codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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COMMENTS ON THE PROPOSEDDRAFT GUIDELINES FOR THE CONTROL OF *LISTERIA MONOCYTOGENES* IN FOODS SUBMITTED BY

Argentina, Australia, United States of America, European Community, FAO/WHO, Consumers International, and International Dairy Federation

GENERAL COMMENTS

ARGENTINA

For this document, we should take into account the fact that studies on the risks for different groups of consumers based on dose and type of food are conducted with empirical and mathematical models and animal studies, and all of this cannot be translated to humans without a high probability of error.

Furthermore, the epidemiological studies that are carried out correspond to countries with a situational reality that is different from ours. We should be very cautious when deciding which model to adopt, and more practical tests should be done to show that the selection has not been erroneous. When errors are detected, the corresponding points should also be modified or, if necessary, the entire model should be modified and/or changed.

AUSTRALIA

Australia would like to express its appreciation to the Delegation of Germany and the drafting group for their valuable work and the progress made on the document. Some comments for consideration and further development of the paper are provided:

The decision tree approach in the paper is consistent with Australia's approach for the development of risk management options for *L monocytogenes* in foods.

Rather than applying such a decision process as required, the reasoning embedded in the decision tree could be incorporated generally into strategies for controlling *L monocytogenes* in food. Australia already identifies high-risk food products with respect to this pathogen and applies a testing protocol for imported and domestic foods based on measures such as a particular risk presented by the food/pathogen combination and compliance history.

The number of samples that are to be tested according to the decision tree outlined in the paper could be quite onerous and costly. It is noted that these are based on ICMSF sampling plans and that practical considerations such as the cost/benefit of such testing needs be taken into consideration.

UNITED STATES OF AMERICA

The United States appreciates the work of Germany and its drafting partners in further revising the *Proposed Draft Guidelines for the Control of Listeria monocytogenes in Foods.* The United States believes that progress has been made in developing risk management guidance for the occurrence of *Listeria monocytogenes* (LM) in foods. There are a number of areas, however, that will require substantial further work, including both the documents technical content and its format, and the United States recommends that the document be held at Step 3 for further work by the Committee and its Drafting Group.

The United States believes that the approach to this document, both in technical content and in format, can serve as a model for CCFH in developing microbiological risk management guidance for Codex and countries. In this regard, the United States believes that the Committee should review the format of this document, keeping in mind the process by which CCFH will undertake its microbial risk management work and the form in which it wishes to provide its guidance to Codex and to countries. The United States notes that this document uses the CCFH document *Principles and Guidelines for the Conduct of Microbiological Risk Management* as a model, including the incorporation of all its section headings. While the United States believes the CCFH microbiological risk management document model is an appropriate model to consider, the United States does not believe that all sections of parent guideline document need be incorporated into specific microbial pathogen risk management guidance documents.

The United States will provide detailed recommendations to Germany in anticipation of at least one additional working group meeting during the upcoming year. As a member of the working group, we are looking forward to participating in the further development of this precedent setting document.

EUROPEAN COMMUNITY

The European Community would like to thank Germany and the drafting group for the work done. The document has developed in a positive direction and it now provides a comprehensive approach to the control of *Listeria*. The Community supports in general the approach presented in the document. However, certain parts of the document need still to be further discussed and elaborated.

In order to facilitate the further development of the document the European Community would like to submit the following detailed comments:

The necessity of keeping the Annex I should be discussed at the CCFH meeting. In case the Annex is to be kept, the inconsistencies between it and the main document should be rectified. For example, there is a discrepancy regarding the role of Codex Alimentarius in establishing ALOPs.

FAO/WHO

The draft risk management document on *Listeria monocytogenes* (Lm) has been under preparation for some time. However, the situation at this year's CCFH meeting is somewhat different from the situation previous years. This year the Lm risk assessment, which was originally initiated through the definition of CCFH priorities and risk management questions in 1999 and 2000, will be ready. While the drafting group of the management paper has not had the benefit of this final version of the risk assessment, FAO and WHO in this short statement suggest that the final risk assessment presents us with an important background for a significant revision of the draft risk management document.

It is suggested that the basic approach to address the problem of *Listeria monocytogenes* (Lm) in foods should attempt an incorporation of the pertinent outcome of the Lm risk assessment. In addition the development of management strategies should be based on the clear premise of reducing the burden of listeriosis through lowering the risk from consumption of Lm contaminated food.

In considering the outcome of the Lm risk assessment the following important issues taken from the assessment are suggested for specific consideration in the future Lm management document:

1. The vast majority of cases of listeriosis are associated with the consumption of high numbers of Lm in food and both control measures focusing on reduction in frequency as well as in levels of contamination will have an impact on reducing the risk of listeriosis. Likewise controlling the growth of Lm after processing and during storage will reduce the risk of listeriosis. Therefore, establishing criteria at a certain specific point of the production chain should only be considered one way of addressing the problem, and other strategies to be considered could include better temperature control, limitation of the shelf life, reformulating or avoiding certain foods.

2. Most listeriosis cases are associated with the consumption of foods where the numbers of Lm do not meet the current standards or criteria (be they absence in 25g or 100cfu/g). The risk assessment suggests that eliminating contaminated products with high concentration of *Lm* will result in a sharp decrease in the number of cases. However, this is under the assumption of 100 % compliance. This means that there needs to be a further focus on measures towards improving compliance as an important part of any strategy to reduce the burden of listeriosis.

3. For foods that do not support growth of *Lm*, the dose level at retail would be the same as the dose at time of consumption, but for food supporting *Lm* growth, increases in *Lm* cell numbers between retail and consumption will have to be assumed, associated with an increase in risk. In the present *Lm* risk management document, it is proposed to use knowledge of growth characteristics to determine an allowable concentration of *Lm* for a specific food. This tends to represent a deterministic view without recognition of the inherent uncertainty surrounding *Lm* growth in certain foods between processing and consumption. It does also presuppose that predictive growth tools available are always reliable under realistic circumstances. The uncertainty related to growth includes the growth rate itself and the factors influencing it, the influence of composition of food, uncertainty on actual storage temperature and actual shelf life. In acknowledging this uncertainty and the present lack of compliance, there is a strong need to promote risk management strategies that will in reality reduce the number of Lm in food. In developing such measures, the public health significance of listeriosis, the outcome of the risk assessment and the difficulties related to compliance with any specific criteria should be taken into consideration.

FAO and WHO suggest a thorough consideration of these important issues as presented in the final Lm risk assessment, which is the final outcome of one of CCFH's first initiatives to base risk management considerations on risk assessment to the extent practically possible. It is suggested that the outcome of the final Lm risk assessment presents CCFH with a very valuable tool in this process, representing a significant improvement of the available scientific basis for future management of this important public health problem.

CONSUMERS INTERNATIONAL

Consumers International notes that while *Listeria monocytogenes* may only cause mild gastroenteritis in healthy individuals, certain susceptible populations face much higher risks. In the view of Consumers International, ready-to-eat foods should be safe for all consumers, including those who are particularly vulnerable to listeria (pregnant women, fetuses, transplant recipients, cancer patients, AIDS patients, etc.). While listeria is ubiquitous in the environment, ready-to-eat foods are processed foods and when properly processed can and should be safe for anyone.

While Consumers International supports consumer education, ready-to-eat foods should be safe for all consumers, regardless of how much they do or do not know about the safety of such foods. Consumer education should only be viewed as a second level of protection. Relying on education as a primary means to prevent listeriosis amongst high-risk individuals puts the burden on the consumer to protect him/herself, rather then on the food industry and government authorities to ensure safe food. Relying on such an approach is also not effective in preventing listeriosis (e.g., particularly for illiterate consumers).

We note that the risk assessment is not yet finalized. Thus, in our view, without better data on exposure and risk from specific foods, there is no basis in science for 100 cfu/g as an estimate of acceptable risk; it is premature to assert that any particular level of listeria in foods will meet a particular numerical food safety objective, as there is not yet an adequate scientific basis for doing so.

In our view, the format used in this draft is a good one and a substantial improvement from previous drafts. While additional data and clarification are needed there is a great deal of useful information in the document.

INTERNATIONAL DAIRY FEDERATION

The FIL/IDF wishes to congratulate the drafting group for providing an improved document.

However, major part of the text has been written as a discussion paper, which may need to be editorially converted into Codex Guidelines.

Our principal comments to CX/FH 03/8 relate to the need for alignment and coherence with other (existing and draft) Codex texts, including:

- Clear distinctions between the risk management options FSOs, performance criteria, and microbiological criteria, and the concept of acceptable levels as used within the HACCP concept;

- Distinguishing between verification of control systems (HACCP and/or GHP systems) and verification of products of unknown history in the establishment and application of microbiological criteria

- Ensuring that the document is focused only on the managing of Listeria monocytogenes and not on managing of hygiene in general

1 SCOPE

INTERNATIONAL DAIRY FEDERATION

We welcome the intention to differentiate between risk management at Codex level and in the national context, respectively.

However, there is also a need to differentiate between risk management at government level and hazard management at industry level. We note that the Guidelines are aimed predominantly at governments. Consequently, guidelines within the document should focus more on how and what to audit and inspect when supervising food manufacturers. Major part of this draft, in particular section 6 seems to be targeting food manufacturers rather than governments.

We note and agree with the statement that the Guidelines should only provide information additional to the Codex Food Hygiene Basic Texts.

3 DEFINITIONS

Performance Criterion:

INTERNATIONAL DAIRY FEDERATION

It is important that there is clear distinction between a FSO, a performance criterion a microbiological criterion, and acceptable level, respectively, as these are <u>different</u> risk management options.

- A FSO is an expression of the required (absolute) <u>combined final outcome of all control measures</u> applied throughout the food chain (e.g. < 100 cfu/g at the time of consumption).

- The acceptable level is used in Codex HACCP Guidelines (e.g. in the definitions of "control measure" and "CCP") as an expression for (absolute) <u>outcome needed at the next step</u> of the process or food chain to ensure food safety; only when the next step is distribution for consumption it refers to the level acceptable in final foods.

- A microbiological criterion is an analytical tool intended for the verification of acceptable levels at a specified point in the food chain. The specified point indicates where sampling for analytical testing is to be carried out – this could e.g. at the reception of raw material, after applying a process step (e.g. heat treatment), after applying a combination of process steps (e.g. at the end of manufacture).

The draft definition of "performance criteria", as included in CX/FH 03/8 also relate to (absolute) outcome and therefore expresses the same as FSOs and acceptable level, depending on at which stage within the food chain it applies.

We note that in section 5.3 (addressing performance criteria), performance criteria are described as an expression for the required food safety outcome at stages in the food chain earlier than consumption, e.g. foods just after manufacture. For this purpose, microbiological criteria, as described in the Codex Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997), and acceptable levels, as described in the Codex HACCP Guidelines, would express the same.

As so many other concepts are available to express (absolute) outcomes at various stages of the food chain, we recommend that the concept of "performance criteria" express something different (not relating to

(absolute) outcome). Instead it should be applied as an expression of the relative effect of control measure(s), such as minimum reduction rates.

On the basis of the above, we suggest the following definition:

*"**Performance criteria** - The required effect of one or more control measures, expressed as the change in the level of hazard(s) in a food."*

4 CONSIDERATION OF THE RESULTS OF THE MICROBIOLOGICAL RISK ASSESSMENT

CONSUMERS INTERNATIONAL

Fourth paragraph, **questions posed by the 33rd CCFH:** In our view the questions are not yet fully and clearly answered, and need to be.

Regarding question i, on the risk for consumers in different susceptible population groups (elderly, infants, pregnant women, and immunocompromised patients), no information on the risk for pregnant women and fetuses is provided. Based on data from one or possibly two countries, it is concluded that transplant recipients are the most vulnerable population, yet no data on fetuses is even considered.

Question ii requested an estimate of the risk from *Listeria monocytogenes* in food when the number of organisms ranges from absence in 25 g to 1000 colony-forming units (CFU) per gram, or does not exceed specified levels at the point of consumption. Table 1 provides information on the predicted number of cases in the United States population at various log cfu/serving. It is not clear to us what serving size is being assumed and how this relates to a specified number of CFU per gram of food. Furthermore, the risk to an average individual and to a susceptible individual is not provided. Providing the predicted number of cases in the US, while of interest, is not as helpful in the international context.

Providing data only at a population level (the US population) obscures the situation for high-risk individuals. It is also unclear how to relate data in one country to the international situation, and to populations with different proportions of susceptible individuals.

Bullet 2: Nevertheless, it is concluded that ingestion of levels below 100/g is associated with a low risk.. It would be most helpful if the paper would state what is the risk estimate, for a healthy individual, and for different susceptible individuals, at different levels, including 100/g, while properly qualifying the risk estimate (as to its limitations).

INTERNATIONAL DAIRY FEDERATION

When considering the results of risk assessments of *Listeria monocytogenes*, the distinguishing between foods where growth can occur and foods where growth cannot occur should be used with caution as many factors impact the probability for growth.

We often observe that the probability of post-manufacturing growth depends on (i) the processing plant, (ii) the preventive measures in place, (iii) the initial levels in the raw material, and (iv) the technology applied to the product.

Although such differentiation would be appropriate when considering performance criteria, acceptable levels and microbiological criteria (all applicable earlier in the food chain), we do not consider that a similar differentiation is appropriate for FSOs. Consequently, we recommend that the same FSO applies to all

ready-to-eat foods, thus leaving it to the food manufacturers to ensure compliance through the application of appropriate control measures and, as necessary, verification and validation procedures.

The above should be taken into account when considering the final Risk Assessment data

5.2 FOOD SAFETY OBJECTIVE (FSO)

EGYPT

EOS refuses the purpose of the draft, which is accepting a "permissible" count of pathogen and refuses setting a standard for the level of pathogenic contamination that is 100 pathogen per gram in the sample of food.

EOS refusal is based on the following:

1. All strains of L. monocytogenes are defined as pathogenic.

2. The pathogenic microbe affects either through a microbial count on food that remains stable when infecting the body or through microbial count that multiplies in number after infecting the body. L. monocytogenes does not stop multiplying when they contaminate food or after infecting the body. The question that arises is how you can make sure that the microbial count will stop at 100 pathogen per 25 gram in the sample food?!

3. The acceptance of a permissible level of pathogenic microbial count is very risky because certain categories of consumers are more affected by this pathogen such as (the elderly, children, pregnant women…..etc.). Because the pathogen or acceptance level of pathogen will not be restricted to certain categories of consumers.

4. Scientific researches and studies show the ability of L. monocytogenes to multiply during storage at refrigerating temperature (4 to 5°c). This means that if food is contaminated with permissible level of pathogen, it will multiply in number even if it is stored in a refrigerator.

5. Scientific research shows that L. monocytogenes is not present in certain type or types of food. However, the pathogen is present in all types of food (raw or cooked). This means that the pathogen cannot be controlled because it is not related to certain type/types of food.

6. From the practical point of view, (quantitative) laboratory testing is extremely difficult and needs programs for developing quality control laboratories. However, (descriptive) testing which is in force and sufficient for the acceptance or refusal of a contaminated food with a pathogen with no need to determine the permissible or non-permissible levels.

7. As indicated in scientific reports and stated in the introduction of the standard, about 10% of the general population are carriers of the pathogen, which means that about 6 to 7 million Egyptians are carriers of the L. monocytogenes. Hence, the acceptance of a permissible level will raise the number of infected people with this pathogen, and the consumers will turn into infected people. This contradicts the Egyptian regulations in force and particular Law No. 10/1966 that prohibits the contamination of food with any microbial contamination.

CONSUMERS INTERNATIONAL

Similarly, it is asserted that Table 1 shows clearly that a 99% reduction in the number of illnesses will be obtained by setting a FSO at < 100 *Listeria monocytogenes* per gram of food at the moment of consumption, when the table does not provide information on the risk at this level.

INTERNATIONAL DAIRY FEDERATION

The document could benefit from addressing how adherence to the FSO can be demonstrated in practice, e.g. by inserting the following:

> "*The food business responsible for specifying the shelf-life and storage conditions should be able to show that the food is capable of meeting the FSO at the end of its shelf-life when stored under the envisaged storage conditions through :*
>
> - *the appropriate design and effective implementation, function and maintenance of the HACCP system and other hygiene control measures, including the purchase, handling and processing of foodstuffs under their control to ensure control of Listeria monocytogenes;*
>
> - *the establishing of verification procedures, including the establishment and application of any necessary microbiological criteria for verification of raw materials, intermediates and end products; and*
>
> - *the provision of verification results that show compliance with the microbiological criteria established.*
>
> *When necessary, shelf life tests should be conducted in order to investigate the capability of the food to comply with the target."*

5.3 PERFORMANCE CRITERIA

INTERNATIONAL DAIRY FEDERATION

We refer to our comments to Chapter 3 (definitions).

The draft text use the term "performance criteria" as the expression of the level of hazards in the food at any point of the food chain before it reaches the time of consumption. The approach should be consistent with CX/FH 03/7.

5.4 MICROBIOLOGICAL CRITERIA FOR *L. MONOCYTOGENES*

INTERNATIONAL DAIRY FEDERATION

This section is structured in two groups – section 5.4.1 relating to foods in international trade and section 5.4.2 relating to foods produced domestically.

What triggers the choice of the one or the other situation should not be related to whether the food is internationally traded or not, but knowledge about history of the product (i.e. of the degree of control during and after manufacturing). (NB! All foods are produced domestically but may be sold domestically or abroad!).

Microbiological testing according to the sampling plan described in the decision tree is only needed, when that testing is the only means of evaluating the safety status of a particular batch of food.

Therefore, section 5.4 should clearly distinguish between:

- the establishing and application of microbiological criteria in verifications procedures to verify and/or validate control systems (HACCP and/or GHP systems)

- the establishing and application of microbiological criteria for evaluation of food batches of unknown history

We suggest the inserting the following text:

"*Application of microbiological criteria:*

Foods manufactured under appropriate controlled conditions

Food manufacturers should establish microbiological criteria for Listeria monocytogenes as necessary for verification of the efficacy of control systems (the HACCP system and other hygiene control measures) in place and to support the demonstration of adherence with the FSO.

The number of sample units to be taken for the verification of the well functioning of control systems depends on the probability of control measure failure and frequency of testing, but will typically be one sample unit.

In case of non-compliance with the microbiological criteria, the manufacturer should take appropriate actions as necessary as to ensure that the non-compliance does not result in consumers being exposed to products exceeding the FSO, including, where relevant, the withholding and/or withdrawal of products from the market.

Competent authorities should evaluate the appropriateness of the criteria, the verification systems used, and the efficacy of the verification procedures using appropriate means, including testing against microbiological criteria.

Foods manufactured under unknown or inappropriate controlled conditions

Foods of which the origin and/or conditions under which they have been produced, manufactured and/or distributed is uncertain or not known should be tested for compliance with the relevant microbiological criteria according an appropriate sampling plan. For the selection of the appropriate sampling plan the decision tree presented in Figure 1 is recommended. The same sampling plan may be useful in the evaluation of the acceptability of food batches produced, manufactured and/or distributed under conditions where monitoring of HACCP and/or GHP systems indicate that control measures have failed."

In the 2nd para. of section 5.4.1, it is stated that "In order not exceed these levels at the point of consumption, lower levels may need to be applied at the port of entry for those foods in which growth can occur".

We consider that the potential for growth is to be taken into account by the manufacturer (as necessary, in consultation with the distributor) to ensure that the food, when leaving the manufacturing establishment, complies with acceptable levels that accommodate for the potential of growth under the distribution conditions, whether the distribution takes place domestically or in other countries. Consequently, it is only in the case where the food manufacturer does not comply with this principle that there is a need to apply

microbiological criteria at the port of entry. In practice, we recommend that, if there is doubt, that the first step be the furnishing of additional information (e.g. available shelf life test results and similar data) from the food manufacturer and/or the distributor responsible for the food lot in question.

5.4.1 Microbiological Criteria for *L. monocytogenes* for foods in international trade.

EUROPEAN COMMUNITY

The use of the sampling plans indicated in Figure 1 are recommended. These sampling plans are appropriate when testing batches of foodstuffs of unknown origin or when there is no assurance that HACCP principles and GHP have been applied. However, when the imported food derives from establishments, where there are guarantees that HACCP and GHP have been applied and *Listeria* risk addressed, less stringent sampling plans could be used on a case by case basis. Therefore, this possibility should be included in the text, and the decision tree in Figure 1 might need to be elaborated accordingly.

CONSUMERS INTERNATIONAL

The document states "…However, the proposed microbiological criteria are not intended to be used for clearly identifiable food, specifically intended for consumption by clearly identifiable vulnerable groups (high risk groups) e.g. geriatric foods, baby foods, enteral foods."

We would suggest that this paragraph be clarified to indicate that these foods should have ZERO tolerance for presence of *Listeria monocytogenes*, and that elsewhere in the document further information be provided to indicate how this can be achieved. In our view, particular care should be taken with foods specifically intended for consumption by high risk groups; but that whether "clearly identifiable" or not, it should be assumed that high risk groups will also consume generally available foods. Information as to where the information for these specific criteria may be found is needed.

FIGURE 1: DECISION TREE FOR MICROBIOLOGICAL CRITERIA FOR FOODS IN INTERNATIONAL TRADE

INTERNATIONAL DAIRY FEDERATION

With reference to our comments above, the title should be changed into "***Decision Tree for microbiological criteria for foods manufactured under unknown or inappropriate controlled conditions***".

With regard to Question 1, the wording should also accommodate for control measures having listericidal effects other than "treatments".

At the end of the decision tree, three bases for rejections are provided. We recommend to add an additional "case" addressing the possibility to obtain additional data from the food manufacturer and/or distributor responsible for the food lot in question.

With regard to case (c), we agree that it represents exceptional situations, in particular if the test for Listeria is complemented with additional test(s) according to Annex 2, and if the additional case recommended above is followed

5.5 PRIMARY PRODUCTION AND FOOD HARVESTING

INTERNATIONAL DAIRY FEDERATION

The text in the first paragraph should accommodate for verification and monitoring systems that evaluate the presence of *Listeria monocytogenes* in the raw materials and ingredients used. Consequently, the second sentence could be deleted.

We refer to the approach followed in the Proposed Draft Code of Hygienic Practices for Milk and Milk Products and suggest that it is recognized within section 5.5 that it is the combined effect of all the control measures applied throughout the food chain that is essential. Consequently, if controls are relatively less effective in primary production, they need to be relatively more effective during manufacture, and vice versa.

5.6 FOOD PROCESSING AND DISTRIBUTION

INTERNATIONAL DAIRY FEDERATION

In the 3rd para., it is stated that specific aspects of managing *L. monocytogenes* in certain food processing, including cheese, are given in chapter 6. Apparently, the content of Chapter 6 is not specific to these foods.

The list of approaches for managing L. monocytogenes is a mixture of control measures and risk management options. We recommend a clear distinction be made between measures taken:

- by the regulatory authority (risk management measures or options that address public health risks according to Risk Analysis definitions)
- by the industry (control measures that address hazards according to HACCP definitions).

Many additional control measures are available. How control measures should be combined should be left to guidance provided in commodity specific Codes of Hygienic Practices.

5.7 CONSUMER EDUCATION

CONSUMERS INTERNATIONAL

It must be clarified in the context of the document that consumer education can not be relied on as the primary means to protect high-risk consumers; ready-to-eat foods should not contain levels of listeria that are unsafe for consumers, including high-risk consumers. However, we strongly support consumer education; an educated consumer will make informed choices. Furthermore, we would like to emphasize the importance of cooperation between all stakeholders in this endeavor. The word “or” should be changed to and/or in the sentence "Use all appropriate and available means (e.g. mass media, distribution of informative cards by retailers, supermarkets **and/or** consumer associations) to allow high-risk consumers to be able to recognize those foods on the packaging and to help them distinguish these specific products from other categories of foods."

INTERNATIONAL DAIRY FEDERATION

We wonder whether parts of this section more appropriately belong to CX/FH 03/7 as general Risk Management options and/or in the General Principles for Hygiene (under section 9).

It should be taken into account that, in order to be effective, consumer education needs to be adapted to the national environment/context.

The recommendations specific to *Listeria* seems to demonstrate that heating automatically leads to the avoidance of contamination and listeriosis. This is not entirely true as efficient control (both in the food manufacturing and in the kitchen) depends primarily on:

- the performance of the heating process,

- the initial level in the food subjected to the heating,

- the matrix of the food subjected to the heating, and

- the probability of post-treatment contamination

We recommend that the recommendations be reviewed accordingly.

Further, we recommend that the text accommodate for different types of consumers. For example, transplanted people should consume sterilized products only. Further, technology other than heat can also result in safe foods.

6 GUIDELINES FOR MANAGING OF *L. MONOCYTOGENES* IN FOOD PRODUCTION

EUROPEAN COMMUNITY

In chapter 6 detailed instructions are given for sanitation of production areas in food industry. However, little emphasis is put on the verification of the effectiveness of these procedures by microbiological sampling. As environmental sampling for *Listeria* has often proved to be an effective tool in the overall control of *Listeria* in food industry, this aspect could be highlighted more in the text.

INTERNATIONAL DAIRY FEDERATION

Major parts of the guidelines are generic hygiene measures not specifically targeted a particular pathogen and which is covered by the General Principles for Food Hygiene and the HACCP approach.

Further, the guidelines provided are very detailed and should not be perceived nor presented as a recommendation for general use.

The chapter 6 should be scrutinized and be focussing only on those measures that are known to be specifically efficient for the control of *L. monocytogenes*. This may include, for instance, specific performance criteria and/or process parameters (criteria) for control measures usually applied in the control of microorganisms. Although, Table 2 could be made more comprehensive, it represents an example of useful Listeria-specific guidance that may assist HACCP teams in designing plant specific HACCP-based control systems.

To avoid contradictions and/or misunderstandings, those guidelines that are specifically recommended/relevant for the control of *L. monocytogenes* in specific commodities for which Codex Codes of Hygienic Practices exist or are being developed should be incorporated in the relevant Codes rather than in this horizontal document.

The Guidelines could benefit from the approach followed in the Proposed Draft Code of Hygienic Practices for Milk and Milk Products by formatting the text into **principles (bold typing)**, guidelines (normal typing) and *explanatory narratives (italic typing)*.

The performances of each GHP need to be related to the performances of control measures for which CCPs have been identified to ensure that the overall effect of the control measure combinations meet the acceptable levels, microbiological criteria, and FSOs. Consequently, the guidelines should be more flexible.

6.3.4. Sanitizers And Sanitization

CONSUMERS INTERNATIONAL

"In addition, peroxyacetic acid sanitizers have been shown to be effective against *biofiL. monocytogenes* containing *L. monocytogenes*."

We believe this should say: "…**against biofilms containing *L. monocytogenes* .**"

6.6. TRAINING

AUSTRALIA

Section 6.6 Training – incorporates a table (Table 2) covering potential sources of *L monocytogenes.* Given that employee hygiene practices are essential in minimising the potential for post-process contamination, it would be important to include employees/people in this table.

Australia considers that the paper needs to reflect the whole food supply chain if at all possible.

Reference should be made to the *Recommended International Code of Practice General Principles of Food Hygiene.*

ANNEX 2: EXPLANATION OF THE *L. MONOCYTOGENES* DECISION TREE

Question I: **HAS THE FOOD RECEIVED A LISTERICIDAL TREATMENT ?**

INTERNATIONAL DAIRY FEDERATION

All control measures that significantly reduce the levels are listericidal and these are not limited to the application of heat include also many other treatments and factors. The Proposed Draft Milk Code defines "microbiocidal treatments" as control measures that substantially reduce or practically eliminate the number of microorganisms present in a food.

Question V: **IS IT LIKELY THAT MULTIPLICATION TO LEVELS OF > 100/G OR ML AT THE MOMENT OF CONSUMPTION WILL TAKE PLACE DURING THE INTENDED CONDITIONS OF STORAGE, DISTRIBUTION AND USE?**

INTERNATIONAL DAIRY FEDERATION

In order to utilize data that should already be available, we suggest combining the first two sentences of the 4th paragraph as follows:

"*In any case where the stabilization of foods can be evaluated as being marginal or questionable, it can be necessary to require documentation from the manufacturer that his product is stabilized against growth of L.m, such as data and results of shelf-life studies/tests.*"

GUIDELINES FOR EVALUATION OF THE STABILITY OF A PRODUCT AGAINST GROWTH OF L. MONOCYTOGENES:

CONSUMERS INTERNATIONAL

last paragraph, first sentence: "Foods are complex eco-systems and experience has shown that interactions among known and unknown hurdles can provide against growth of L. monocytogenes without *fulfiL. monocytogenes,* and of above mentioned criteria." This needs to be re-worded; for example: "Foods are complex eco-systems and experience has shown that interactions among known and unknown hurdles can provide against growth of *L. monocytogenes* **under the criteria mentioned above."**