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

Prepared by the Working Group lead by Germany with the assistance of Australia, Austria, Brazil, Canada, Denmark, EC, Finland, France, Hungary, Italy, Jamaica, The United Kingdom, The United States of America, FAO, CIAA, and IDF

Governments and interested international organizations are invited to submit comments on the attached Microbiological Criteria at Step 3 (see Appendix) 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, Sixteenth Edition)* **to**: Mr 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 Fax: +39-06-5705-4593 or email codex@fao.org by **1 October 2007.**

BACKGROUND

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 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,

- to establish a physical working group (Australia, Austria, Brazil, Canada, China, Denmark, EC, Finland, France, Greece, Hungary, Italy, Jamaica,Japan, Norway, Sweden, Switzerland, the United Kingdom, Uruguay, The United States of America, FAO, WHO, ICMSF, IDF and IFT) to be led by Germany

- with the terms of reference "development of microbiological criteria on *Listeria monocytogenes* in ready-to-eat foods" (Annex II of the Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods), 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 microbiological criteria (and other microbiological metrics) presented in this Annex 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 (*and Annex I: Recommendations for an Environmental Monitoring Program in Processing Areas).

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 *Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* which is under development.

Generally, as mentioned in the introduction of the main document the microbiological criteria recommended in this draft Annex II are based on risk assessment.

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 food borne 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 risk assessment of 23 categories of ready-to-eat foods conducted by the U.S. Food and Drug Administration and the 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, and

- a product/process pathway analysis conducted by the U.S. Food Safety and Inspection Service for processed meats, which examined the risk of product contamination from food contact surfaces.

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

Based on the FAO/WHO JEMRA risk assessment it is 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 zero tolerance (e.g. "negative" in 25g = 0.04 cfu/g) or 100 cfu/g. Raising a zero tolerance standard to a higher value (e.g. changing the standard from 1 cfu/25 g to 100/g) would be expected to result in increased incidence of listeriosis. However, if by relaxing the standard, there was a greater level of compliance with that standard through the improved adoption of control measures that significantly decreased the incidence of RTE food servings that exceed the standard, particularly the number of servings with elevated levels of *L. monocytogenes*, then increasing the standard would actually have a positive impact on public health. 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*

–All risk assessments agree that foods supporting the growth of *L. monocytogenes* to high levels should be the 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

–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

- Countries expressed the need for international 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 a RTE food and reflect its capability to support or not support the pathogens' growth.

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, i.e. at the port of entry, although their application can be broader than international trade. 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. Moreover, the working group agreed to apply "packaging" as the frame for application, either for international purposes or at national level, and the responsibilities for meeting the microbiological criteria.

However, some members of the working group also noted that Annex II, as a document that augments section V.2.3 of the "Recommended International Code of Practice General Principles of Food Hygiene" considers the use of microbiological testing/criteria in the context of the "control of operations," it should include reference to other types of microbiological criteria employed by competent authorities. Accordingly, the use of microbiological criteria based environmental testing and process control testing are introduced but not discussed in detail in terms of specific criteria being recommended.

APPENDIX

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

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 (RTE) 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 of the *Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* which is under development.

The risk assessments referenced in the Introduction to the *"Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-Eat Foods"*, as well as more recent commodity-specific RTE studies[1], 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.

2. SCOPE

These microbiological criteria apply to categories of RTE foods within their intended shelf-life at the points indicated in section 3 and 4. However, testing of some RTE foods against the microbiological criteria may not be useful (see 3.1), and therefore the microbiological criteria do not apply to these foods.

Governments may apply these criteria to assess the acceptability of RTE foods at port of entry, particularly when there is no information available on the microbiological safety of the food (specifically on *L. monocytogenes*). In addition, they may be used to develop, where appropriate, national requirements.

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 (e.g., control of operations and establishment sanitation) to ensure compliance with these guidelines.

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

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 and where they are expected to improve the degree of protection offered to the consumer.

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.

[1] Sanaa, Coroller and Cerf. Risk assessment of listeriosis linked to the consumption of two soft cheeses made from raw milk: Camembert of Normandy and Brie de Meaux. 2004, Risk Analysis, 24:389-399), for smoked salmon and trouts (Lindquist and Wetsöö. Quantitative risk assessment for *Listeria monocytogenes* in smoked or graved salmon/rainbow trout in Sweden. 2000, Int. J. Food Microbiol., 58:181-196), or for Parma ham (Giovannini et al. Risk assessment for listeriosis in consumers of Parma and San Daniele hams. 2007. Food Control, 18:789-799)

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

3.1 Foods for which no criteria are needed

Testing against microbiological criteria is not useful for this group of RTE foods and would not contribute to the protection of public health. The primary foods in this category are RTE foods for which production/processing ensures killing of *L. monocytogenes* and for which recontamination is not possible, and which are processed and handled under Good Hygienic Practice (GHP) systems.

Additionally information like the lack of a history or epidemiological data linking specific RTE foods to cases of listeriosis may be helpful to inform the decision for grouping RTE foods into this category of foods for which no criteria are needed.

icrobiological criteria are not useful when the probability of detecting the organism and the risk to public health are very low. Foods that receive a listericidal treatment under GHP sufficient to ensure that there are no detectable *L. monocytogenes,* by the sampling plans described in this document, throughout the shelf life of the product when the package is unopened would not benefit from the establishment of microbiological criteria. The treatment eliminates *L. monocytogenes* that are present and recontamination after the treatment cannot occur until the package is opened. Therefore *L. monocytogenes* would not be detected through these sampling plans. This group includes products given a listericidal treatment in the package and those that are produced through aseptic processing and packaging. This group includes dehydrated products such as powdered milk, infant formula, follow-on formula and growing up milks where processing eliminates the organism and recontamination and growth of the organism in the product are unlikely to occur. The group also includes dehydrated soup mixes, dehydrated herbs and spices, fresh, uncut and unprocessed vegetables and fruits (excluding sprouted seeds) or soft drinks, beer and spirits.

Foods included in this group may fall into a different group when they are used in a different manner (e.g., cut fruits and vegetables) or in combination with other foods.

In instances where the history, identity, or status of the product or the process by which the product was produced is in question, such foods should be considered as if they were a food for which a criterion is appropriate.

3.2 Foods for which criteria are appropriate

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. Microbiological criteria would be practical and would contribute to protection of public health for

(a) RTE foods in which growth of *L. monocytogenes* will not occur, and

(b) RTE foods in which growth of *L. monocytogenes* can occur.

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

Foods in which growth of *L. monocytogenes* will not occur would be determined based on scientific justification[2]. Factors such as pH, a_w, and inhibitors are useful in preventing growth. *L. monocytogenes* growth can be controlled in foods that have a pH below 4.4, an $a_w < 0.92$, or a combination of factors (pH, a_w, inhibitors), e.g. the combination of pH < 5.0 with $a_w < 0.94$, or by freezing. Products with a shelf life of less than five days can be considered to fall into this category. Demonstration that *L. monocytogenes* will not grow in a RTE food can be determined by, for example, the study of naturally contaminated food, challenge

[2] References that have been addressed for identifying properties of RTE 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).

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 [***include reference for the "Proposed Draft Guidelines for the Validation of Food Safety Control Measures"]***.

The demonstration that *L. monocytogenes* will not grow in a RTE food should take into account the measurement error of the validation method. 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 *L. monocytogenes* will not occur. For refrigerated foods, studies conducted at 8°C would be appropriate to address temperatures frequently seen in distribution, sale and consumer refrigerators. If information is lacking to demonstrate that *L. monocytogenes* will not growth in a RTE food during its shelf life, the food should be treated as an RTE food in which growth of *L. monocytogenes* can occur.

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

A food in which there is ≥ 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 *L. monocytogenes* can occur.

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

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

The criterion in Table1 is intended for foods in which *L. monocytogenes* will not grow under the conditions of storage and use that have been established for the product (see section 3.2.1). The criterion can be applied at "port of entry" for imported products, at end of manufacture (finished product), and point of sale over the product's entire shelf-life. This criterion is based on the product being produced under GHP and/or HACCP ***(ref. to guideline / main document)*** 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 3.2.1). If these factors cannot be confirmed, the product should be evaluated based on criteria for RTE foods in which growth of *L. monocytogenes* can occur (see section 4.2).

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]

[a] This criterion is based on the use of the ISO 11290-2 method. **[**A 25 g sample unit is taken, diluted in 225 ml and homogenized. Duplicate 1 ml portions of this 1:10 dilution of a 25 g sample unit are divided equally onto three standard agar plates (90 mm diameter) or one big agar plate (140 mm diameter) and plated. Thus, two replicate analytical portions containing 0.1 g of food are plated for each original 25-g sample. A total of 20 colonies is equivalent to 100 cfu/g. If one of the five 25g samples has a total of 20 or more colonies of L. monocytogenes, the food lot fails.**]** Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated. 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 sampling plan would provide 95% confidence that a lot of food containing an average 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 being positive for *L. monocytogenes*.**]**

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

The criteria in Table 2 are intended for foods in which *L. monocytogenes* can grow under storage and use conditions that have been established for the product (see section 3.2.2). The purpose of these criteria is to provide a high degree of confidence that *L. monocytogenes* is not present in foods in which it can attain high levels that represent a risk to consumers. The criteria can be applied at "port of entry" for imported products, at end of manufacture (finished product), and point of sale over the product's entire shelf-life. The criteria are based on the products being produced under GHP and/or HACCP with appropriate evaluation of the production environment and process control.

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]]

[a] Absence in a 25-g analytical unit.This criterion is based on the use of ISO 11290-1 which, in turn, is based on the enrichment of a 25 g sample unit and its subsequent detection using a validated detection protocol. The detection of any level of *L. monocytogenes* in the sample unit is considered a positive finding. Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated. 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 sampling plan would provide 95% confidence that a lot of food containing an average concentration of 0.037 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.*

[[c] This microbiological criterion is applicable ***only*** when the manufacturer is able to demonstrate to the satisfaction of the competent authority that the product will not exceed the limit m throughout the shelf-life. Environmental monitoring and process control systems shall be in place. If this is not reliably demonstrated m becomes <0.04/g.

[d] This criterion is based on the use of the ISO 11290-2 method. A 25 g sample unit is taken, diluted in 225 ml and homogenized. Duplicate 1 ml portions of this 1:10 dilution of a 25 g sample unit are divided equally onto three standard agar plates (90 mm diameter) or one big agar plate (140 mm diameter) and plated. Thus, two replicate analytical portions of 0.1 g are plated for each original 25-g sample. A total of 20 colonies is equivalent to 100 cfu/g. If one of the five 25g samples has a total of 20 or more colonies of *L. monocytogenes*, the food lot fails. Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated. National governments should provide guidance on how samples should be collected and handled, and the degree to which compositing of samples can be employed.

[e] This sampling plan would provide 95% confidence that a lot of food containing an average 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 being positive for *L. monocytogenes*.]

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

Competent authorities should establish the actions that should be taken when the results of testing against the above criteria are unsatisfactory. Examples of such actions include:

- Prevent release of the food
- Withdraw or recall the food

- Destroy, rework or divert the food
- Re-evaluate the manufacturer's Good Hygienic Practices, HACCP plans, environmental and process control systems, or other related control measures
- Other appropriate regulatory actions by the competent authority

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

In addition to the microbiological testing of individual lots of RTE foods as described above (sections 4.1 and 4.2), competent authorities use alternate forms of microbiological criteria, based on environmental monitoring or process control testing, to verify control of operations. Such testing may be conducted directly by the competent authority or may be required of business operators as a means of verifying the effectiveness of GHP programs and food safety control systems (e.g., HACCP). Two types of testing programs, as described below, are particularly indispensable to ensure food safety: an environmental monitoring program is an important tool for discovering sources of contamination, and process control testing will confirm correction of possible contamination and monitor the continuity of process control. As with microbiological testing of lots, such testing will require the development of decision criteria before such programs are implemented. Recommendation of specific decision criteria to competent authorities is beyond the scope of the current document due to the diversity in products and manufacturing technologies, but the basis for such testing is described below.

4.4.1 Environmental Monitoring

The importance of controlling the food manufacturing environment is recognized in Annex I, which contains guidance for industry on the design and implementation of programs to assess ongoing GHP control of this potential source of *L. monocytogenes*. 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. This can include sampling by a competent authority as part of its inspectional activities or sampling performed by an individual food business operator, which the competent authority can review as part of its verification of the business operator's controls. The aim of conducting and/or reviewing environmental testing programs by a competent authority is to verify that an individual food business operator has successfully identified and controlled niches and harbourages sites for *L. monocytogenes* in the food plant and that sanitation programs have been appropriately designed and implemented to control *L. monocytogenes*.

In developing environmental testing programs and the decision criteria for actions to be taken based on the results obtained by or for the competent authority, there should be a clear distinction between sampling of food contact surfaces and non-food contact surfaces. Competent authorities should provide guidance on the location and frequency of sampling, including consideration of past experience that *L. monocytogenes* is likely to occur in areas or under conditions in the food manufacturing environment such as

- hard to clean areas,
- potential harbourage sites (e.g., grooves, rough weld marks, hollow legs, drains),
- use of the equipment in a way other than how it was originally intended, and
- periods of construction or alteration.

Competent authorities should consider use of a variable sampling frequency based on the results of prior results (i.e., increase frequency of sampling when there is an increase in positive findings). Investigation of the source of contamination will generally be a universal action to be taken if the number of positive samples exceeds the decision criterion.

In the design of the environmental verification programs, competent authorities should consider whether the operator produces products in which *L. monocytogenes* can grow and products in which it will not grow on the same production lines, with the same employees, or in the same facility.

As with the microbiological criteria discussed in section 4.1 and 4.2, the competent authorities should articulate the

- size, method and frequency of sampling
- method to be employed
- locations where samples should be taken
- decision criteria
- actions to be taken if a decision criterion is exceeded.

Sampling techniques and testing methods should be sufficiently sensitive for the decision criteria established and appropriate for the surface or equipment being evaluated.

4.4.2 Process Control

One of the goals of both industry and competent authorities is that corrective actions related to control of *L. monocytogenes* be taken before exceeding a microbiological criterion. One such tool to accomplish this goal is process control testing which employs "cross-lot microbiological testing" to assess the continuing performance of a food safety control system. Process control testing can be specifically implemented as a separate microbiological metric or in certain instances it may be possible to design a process control criterion to take advantage of the data collected as part of a testing program to verify an implemented microbiological criterion (see Section 4.2). One of the advantages of having an appropriately designed numerical or attribute-based microbiological criterion where $c \neq 0$ is that it allows the level of control to be assessed and corrective actions taken before the criterion is exceeded. Details of process control testing principles and guidelines are beyond the scope of this annex but are available through standard references.

Process control testing has largely been used by industry to detect changing patterns or contamination and distinguish occasional "in control" positive samples from an emerging loss of control. 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 to verification of HACCP or other food safety control systems. This can include sampling by competent authorities as part of its inspectional activities or sampling performed by an individual food business operator, which the competent authority can review as part of its verification of the business operator's controls.

As with other forms of verification via microbiological testing, the use of process control testing requires the establishment of decision criteria, specification of analytical methods, specification of a sampling plan, actions to be taken, etc. 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 *L. monocytogenes* 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.**]**