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Agenda Item 6 (a)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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COMMENTS ON THE

DRAFT GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF *LISTERIA MONOCYTOGENES* IN READY-TO-EAT FOODS

Submitted by: Australia, Brazil, European Community, Thailand, New Zealand, the United States of America and International Commission on Microbiological Specifications for Foods (ICMSF)

GENERAL

AUSTRALIA

The Draft Guidelines are based on the structure and headings of the *Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 4-2003)* (the RICP) and often refer back to that document. The Draft Guidelines are intended to provide advice on additional measures needed to control *L. monocytogenes* beyond those described in the RICP. However, there are instances where it might have been useful to reinforce the particular need for strict attention to temperature control in handling RTE products that support the growth of the organism rather than just cross-referencing the RICP (see specific comments below).

EUROPEAN COMMUNITY

In response to CL 2005/42-CCFH, the European Community (EC) has no particular comment to present, at this stage, on “*Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Ready-to-eat Foods*”.

UNITED STATES OF AMERICA

The United States would like to thank and congratulate Germany and the other members of the drafting group for the significant progress shown in this document, resulting in the adoption of the Draft Guidelines by the Commission at Step 5 of the elaboration procedure. We are generally very pleased with and strongly support these Draft Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready-to-Eat Foods.

ICMSF

The ICMSF recognizes the great improvements that have been made to the draft guidelines on *Listeria monocytogenes* (“Lm” for short). The several pages of introduction and the objectives are very well done and contribute a great deal to the document.

INTRODUCTION**First Paragraph****New Zealand**

Last sentence, “... ready-to-eat, long shelf-life, refrigerated foods ... and ~~often~~ usually involves ...”

Third Paragraph**United States of America**

In the 3rd paragraph, we recommend adding the word “relative” before the word “virulence” in the 3rd sentence.

Eighth Paragraph**New Zealand**

The draft document quotes the FDA/FSIS indicating that a combination of interventions are generally more effective in controlling *Listeria* than a single intervention. While this is correct, New Zealand thinks that the paragraph also needs to note that many countries are able to control *Listeria* through adequate implementation of good hygienic practice (GHP)/sanitation standard operating procedures (SSOP). Specific intervention is unnecessary.

Ninth Paragraph**United States of America**

In the 9th paragraph, we recommend the following wording for the second sentence: “The ability of foods to support growth during the normal shelf life of a product increases substantially the risk that the food will contribute to foodborne listeriosis.”

Last Paragraph**New Zealand**

A comment in this section about the importance of SSOPs would add greatly to this section.

Foot Note No. 5

Italicize *Listeria monocytogenes*.

SECTION I – OBJECTIVES**Second sentence****New Zealand**

~~“Their~~ The ...

2.1 scope**First Paragraph****ICMSF**

In the scope it is stated that (third sentence) “These guidelines highlight key control measures that affect key factors that influence the frequency and extent of contamination of ready-to-eat foods with *L. monocytogenes* and thus the risk of listeriosis.” Considering this, it is confusing that in several places in the document (3.4; 4.3.1; 4.4.6), mention is made of condensate as being a source/means of distribution for Lm that needs to be controlled. While there is very little scientific support for this, condensate is

really a general problem in many plants and is certainly not “a key factor” that is specific for Lm. It is a factor that should be controlled through applying GHP. With the overemphasis on condensation regarding Lm, it almost gives the impression that it is almost a unique factor to control ref. this pathogen. It would be better to refer to the relevance as condensation in a more general sense somewhere in the guidelines, but not under the sections where specific control measures are outline.

Last Paragraph

ICMSF

The last paragraph under Scope would better be deleted. The last sentence of this paragraph is a repetition of what the main paragraph under scope already has said and to control the pathogen in non-RTE foods not only GHP are needed but also an adequate design and implementation of the measure (e.g. pasteurization) that controls Lm.

2.2 Definitions

AUSTRALIA

The latest version of the *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management* (ALINORM 05/28/13, Appendix III, pp67-81) could be referenced as a footnote.

Ready-to-eat food

New Zealand

“...normally eaten ...”. Suggest use the term bactericidal rather than listericidal as this is a generic definition for RTE foods for all pathogens.

SECTION III - PRIMARY PRODUCTION

Second Paragraph

ICMSF

Second paragraph contains in parenthesis examples that are not consistent. The first gives an example of control while the others give examples of possible problems so issues to be controlled). It would be simpler to leave out the examples and have the paragraph read: “In those ready-to-eat foods that are manufactured without a listericidal treatment, extra attention at primary production is needed to assure specific control of the pathogen, including increased focus on personal hygiene and water management programs at the primary production sites.”

Third Paragraph

THAILAND

According to the verification process at the raw material receiving step, it has stated that analysis of *Listeria monocytogenes* is considered an efficient tool to verify the control measure of primary production. We are wondering whether the efficiency would be the same if analysis of *Listeria* spp. is done by preference. If appropriate, an addition of “*Listeria* spp” would be another helpful alternative to the manufacturers in terms of saving cost and time of analysis. The sentence in the third paragraph would then read :

“Analysis of raw material for *L. Monocytogenes* or *Listeria* spp. can be, where appropriate, an important tool for verifying that the control measures at the primary production level are adequately limiting the frequency and level of contamination to that needed to achieve the required level of control during subsequent manufacturing”.

New Zealand

This paragraph is misleading as testing raw material to verify absence, or low numbers, of *Listeria* is unlikely to give a robust result unless the contamination is extremely bad. New Zealand believes it

better to properly validate any on-farm *Listeria* control measure, and then monitor the physical process parameter(s) associated with the measure.

3.3 HANDLING, STORAGE AND TRANSPORT

AUSTRALIA

This section contains only a reference to the RICP. The only mention of temperature control in this section of the RICP states that:

Care should be taken to prevent, so far as reasonably practicable, deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.

Given the importance of temperature control to the management of *L. monocytogenes* and the potential for temperature abuse of RTE foods throughout the distribution chain, it is suggested that this section should contain a stronger reminder of this factor in line with that given in other sections, eg:

*Where feasible and appropriate for the food product, and where food ingredients and products support growth of *L. monocytogenes*, product temperature during handling, storage and transport should not exceed 6°C, (preferably 2°C - 4°C) to minimise growth. Raw materials should be handled, stored and transported separately from finished, processed products.*

SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES

Objectives

First Dash

New Zealand

Italicise *L. monocytogenes*.

New Zealand considers it would be useful to include drainage considerations at this point (design/placement of drains and building design to prevent liquid pooling on the floor). Drainage is considered later under Maintenance and Sanitation, however some of the issues highlighted in the latter section can be greatly minimised if first considered in the design of the premises.

Second Dash

ICMSF

The term "Harbourage site" is mentioned 13 times in the document, but has nowhere in the guidelines been described or defined. It may be helpful for readers when such a description would be provided. It is also confusing that biofilms are mentioned in several places (3.4; 4.1.2.; 4.3.1) in sentences such as "biofilms containing *L. monocytogenes* and harbourage sites." This puts very much emphasis on the importance of biofilms as a source of Lm. While biofilms indeed can occur, in most instances the source of Lm from harbourage sites is not a true biofilm as that term is understood. The term "harbourage site" is the broader term and captures all possible sources of a target microorganism, which can include a true biofilm, but generally will be of another type of source. The better wording thus would be "harbourage sites containing *L. monocytogenes*, including biofilms" when it is important to mention biofilms as a particularly relevant source.

4.1.1 Establishments

United States of America

We recommend adding the reference (CAC/RCP 1-1969, Rev. 4-2003) after *General Principles of Food Hygiene*. We recommend adding the same reference in 4.2.3 Temporary/mobile premises and vending machines.

4.2.1 Design and Layout

Second paragraph

New Zealand

Consider mentioning where clothing change/personnel hygiene/toilet facilities should be placed in relation to finished product.

It is interesting that this document advocates separation of raw and finished product in a physical sense (either spatially or with partitioning) and doesn't comment on separation by time/function (e.g. process raw and non-RTE products, clean, wait, and then process RTE products). New Zealand believes that there would be value in outlining those control mechanisms and the appropriate standard of implementation/verification where physical separation is not feasible.

4.2.2 NEW CONSTRUCTION/RENOVATIONS

AUSTRALIA

The reference to Section 6.3 (which is entitled Pest Control Systems) at the end of this section seems to be an error. Since the guidance seems to be about environmental monitoring, the reference should probably be to Section 6.5 – Monitoring Effectiveness.

ICMSF

Under section 4.2.2 (New construction/renovations) readers are referred to section 6.3. That is the section on pest control and may not be the intended reference section. It seems 5.9 or 6.5 would be more appropriate.

4.3.1 General

First Paragraph

New Zealand

Consider adding that surfaces, etc should be of an impervious nature where possible e.g. not wood, etc. This may be covered in General Principles, but stressing this in relation to *Listeria* would be useful.

Third Paragraph

United States of America

In the third paragraph, first sentence, we recommend deleting the word “any” in front of “psychrotrophic bacteria.”

4.4.8 Storage

New Zealand

The draft document states that raw materials should be stored separately to finished processed product. Similarly, the box states that “processing operations should be controlled ...” Surely, both these requirements are a “must” and in footnote 6 italicise *Listeria*.

SECTION V – CONTROL OF OPERATIONS

New Zealand

The box (first sentence) states that “processing operations should be controlled ...” Substitute “should” by “must.”

5.2.1 Time and temperature control

SECOND PARAGRAPH

New Zealand

The turn of phrase in the second and third paragraphs is confusing. The sentence about temperature abuse and shelf-life is irrelevant. More important is that temperature abuse could elevate the levels of *Listeria*.

UNITED STATES OF AMERICA

We recommend modifying the 2nd sentence to read, “Temperature abuse can increase the rate of *L. monocytogenes* growth in products that support growth, thereby increasing consumers’ exposure and their risk of listeriosis.”

THIRD PARAGRAPH

New Zealand

The third paragraph needs to simply state that “Since, in the absence of specific antimicrobial additives, *Listeria* is able to grow under refrigeration conditions, the storage temperature and stated shelf-life, as determined by validation studies (traditional culture or microbiological modeling), should be such that the numbers of *Listeria* do not reach inappropriate levels. Validation studies should take account of fluctuations in temperature during transport and storage to the point of consumption.”

UNITED STATES OF AMERICA

In the second to the last sentence of the 3rd paragraph, we recommend adding “(e.g., pH, water activity)” after “intrinsic factors.”

5.2.2 Specific process steps

FIRST PARAGRAPH

AUSTRALIA

The reference to Section V of the RICP does not seem correct. Section V provides examples of processing steps but does not discuss validation. Since the guidance seems to be about validation of listericidal processes, the reference should probably be to the HACCP Annex to the RICP (*Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*)?

SECOND PARAGRAPH

NEW ZEALAND

Paragraph two requires a definition of “bacteriostatic”.

UNITED STATES OF AMERICA

In the first sentence of the 2nd paragraph the pH should be 4.4, not 4.0. Scientific studies indicate that growth of *L. monocytogenes* is prevented at 4.4 and below.

THIRD PARAGRAPH

NEW ZEALAND

Paragraph three requires reordering for clarity. “Products that have undergone a listericidal treatment but which can support the growth of *L. monocytogenes* may still present a risk if contaminated/recontaminated before final packing. In such cases, additional control measures may need to be applied, (e.g. ... or prevent growth of *L. monocytogenes*.”

FOURTH PARAGRAPH**NEW ZEALAND**

Paragraph four also needs rewriting. “In addition, raw RTE foods such as lettuces that are never subjected to an antimicrobial intervention but which can support the growth of *L. monocytogenes* pose a similar risk and may require the application of specific control measures to limit the extent ...”

5.2.4 Microbiological cross-contamination**SECOND PARAGRAPH****NEW ZEALAND**

First sentence, after “... and equipment”, delete “should be ...area(s) and substitute “ between raw processing, storage areas and finished product areas should be controlled ...”

Last sentence, after “... to identify personnel” add “or equipment ...”

UNITED STATES OF AMERICA

Second sentence, we recommend deleting the comma after “footwear” and adding the word “or” there.

FIFTH PARAGRAPH**NEW ZEALAND**

First sentence, modify to read “... of *L. monocytogenes* but which may be contaminated with low numbers of *Listeria* should not be ...contamination for other ... support growth of *L. monocytogenes*.”

Second sentence, after ..requirements..” add “... formulations ...”, and also in second and third sentence New Zealand suggests that the term “vector” be replaced with “source”.

UNITED STATES OF AMERICA

In the last sentence of the fifth paragraph, we suggest the following rewording: “..., that are handled after opening may present higher risk for being a vector for cross contaminating other ready-to-eat products if neither ready-to-eat product is rapidly consumed.” **5.8 Recall Procedures**

5.8 Recall Procedures**NEW ZEALAND**

Second sentence, what does “need for public warnings” mean? Labels on packs, retailer notices, advertising campaigns? Suggest needs to be more specific, describing the various means to “educate consumers”. Refer Section 9.3.

5.9 MONITORING OF EFFECTIVENESS OF CONTROL MEASURES FOR L. MONOCYTOGENES**NEW ZEALAND AND THE UNITED STATES OF AMERICA**

The word *Listeria* in the first sentence should be italicized.

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION**OBJECTIVES****RATIONALE:****UNITED STATES OF AMERICA**

In the box, under Rationale, the word *Listeria* should be italicized.

NEW ZEALAND

Last paragraph, the document states that “Basic cleaning and disinfection programs are critical ...” New Zealand suggests that the cleaning programmes required for RTE premises are not basic, in fact are “enhanced”. Indeed Section X under Rationale states that “controls specific to ... are generally more stringent than routine GHP” and Italicise *Listeria*.

6.1.1 General**NEW ZEALAND**

The discussion about “support structures for equipment is repeated”.

THIRD PARAGRAPH**UNITED STATES OF AMERICA**

We recommend that the fourth sentence begin “Food contact surfaces on equipment” rather than “Equipment food contact surfaces.”

6.1.2 Cleaning procedures and methods**First Paragraph****NEW ZEALAND**

Fist sentence, after “..cleaning ...” add “without physical abrasion.”

Third Paragraph**NEW ZEALAND**

Last sentence, the document uses the term “antimicrobial resistance” which may be confused with antibiotic resistance. New Zealand suggests use of the alternative statement “The development of resistance to the antimicrobial effect of chemical disinfectants ...”

Fifth Paragraph**NEW ZEALAND**

Para 5: New Zealand recommends adding that high pressure air hoses as well as high pressure water hoses can spread contamination.

Sixth Paragraph**NEW ZEALAND**

A statement on flushing drains with hot water to prevent fat blockage is required, or rather, resisting the temptation to reduce the wash water temperature due to financial or occupational safety and health (OSH) concerns.

New Zealand also recommends the addition of sections describing issues with floor integrity (cracks, poorly fitting covings, permeable coverings, etc). Also seals around doors and capillary action up into door and wall panels, especially in modern sandwich board construction. This information should also be inserted under Section 4.2, Premises & Rooms.

SECTION VIII – TRANSPORTATION**UNITED STATES OF AMERICA**

In the second bullet in the box, we recommend rewording the language in the parentheses to read “(so that product temperature does not exceed 6 C, preferably 2C – 4C).”

8.1 GENERAL

NEW ZEALAND

Consider adding guidance around use and hygiene of flexible hoses and pumps associated with transportation vehicles (assessment for pathogen harbourage, cleaning, suitability etc).

9.3 LABELLING

NEW ZEALAND

Second sentence, after “handling practices” add “at-risk populations (Young, Old, Pregnant, Immuno-compromised)”

9.4 COMMUNICATION EDUCATION

SECOND BULLET

BRAZIL

Fourth indented example, the provision that glass Mercury-bulb thermometers should not be used in domestic refrigerators due to the risk of physical contamination (glass), and chemical contamination (Mercury), should they eventually come to be broken.

NEW ZEALAND

Editorial, after “... 4°C): add a space.

THIRD PARAGRAPH

NEW ZEALAND

Third paragraph, replace “-“ (hyphen) “ with “,” (comma).

UNITED STATES OF AMERICA

We suggest that the fourth indented example under the second bullet begin with “using” rather than “use of” to make it consistent with the other examples.

ANNEX I: RECOMMENDATIONS FOR AN ENVIRONMENTAL MONITORING¹ PROGRAM FOR *LISTERIA MONOCYTOGENES* IN PROCESSING AREAS

NEW ZEALAND

These sections appear incomplete/still under development. Without getting prescriptive, New Zealand considers it would be useful to provide some further guidance around development of statistically sound sampling and testing regimes for a) establishing a data set to inform on-going appropriate environmental sampling frequencies,

- b) traceback sampling (environmental),
- c) use of product testing for verification of controls, and
- d) verification that product implicated in traceback situations is 'safe'.

At the moment the advice is almost too generic - there is allusion that sampling/testing in each of the above situations is different, but nothing to say how different or why or even to indicate what kinds of references might be available/used to assist in determining what is appropriate at each stage.

Title, foot note 8, “... in HACCP.” “... require formal monitoring.”

¹ Environmental monitoring is not to be confused with monitoring as defined in the HACCP.

b) Type of samples**NEW ZEALAND**

The discussion needs to more fully describe the need to sample the non-contact areas of food contact surfaces, e.g. the underside back of the lip on the edge of slicing tables where fingers wrap if staff lean on the edge of the table. Also need to consider the hidden surfaces of non-food contact surfaces, e.g. the backs of door handles. Both of these surfaces are often forgotten.

UNITED STATES OF AMERICA

Under section b) Type of samples, we recommend that the second sentence be reworded as follows: "Food contact surfaces, in particular those after the listericidal step and prior to packaging, have a higher probability of directly contaminating the product, while for non-food contact surfaces the likelihood will depend on the location and practices."

c) Target organism**NEW ZEALAND**

Editorial, delete spaces before after “,” (comma) and footnote 1, (Page 65) , footnote “... in HACCP.” “... require formal monitoring.”

i) Actions in case of positive results**AUSTRALIA**

Suggest add “*or recall*” after “*testing*” in final sentence.

NEW ZEALAND

The document alludes to actions of different degree based on circumstance or ‘escalating’ responses. New Zealand would like to see this section use these terms and perhaps provide examples.

UNITED STATES OF AMERICA

We suggest in the third sentence deleting the word “anticipated” before “action plan” and adding “and established” after “designed.”