INTRODUCTION

1. During the 50th session of the Codex Committee on Food Hygiene (CCFH) (CCFH50; 12 to 16 November 2018)\(^1\), the Committee agreed to include the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods (CXG 61-2007)*\(^2\) in the forward workplan in response to information from recent outbreaks. During CCFH51 (4 to 8 November 2019)\(^3\), the Food and Agriculture Organization of the United Nations (FAO) Representative informed the committee of the plan to host a Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) on *Listeria monocytogenes* in 2020 as this would help to inform possible future revision of CXG 61-2007.

2. From 20 October to 6 November 2020, a virtual meeting of JEMRA on *Listeria monocytogenes* in ready-to-eat (RTE) foods: attribution, characterization and monitoring, principally recommended expanding future risk assessments on *L. monocytogenes* in RTE foods to diverse commodity sub-groups, incorporating a primary-production-to-consumption perspective, and reviewing groupings of susceptible populations. The final report which focuses on the deliberations and conclusions of the expert meeting (Microbiological Risk Assessment (MRA) Series No. 38; MRA38)\(^4\) was published on 14 December 2022.

3. CCFH52 (28 February to 4 March and 9 March 2022)\(^5\) supported the proposal that JEMRA further undertake full farm to table risk assessments of *L. monocytogenes* in foods to inform a possible revision of the CXG 61-2007. As such, JEMRA convened two meetings, one each in 2022 and 2023, for the preparation and development of these risk assessments.

4. At CCFH53 (29 November to 2 December 2022)\(^6\), the forward work plan was revised to reflect the intent of Canada, France and the United States of America to develop a discussion paper on the possible revision of CXG 61-2007 for consideration at CCFH54 (11 to 15 March 2024).

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\(^1\) REP19/FH paragraph 78
\(^3\) REP20/FH paragraph 13
\(^5\) REP22/FH paragraph 105ii
\(^6\) REP23/FH paragraph 151
BACKGROUND

Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment

5. The FAO and World Health Organization (WHO) have undertaken risk assessments of *L. monocytogenes* in various foods since CCFH first requested a risk assessment in 2000. Since the publication of the FAO/WHO risk assessment in 2004 (MRA4 and MRA5), outbreaks of listeriosis continue to occur across the globe associated with previously reported foods, but also with many previously unreported food vehicles, including fresh and minimally processed fruits and vegetables. As such, an updated risk assessment that considers an examination of produce vehicles from primary production to consumption is needed.

6. During the JEMRA meeting (Part 1 expert meeting on risk assessment) convened in Rome, Italy from 24 to 28 October 2022, the expert group elaborated formal models for the risk assessment of *L. monocytogenes* for lettuce, cantaloupe, frozen vegetables and RTE fish and concluded that these models should be programmed, tested and reviewed. From 29 May to 2 June 2023, an additional JEMRA meeting (Part 2 expert meeting on risk assessment) was convened in Geneva, Switzerland. Several risk assessment models were developed and evaluated to characterize the risk of listeriosis due to the consumption of diced RTE cantaloupe, frozen vegetables, and cold-smoked RTE fish. A full report of the meetings will be published as part of the FAO and WHO MRA Series. Furthermore, recommendations and considerations have been made to inform a possible revision of CXG 61-2007.

The Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods (CXG 61-2007)

7. The current CXG 61-2007 was adopted in 2007, with the primary purpose of minimising the likelihood of illness arising from the presence of *L. monocytogenes* in RTE foods. CXG 61-2007 is intended for RTE foods and is applicable throughout the food chain, from primary production to consumption.

8. CXG 61-2007 contains three annexes, two of which (Annexes II and III) were adopted in 2009: Recommendations for an Environmental Monitoring Program for *Listeria monocytogenes* in Processing Areas (Annex I), Microbiological Criteria for *Listeria monocytogenes* in Ready-to-Eat Foods (Annex II) and Recommendations for the Use of Microbiological Testing for Environmental Monitoring and Process Control Verification by Competent Authorities as a Means of Verifying the Effectiveness of HACCP and Prerequisite Programs for Control of *Listeria monocytogenes* in Ready-to-Eat Foods (Annex III).

ANALYSIS

9. An analysis was conducted of the current texts in CXG 61-2007, the scientific advice provided by JEMRA (MRA38), and the summary and conclusions of the two JEMRA meetings in 2022 and 2023. The results of this analysis are provided in Appendix 1, Part 1 of this document. This analysis identified several themes on which the information provided in CXG 61-2007 could be revised and updated. Further to the advice provided by JEMRA, additional elements for the possible revision of CXG 61-2007 have been proposed in Appendix 1, Part 2 for consideration by CCFH54.

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RECOMMENDATIONS

10. Based on the above-mentioned analysis and the potential revisions that have been identified in Appendix 1, it is recommended that CCFH undertake new work to revise and update the appropriate text in CXG 61-2007. A project document for this work is provided in Appendix 2 for consideration by CCFH54.
Appendix 1

This Appendix identifies areas of the current CXG 61-2007 text that could be updated and revised to reflect the information provided by JEMRA in MRA38, as well as the summary and conclusions of the subsequent JEMRA meetings in 2022 and 2023. Furthermore, it includes additional considerations for the possible revision of CXG 61-2007.

Part 1: Results of the analysis comparing the text of CXG 61-2007 with information provided by the JEMRA

Scope of document

- **New notable outbreaks**: The list of recent food vehicles linked to listeriosis outbreaks since the latest publication of CXG 61-2007 should be updated.

- **Primary production**: As primary production has an impact on the risk of *L. monocytogenes* in foods, CXG 61-2007 should recognize the full primary-production-to-consumption continuum.
  
  o Information about the introduction of *L. monocytogenes* in raw materials being affected by the following should be considered:
    
    ▪ Season
    
    ▪ Agrifood practices (e.g., irrigation, fertilization, use of water and sanitizers) in respective farms (field, controlled environment, hydroponics, open sea, aquaculture)
    
    ▪ Climatic changes (e.g., extreme weather events) during farming and harvesting
  
  Food business operators could then assess their specific situation and, as needed, put in place effective control measures
  
  o The final decision of whether recommendations for primary production are to be included in a separate Annex or by modifying and/or expanding the existing Annexes I and III should be made during the revision of CXG 61-2007.

Control measures

- CXG 61-2007 would benefit from giving consideration to the entire primary-production-to-consumption continuum via the incorporation of any new pertinent information regarding the following factors, which could impact the risk of *L. monocytogenes* in food:
  
  o Contamination of raw materials
  o Climatic changes
  o Time-temperature control and profiles
  o Environmental hygiene practices
  o Water management
  o Cross-contamination
  o Sampling schemes, including during processing
  o Consumers’ practices related to handling and storage

- Given that the implementation of a comprehensive and effective food safety management system is key in proactively managing and controlling *L. monocytogenes* in foods (including those foods that do not support growth), the importance of the environmental monitoring program should be added.

- Assessing incursions and persistence in processing facilities should be stressed during environmental monitoring.

- Source tracing and root cause analysis should be considered as recommended actions in response to positive test results.
Advances in technology

- Since the publication of CXG 61-2007, new technologies and methods have been developed and should now be recognized, stressing that they should be validated so that they are fit-for-purpose and provide reliable results to support an effective food safety management system:
  - Emerging methods (e.g., for rapid confirmation) should be used to complement conventional cultural methods, especially during a food safety event.
  - In the context of monitoring and surveillance, characterizing human, food and environmental isolates (e.g., subtyping WGS) obtained from standardized and validated cultural method would be best practice. Data should be retained in a database, used in trend analysis, and shared for risk assessment.
  - The recovery of sub-lethally injured cells from food and environmental samples should be considered.

Tools for informing risk management strategies

- Microbiological criteria: Tables 1 and 2 in Annex II should be reviewed for clarity and precision, considering specific recommendations by JEMRA (Part 1 meeting, 2022).
- New risk assessments models: From October 2022 to June 2023, JEMRA developed risk assessment models from primary production to consumption, which are to be used to assess the risk of *L. monocytogenes* in various food commodities. Namely, models on diced RTE cantaloupe, frozen vegetables and cold-smoked fish have been developed. As these models have been implemented with open-source software and are intended to be made publicly available, their reference in CXG 61-2007 should be considered as they could be used to inform local risk management strategies.
- Networks: In the context of recalls in the worldwide food trading environment, a reference to the International Food Safety Authorities Network (INFOSAN), the global network of national food safety authorities managed jointly by the FAO and WHO, should be added to CXG 61-2007. This international network is key in efficiently exchanging information to mitigate the risks posed by unsafe foods during food safety events.

Role/impact of consumers

- Factors impacting the risk of listeriosis: CXG 61-2007 should recognize that the following factors could also impact the risk of listeriosis differently in various regions of the world:
  - Social, administrative and economic issues
  - Access to healthcare and surveillance of infectious diseases
  - Behavioural and cultural factors
  - Burden of other diseases or underlying health issues
- Underlying health conditions for population at risk: As an update to the dose-response model was performed, new information about the relative risk associated with invasive listeriosis in different subpopulations was estimated. These subpopulations should be mentioned in the updated CXG 61-2007 so those at-risk population can be recognized.
- Varying practices: CXG 61-2007 should clearly recognize that risk reduction is the responsibility of the food industry and government, but it is as well one of consumers. As such, it should be recognized that:
  - The same product may be subjected to different marketing practices
  - Continued efforts to minimize confusion and misunderstanding of labels by consumers are needed to improve food safety
  - Consumers’ practices can vary from the original intent of the manufacturer (e.g., storage, further preparation), so this should be considered in the context of enhanced and targeted risk communication (e.g., better labelling and targeted consumer education)
  - At-risk populations should specifically be advised to seek lower risk alternatives to high-risk foods to maintain a healthy diet
Part 2: Additional considerations for the possible revision of CXG 61-2007

Potential addition of new concepts

- The impact that intended consumers of RTE foods may have on monitoring programs and microbiological criteria should be considered:
  - It is recognized that invasive listeriosis disproportionally affects vulnerable populations
  - As per the General Principles of Food Hygiene (CXC 1-1969), food business operators could include in their product description that the food is specifically intended for vulnerable consumer groups. As such, these specific intended consumers, when identified (e.g., RTE foods that will be consumed in a hospital setting, convalescent care centres, long-term care facilities), could impact the monitoring program (e.g., frequency of testing) and the microbiological criteria of the RTE food.
  - As an example, the application of the microbiological criterion in Table 2 of CXG 61-2007 (i.e., for RTE foods in which growth of *L. monocytogenes* can occur) along with increased monitoring frequency could be further discussed for RTE foods specifically produced for consumption by vulnerable populations.
- In the context of frozen RTE foods, the impact that labelling may have on monitoring programs and microbiological criteria should be considered:
  - It is recognized that thawing times and temperatures as well as refrigerated shelf-life after thawing may impact the growth of *L. monocytogenes* prior to consumption.
  - As an example, the impact of labelled handling instructions regarding thawing of frozen RTE foods and refrigerated shelf-life after thawing could be considered in the context of monitoring frequency and the application of microbiological criteria.

Proposed expansion of existing text and other considerations

- Update of the introduction section
  - The possibility of chronic effects from listeriosis should be recognized.
  - Since the adoption of CXG 61-2007, new information has been published on the incidence of listeriosis in various jurisdictions. Data from these reports should be reflected in the new work.
  - Factors contributing to the risk of listeriosis should be expanded upon:
    - Extent of contamination
    - Potential growth of *L. monocytogenes*
    - Consumer’s practices which may deviate from the intended use of the food
- The responsibilities of manufacturers of “second-generation” RTE foods (e.g., businesses that use RTE foods as initial ingredients for the manufacturing, processing, preparation or preservation of their own RTE foods, including businesses that solely perform re-packing) and applicable control measures could be recognized
- The following could be considered in the context of an effective environmental monitoring program:
  - Reinforcement of the importance of testing for *Listeria spp.*
  - Additional considerations when testing for *L. monocytogenes*
  - Expansion of recommendations for data management
- The importance of reacting to positive environmental testing results in a timely manner, and verifying corrective actions to confirm their effectiveness should be recognized
- The ability of the food to support the growth of *L. monocytogenes* as a factor that will affect the action(s) taken in case of positive environmental testing results could be considered
- The means of communication, e.g., social networks, delivered by medical staff, should be considered in the context of enhanced and targeted risk communication to consumers
• The examples provided in Annex II of categories of products for which testing against microbiological criteria for *L. monocytogenes* may not be useful would benefit from being reviewed

• Guidance to assist in determining RTE foods in which the growth of *L. monocytogenes* can occur, or will not occur, should be referenced (e.g., challenge tests, etc)

• In the context of microbiological criteria for RTE foods (Annex II), the reference about “national governments providing or supporting the provision of guidance regarding the degree to which compositing of samples can be employed” could be:
  - Re-assessed in the context of Table 1 (superscript a) for RTE foods in which growth of *L. monocytogenes* will not occur, as the compositing of analytical units when using an enumerative method may not be appropriate.
  - Re-assessed in the context of Table 2 (m) for RTE foods in which growth of *L. monocytogenes* can occur, i.e., consider removing “(< 0.04 cfu/g)”, as it may raise confusion if compositing of samples is employed

• Alignment of terminology
  - For consistency and improved clarity, the refinement of terminologies within CXG 61-2007 and alignment with other Codex standards and related texts should be considered
  - For ease of understanding, a plain language review of CXG 61-2007 should be performed for clarity and conciseness
Project Document

NEW WORK PROPOSAL FOR THE REVISION OF THE GUIDELINES ON THE APPLICATION OF GENERAL PRINCIPLES OF FOOD HYGIENE TO THE CONTROL OF LISTERIA MONOCYTogenES IN FOODS (CXG 61-2007)

1. **Purpose and scope of the standard**

The purpose and scope of the work is to revise and update the *Guidelines on the Application of General Principles of Food Hygiene to the Control of Listeria monocytogenes in Foods* (CXG 61-2007) to provide advice to governments on a framework for the control of *L. monocytogenes* in ready-to-eat foods. Furthermore, as everyone has a role to play in reducing the risk of foodborne listeriosis, CXG 61-2007 will also provide information to food business operators and consumers to this end. This revision will be mainly based on the latest scientific advice from JEMRA and will incorporate relevant aspects of the revision of *General Principles of Food Hygiene* (CXC 1-1969).

The original intent of CXG 61-2007 will not change.

2. **Relevance and timeliness**

In 2020, a virtual meeting of the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) reviewed recent data on *L. monocytogenes* to assess the need to modify, update, or develop new risk assessment models and tools for this pathogen. A public call for data and experts was issued in 2019 to support this work.

A full report of the meeting entitled “*Listeria monocytogenes* in ready-to-eat (RTE) foods: attribution, characterization and monitoring” was published in 2022 (Microbiological Risk Assessment (MRA) Series No. 38; MRA38) principally recommending expanding future risk assessments on *L. monocytogenes* in RTE food to diverse commodity sub-groups, incorporating a primary-production-to-consumption perspective, and reviewing groupings of susceptible populations. Several critical gaps in the current JEMRA risk assessment model were identified and the expert group collectively agreed that updating the model would be valuable for informing risk analysis strategies, including in low- and middle-income countries.

At the 52nd session of the Codex Committee on Food Hygiene (CCFH52) in 2022, the Committee supported the proposal that JEMRA undertake full primary-production-to-consumption risk assessments of *L. monocytogenes* in foods. In response, a second call for data and experts was issued on 29 April 2022 to inform two meetings, one each in 2022 and 2023. Summaries and conclusions of the meetings were published thereafter, which included recommendations and considerations to inform a possible revision of CXG 61-2007. A full report of the meetings on microbiological risk assessment of *L. monocytogenes* in foods is still pending publication.

New scientific information provided by JEMRA justifies the need and timeliness of the revision of CXG 61-2007. While the fundamental principles in the original CXG 61-2007 are likely to largely remain the same, an update to CXG 61-2007 will continue to provide current advice to governments on a framework for the control of *L. monocytogenes* in RTE foods, with a view towards protecting the health of consumers and ensuring fair practices in food trade.

3. **Main aspects to be covered**

The new work is intended to update CXG 61-2007 based on the latest scientific information. CXG 61-2007 will provide advice to governments on a framework for the control of *L. monocytogenes* in RTE foods. It will also provide information that will be of interest to the food industry, consumers, and other relevant parties. To reduce the risk of foodborne listeriosis, everyone has a role to play.

The new work should consider various factors relevant to the control of *L. monocytogenes*, including:

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Activities at primary production, including the need for food business operators (including primary producers) to apply effective control measures as appropriate to their operations

New and pertinent information to be considered throughout the primary-production-to-consumption continuum regarding resource management, time-temperature control, environmental hygiene practices, and climate change

Microbiological monitoring methods, particularly molecular- or genomic-based approaches as complements to conventional cultural methods

Consumer practices and the relevance of factors impacting listeriosis risk among different regions of the world including underlying health conditions, socio-economic factors, as well as behavioural and cultural factors

Other recently available scientific information, including new risk assessment models and listeriosis outbreaks

4. An assessment against the Criteria for establishment of work priorities

General criterion

Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries

The proposed new work will broadly support competent authorities and food business operators in implementing control measures against *L. monocytogenes*, which is a worldwide microorganism of public health significance in RTE foods.

Criteria applicable to general subjects

Diversification of national legislations and apparent resultant or potential impediments to international trade

The large scope of food covered under CXG 61-2007 suggests a global impact to food trade. The updated CXG 61-2007 is anticipated to assist countries in the adoption of practices to reduce the risk of listeriosis and support international fair trade practices.

Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)

JEMRA has already initiated work on *L. monocytogenes* in food. The Terrestrial Manual of the World Organization for Animal Health (WOAH) includes a chapter (Chapter 3.10.5) dedicated to the detection and identification methods for *L. monocytogenes* (last revisions in May 2021).

Consideration of the global magnitude of the problem or issue

Listeriosis cases have been reported widely around the world, hence making this a global concern. There are multiple venues throughout the primary-production-to-consumption continuum by which a wide range of food can be contaminated by *L. monocytogenes*. CXG 61-2007 is key in supporting the reduction of the public health burden of listeriosis.

5. Relevance to the Codex strategic objectives

The proposed work directly relates to the following goals from the *Codex Strategic Plan 2020–2025*.

**Goal 1: Address current, emerging and critical issues in a timely manner**

The review and update of CXG 61-2007 is in response to recommendations by JEMRA, as indicated in MRA38 and in response to recent information that impacts the control of *L. monocytogenes* in RTE foods. This work will address the gap in guidance, in particular related to primary production.

**Goal 2: Develop standards based on science and Codex risk-analysis principles**

Following scientific recommendations from JEMRA, the review and update of CXG 61-2007 has been flagged to provide current advice for the control of *L. monocytogenes* in RTE foods throughout the entire food chain. CXG 61-2007 will continue providing important principles to consider in reducing the risk of listeriosis which can be implemented through food safety control systems. During this review process, developments in recently available scientific information will be considered with input from member countries.

**Goal 3: Increase impact through the recognition and use of Codex standards**
The practical use of science-based Codex standards and related texts in food trade contributes to a high level of food safety. The update and review of CXG 61-2007 should promote better understanding and application of their principles internationally.

**Goal 4: Facilitate the participation of all Codex Members throughout the standards setting process**

The review and update of CXG 61-2007 should generate interest and participation and will be open to all Members in order to obtain constructive and relevant contributions.

**Goal 5: Enhance work management systems and practices that support the efficient and effective achievement of all strategic plan goals**

The consensus-driven review and update of CXG 61-2007 will be performed effectively and with transparency for timely adoption. Initial discussions are likely to take place through an electronic working group (EWG) to establish a framework and approach in undertaking the update. Wide participation will be encouraged as free web-based technologies will be used. Translation of the latest versions of the texts, to the official languages of the Committee, will be performed ahead of the annual Committee meetings.

6. **Information on the relation between the proposal and other existing Codex documents as well as other ongoing work**

The review of CXG 61-2007 will complement existing CCFH texts. As such, the updated CXG 61-2007 will consider, for example, the 2022 revision to *General Principles of Food Hygiene* (CXC 1-1969) and the 2013 revision to the Guidelines - *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997) to refer to the latest information and provide special attention related to *L. monocytogenes* in RTE food, as needed.

7. **Identification of any requirement for and availability of expert scientific advice**

Given that JEMRA have already provided recommendations for the update of CXG 61-2007, these will be used as the basis for the work. To maintain consistency among all existing CCFH texts that reference the *General Principles of Food Hygiene* (CXC 1-1969), CCFH will likely engage with the Members that are leading the review and update of these documents and also take into consideration the ongoing work on the alignment of CCFH developed texts with the *General Principles of Food Hygiene* (CXC 1-1969).

8. **Identification of any need for technical input to the standard from external bodies so that this can be planned for**

Additional scientific expert advice is not anticipated.

9. **Proposed timeline for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years**

Provided the new is agreed upon by CCFH54 in 2024 and approved by CAC47 in 2024, conceivably it could be considered at Step 4 by CCFH55 depending on the timing of this meeting, followed by Steps 5 and 8 by CCFH56 and CCFH57 respectively. The timeline, i.e., within 3 sessions of CCFH, is envisioned since scientific advice from JEMRA is close to completion.