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**
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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 at Step 3

Prepared by the Working Group led by Germany with the assistance of Canada, Denmark, Finland, France, Italy, Japan, New Zealand, Norway, Thailand, The United Kingdom, The United States of America and representatives from the EC, CIAA, IACFO, ICMSF, IDF and WHO

Governments and interested international organizations are invited to submit comments on the attached two Annexes at Step 3 (see Appendix) which were prepared to cover the proposed draft criteria for *Listeria mocytogenes* in ready-to-eat foods and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission, Seventeenth Edition*) to: Mr S. Amjad Ali, Staff Officer, Food Safety and Inspection Service, U.S. Department of Agriculture, Room 4861, 1400 Independence Avenue, SW, Washington, D.C. 20250, USA, FAX +1-202-720-3157, or email syed.ali@fsis.usda.gov with a copy to: Secretary, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy, by email codex@fao.org or fax: +39-06-5705-4593 **by 15 November 2008.**

ANNEX II: MICROBIOLOGICAL CRITERIA FOR *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS AND 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[1]

BACKGROUND to Annexes II and III

The scope of this background information is to inform interested parties on the subject of *Listeria monocytogenes* in ready-to-eat (RTE) foods, e.g. on risk assessments that have been performed for this pathogen-food commodity combination and on published approaches for categorization of RTE foods with regard to their associated listeriosis risk. Moreover, the information is intended to inform

[1] Prepared to address the proposed draft criteria for *Listeria mocytogenes* in ready-to-eat foods.

the CCFH about the progress made in the working group. The background information will not be included in the official document.

During the 38th Session from 4 - 9 December 2006 in Houston/USA the Codex Committee on Food Hygiene took the following decisions on the "Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods" and on Annex II (paragraphs 144 and 145 of ALINORM 07/30/13):

- to forward the Draft Guidelines, including Annex I, to the 30th session of the Codex Alimentarius Commission for final adoption at Step 8 (CAC/GL 61-2007),

- to establish a physical working group with the terms of reference "development of microbiological criteria on *Listeria monocytogenes* in ready-to-eat foods" as the Annex II of the 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), and

    - that this work on microbiological criteria would be completed over two sessions of the Committee (by 2008) for adoption by the CAC in 2009.

The 39th session from 30 October - 4 November 2007 in New Delhi, India agreed to confirm the original mandate given by the 38th Session of the Committee and to return Annex II to Step 2 for further elaboration. The Committee noted the need to provide a more robust scientific basis for the proposed *L. monocytogenes* criteria and that the document should be applicable for food intended for both domestic and international trade. The Committee agreed to establish a physical working group open to all interested parties and led by Germany working in English language only, in Bonn (Bad Godesberg) Germany from 27 – 29 May 2008. The Committee requested the working group to start working electronically and to consider all written comments submitted to the current session, and to prepare a revised version of the document to be circulated at Step 3 well in advance of the next session of the Committee. (ALINORM 08/31/13, para 85-97)

The following main points to be considered by the working group for revision were:

- to resolve issues on which the working group did not reach agreement (in square brackets) with respect to the additional guidance provided by the Committee on the approach taken, including the proposed categorization of RTE foods and the numerous comments received,

- to further work on the criterion or criteria for RTE foods in which growth of *L. monocytogenes* can occur;

- to refine the definitions for the three RTE food categories,

- to clarify the point of application of the criteria in the food chain,

- to clarify the scope of the document to whom this annex is addressed,

- more emphasis should be given on information on the impact of *L. monocytogenes* on public health.

- to address the view of some delegations that the mandate should be expanded to include elaboration of other appropriate risk management metrics.

The microbiological criteria presented in Annex II are intended to be used within the context of the main document and are specifically linked to section *5.2.3 Microbiological and other specifications* of the *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). A new Annex III is created that expands previous portions from earlier drafts of Annex II to provide further recommendations to competent authorities for the use of microbiological testing for *Listeria monocytogenes*.

Annex II references and takes into account the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21 – 1997) and uses definitions, e.g. for microbiological criterion, as included in these principles. The provisions of this Annex should be

used in conjunction with Annex II of the *Principles and Guidelines for the Conduct of Microbiological Risk Management*.(CAC/GL 63-2007).

Generally, as mentioned in the introduction of the main document, risk assessments were consulted for the development of the microbiological criteria recommended in this draft Annex II. As has been pointed out in the introduction of these guidelines, the large number of ready-to-eat foods in which *L. monocytogenes* is at least occasionally isolated has made it difficult to effectively focus food control programs on those specific foods that contribute the greatest risk to foodborne listeriosis. As a means of addressing this and a number of related questions, several formal quantitative risk assessments have been undertaken to address issues related to the relative risks among different ready-to-eat foods and the factors that contribute to those risks.

Available risk assessments currently include:

- a comparative retail-to-table risk assessment of 23 categories of ready-to-eat foods conducted by the U.S. Food and Drug Administration and the U.S. Food Safety and Inspection Service (FDA/FSIS, 2003)

- a comparative risk assessment of four ready-to-eat foods conducted by FAO/WHO JEMRA at the request of the Codex Committee on Food Hygiene

- a plant-to-table risk assessment conducted by the U.S. Food Safety and Inspection Service to evaluate the effectiveness of *Listeria monocytogenes* control measures (product formulation, post-packaging lethality interventions, and testing and sanitization of food contact surfaces) alone and in combination (FSIS, 2003)

Each of these assessments articulates concepts that countries can use to identify and categorize those ready-to-eat products that represent a significant risk of food borne listeriosis. Five key factors were identified as contributing strongly to the risk of listeriosis associated with ready-to-eat foods:

- Amount and frequency of consumption of a food,
- Frequency and extent of contamination of a food with *L. monocytogenes*
- Ability of the food to support the growth of *L. monocytogenes*
- Temperature of refrigerated/chilled food storage
- Duration of refrigerated/chilled storage

The FAO/WHO JEMRA risk assessment concluded that the vast majority of cases of listeriosis are associated with the consumption of foods that do not meet current standards for *L. monocytogenes* in foods, whether the standard is absence in 25 g or 100 cfu/g. One of the key findings of the risk assessment is that the greatest benefit to public health would be to effect a significant reduction in the number of servings contaminated with high numbers of *L. monocytogenes*. Another key finding of the JEMRA risk assessment is the indication that control measures that reduce the frequencies of

contamination will have a proportional reduction in the rates of illness, provided the proportions of high contaminations are reduced similarly. The results of the JEMRA risk assessment clearly show that prevention and control of listeriosis cases is the result of a combination of preventive and control measures. Application of microbiological criteria at a given point of the production chain is only one of the measures to be applied.

The following general findings of the above mentioned risk assessments have been considered by the working group throughout the development of microbiological criteria for *L. monocytogenes* in RTE foods as presented in draft Annex II:

- Nearly all cases of listeriosis result from the consumption of high numbers of the pathogen

- The analyses conducted within risk assessments clearly indicate that the greatest risk associated with ready-to-eat products is the small portion of the products with high contamination levels of *L. monocytogenes*

- Most risk assessments agree that RTE foods in which growth of *L. monocytogenes* will occur should be a major target of risk management efforts

- Key component of a successful risk management program is assurance that the control measures (e.g., preventing contamination and growth of the pathogen) can be achieved consistently.

However, *L. monocytogenes* growth on foods is not the only determinant of risk of listeriosis. Additional factors that affect the risk associated with any food, regardless of whether it does or does not support *L. monocytogenes* growth, include: frequency of contamination; level of contamination; frequency of consumption; and susceptibility of consuming population.

The following were taken into consideration:

- 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. However, there is uncertainty associated with epidemiological data regarding the infective dose of *L. monocytogenes* in consumed RTE foods

- Some countries have concluded, while others have not, 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.

- Countries expressed the need for internationally applicable microbiological criteria for *L. monocytogenes* in RTE foods supplementing other preventive control measures as laid down in the main document.

- These microbiological criteria should depend on the listeriosis risk of an RTE food and reflect its capability to support or not support the pathogen's growth.

- RTE foods in which growth of *L. monocytogenes* will not occur should be considered as potential sources of cross-contamination to RTE foods in which growth of *L. monocytogenes* will occur

With regard to the definition of groups of RTE foods, the working group decided to use the terms "RTE foods in which growth of *L. monocytogenes* will not occur" and "RTE foods in which growth of *L. monocytogenes* can occur". These definitions differ from the definition in the main guideline

document. However, from a practical side, the working group saw a better applicability of these terms than for using the term “foods that support / do not support growth”.

During the meeting the working group decided to focus on the application/elaboration of microbiological criteria in international trade, although their application can be at national level as well. The reason for this decision was that the microbiological criteria could be linked to verification, therefore they could be used before exporting, e.g., as an end product control measure.

Annex II provides useful guidance to governments regarding microbiological criteria. In addition to recommended criteria for the end product control approach in Annex II, Annex III gives recommendations to the competent authorities for verification of the control of operation, by environmental testing or process control. Whereas Annex I provides recommendations to industry on environmental monitoring programs in processing areas, Annex III gives recommendations for competent authorities to effectively verify the *L. monocytogenes* control programs established by industry and – according to the definition of an MC – to develop the specific actions to be taken if a lot fails the criteria. 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 sections of Annex III strike the right balance between identifying the key factors to be considered without specifying the microbiological criteria that would be more appropriately developed by individual governments.

APPENDIX

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

(ANNEX II OF THE GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS (CAC-CL 61/2007))

1. INTRODUCTION

The microbiological criteria presented in this Annex are intended as advice to governments within a framework for control of *L. monocytogenes* in ready-to-eat foods with a view towards protecting the health of consumers and ensuring fair practices in food trade. They also provide information that may be of interest to industry.

This Annex references and takes into account the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21 – 1997) and uses definitions, e.g. for microbiological criterion, as included in these principles. The provisions of this Annex should be used in conjunction with *ANNEX II: Guidance on Microbiological Risk Management Metrics of the Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007).

The risk assessments referenced in the introduction to the *Guidelines on the Application of General Principles of Food Hygiene to the Control of L. monocytogenes in Ready-to-Eat Food* [2] have indicated that food can be categorized according to the likelihood of *L. monocytogenes* being present and its ability to grow in the food. Available risk assessments have been taken into account in the development of the microbiological criteria in this Annex. In addition, factors that might impact upon the ability of governments to implement these microbiological criteria such as methodological limitations, costs associated with different types of quantitative testing, and statistics-based sampling needs were taken into account.

2. SCOPE

These microbiological criteria apply to specific categories of ready-to-eat foods, as described herein. The competent authority should consider the intended use and how specific ready-to-eat foods are likely to be handled during marketing, catering, or by consumers to determine the appropriateness of applying the microbiological criteria. Governments may apply these criteria, where appropriate, to assess the acceptability of ready-to-eat foods in international trade for imported products, at end of manufacture (finished product) for domestic products, and at point of sale for at least the expected shelf life[3] under reasonably foreseeable conditions of distribution, storage and use.

The microbiological criteria may be used as the basis for the development of additional criteria (e.g., process criteria, product criteria, performance objectives) within a food safety control system[4] to ensure compliance with these guidelines.

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[2] See: 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

[3] See: Code of Hygienic Practice For Milk and Milk Products, CAC/RCP 57–2004

[4] See: Proposed Draft Guidelines for the Validation of Food Safety Control Measures. (ALINORM 08/31/13, Appendix III)

Alternative criteria or other limits may be applied when the competent authority determines that the use of such an approach provides an equivalent level of public health or when the competent authority determines a more stringent criterion is necessary to protect public health.

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

There are various applications for microbiological criteria. As described, microbiological testing by lot can be used as a direct control measure, i.e., sorting of acceptable and unacceptable lots[5]. 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, the application of the Hazard Analysis and Critical Control Point (HACCP) System describes how microbiological testing against a criterion can be used as a means of verifying the continuing effectiveness of a food safety control system[6]. 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 (see Annex III).

A microbiological criterion defines the acceptability of a product or food lot based on the absence or presence or number of microorganisms in the product. Testing for compliance with a microbiological criterion may be conducted on a lot by lot basis when there is little information about the conditions under which the product has been produced. Where there is information about the conditions of production, testing of lots for verification purposes may be conducted less frequently.

The competent authority should use a risk-based approach to sampling. It may consider modifying the frequency of testing for process control verification based on additional consideration of the likelihood of contamination, characteristics of the food, product history, conditions of production and other relevant information. For example, testing against microbiological criteria may have limited utility immediately following certain processing steps or if the level of *L. monocytogenes* in a ready-to-eat food is consistently well below the limit of detection taking into account practical limits for sample sizes.

In particular, testing against microbiological criteria for *L. monocytogenes* may not be useful for:

(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[7] , and

(c) products that contain a listericidal component that ensures rapid inactivation of the pathogen if recontaminated (e.g., products that contain > 5 % ethanol)

Competent authorities may define other categories of products for which testing against microbiological criteria are not useful.

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[5] See: Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997)
[6] See: Recommended International Code of Practice: General Principles of Food Hygiene (CAC/RCP 1-1969, Rev.4 (2003))
[7] See: Code of Hygienic Practice For Aseptically Processed And Packaged Low-Acid Foods (CAC/RCP 40-1993)

Different types of food present different risks from *L. monocytogenes*, hence different microbiological criteria could apply for the following categories of foods:

(a) ready-to-eat foods in which growth of *L. monocytogenes* will not occur, and

(b) ready-to-eat foods in which growth of *L. monocytogenes* can occur.

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

Ready-to-eat foods in which growth of *L. monocytogenes* will not occur would be determined based on scientific justification[8], including the inherent variability of factors controlling *L. monocytogenes* in the product. Factors such as pH, aw, are useful in preventing growth. For example, *L. monocytogenes* growth can be controlled in foods that have

- a pH below 4.4,
- an aw < 0.92,
- a combination of factors (pH, aw,), e.g. the combination of pH < 5.0 with aw < 0.94,

and by freezing (during that period when the product remains frozen).

In addition, inhibitors can control the growth of *L. monocytogenes* and synergy may be obtained with other extrinsic and intrinsic factors that would result in no growth.

Demonstration that *L. monocytogenes* will not grow in a ready-to-eat food can be based upon, for example, food characteristics, 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 (or by the appropriate product board, sector organizations or contract laboratories) and must be appropriately designed to validate that *L. monocytogenes* will not grow in a food [9].

The demonstration that *L. monocytogenes* will not grow in a ready-to-eat food should take into account the measurement error of the quantification method. Therefore, for example, for practical purposes, a food in which growth of *L. monocytogenes* will not occur will not have an observable increase in *L. monocytogenes* levels greater than (on average) 0.5 log CFU/g[10] for at least the expected shelf life as labelled by the manufacturer under reasonably foreseeable conditions of distribution, storage and use (including a safety margin, e.g., 1.3 times the period specified).

For refrigerated foods, where manufacturers cannot assure a storage and distribution chain at lower temperatures, studies conducted at 8°C would be appropriate to address temperatures frequently seen in distribution, sale and consumer refrigerators, or studies could otherwise reflect actual conditions and practices where they are known.

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[8] References that have been addressed for identifying properties of ready-to-eat foods which will categorize them as foods in which growth of *L. monocytogenes* will not occur, or as foods in which growth of the pathogen can occur, include *Microorganisms in Foods 5 – Characteristics of Microbial Pathogens* (ICMSF, 1996) and *Microbiological Risk Assessment Series 4 and 5: Risk assessment of Listeria monocytogenes in ready to eat foods: Interpretative Summary and Technical Report* (FAO/WHO, 2004).

[9] See "Guidelines for the Validation of Food Safety Control Measures." , CAC/GL 69-2008

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

National governments should provide guidance on the specific protocols that should be employed to validate the studies demonstrating that growth of *L. monocytogenes* will not occur in a food during the expected shelf life.

If information is lacking to demonstrate that *L. monocytogenes* will not grow in a ready-to-eat food during its expected shelf life, the food should be treated as a ready-to-eat food in which growth of *L. monocytogenes* can occur.

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

A ready-to-eat food in which there is greater than an average of 0.5 log CFU/g[11] increase in *L. monocytogenes* levels for at least the expected shelf life under reasonably foreseeable conditions of distribution, storage and use is considered a food in which growth of *L. monocytogenes* can occur.

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

Microbiological criteria for *L. monocytogenes* in ready-to-eat foods are described .

Another procedure for establishing microbiological criteria for *L. monocytogenes* other than the criteria at specified points in the food chain that are described below, would be through the application of risk-based metrics (e.g., Food Safety Objective (FSO), Performance Objective (PO)) according to the general principles established in the *Proposed Draft Annex II: Guidance on Microbiological Risk Management Metrics of the Principles and Guidelines for the Conduct of Microbiological Risk Management* (CAC/GL 63-2007).

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

The criterion in Table 1 is intended for foods in which *L. monocytogenes* growth will not occur under the conditions of storage and use that have been established for the product (see section 3.1).

This criterion is based on the product being produced under application of the provisions of the general principles of food hygiene to the control of *L. monocytogenes* in ready-to-eat foods [12] 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 (see section 3.1).

If the factors that prevent growth cannot be demonstrated, the product should be evaluated based on criteria for ready-to-eat foods in which growth of *L. monocytogenes* can occur (see section 4.2).

Another approach can also be used (see 4.3).

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

[12] See "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

Table 1:

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

Point of application	Microorganism	n	c	m	M	Class Plan
Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale	*Listeria monocytogenes*	5 [a]	0	100 cfu/g [b]	NA	2 [c]

[a] National governments should provide guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.

[b] This criterion is based on the use of the ISO 11290-2 method.

Other methods that provide or support the provision of equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g., based on ISO 16140).

[c] This sampling plan would provide 95% confidence that a lot of food containing an average (geometric) concentration of 93.3 cfu/g and an analytical standard deviation of 0.25 log cfu/g would be detected and rejected based on any of the five samples *exceeding 100 CFU/g L. monocytogenes.*

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

The criterion in Table 2 is intended for foods in which *L. monocytogenes* growth can occur under the conditions of storage and use that have been established for the product (see section 3.2).

This criterion is based on the product being produced under application of general principles of food hygiene to the control of *L. monocytogenes* in ready-to-eat foods [13] with appropriate evaluation of the production environment and process control (see Annex III).

The purpose of this criterion is to provide a high degree of confidence that *L. monocytogenes* will not be present in foods at unacceptable levels that represent a risk to consumers.

Another approach can also be used (see section 4.3).

[13] See "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

Table 2:

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

Point of application	Microorganism	n	c	m	M	Class Plan
Ready-to-eat foods from the end of manufacture or port of entry (for imported products), to the point of sale	*Listeria monocytogenes*	5 [a]	0	Absence in 25 g (< 0.04 cfu/g) [b]	NA	2 [c]

[a] National governments should provide guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.

[b] Absence in a 25-g analytical unit. This criterion is based on the use of ISO 11290-1 method. Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (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.

[c] This sampling plan would provide 95% confidence that a lot of food containing an average (geometric) concentration of 0.023 cfu/g and an analytical standard deviation of 0.25 cfu/g would be detected and rejected if any of the five samples are positive for *L. monocytogenes.*

4.3 Alternative approach

As an alternative approach to microbiological criteria described in sections 4.1. and 4.2 competent authorities may choose to establish and implement other validated limits for the *L. monocytogenes* concentration at the point of consumption that provide the equivalent level of consumer protection for foods in which *L. monocytogenes* will not grow as well as foods in which *L. monocytogenes* growth can occur.

Due to the large diversity among ready-to-eat food products in which growth of *L. monocytogenes* can occur, this approach would primarily be applied for specific categories or subcategories of ready-to-eat foods being produced under application of the provisions of the general principles of food hygiene to the control of *L. monocytogenes* in ready-to-eat foods [14] and that have a limited potential of growth over a specified shelf life.

In establishing such limits for *L. monocytogenes*, the competent authority needs to clearly articulate the types of information required of business operators to verify that these limits are achieved in practice. Information needed by competent authorities should be obtained through validation studies or other sources, and may include

- specification for physicochemical characteristics of the products, such as pH, a_w, salt content, concentration of preservatives and the type of packaging system, taking into

[14] See "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

account the storage and processing conditions, the possibilities for contamination and the foreseen shelf life[15], and

- consultations of available scientific literature and research data regarding the growth and survival characteristics of the microorganisms of concern.

When appropriate on the basis of the above mentioned studies, additional studies should be conducted, which may include:

- predictive mathematical modelling established for the food in question, using critical growth or survival factors for the microorganisms of concern in the product,

- challenge tests and durability studies to evaluate the growth or survival of the microorganisms of concern that may be present in the product during the shelf life under reasonably foreseeable conditions of distribution, storage and use including seasonal and regional variations.

[15] e.g. 1.3 times the period specified

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.

(Annex III of the Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-To-Eat Foods (CAC-CL 61/2007))

Introduction

These recommendations are for use by competent authorities if they intend to include environmental monitoring and/or process control testing as part of their regulatory activities. It is also anticipated that the annex will provide guidance that the competent authority can provide to industry. The recommendations provide an elaboration of the concepts in Sections 5 and 6 of the main text of this Code.

Guidance within Codex regarding microbiological testing is often restricted to the testing of end products using traditional lot-by-lot testing. However, the guidance provided in the main text of this Code emphasizes the criticality of enhanced control of sanitation, including the appropriate use of environmental monitoring. This is further elaborated in *Annex I: Recommendations for an Environmental Monitoring Program for* Listeria monocytogenes *in Processing Areas,* which provides recommendations to industry on implementation of environmental monitoring programs. The *Recommended International Code of Practice General Principles of Food Hygiene (CAC/RCP 1-1969)* emphasizes the need to apply control measures in a systematic manner using HACCP or other food safety control systems, including the testing of in-line or finished product samples for process control verification. This annex provides general recommendations on how competent authorities can use microbiological testing to verify the effectiveness of (a) general hygiene programs in the food operation environment and (b) control measures in facilities employing HACCP or other food safety control systems.

The two types of microbiological testing programs described below can be an important part of the ability of competent authorities to verify the effectiveness of *L. monocytogenes* control programs over time (see Section 5.9). In developing these recommendations, no attempt is made to establish specific decision criteria for the two types of microbiological testing or the specific actions that should be taken to re-establish control. Establishment of such specific criteria and actions is more appropriately the responsibility of competent authorities due to the diversity in products and manufacturing technologies.

a) Environmental Monitoring

In certain instances, competent authorities may incorporate the testing of the environment (food contact and/or non-food contact surfaces) for *L. monocytogenes* (or an appropriate surrogate microorganism (e.g., *Listeria* spp.)), as part of their regulatory requirements or activities. This can include sampling by a competent authority as part of its inspection activities or sampling performed by the individual food business operator that the competent authority can review as part of its verification of the business operator's controls (see Section 5.9). The aim of conducting and/or reviewing environmental testing programs by a competent authority is to verify, for example, that a manufacturer has successfully identified and controlled niches and harbourage sites for *L. monocytogenes* in the food plant and to verify that sanitation programs have been appropriately designed and implemented to control contamination by *L. monocytogenes*.

In developing environmental testing programs and the decision criteria for actions to be taken based on the results obtained, competent authorities should clearly distinguish between sampling of food contact surfaces and non-food contact surfaces. For example, sampling locations for competent authorities would be similar to those used by food business operators (See Annex I). In evaluating facilities that produce multiple products where at least one can support growth of *L. monocytogenes*, competent authorities should consider the importance of environmental sampling as a means of verifying that there is no cross contamination between the products (see section 5.2.4). In the design of an environmental verification program, the competent authority should articulate the testing and sampling techniques that would be employed, including size, method and frequency of sampling, analytical method to be employed, locations where samples should be taken, decision criteria, and actions to be taken if a decision criterion is exceeded (similar to recommendations in Annex I).

The competent authority should establish decision criteria that include specific conditions (e.g., specific number of positive samples) that will initiate follow-up actions (including additional testing) when an environmental sample is positive for *L. monocytogenes* or *Listeria* spp. The competent authority should also establish actions that the business operator should anticipate if the criteria are exceeded. Detection of positive environmental samples by the competent authority exceeding the decision criteria should lead to an investigation by the business operator and/or the competent authority to identify the source of contamination and action that should be taken by the business operator to correct the problem. In reporting results of their analyses to business operators, competent authorities should provide advice on the possible inferences the data provide in order to assist the business operator in finding and correcting the source of contamination. For example, the competent authority could point out that the repetitive isolation of a specific subtype of *L. monocytogenes* is indicative of a harbourage site that current sanitation activities are insufficient to control.

Overall, sampling techniques and testing methods should be sufficiently sensitive for the decision criteria established and appropriate for the surface or equipment being evaluated. Methods used should be appropriately validated for the recovery of L. monocytogenes from environmental samples.

b) Process Control

Business operators ensure the effectiveness of HACCP and other programs for the control of *L. monocytogenes* in their operating facilities. Further, business operators validate the food safety control systems they have in place. Competent authorities verify that the controls are validated and being implemented as designed, through activities such as monitoring of records and actions of production personnel.

For a well-designed food safety control system, a competent authority may consider establishing process control criteria that identify trends that can be corrected before decision criteria are exceeded. When decision criteria are exceeded, the business operator will investigate the food safety control system to determine the cause and take corrective action(s). The competent authority verifies that appropriate actions are taken when criteria are exceeded.

In addition to verifying that the process controls within the food safety control system are validated and operating as designed, process control testing of finished product (sometimes referred to as cross-lot or between-lot testing) has been used by business operators and/or competent authorities to detect changing patterns of contamination, which allows distinction between occasional ‘in control’ positive samples and an emerging loss of control. Process control testing of finished product helps assess the continuing performance of a food safety control system and helps ensure corrective actions are implemented before microbiological criteria are exceeded. The competent authority

verifies that the food safety control system remains 'in control' or ensures actions are taken to prevent loss of control, which could include changes to the food safety control system itself.

In certain instances, competent authorities may find it useful to establish an industry-wide process control-based criterion for *L. monocytogenes* for the purpose of ensuring that specific RTE foods undergo a consistent approach for verification of HACCP or other food safety control systems. This can include sampling by competent authorities as part of their inspection activities or sampling performed by the business operator that the competent authority can review as part of its verification of the business operator's records.

As with other forms of verification via microbiological testing, the use of process control testing involves the establishment of decision criteria, specification of analytical methods, specification of a sampling plan, and actions to be taken in case of a loss of control. The decision criteria for process control testing would be the frequency of contamination that would be indicative of a process no longer in control and likely to produce RTE foods that do not meet the microbiological criteria established in Annex II. Details of process control testing principles and guidelines are beyond the scope of this annex, but are available through standard references.