly requested to bring with them to the meeting all documents which have been distributed, as the number of additional copies which can be made available at the session is limited.

- Current epidemiological information from several countries shows that a concentration of *L. Monocytogenes* not exceeding 100 cfu/g of food at the time of consumption is of low risk to consumers;

- Based on risk assessment, some countries have concluded that an absence of *L.Monocytogenes* for certain RTE foods is an unrealistic and unattainable requirement that limits trade without having a positive impact on public health.

PERU

Peru appreciates the opportunity to express its views regarding the information requested.

Listeria monocytogenes (L. monocytogenes) is a bacterium that commonly occurs in the agricultural environment (soil, vegetation & water) as well as in the food processing and storage environments. This bacterium resides temporarily in the intestinal tract of human beings; it is found in 2 to 10% of the general population. Its carriers can be asymptomatic. It is resistant to various adverse conditions, such as high salinity or acidity (Ryser and Marth, 1991).

Listeria monocytogenes has been isolated in foods such as raw and pasteurized milk, cheeses (particularly soft-ripened and traditionally made varieties), ice cream, raw vegetables, fermented raw meat sausages, raw and cooked chicken, raw meats (all types), and raw and smoked fish.

In general, the food products involved have presented concentrations of *Listeria monocytogenes* greater than 10^3 CFU/g (CE, 1999; FDA/FSIS, 2001), but in some cases, the concentration of *Listeria monocytogenes* observed in the food product involved has been significantly less.

Peru's National Sanitary Standard, 'Microbiological Criteria for Sanitary Quality and Safety for Food and Beverages for Human Consumption' ("*Criterios Microbiológicos de Calidad Sanitaria e Inocuidad para los Alimentos y Bebidas de Consumo Humano*"), establishes that in the case of food products that do not support the proliferation of *L. monocytogenes*, m is considered < 100. (Reference: Risk assessment of *L. monocytogenes* in ready-to-eat foods. FAO/WHO 2004, Codex Committee on Food Hygiene, adopted by the European Community, COMMISSION REGULATION (EC) Nº 2073/2005 - OJEU of 12/22/05 - on microbiological criteria for foodstuffs.)

Listeria monocytogenes can cause problems that must be prevented through the use of hygiene measures. In this regard, the sanitary authorities and the industry must base their control on the appropriate application and verification of Good Handling Practices, a Hygiene and Sanitation Program, and the application of the HACCP Plan.

These guidelines provide a management framework for *Listeria monocytogenes* in food. These are intended primarily for governments and are related to both management at the national level and to facilitating international trade. They also offer, however, data that can be useful for the food industry, the consumer, and other interested parties.

UNITED STATES OF AMERICA

The United States appreciates the work of Germany and the members of the working group[1] in developing this Annex. The working group is to be commended for the progress it has achieved in addressing this highly complex topic. The United States does feel that there are several areas within the document that need further refinement if it is going to be both scientifically supportable and of practical use.

[1] Australia, Austria, Brazil, Canada, Denmark, EC, Finland, France, Hungary, Italy, Jamaica, The United Kingdom, The United States of America, CIAA, FAO, and IDF.

IDF

According to the Codex Principles for the establishment and Application of Microbiological Criteria for Foods (CAC/GL 21), MC should only be established where evidence show a need, i.e. there are no other means of ensuring food safety. The burden of evidence as regards the need for the MC lies with the body responsible for establishing the MC.

In this case, however, a totally different approach is taken. A MC is established in general (all ready-to-eat foods), but in recognition of the obvious inappropriateness of testing all RTE-foods, foods have been roughly divided into two categories, based upon the appropriateness of testing. The burden of evidence as regards the need for testing lies with the body that implements the MC.

This awkward situation illustrates the need for an FSO approach to manage risk associated with the presence of *Listeria monocytogenes* in RTE-foods (or at least a PO at the end of shelf life) rather than establishing (a) general MC.

An FSO (or PO) would provide a straighter forward and understandable risk management strategy, and would enable consideration in the field of the need for verification through analytical testing (and thus the MC) – in accordance with CAC/GL 21.

Therefore, we regret that previous work of the CCFH that aimed at addressing the relationship between FSO, PO and MC for *Listeria monocytogenes* (included in CX/FH 05/37/5[2]) seems to have been lost.

BACKGROUND

PARAGRAPH 9

UNITED STATES OF AMERICA

Paragraph 9, 2nd and 3rd sentences. These sentences should be modified as indicated below to more directly convey the conclusions of the risk assessment.

> "Raising the current standard employed by a number of governments (e.g., "absence in 25 g") to a higher value (e.g., 100 CFU/g) could be expected to increase exposure to *L. monocytogenes* and thus increase the potential risk to consumer. However, the risk assessment also concluded that if raising the standard would result in greater compliance through increased adoption of effective control measures that significantly reduced the number of servings that had elevated levels of *L. monocytogenes*, there would be net gain in public health protection."

It is also noted that all references to "zero tolerance" should be deleted from the background section. This is not a scientifically-based term in relation to microbiological criteria. Instead, the actual sensitivity of the sampling plan upon which current criteria are based should be the one used to provide a basis for comparison. This is particularly important considering that the criterion for foods that will support growth of *L. monocytogenes* in the draft Annex is 5-times more stringent than the "zero tolerance" criterion discussed in the background section, i.e., absence in 125 g versus absence in 25 g).

SIXTH PARAGRAPH FROM END OF BACKGROUND (- "BASED ON ….PUBLIC HEALTH")

UNITED STATES OF AMERICA

This paragraph presumes knowledge about the risk management deliberations of different countries. Unless specific documentation can be provided, the paragraph should be revised to read:

> "Some countries have concluded that an absence of *L. monocytogenes* for certain RTE foods is not feasible and unnecessarily limits trade without having a positive impact on public health."

[2] "Deriving Microbiological Limits and Sampling Plans in Microbiological Criteria from Food Safety Objectives; Example: *Listeria monocytogenes* in Ready-To-Eat Food Products"

NEXT TO LAST PARAGRAPH OF BACKGROUND

First sentence, although the United States agrees that the focus of Annex II is on acceptance criteria, it believes that these should not be referred to as a focus on "port of entry" applications. In today's world of the WTO/SPS agreement, the term has lost its meaning, i.e., if a country implements this type of microbiological criteria at port of entry it must also do so for its domestic industry. The use of a term other than "port of entry" is more appropriate to the scope and purpose of the document which is to inform governments.

NEXT TO THE LAST PARAGRAPH OF BACKGROUND.

UNITED STATES OF AMERICA

The specific meaning of the last sentence is unclear, and does not appear to have been discussed at the working group meeting. It is recommended that the sentence either be deleted or revised to clarify its meaning and impact on the subsequent criteria articulated in the annex.

MICROBIOLOGICAL CRITERIA FOR *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS AT STEP 3

2. SCOPE

PARAGRAPH 1

CANADA

First sentence, insert "***specific***" before the word "*categories*".

UNITED STATES OF AMERICA

The first sentence should be modified to read:

> "These microbiological criteria apply to categories of RTE foods at the points indicated in sections 3 and 4, with consideration given to how specific RTE foods are likely to be handled during marketing, catering, or by consumers."

It is the opinion of the United States that stating that a product has a short shelf-life when the competent authority or industry is aware that a substantial portion of the consumers hold the product beyond the stated shelf-life should not be a means of applying a microbiological criterion that is inappropriate for the food category. In addition, greater consideration of shelf-life in applying criteria and parameters for doing so are given later in the document. The criteria should focus on the likelihood of growth in the food during actual commercial, retail and consumer storage and handling; a short designated shelf-life is not an appropriate criterion by itself.

PARAGRAPH 2

CANADA

First sentence: It should be clarified within the scope that these criteria could be applied at the port of entry for imported foods or within a domestic monitoring and verification scheme. We suggest to reword the sentence as follows:

"*Governments may apply these criteria to assess the acceptability of RTE foods at the "port of entry" for imported products, end of manufacture (finished product), and at point of sale over the product's entire shelf life,*"

UNITED STATES OF AMERICA

The second paragraph should be revised to read:

> "Governments may apply these criteria to assess the acceptability of RTE foods at point of manufacture for domestic products, at port of entry for imported products, and at other locations where the criteria are appropriate and useful. In applying these criteria, governments should consider the potential for these products to be co-located or handled in conjunction with other RTE and non-RTE foods."

As indicated earlier in our comments, it is inappropriate within a WTO/SPS framework to indicate that a microbiological criterion is limited to a port of entry. The criterion must indicate an equivalent point for the domestic food industry. That point has traditionally been the point of manufacture, i.e., the point of entry (imported products) and the point of manufacturer (domestic products) are the points when the RTE food effectively enters commerce within a country. Additionally, the rewording makes the paragraph more consistent with the principles outlined in "Principles for the Establishment and Application of Microbiological Criteria for Foods."

PARAGRAPH 3

CANADA

End of the paragraph, it is suggested to delete the second example in parentheses, intended to illustrate a food safety control system, i.e., "*(e.g., control of operations and establishment sanitation)*" and to replace it with a footnote reference to the draft definition of a Food Safety Control System in the Proposed Draft Guidelines for the Validation of Food Safety Control Measures (*the combination of control measures that, when taken as a whole, ensures that the food is safe for its intended use*).

3. USE OF MICROBIOLOGICAL CRITERIA FOR *L. MONOCYTOGENES* IN RTE-FOODS

PARAGRAPH 1

UNITED STATES OF AMERICA

The first paragraph should be revised to read: "As described in CAC/GL 21-1997, microbiological testing of each lot can be used as a direct control measure, i.e., sorting of acceptable and unacceptable lots. In this instance, microbiological criteria are implemented for those products and/or points of the food chain when other more effective tools are not available and where the microbiological criteria would be expected to improve the degree of protection offered to the consumer. In addition "CAC/RCP 1 – Annex (Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application)" describes how microbiological testing against a criterion can be used as a means of verifying the continuing effectiveness of a food safety control system. Typically, such applications involve testing on less than a lot-by-lot basis and may be formalized into a system of process control verification testing."

The United States feels that mentioning this application for microbiological testing is critical because (1) this type of application of microbiological criteria is most often used by both governments and industry, and (2) this is consistent with CCFH's recommendation that food safety risk management should be done through HACCP or an equivalent food safety control system.

IDF

The phrase "*when no other more effective tools are available and where they are expected to improve the degree of protection offered to the consumer*" is a cut & paste from CAC/GL-21. However, without the context in which this phrase is placed in GL-21, the phrase may be misunderstood.

We recommend that the phrase be put into the same context as in GL-21, by adding the underlined text as follows:

> "*According to CAC/GL 21-1997, mandatory microbiological criteria shall apply to those products and/or points of the food chain when no other more effective tools are available <u>to define and check compliance with the microbiological requirements</u> and where they are expected to improve the degree of protection offered to the consumer*."

PARAGRAPH 2

CANADA

First sentence: The definition of a microbiological criterion presented in this sentence varies slightly from the definition in CAC/GL 21-1997. It is suggested to either refer to the Principles and Guidelines for this definition or to quote the definition presented in CAC/GL 21-1997.

UNITED STATES OF AMERICA

The third sentence of the second paragraph should be revised to read:

> "…conditions of production, testing of lots for process control verification purposes may be conducted…"

This will make the sentence more consistent with this type of application as indicated in the HACCP Annex.

The addition of an additional sentence should be considered to provide additional flexibility in relation to the frequency of testing.

> "Governments may consider modifying the frequency of testing for process control verification testing based on additional consideration of the likelihood of contamination, characteristics of the food, product history, conditions of production and other relevant information."

3.1 Foods for which no criteria are needed

UNITED STATES OF AMERICA

Modify title of this section to read. "Foods for which testing against microbiological criteria is not necessary."

The United States feels that this section should be positioned after section 3.2.

The United States feels that the classes and characteristics of RTE foods that would not be covered by the microbiological criteria for *L .monocytogenes* are not clearly enough defined to provide information to governments that is sufficiently unambiguous. Accordingly, this section needs additional work to more carefully provide the concepts and factors that would lead to a food being included within this category. Accordingly, the United States suggests the following changes to section 3.1.

FIRST PARAGRAPH

CANADA

Paragraphs 1 & 3: The information provided in the first paragraph is repeated in the 3rd one. It is suggested to delete the first paragraph and move the 3rd paragraph to the beginning of the section.

UNITED STATES OF AMERICA

The first paragraph should be modified to read:

> "Testing against a microbiological criterion may not have utility for certain specific types of RTE foods, i.e., testing would not contribute to the protection of public health. The primary foods in this category are RTE foods for which production, processing, or product characteristics ensures killing of *L. monocytogenes* and there is no potential for recontamination until used by the consumer. "

It is worth noting that in this revised sentence, the phrase "processed and handled under Good Hygienic Practice (GHP) systems" was deleted because all foods are supposed to be processed and handled under GHPs.

SECOND PARAGRAPH

UNITED STATES OF AMERICA

The United States has concerns about the inclusion of the second paragraph and recommends its deletion. The history of foodborne listeriosis is replete with examples of foods for which there was no epidemiological data until an outbreak occurred. Furthermore, the nature of listeriosis and outbreaks associated with foodborne contamination is often such that traditional epidemiological tools have severe limitations. Many foods may cause only sporadic cases that are very difficult to detect by epidemiological tools, particularly with the long incubation period for listeriosis.

THIRD PARAGRAPH

BRAZIL

First sentence, it is suggested to replace "*icrobiological*" with "*microbiological*", considering that was identified a misspelling.

CANADA

Paragraph 3: it is suggested to present the list of foods in the second part of this paragraph in a bulleted form.

MEXICO

The third paragraph of item 3.1 presents potential processes or treatments needed in order to categorize a food as one for which no criteria are needed. It is not clear whether these processes or treatments are examples or if they must be considered as a definite list of processes/treatments for foods for which no *Listeria monocytogenes* criteria are needed.

UNITED STATES OF AMERICA

Third Paragraph, 1st sentence. There is a typo in the first word "Microbiological"

The third paragraph provides a series of foods that are proposed for exemption without providing a consistent rationale for their exclusion. In several cases, available scientific data do not support their exclusion and in others the foods are more appropriate for inclusion under the criterion for foods that do not support growth. We think that it would be more appropriate not to mention specific products, since such designations take on a life of their own and make it difficult to change if the exclusion is no longer appropriate in the future. Accordingly, the United States recommends that the scope of the paragraph be limited by revising it to read:

> "Testing against microbiological criteria may have limited utility if the level of *L. monocytogenes* in a RTE food is consistently well below the practical limits for sample sizes and method sensitivity. In particular, testing against microbiological criteria for *L. monocytogenes* may not be warranted for three classes of RTE foods: (a) products that receive a listericidal treatment after being sealed in final packaging that ensures prevention of recontamination until opened by the consumer or otherwise compromised, (b) foods that are aseptically processed and packaged, and (c) products that contain a listericidal component that ensures rapid inactivation of the pathogen if recontaminated (e.g., products that contain >1.0% ethanol). In all cases, consideration for exempting such products should take into account the product's characteristics in relation to production environment, processing consistency, and compositional attributes that render the product effectively free of *L. monocytogenes*. In such instances, consideration should be given to identifying alternative means of verifying that these factors are being consistently achieved in the product."

IDF

- An "M" is missing in the first word.
- We suggest that it is specified that, when in doubt, governmental inspectors should contact the manufacturer in question and consult the documentation for their control of *Listeria monocytogenes*.
- Finally, it should be noted that the reasons for a very low probability of detecting Lm have many causes and is not only linked to the type of food, but also to many other factors such as prevalence and concentration in raw materials, effectiveness of GHP (e.g. maintaining a *Listeria*-free processing environment). The text should reflect this.

FOURTH AND FIFTH PARAGRAPH

UNITED STATES OF AMERICA

The United States recommends that paragraphs 4 and 5 be deleted.

CANADA

Paragraph 4: the text should include an example of foods used "*in combination with other foods*".

3.2 Foods for which criteria are appropriate

FIRST PARAGRAPH

UNITED STATES OF AMERICA

In the first sentence of the first paragraph, the phrase, "that do not fall into the group described in section 3.1," should be deleted. The second sentence in the first paragraph should be deleted in its entirety.

IDF

1st sentence, to be in compliance with the scope, add the following underlined text in beginning of the sentence:

> "*When no other more effective tools are available to define and check compliance with the microbiological requirements, testing against microbiological criteria may be useful for the following groups of RTE foods that do not fall into the group described in section 3.1*."

3.2.1 RTE foods in which growth of *L. monocytogenes* will not occur

MEXICO

Text must be inserted to point out that, in principle, this food group includes those foods that due to their chemical or physicochemical nature (e.g., pH < 4.4 or a_w <0.92) can control the growth of *Listeria monocytogenes*. This will allow for differentiating this group of foods from the foods included in item 3.1 (Foods for which no criteria are needed), which considers that it is the process/treatment itself that ensures the elimination of the microorganism.

Furthermore, it is advisable to consider that a food belonging to this last group (3.2.1) can be subjected to a process/treatment that would allow for its inclusion in the food group for which no criteria are directly needed (3.1).

PARAGRAPH 1

CANADA

Fourth sentence, regarding the 5-days shelf life:

- The word "refrigerated" should be added before "shelf life";
- A rationale should be provided, either in this paragraph or as a footnote, with respect to the selection of a 5-days shelf life limit for inclusion of products in this category.

MALAYSIA

Last sentence, Malaysia proposes to delete the text in the square brackets in view that the Proposed Draft Guidelines for the Validation of Food Safety Control Measures is still under discussion in the Codex Committee on Food Hygiene.

UNITED STATES OF AMERICA

First paragraph, 3rd sentence: Delete the phrase, "e.g., the combination of pH < 5.0 with a_w <0.94." The following parenthesis should be added immediately after freezing "(during that period when the product remains frozen)".

First paragraph, 4th sentence. This sentence should be deleted. As indicated elsewhere in our comments, the United States thinks that there should not be a blanket exemption of products solely on the basis of the stated shelf life of a product. As indicated throughout the rest of the Annex, the determining criteria should be the inherent ability of *L. monocytogenes* to grow in the product and the conditions of storage and use.

First paragraph, last sentence. The phrase "and require appropriate validation" should be deleted. This is covered in the second paragraph.

IDF

- The referenced values for pH and aw are default values. In practice, synergy can be obtained with other intrinsic factors that would result in no growth at other pH and aw-values. We recommend that such values be specified only as examples.

- The 3rd sentence addresses products with short shelf lives. We find the wording too deterministic and suggest that the term "Some" be added in the beginning of the sentence.

- We suggest removing the square brackets around the reference to the validation guidelines.

- To avoid any misunderstandings, we also suggest that it is specifically mentioned that foods in which the concentration of any *Listeria monocytogenes* declines with time is included in this category of foods (e.g. hard cheeses with dry rind)

FIRST PARAGRAPH

EUROCOMMERCE

We support the following statements, as they are in agreement with Regulations (EC) No 2073/2005 on microbiological criteria for foodstuffs:

- .. .would be determined based on scientific justification... Lm growth can be controlled in foods that have a pH below 4.4, an aw < 0.92, or a combination of factors (pH, aw, inhibitors), e.g. the combination of pH < 5.0 with aw < 0.94, or by freezing.

- Products with a shelf life of less than five days can be considered to fall into this category.

- Demonstration that Lm will not grow in a RTE food can be determined by, for example, the study of naturally contaminated food, challenge tests, predictive modelling, information from the scientific literature and risk assessments, historic records or combinations of these. Such studies would generally be conducted by food business operators and require appropriate validation.

PARAGRAPH 2

CANADA

First sentence: this text should be further clarified.

Second sentence: a rationale or reference should be included with respect to the selection of "*1.3 times the expected shelf life*".

UNITED STATES OF AMERICA

Second paragraph, 2nd sentence. Referring to "less than 1.0 log growth during 1.3 times the expected shelf life…" seems inconsistent with the rationale that this value represents practical limitations associated with analytical methods. The error associated with methods used to quantitatively determine the levels of *L. monocytogenes* is generally better than the 1-log criterion identified. Furthermore, for most foods that do not support the growth of *L. monocytogenes* the levels of the microorganism would be expected to decrease. Accordingly, the United States recommends that the sentence be revised to read:

> "… a food in which growth of *L. monocytogenes* will not occur will not have observable increases in *L. monocytogenes* levels equal to or greater than 0.5 log CFU/g during 1.3 times the expected…"

An additional sentence should be inserted before the last sentence.

> "National governments should provide guidance on the specific protocols (e.g., number of replicates, analytical methods) that should be employed to validate that growth of *L. monocytogenes* will not occur in a food."

SECOND PARAGRAPH

EUROCOMMERCE

Second sentence, we are not convinced about the practicability of the following approach and would like clarification on the evidence used to derive the value of 1.3 times the expected shelf life:

- For practical purposes, a food in which there is less than 1 log growth during 1.3 times the expected shelf life under reasonably foreseeable conditions of distribution, storage and use is considered a food in which growth of Lm will not occur.

Third sentence, for refrigerated foods, studies conducted at 8°C would not necessarily reflect the temperature profiles seen in distribution, sale and consumer refrigerators.

Fourth sentence, we are sceptical about the practicability of the statement. We do not see how this could be checked at port of entry without additional information having to be provided by manufacturers. We are therefore concerned about possible rejection of consignment without a good reason.

3.2.2 RTE foods in which growth of *L. monocytogenes* can occur

UNITED STATES OF AMERICA

This sentence should be modified to read: "… food in which there is ≥ 0.5 log CFU/g increase in *L. monocytogenes* levels during …"

The U.S. believes a second sentence needs to be added to section 3.2.2:

"In applying this criterion, governments should consider the potential for these products to be co-located or handled in conjunction with other RTE and non-RTE foods."

4. MICROBIOLOGICAL CRITERIA [AND OTHER MICROBIOLOGICAL METRICS] FOR *L. MONOCYTOGENES* IN RTE FOODS

TITLE

MALAYSIA

Malaysia proposes the remove the text in the square brackets and the related text in Para 4.4. Malaysia is of the opinion that the document should focus on microbiological criteria. We note that other Microbiological Metrics was included under the provisions of General Principles of Food Hygiene.

IDF

The use of the term "metrics" in this context is confusing, in particular in light of the same term being used for FSOs, POs, PC, etc. Since the text only refers to microbiological criteria, we suggest using that term.

4.1 Microbiological criteria for RTE foods in which growth of *L. monocytogenes* will not occur

PARAGRAPH 1

UNITED STATES OF AMERICA

1st sentence, for consistency, modify the sentence to read: "…in which *L. monocytogenes* growth will not occur under the …"

2nd sentence, the phrase "over the course of the product's entire shelf-life" is not needed and has caused confusion when we have had individuals try to interpret its meaning. The United States recommends its deletion.

3rd sentence, the implementation of HACCP cannot take place without implementation of GHPs. To be factually correct, the sentence needs be modified to read "…produced under GHP or GHP + HACCP with…"

IDF

In the 4th sentence, it is stated that the *"criterion is based on the product being produced under GHP and/or HACCP with appropriate evaluation of the production environment and process control and validation that the product meets the requirements of a food in which growth of* L. monocytogenes *will not occur"*.

We suggest that this notion be moved to another section (e.g. scope), as the current location may be seen as being in contradiction to the first paragraph in section 3 (introductory text), where it is stated that the MC apply only, when no other more effective tools are available. (Normally, an effective HACCP/GHP system is considered as such more effective tools).

The last sentence should receive more attention (a paragraph on its own). The word "*demonstrated*" should replace "*confirmed*", as this term relates to validation, whereas "confirmed" relates to verification.

Table 1: Microbiological criteria for RTE foods in which growth of *L. monocytogenes* will not occur

Microorganism	n	c	m	M	Class Plan
Listeria monocytogenes	5	0	100 cfu/g [a]	NA	2 [b]

PHILIIPPINES

We support **a level (m) of <100 cfu/g** *Listeria monocytogenes* in Ready-To-Eat Foods because according to JEMRA the risk to public health from the consumption of ready-to-eat foods at above level is low. (Risk Assessment of *Listeria monocytogenes* in ready-to-eat foods, Technical report. Series 5 2004).

IDF

The MC should differentiate between situations where it supplements GHP/HACCP/validation and where it is applied on its own (e.g. lot-by-lot testing where no historical information is available). The differentiation could be made with regard to number of samples (e.g. n=1 for the known history scenario and n=5 for the unknown historical scenario)

We recommend retaining the information that is currently square bracketed

FOOTNOTE a,

CANADA

The information on sampling, dilution and plating should be deleted from the text under section 4.1 (Footnote a, information in [ ]). The description provided is insufficient to replicate the method, if that is the purpose of the text. It would be more useful to include the performance characteristics of the method.

UNITED STATES OF AMERICA

The sentences in square brackets need to be reexamined. In particular, the instructions to divide a 1.0 ml portion onto three plates needs to be replaced with a specific volume per plate. Otherwise there is the potential for increased analytical error which could call into question any decisions based on subsequent enumeration of the colonies observed. It may be better to simply delete the material in the square brackets.

EUROCOMMERCE

Based on the use of the ISO 11290-2 method (enumeration). Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated. A total of 20 colonies is equivalent to 100 cfu/g. [This needs some explanation]. If one of the five 25g samples has a total of 20 or more colonies of Lm, the food lot fails

FOOTNOTE b,

MALAYSIA

Malaysia proposes to retain the text in the square brackets and to provide an explanation for the letters used in the sampling plan.

UNITED STATES OF AMERICA

Table 1, footnote b,.the square brackets should be removed after the footnote has been modified to read: "…any of the five samples exceeding 100 CFU/g *L. monocytogenes*."

4.2 Microbiological criteria for RTE foods in which growth of *L. monocytogenes* can occur

FIRST PARAGRAPH

UNITED STATES OF AMERICA

1st sentence, for consistency the sentence should be modified to read: "…in which the growth of *L. monocytogenes* can occur under reasonably foreseeable conditions of distribution, storage and use…"

3rd sentence, the specified sampling points are only true for the first criterion in Table 2. It is not true for the second criterion which is only applicable at point of consumption (see more detailed discussion in our comments on Table 2).

3rd sentence, delete the phrase "…over the product's entire shelf-life"

4th sentence, this sentence should be modified to read: "… produced under GHP or GHP + HACCP with …"

IDF

In the 4th sentence, it is stated that the *"criterion is based on the product being produced under GHP and/or HACCP with appropriate evaluation of the production environment and process control and validation that the product meets the requirements of a food in which growth of* L. monocytogenes *will not occur"*.

We suggest that this notion be moved to another section (e.g. scope), as the current location may be seen as being in contradiction to the first paragraph in section 3 (introductory text), where it is stated that the MC apply only, when no other more effective tools are available. (Normally, an effective HACCP/GHP system is considered as such more effective tools).

Table 2: Microbiological criteria for RTE foods in which growth of *L. monocytogenes* can occur

Microorganism	**n**	**c**	**m**	**M**	**Class Plan**
Listeria monocytogenes	5	0	<0.04 cfu/g [a]	NA	2 [b]
[*Listeria monocytogenes* [c]	5	0	100 cfu/g [d]	NA	2 [e]]

PHILIIPPINES

We support **a level (m) of <100 cfu/g** *Listeria monocytogenes* in Ready-To-Eat Foods because according to JEMRA the risk to public health from the consumption of ready-to-eat foods at above level is low. (Risk Assessment of *Listeria monocytogenes* in ready-to-eat foods, Technical report. Series 5 2004).

UNITED STATES OF AMERICA

Table 2. The bracketed material in Table 2 and accompanying footnotes c, d, and e should be deleted. The United States cannot support the second microbiological criterion in Table 2 and recommends its deletion. Our concern about this criterion is two-fold: 1) the proposed criterion does not fulfill the Codex requirements for a microbiological criterion as specified in "Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21 – 1997) and 2) the proposed criterion does not adequately take into account consumer behavior in establishing the criterion.

- The guidelines for establishing a microbiological criterion clearly indicate that the requirements include the need to articulate both the microbiological limit and the specific point in the food chain where that limit is applicable and establish the practicality of testing the product at that point. The proposed criterion fulfills neither of these considerations. Sampling at the point of consumption (where the criterion actually applies) is not practical and, therefore, sampling would instead likely occur at the point of import, point of manufacture, or point of sale. Accordingly, the criterion (or criteria) should state the specific microbiological limit that must be achieved at the specific sampling point. Since *L. monocytogenes* will grow in these products, each sampling point will require that a separate microbiological limit be established, each of which will need to be substantially more stringent than the specified 100 CFU/g at point of consumption. Before considering this criterion any further, the United States would need to see the specific values that would be used to make a decision at each of the potential sampling points and the model upon which this is based. Furthermore, since the growth characteristics of *L. monocytogenes* differ substantially among foods, the United States assumes that those values would have to be based on consideration of individual foods and not on a general RTE foods basis.

- This criterion does not adequately consider the diversity in consumer behavior, the methodological error associated with the analytical protocols, or the error (uncertainty) in the model upon which the criterion is presumably based. For example, in section 3.2 the current document attempted to take into account such error in establishing the criteria for foods in which *L. monocytogenes* will not grow by considering the potential increases in *L. monocytogenes* levels at 1.3 times the proposed shelf-life at a minimally marginal abuse temperature. Consideration of likely consumer behavior is a well-established concept in Codex Alimentarius. Considering that the proposed criterion for foods in which *L. monocytogenes* can grow applies to food in which the pathogen has attained exponential growth, even a small error in the model or consumer storage conditions could be the difference between 100 CFU/g and 1,000,000 CFU/g.

IDF

- We recommend removing the square brackets around the second MC (m=100 cfu/g), provided that note "c" is retained, however with an appropriate reference to the validation guidelines currently being developed by CCFH.

- The first MC (m=<0.04 cfu/g) should be regarded as a default approach, which in some cases will be more restrictive than needed (e.g. any sporadic insignificant contamination may be detected)

- The MC, in particular the first MC (m=<0.04 cfu/g), should differentiate between situations where it supplements GHP/HACCP/validation and where it is applied on its own (e.g. lot-by-lot testing where no historical information is available). The differentiation could be made with regard to number of samples (e.g. n=1 for the known history scenario and n=5 for the unknown historical scenario)

FOOTNOTE C

CANADA

Considering the potential for lack of understanding and abuse by consumers and retailers of the information on the package indicating the shelf-life, it may not be practical to have a maximum level linked to a shelf-life. Therefore, we would support deleting the criteria in [ ] and footnote c.

EUROCOMMERCE

last sentence, we are concerned about the lack of definition of "reliably demonstrated"] m becomes <0.04/g [it is not clear how ports will know what the manufacturer has taken into account in setting shelf life in relation to lm growth potential.

FOOTNOTE D

CANADA

The information on sampling, dilution and plating should be deleted from the text under section 4.2 (Footnote d, 2nd, 3rd, and 4th sentence). The description provided is insufficient to replicate the method, if that is the purpose of the text. It would be more useful to include the performance characteristics of the method.

FOOTNOTE C, D, AND E

MALAYSIA

Malaysia proposes to retain the text in the square brackets and to provide an explanation for the letters used in the sampling plan.

IDF

We suggest retaining the information that is currently square bracketed in notes "d" and "e"

4.3 The actions to be taken when a criterion is not met

UNITED STATES OF AMERICA

The purpose of this section is to identify to the competent authority the need to establish the actions that should be taken when a criterion is not met. However, as written, it is not clear who should take these actions; the bullets are a mixture of actions to be taken by a manufacturer and by a competent authority. We suggest the bullets be written as follows:

- The manufacturer should not release the food into commerce.

- Food that has been released into commerce should be recalled or withdrawn by the manufacturer.
- The manufacturer should destroy, rework or divert the food.
- The competent authority should reevaluate the manufacturer's Good Hygienic Practices and HACCP plans, environmental and process control systems, or other related control measures.
- The competent authority should take other appropriate regulatory actions.

BULLETT 3

MALAYSIA

Malaysia is of the view that the terms "divert" is vague and should be clarified.

BULLETT 4

ISLAMIC REPUBLIC OF IRAN

Add *GLP* to the Bullet 4 sentence, so as to read as follows: Re-evaluate the manufacturer's Good Hygienic Practices, *Good Laboratory Practices (GLP)*, HACCP plans…….

Rationale: The reason for this addition is that a count may be erroneous *due to unsound/inappropriate laboratory practices.*

IDF

Most of the actions listed are typically taken by the food business and not by the competent authority. The role of the competent authority is (or should be) to make sure that the food business in question acts appropriately.

In order to convey this message, we recommend replacing the current text with the following (additional text underlined, removed text ~~stricken out~~):

> *"When the results of testing against the above criteria are unsatisfactory, competent authorities should inform the food business responsible for the food in question and make sure that the food business establishes appropriate ~~the~~ actions to identify and control affected lots, to detect the cause of deviation and to restore control of* Listeria monocytogenes ~~*that should be taken when the results of testing against the above criteria are unsatisfactory*~~*. Examples of such actions include:*
>
> - *Control of affected lots (corrections):*
> - *Prevent release of the food*
> - *Withdraw or recall the food*
> - *Destroy, rework or divert the food*
> - *Detection of the cause of deviation and taking actions that regain control (corrective measures:)*
> - *Review monitoring and verification results*
> - *Increase monitoring and/or verification activities*
> - *Re-evaluate the ~~manufacturer's~~ Good Hygienic Practices, HACCP plans, environmental and process control systems, or other related control measures in place*
> - *Other appropriate actions*

In case of continued deviation, additional regulatory actions may be taken by the competent authority."

[4.4 Other microbiological metrics that may be used by competent authorities

CANADA

We are of the view that this section should be deleted in its entirety. The main document, *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Foods (CAC/GL 61-2007)* provides adequate guidance on environmental monitoring.

UNITED STATES OF AMERICA

The United States strongly supports the removal of the square brackets from these sections(Sections 4.4, 4.4.1, and 4.4.2) . Considering that the purpose of Annex II is to provide useful guidance to governments regarding microbiological criteria, the inclusion of alternative microbiological testing approaches that are used by competent authorities is an important addition to this document. The importance of the material is emphasized by the fact that such tools are recommended for industry in Annex I and that the definition of an MC requires specification of actions to be taken if a lot fails the criteria. Competent authorities need to have the same tools if they are going to effectively verify the *L. monocytogenes* control programs established by industry. In addition, these sections are fitting in that the microbiological criteria in this Annex are referenced in Section V "Control of Operation" of the main document. The United States believes these sections strike the right balance between identifying the key factors to be considered without specifying the microbiological criteria that would be more appropriately done by individual governments.

UNITED STATES OF AMERICA

In the first paragraph of 4.4, in the third sentence, the term "particularly indispensable" should be changed to "effective tools," so the sentence reads "Two types of testing programs, as described below, are effective tools to ensure food safety…"

IDF

The use of the term "metrics" in this context is confusing, in particular in light of the same term being used for FSOs, POs, PC, etc. Since the text only refers to microbiological criteria, we suggest using that term.

The CCFH should consider whether this information is more appropriately integrated into Annex I to the "Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods"

If retained in Annex II, we think it is important to introduce this section with a statement that environmental monitoring and process control is most effective, if it is planned and implemented by the individual food business (ownership). Only, where this is considered necessary, competent authorities should conduct (i.e. take over) such activities.

4.4.1 Environmental Monitoring

PARAGRAPH 2

UNITED STATES OF AMERICA

1st sentence, the sentence should be modified to read:

> "…there should be a clear distinction between sampling of food contact surfaces and non-food contact surfaces, so the relative risk of product becoming contaminated is adequately considered."

3rd sentence, the sentence should be modified to read:

"… or sampling performed by the business operator that is required by a competent authority as part of a regulatory GHP verification program."

PARAGRAPH 5

ISLAMIC REPUBLIC OF IRAN

First sentence, when speaking about the design of the environmental *verification program…* give reference to the Verification Document

UNITED STATES OF AMERICA

1st sentence, the sentence should be modified to read:

"…sections 4.1 and 4.2, when environmental testing is conducted or required by the competent authority, the competent authority should …"

4.4.2 Process Control

EUROCOMMERCE

Second paragraph, second and third sentences, The decision criterion in this instance would be the frequency of contamination that would be indicative of a decrease in the expected level of control but still sufficient not to consider the product/process as out of control. In this instance the primary action to be taken would be to investigate the food safety control system to determine the cause of the deviation and take corrective action. Successful implementation of this approach would be sufficient knowledge on the part of the competent authority of the industry's current capability to control Lm in the RTE food under consideration. Such information can be initially generated by targeted baseline studies and ultimately by data generated as a result of implementation of the process control criteria." [We are concerned about the practicability of this approach].