CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda item 8 **CX/FH 19/51/8**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FOOD HYGIENE
Fifty-first Session
Cleveland, Ohio, United States of America, 4 - 8 November 2019

PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING *ESCHERICHIA COLI* (STEC) IN BEEF MEAT, LEAFY GREENS, RAW MILK AND CHEESE PRODUCED FROM RAW MILK, AND SPROUTS

Prepared by the Electronic Working Group co-chaired by Chile and the United States of America

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2019/72-FH available on the Codex webpage/Circular Letters 2019:

http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/.

INTRODUCTION

1. At the 50th Session of the Codex Committee on Food Hygiene (CCFH50)[1], Chile, the United States of America, and Uruguay introduced a discussion paper and project document on Control of Shiga Toxin-Producing *Escherichia coli* (STEC) in Beef, Unpasteurized Milk and Cheese produced from Unpasteurized Milk, Leafy Greens, and Sprouts. The discussion paper and project document were discussed at the Physical Working Group on CCFH Work Priorities at CCFH50, where delegations agreed the work was important and recommended that CCFH take on development of these guidelines as new work.

2. CCFH50 agreed to taking on this new work and that the structure of the document should include overarching guidance followed by commodity-specific guidance. CCFH50 recommended revising the project document to reflect that the guidelines should be developed using a step-wise approach, with beef meat and leafy greens being the first priorities. CCFH50 also agreed to replace the term “unpasteurized milk” with “raw milk” to avoid confusion with milk that may have received a thermal treatment but not pasteurization.

3. CCFH50 agreed to submit a revised project document to the 42nd session of the Codex Alimentarius Commission (CAC42) for approval as new work and to establish an EWG, co-chaired by Chile and the United States of America, working in English and Spanish, to prepare, subject to the approval of the Commission, the proposed draft guidelines for circulation for comments at Step 3 and consideration at CCFH51.

4. CAC42[2] approved the new work in July 2019.

Work of the EWG

5. An invitation was sent to all Codex members and observers to participate in the EWG. Participants from 41 Codex member countries, one Member Organisation and 10 Observer Organisations were registered as participants of the EWG. The list of Participants is attached as Appendix II. The EWG work was conducted on line using the Codex Alimentarius Forum.

6. A first draft of the General Section in English was posted on the Forum May 31 (July 3 in Spanish) and a draft of the beef annex was posted June 13 (English) and July 3 (Spanish). The draft annex on fresh leafy green vegetables was not completed in time to post for EWG input.

7. The draft is generally based on the format of the *Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork Meat* (CXG 87-2016). The General section provides an introduction describing STEC, illnesses and the primary sources. It indicates the purpose is to provide information on control of STEC for the specified commodities to inform risk management decisions. It contains sections on Scope and Use, Definitions, principles for applying control measures, general control measures, and their implementation. Annex I addresses specific aspects of STEC control for beef meat, using the flow diagram for beef from (CAG 87-2016). In the annex the Chairs asked for input from the EWG on a number of issues, including the approach for the annexes, whether certain sections (such as validation, monitoring, verification and

[1] REP19/FH, para 76
[2] REP19/CAC, para 96 and Appendix V

laboratory analysis) should be moved to the General section because they apply to multiple commodities, whether the control measures should be organized based on the steps in the flow diagram at which they could be applied, and whether the control measures should be designated as GHP-based or risk-based. Annex 2 for fresh leafy green vegetables follows a format similar to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003). The approach for formatting the annexes should be addressed by CCFH51.

8. Comments were received from 12 countries, one Member Organisation and one Observer Organisation. A number of comments requested that the Introduction provide more detail on illness symptoms, virulence factors and risk; indicate that the primary source of STEC be specified as ruminants; and clarify certain statements related to verification. A number of comments addressed definitions, including revising the definition of STEC, using the definition of raw milk from the milk code, moving certain definitions (i.e., cattle, lairage) to the appropriate annex when they are not used in the General section, and deletion of the definition of raw milk cheese. A number of comments support moving the verification, validation and laboratory analysis sections to the General section, but they noted that where there are aspects of these specifically related to a commodity in an annex, this information should be included in the annex for the commodity. Based on comments related to sampling and testing, a paragraph on the limitations due to typically low levels and low prevalence of STEC and the use of indicator organisms, supplemented with periodic testing for STEC, has been included. Several comments support the inclusion of consumers section. Sections related to training and product information have also been included.

9. Based on the comments received, the Chairs have revised the General section and the Beef Meat annex. A new annex on Fresh Leafy Green Vegetables has been included. We have used the term “fresh leafy green vegetables” in that annex rather than “leafy greens” (since it seems more descriptive of the products of concern); the Committee should determine if that term is acceptable or another one is preferred.

RECOMMENDATIONS

10. The EWG recommends that CCFH51 consider the proposed draft Guidelines as presented in Appendix I: General Section and the annexes on Raw Beef Meat and Fresh Leafy Green Vegetables.

APPENDIX I

GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING *E. COLI* (STEC) IN BEEF MEAT, LEAFY GREENS, RAW MILK AND CHEESE PRODUCED FROM RAW MILK, AND SPROUTS

(Request for comments at Step 3 through CL 2019/72-FH)

1. INTRODUCTION

1. Shiga toxin-producing *Eschericia coli* (STEC)[3] are increasingly recognized as foodborne pathogens of concern, causing human illnesses with a range of mild to severe gastrointestinal presentations, occasionally leading to severe haemolytic uremic syndrome with kidney failure and death. The burden of the disease and the cost of control measures are significant; the pathogen has been associated with diverse commodities, and these associations appears to be regional, and thus STEC have the potential to disrupt trade between countries.

2. Most clinical symptoms of the disease in humans arise as a consequence of the production of Shiga-toxin type 1 (*stx*1), type 2 (*stx*2) or a combination of these genes. An adherence gene, Intimin, encoded by *eae* and a plasmid-encoded enterohemolysin (*ehx*A) has been used as a possible epidemiological marker for pathogenic STEC. These virulence genes and the O157:H7 specific single-nucleotide polymorphism (SNP) at position +93 of the *uid*A housekeeping gene (+93 *uid*A) have been related to assess the potential pathogenicity of STEC isolates. It must be pointed out that additional adherence genes such as *aggR* have been identified as associated with causing illness. These genes are mobile and can be transmitted to related organisms or be lost. Symptoms and their severity are determined by the variability in these genes. Because STEC are primarily a genotype-based hazard, this has implications for hazard identification and characterization, which will be discussed in this Guidance document. The utility of genotyping, serotyping and culture-based detection in hazard identification and characterization will also be discussed in this document.

3. While historically STEC illnesses have been linked to the consumption of undercooked beef products, leafy greens, sprouts, and dairy products have been increasingly recognized as at-risk commodities. Sources of STEC in these foods can vary, as does the ability of the organism to persist, survive and multiple within them. This guidance document will identify commodity-specific practices for source attribution in these different foods, and practices for monitoring STEC in perishable and shelf-stable products and the utility of indicators. STEC illnesses have also been linked to flour, seafood and vine-stalk vegetables. It is not yet clear whether these foods are significant emergent sources of individual illnesses or outbreaks. The association of specific food categories with STEC illness reflects the historical and current practices of food production, distribution and consumption. Changes in food production, distribution and consumption can cause changes in STEC exposure. Consequently, microbial risk management should be informed by an awareness of current local sources of STEC exposure.

4. It is generally accepted that animals, in particular ruminants, are the primary source of STEC. STEC-positive ruminants are typically asymptomatic. Contamination with intestinal content or feces is the likeliest ultimate source of STEC in most foods. STEC outbreaks associated with field-grown leafy greens have been linked to contaminated irrigation water. Raw milk is most commonly contaminated as a result of soiled udders and teats as well as poor hygiene at processing. [Note to EWG – this paragraph needs to be expanded on sources and to include the other commodities.]

5. The large degree of variation exhibited by STEC in their biological properties, host preferences, and environmental survival presents a particular challenge for controlling the presence of STEC in animal and plant production. In practice, this means that there is no “one size fits all” solution, and different production systems may require different approaches to control the various serovars of STEC.

6. These Guidelines apply a risk management framework (RMF) approach as advocated in Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CAC/GL 63-2007). “Preliminary Risk Management Activities” and “Identification and Selection of Risk Management Options” are represented by the guidance developed for control measures at each step in the food chain. The following sections on “Implementation” and “Monitoring” complete the application of all the components of the RMF.

7. The Guidelines build on general food hygiene provisions already established in the Codex system and propose potential control measures specific for STEC strains of public health relevance in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts. In this context, the Codex

[3] Human pathogens of public health relevance only. For the purposes of this document, all references to STEC relate only to human pathogens.

Alimentarius Commission (CAC) is committed to develop standards that are based on sound science[4]. Potential control measures for application at single or multiple steps of the food chain are presented in the following categories:

- Good hygienic practice (GHP) – based: They are generally qualitative in nature and are based on empirical scientific knowledge and experience. They are usually prescriptive and may differ among countries.
- Hazard – based: They are developed from scientific knowledge of the likely level of control of a hazard at a step (or series of steps) in a food chain. They are based on a quantitative base estimate in the prevalence and/or concentration of STEC and can be validated as to their efficacy in hazard control at a specific step. The benefit of a hazard-based measure cannot be exactly determined without a specific risk assessment; however, any significant reduction in pathogen prevalence and / or concentration is expected to provide a certain level of human health benefit.

8. Examples of control measures in each commodity specific annex that are based on quantitative levels of hazard control have been subjected to a rigorous scientific evaluation in development of the Guidelines. Such examples are illustrative only and their use and approval may vary amongst member countries. Their inclusion in the Guidelines illustrates the value of a quantitative approach to hazard reduction throughout the food chain.

9. The Guidelines are presented in a flow diagram format so as to enhance practical application of a primary production-to-consumption approach to food safety.

10. This format:

- Provides an opening general section to provide STEC guidance applicable to all commodities and provides a format for the sections in each commodity specific annex.
- Demonstrates the range of the approaches of control measures for STEC.
- Illustrates relationships between control measures applied at different steps in the food chain.
- Highlights data gaps in terms of scientific justification / validation for control measures.
- Facilitates development of hazard analysis and critical control points (HACCP) plans at individual establishments and at national levels.
- Assists in judging the equivalence[5] of control measures for beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts applied in different countries.
- Illustrates the interdependent relationship between Codex guidelines and OIE standards throughout the food chain. These Guidelines do not deal with matters of animal health unless directly related to food safety or suitability. [Note – inclusion of this bullet may be dependent on OIE taking up work on STEC.]

In doing so, the Guidelines provide flexibility for use at the national (and individual processing) level.

2. OBJECTIVES

11. These Guidelines provide information to governments and industry on the control of STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts that aim to reduce foodborne disease whilst ensuring fair practices in the international food trade. The Guidelines provide a scientifically sound international tool for robust application of GHP- and hazard-based approaches for control of STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts according to national risk management decisions. The control measures that are selected can vary between countries and production systems.

12. The Guidelines do not set quantitative limits for STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts in international trade. Rather, the Guidelines follow the examples of the overarching *Code of Hygienic Practice for Meat* (CXC 58-2005) and *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) and provide an "enabling" framework which countries can utilize to establish control measures appropriate to their national situation.

[4] Strategic Goal 2 of the Strategic Plan of the Codex Alimentarius Commission is to "Ensure the application of risk analysis principles in the development of Codex standards" and the CAC Procedural Manual states that "Health and safety aspects of Codex decisions and recommendations should be based on a risk assessment, as appropriate to the circumstances".

[5] *Guidelines on the Judgement of Equivalence of sanitary Measures Associated with Food Inspection and Certification Systems* (CXG 53-2003)

3. SCOPE AND USE OF THE GUIDELINES

3.1. Scope

13. These Guidelines are applicable to public health relevance STEC that may contaminate raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts and cause foodborne disease. The primary focus is to provide information on practices that may be used to prevent, reduce, or eliminate STEC in raw beef meat[6], leafy greens, raw milk and cheese produced from raw milk, and sprouts. Other measures, in addition to those described here, may be needed to control STEC in offal.

14. These Guidelines in conjunction with the relevant OIE (World Organisation for Animal Health) standards can apply from primary production-to consumption for raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts produced in commercial production systems.

3.2. Use

15. The Guidelines provide specific guidance for control of STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts according to a primary production-to-consumption food chain approach, with potential control measures being considered at each step, or group of steps, in the process flow. The Guidelines are supplementary to and should be used in conjunction with the General Principles of Food Hygiene (CXC 1-1969), the Code of Hygienic Practice for Meat (CXC 58-2005), the Code of Practice on Good Animal Feeding (CXC 54-2004), Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003), Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004), and the Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008).

16. These general and overarching provisions are referenced as appropriate and their content is not duplicated in these Guidelines.

17. The primary production section of these Guidelines is supplementary to and should be used in conjunction with relevant chapters of the OIE Terrestrial Animal Health Code[7]. [OIE has indicated they will take up work in this area in conjunction with this work]

18. The Guidelines systematically present GHP-based control measures. GHPs are prerequisites to making choices on hazard-based control measures. Hazard-based measures will likely vary at the national level and therefore these Guidelines only provide examples of hazard-based controls. Examples of hazard-based control measures are limited to those that have been scientifically demonstrated as effective. Countries should note that these hazard-based control measures are indicative only. The quantifiable outcomes reported for control measures are specific to the conditions of particular studies and would need to be validated under local commercial conditions to provide an estimate of hazard reduction[8]. Government and industry can use choices on hazard-based control measures to inform decisions on critical control points (CCPs) when applying HACCP principles to a particular food process.

19. Several hazard-based control measures as presented in these Guidelines are based on the use of physical, chemical and biological decontaminants to reduce the prevalence of STEC-positive carcasses and/or their concentration on positive carcasses from slaughtered cattle. The use of these control measures is subject to approval by the competent authority, where appropriate, and varies based upon the type of product being produced. Also, these Guidelines do not preclude the choice of any other hazard-based control measure that is not included in the examples provided herein, and that may have been scientifically validated as being effective in a commercial setting.

20. A provision of flexibility in application of the Guidelines is an important attribute. They are primarily intended for use by government risk managers and industry in the design and implementation of food safety control systems. The control measures are articulated in this guideline at appropriate steps; however, if they could be performed hygienically and effectively they could be applied in other steps in the food chain.

21. The Guidelines should be useful when comparing, or judging equivalence of, different food safety measures for beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts in different countries.

4. DEFINITIONS

Cattle: Animals of the species of *Bos indicus*, *Bos taurus*, and *Bubalus bubalis*.

Leafy Greens: Vegetables of a leafy nature where the leaf is intended for consumption.

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[6] *Code of Hygienic Practice for Meat* (CXC 58-2005)
[7] http://www.oie.int/en/international-standard-setting/terrestrial-code/access-online/
[8] FAO/WHO 2009. Risk characterization of microbiological hazards in food. Microbiological risk assessment series 17. Available at http://www.fao.org/docrep/012/i1134e/i1134e00.htm and http://www.who.int/foodsafety/publications/riskcharacterization/en/

Raw Milk: Milk which has not been pasteurized by heating beyond 40°C or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level.

Shiga Toxin-Producing E. coli (STEC): A large, highly diverse group of bacterial strains that are demonstrated to carry *stx* and produce Shiga toxin (Stx), pathogenesis to humans by entry into the human gut, attachment to the intestinal epithelial cells and production of Stx[9].

Sprouts: Germinated seeds used for human food.

5. PRINCIPLES APPLYING TO CONTROL OF STEC IN BEEF MEAT, LEAFY GREENS, RAW MILK AND CHEESE PRODUCED FROM RAW MILK, AND SPROUTS

22. Overarching principles for good hygienic practice for meat production are presented in the *Code of Hygienic Practice for Meat* (CXC 58-2005), Section 4: General Principles of Meat Hygiene. For fresh and fresh pre-cut leafy greens are presented in the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003), Annex I For Ready-To-Eat Fresh Pre-Cut Fruits and Vegetables, and Annex III on Fresh Leafy Vegetables. Two principles that have particularly been taken into account in these Guidelines are:

> a) The principles of food safety risk analysis should be incorporated wherever possible and appropriate in the control of STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts from primary production-to-consumption.
>
> b) Wherever possible and practical, competent authorities should formulate risk management metrics[10] so as to objectively express the level of control of STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts that is required to meet public health goals.

6. PRIMARY PRODUCTION-TO-CONSUMPTION APPROACH TO CONTROL MEASURES

23. These guidelines incorporate a “primary production-to-consumption” flow approach that identifies the main steps in the food chain where control measures for STEC may potentially be applied in the production of each commodity. The systematic approach to the identification and evaluation of potential control measures allows consideration of the use of controls in the food chain and allows different combinations of control measures to be developed and implemented. This is particularly important where differences occur in primary production and processing systems between countries. Risk managers need the flexibility to choose risk management options that are appropriate to their national context.

7. PRIMARY PRODUCTION CONTROL MEASURES

24. Controls in the primary production phase of the process flow can decrease the number of animals from carrying and/or shedding STEC as well as plants being contaminated with STEC on the farm.

8. PROCESSING CONTROL MEASURES

25. STEC controls during processing are important to prevent the contamination and cross contamination of commodities during processing.

9. DISTRIBUTION CHANNEL CONTROL MEASURES

26. STEC control measures during distribution are important to ensure product is stored at an appropriate temperature to prevent growth beyond a detectable level, minimize cross contamination, and provide consumers with the necessary product information to know the potential risk associated with the product and how to properly prepare the product for safety.

27. Specific control measures for STEC are described in each commodity-specific annex where appropriate. The raw beef meat specific control measures are found in Annex I; the leafy green are found in Annex II, the raw milk and cheese produced from raw milk are found in Annex III, and the sprouts are found in Annex IV.

10. CONTROL MEASURES

28. GHPs provide the foundation for most food safety control systems. Where possible and practicable, food safety control measures for STEC should incorporate hazard based control measures and risk assessment. Identification and implementation of risk-based control measures based on risk assessment can be elaborated by application of a risk management framework (RMF) process as advocated in the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007).

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[9] FAO/WHO (Food and Agriculture Organization of the United Nations/ World Health Organization). 2018. Shiga toxin-producing *Escherichia coli* (STEC) and food: attribution, characterization, and the monitoring the risk. http://www.fao.org/3/ca0032en/CA0032EN.pdf..

[10] *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007)

29. While these Guidelines provide generic guidance on development of GHP-based and hazard-based control measures for STEC, development of risk-based control measures for application at a single or at multiple steps in the food chain are primarily the domain of competent authorities at the national level. Industry may derive risk-based measures to facilitate application of process control systems.

10.1 Development of risk-based control measures

30. Competent authorities operating at the national level should develop risk-based control measures for STEC where possible and practical.

31. When risk-modelling tools are developed, the risk manager needs to understand the capability and limitations[11].

32. When developing risk-based control measures, competent authorities may use the quantitative examples of the likely level of control of a hazard in this document.

33. Competent authorities formulating risk management metrics[12] as regulatory control measures should apply a methodology that is scientifically robust and transparent.

11. IMPLEMENTATION OF CONTROL MEASURES

34. Implementation[13] involves giving effect to the selected control measure(s), development of implementation plan, communication on the decision on control measure(s), ensuring a regulatory framework and infrastructure for implementation exists, and a monitoring and evaluation process to assess whether the control measure(s) have been properly implemented.

11.1 Prior to Validation

35. Prior to validation of the hazard-based control measures for STEC, the following tasks should be completed:

- Identification of the specific measure or measures to be validated. This would include consideration of any measures agreed to by the competent authority and whether any measure has already been validated in a way that is applicable and appropriate to specific commercial use, such that further validation is not necessary.
- Identification of any existing food safety outcome or target, established by the competent authority or industry. Industry may set stricter targets than those set by the competent authority.

11.2 Validation

36. Validation of measures may be carried out by industry and/or the competent authority.

37. Where validation is undertaken for a measure based on hazard control for STEC, evidence will need to be obtained to show that the measure is capable of controlling STEC to a specified target or outcome. This may be achieved by use of a single measure or a combination of measures. The *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008) (Section VI) provides detailed advice on the validation process.

11.3 Implementation

38. Refer to the Section 9.2 of the *Code of Hygienic Practice for Meat* (CXC 58-2005), the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) and the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004).

11.3.1 Industry

39. Industry has the primary responsibility for implementing, documenting, applying and supervising process control systems to ensure the safety and suitability of raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts, and these should incorporate GHP and hazard-based measures for control of STEC as appropriate to national government requirements and industry's specific circumstances.

40. The documented process control systems should describe the activities applied including any sampling procedures, specified targets (e.g. performance objectives or performance criteria) set for STEC, industry verification activities, and corrective and preventive actions.

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[11] *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999)

[12] *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007)

[13] See Section 7 of the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007).

11.3.2 Regulatory systems

41. The competent authority should provide guidelines and other implementation tools to industry as appropriate, for the development of the process control systems.

42. The competent authority may assess the documented process control systems to ensure they are science based and establish verification frequencies. Microbiological testing programmes should be established for verification of HACCP systems where specific targets for control of STEC have been identified.

11.4 Verification of control measures

43. Refer to Section 9.2 of the *Code of Hygienic Practice for Meat* (CXC 58-2005), *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003), *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004), and Section IV of the Guidelines for the Validation of Food Safety Control Measures (CXG 69 -2008).

11.4.1 Industry

44. Industry verification should verify that all control measures for STEC have been implemented as intended. Verification should include observation of monitoring activities such as a program employee observing the monitor perform monitoring procedures at a specified frequency, documentary verification by reviewing monitoring and verification records, and sampling for STEC and other microbiological testing as appropriate.

45. Verification frequency should vary according to the operational aspects of process control, the historical performance of the establishment and the results of verification itself.

46. Record keeping is important to facilitate verification and for traceability purposes.

11.4.2 Regulatory systems

47. The competent authority and/or competent body should verify that all regulatory control measures implemented by industry comply with regulatory requirements, as appropriate, for control of STEC.

12. MONITORING AND REVIEW

48. Monitoring and review of food safety control systems is an essential component of application of a riskmanagement framework (RMF)14. It contributes to verification of process control and demonstrating progress towards achievement of public health goals.

49. Information on the level of control of STEC at appropriate points in the food chain can be used for several purposes, e.g. to validate and/or verify outcomes of food control measures, to monitor compliance with hazard-based and risk-based regulatory goals, and to help prioritize regulatory efforts to reduce foodborne illness. Systematic review of monitoring information allows the competent authority and relevant stakeholders to make decisions in terms of the overall effectiveness of the food safety control systems and make improvements where necessary.

12.1 Monitoring

50. Monitoring should be carried out at appropriate steps throughout the food chain using a validated diagnostic test and randomized or targeted sampling as appropriate[15].

51. For instance, the monitoring systems for STEC and/or indicator organisms, where appropriate, in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts may include testing at the farm, animal level, in the slaughter and processing establishments, and the retail distribution chains where appropriate.

52. Regulatory monitoring programmes should be designed in consultation with relevant stakeholders, taking into account the most cost-efficient resourcing option for collection and testing of samples. Given the importance of monitoring data for risk management activities, sampling and testing components should be standardized on a national basis and be subject to quality assurance.

[14] See Section 8 of the *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63-2007).

[15] Refer to the relevant Chapters of the OIE Manual and Code on the OIE website: Manual of Diagnostic Tests and Vaccines for Terrestrial Animals at http://www.oie.int/en/international-standard-setting/terrestrial-manual/access-online/ and the OIE Terrestrial Animal Health Code at http://www.oie.int/en/international-standard-setting/terrestrialcode/access-online/.

53. The type of samples and data collected in monitoring systems should be appropriate for the outcomes sought. Enumeration and sub-typing of microorganisms generally provides more information for risk management purposes than presence or absence testing.

54. However, due to typically low levels and low prevalence of STEC in food, enumerative monitoring of STEC is impractical and the utility of presence/absence testing in monitoring process performance is also limited (FAO/WHO 2018). Consequently, for process performance monitoring enumeration of sanitary and hygiene indicator organisms may provide a more efficient and effective measure of controlling microbial contamination, including STEC, in the product and processing environment. Indicator monitoring can be supplemented by periodic testing for STEC.

55. Monitoring information should be made available to relevant stakeholders in a timely manner (e.g. to producers, processing industry, consumers).

56. Monitoring information from the food chain should be used to affirm achievement of risk management goals. Wherever possible, such information should be combined with human health surveillance data and food source attribution data to validate risk-based control measures and verify progress towards risk-reduction goals.

57. Activities supporting an integrated response include:

- Surveillance of clinical illness from STEC in humans
- Epidemiological investigations including outbreaks and sporadic cases

12.2 LABORATORY ANALYSIS CRITERIA FOR DETECTION OF STEC

58. The choice of analytical method should reflect not only the type of sample to be tested, but also the purpose for which the data collected will be used. The purpose of analysis for bacterial foodborne pathogens, including STEC, can be divided into the following categories:

- product batch or lot acceptance;
- process performance control to meet domestic food regulation;
- to meet market access requirements; and
- public health investigations.

59. The risk of severe illness from STEC infections is best predicted based on virulence factors (encoded by genes) identified for an STEC strain and should be used as an analysis criterion for detection of STEC in food samples. Based on current scientific knowledge, STEC strains with *stx2a* and adherence genes, *eae* or *aggR*, have the strongest potential to cause diarrhoea, bloody diarrhoea (BD), and haemolytic uremic syndrome (HUS). Strains of STEC with other *stx* subtypes may cause diarrhoea but their association with HUS is less certain and can be highly variable. Thus, to appropriately manage the risk of STEC in beef meat, tests that detect virulence factors such as these should be used. The risk of severe illness may also depend on virulence gene combinations and gene expression, the dose ingested, and the susceptibility of the human host, so a risk management framework should also be applied when laboratory methodologies for STEC detection are selected by countries.

60. The number of foods identified as a risk for STEC transmission has increased over time. Baseline studies and targeted surveys are conducted to provide prevalence data and identify risk factors along the food chain. These data, together with public health surveillance data, are used in risk assessments and risk profiles of STEC /food combinations to prioritize foods and STEC of the highest public health relevance.

Analytical methods should be chosen that are fit for purpose, that will provide answers to risk management questions, and that are within the resources of governments and industry (FAO/WHO STEC Expert Report, 2018).

61. A recommendation of a set of criteria that includes 5 risk levels (highest to lowest) based on virulence gene combinations, which can be used to identify risk management goals for STEC and the testing regimes that would be needed to monitor achievement of those goals is presented in the FAO/WHO Shiga toxin-producing *Escherichia coli* (STEC) and food: attribution, characterization, and monitoring expert report (FAO/WHO 2018).

Table 1 STEC virulence genes and the potential to cause diarrhoea (D), bloody diarrhoea (BD) and haemolytic uremic syndrome (HUS) *

LEVEL	**TRAIT (GENE)**	**POTENTIAL FOR**
1	stx_{2a} + *eae* or *aggR*	D/BD/HUS
2	stx_{2d}	D/BD/HUS**

3	*stx*$_{2c}$ + *eae*	D/BD^
4	*stx*$_{1a}$ + *eae*	D/BD^
5	Other *stx* subtypes	D^

* depending on host susceptibility or other factors; e.g.: antibiotic treatment

**association with HUS dependent on *stx*$_{2d}$ variant and strain background

^ some subtypes have been reported to cause BD, and on rare occasions HUS

12.3 Review

62. Periodic review of monitoring data at relevant process steps should be used to inform the effectiveness of risk management decisions and actions, as well as future decisions on the selection of specific control measures and provide a basis for their validation and verification.

63. Information gained from monitoring in the food chain should be integrated with human health surveillance, food source attribution data, and withdrawal and recall data, where available to evaluate and review the effectiveness of control measures from primary production to consumption.

64. Where monitoring of hazards or risks indicates that regulatory performance goals are not being met, risk management strategies and/or control measures should be reviewed.

12.4 Public health goals

65. Countries should consider the results of monitoring and review when revaluating and updating public health goals for control of STEC in foods, and when evaluating progress. Monitoring of food chain information in combination with food source attribution data and human health surveillance data are important components[16].

[16] International organizations such as WHO provide guidance for establishing and implementing public health monitoring programmes. WHO Global Foodborne Infections Network (GFN) http://www.who.int/gfn/en/

ANNEX 1: SPECIFIC CONTROL MEASURES FOR RAW BEEF MEAT

INTRODUCTION

1. Foodborne outbreaks of Shiga toxin-producing *Escherichia coli* (STEC) have historically been linked to meat products, in particular, beef meat, and more specifically to preparations such as ground raw or undercooked beef. STEC are commonly carried by cattle, with reported prevalence in faeces ranging from 0.3% to 27.8% of animals for STEC O157 and 3.6% to 19.4 % of animals for all STEC (Hussein and Bollinger, 2005). STEC shedding by individual cattle is transient and episodic (Williams et al., 2014; Williams et al., 2015), thus it appears that almost all cattle will carry and shed STEC at some time during their life. In addition, STEC are widespread within the farm environment, so it should be expected that a significant proportion of cattle arriving for slaughter will have hides contaminated to some extent with STEC. As with faecal prevalence, the prevalence of STEC on animal hides varies greatly among studies, with prevalence greater than 70% having been reported in some studies (Stromberg et al 2018).

2. Zoonotic pathogens such as STEC carried by cattle could be spread to carcasses during slaughter. The muscle tissue of healthy cattle is essentially sterile, with microbiota, potentially including STEC, transferred to carcass surfaces from the gastrointestinal tract or hide during the operations of dehiding, head removal, bunging and evisceration (Gill and Gill, 2012). STEC contamination of meat also potentially occurs during further processing, if the product comes into contact with contaminated surfaces. Generally, contamination is confined to the carcass surface and is not found in deep muscle tissues of intact beef.

3. Disputes in trade have arisen with respect to whether beef meat contaminated with certain strains of STEC is acceptable for consumption. The purpose of this guidance is to provide information on measures that can reduce contamination of beef meat with STEC and guidance on when beef meat contaminated with STEC should be considered fit for human consumption in order to minimize the potential for disputes and facilitate global trade.

1. SCOPE

4.This guidance applies to control of STEC in fresh beef meat, including cuts such as steaks and ground meat products.

2. DEFINITIONS

Beef meat: All parts of a cattle that are intended for, or have been judged as safe and suitable for, human consumption.

Carcass: The body of an animal after dressing.

Dressing: The progressive separation of the body of an animal into a carcass and other edible and inedible parts.

Fresh Meat: Meat that apart from refrigeration has not been treated for the purpose of preservation other than through protective packaging and which retains its natural characteristics.

Manufactured Meat Products: resulting from the processing of raw meat or from the further processing of such processed products, so that when cut, the cut surface shows that the product no longer has the characteristics of fresh meat.

Meat: All parts of an animal that are intended for, or have been judged as safe and suitable for, human consumption.

Meat hygiene: All conditions and measures necessary to ensure the safety and suitability of meat at all stages of the food chain. Meat preparation Raw meat which has had foodstuffs, seasonings or additives added to it.

Raw meat: Fresh meat, minced meat or mechanically separated meat.

3. PRIMARY PRODUCTION-TO-CONSUMPTION APPROACH TO CONTROL MEASURES

5. These Guidelines incorporate a “primary production-to-consumption” flow diagram that identifies the main steps in the food chain where control measures for STEC may potentially be applied in the production of beef meat. While control in the primary production phase can decrease the number of animals carrying and/or shedding STEC, controls after primary production are important to prevent the contamination and cross-contamination of carcasses and meat products. The systematic approach to the identification and evaluation of potential control measures allows consideration of the use of controls in the food chain and allows different combinations of control measures to be developed. This is particularly important where differ-

ences occur in primary production and processing systems between countries. Risk managers need the flexibility to choose risk management options that are appropriate to their national context.

6. STEC have a wide range of potential hosts (Persad and LeJeune, 2014), and STEC cells can potentially persist for over a year in the environment (Jang et al., 2017; Nyberg et al., 2019). These features of the ecology of STEC indicate that control strategies based on denying STEC access to hosts or habitat will be highly challenging to implement in a manner which reliably prevents exposure of cattle to STEC.

7. Interventions to control enteric pathogens should always be seen as part of an integrated food safety system that includes all the stages from "farm to fork." Measures to reduce STEC shedding or hide contamination prior to harvest have the potential to reduce environmental exposure to STEC and may improve beef meat safety, but they cannot prevent STEC contamination or compensate for poor hygiene practices during slaughter, processing and distribution. Conversely, there is evidence that the adoption of the best hygienic practices during slaughter and processing can minimise contamination with STEC and other enteric pathogens (Brichta-Harhay et al., 2008; Pollari et al., 2016). Consequently, the adoption of best practices for pre-harvest management of cattle should be promoted as a support to hygienic slaughter and processing.

8. Similarly, operations to decontaminate carcasses or beef meat cuts will be of limited effectiveness if poor hygiene practices during subsequent processing and distribution permit recontamination.

4. GENERIC FLOW DIAGRAM FOR APPLICATION OF CONTROL MEASURES

Process Flow Diagram 1: Primary Production-to-Consumption of Beef

9. These process steps are generic, and the order may be varied as appropriate. This flow diagram is for illustrative purposes only. For application of control measures in a specific country or an establishment, a complete and comprehensive flow diagram should be drawn up.

Process Flow Diagram: Primary Production to Consumption of Beef (from CXG 087)

1. Primary Production
2. Transport to Slaughter

Primary Production

3. Receive and Unload
4. Lairage and Ante morten inspection
5. Stunning
6. Sticking/Bleeding
7. Shackling
8. Dehiding
9. Head Removal/ Head Washing
10. Bunging
11. Brisket Opening
12. Rodding/Tying the Weasand
13. Evisceration

Processing

14. Splitting
15. Post Mortem Inspection
16. Pre Chilling

⇩

Processing

17. Chilling

⇩

18. Carcass Fabrication

⇩

19. Trim Rail/Grinding

⇩

20. Packaging and Storage

⇩

Distribution Channels

21. Transport to Distribution Channels

⇩

22. Cold Storage/Aging

⇩

23. Receiving at Purveyor

⇩

24. Finished Product Fabrication

⇩

25. Mechanical Tenderization

⇩

26. Distribution/Retail

⇩

27. Consumers

5. PRIMARY PRODUCTION

10.Control measures to reduce the carriage of STEC in ruminants prior to slaughter that have the potential to reduce the prevalence of STEC are described in this section.

- Specific Control measures at farm level

11. The herd prevalence and individual animal shedding status is generally unpredictable, although some possible risk factors are observed.

12. A variety of control measures to reduce the prevalence of carriage or the level of shedding of STEC in ruminants prior to slaughter have been proposed. Many of these proposed pre-harvest control methods have not been demonstrated to reliably reduce the prevalence or the level of STEC shedding from ruminants in a commercial setting. Research into pre-harvest control of STEC in cattle has focused on the serotypes O157:H7 and O157:NM and so there is often limited data available on the impact on other STEC serotypes. Additionally, some of the proposed methods are focused on specific subpopulations of STEC (e.g. vaccines, bacteriophage).

13. Potential ways to minimize animal carriage of STEC that have been proposed and investigated for decreasing faecal shedding, include animal vaccination, additives and manipulation of animal feeds, and farm practices.

Diet

14. A wide variety of cattle diets have been investigated for their impact on STEC O157 prevalence and/or shedding, including hay, barley, distillers and brewers grains, sage brush, millet, alfalfa, (Callaway et al., 2009). Both STEC O157 and generic *E. coli* populations have been demonstrated to respond to changes in diet, but replication of results indicating STEC O157 reduction has been poor and no dietary composition has been identified that reliably reduces STEC O157. Some diets that have been proposed increase STEC O157 shedding (Thomas and Elliott, 2013).

15. In general, research supports that cattle on grain-based diets appear to shed higher levels of generic *E. coli* in their faeces than cattle on forage diets but the effect of forage diets on faecal shedding of E. coli O157:H7 is inconclusive.

Feed Additives

16. Probiotics. Inclusion of probiotics in the diet is based on feeding animals with viable microorganisms antagonistic toward pathogens via either modifying environmental factors in the gut or producing antimicrobial compounds (Norrung et al, 2008).

17. β-adrenergic agonists (e.g. ractopamine, zilpaterol). An early study reported reduced prevalence of STEC O157 in cattle treated with ractopamine (Edrington et al. 2006). Subsequent studies have not reported any significant impact on STEC prevalence or shedding levels (Edrington et al. 2009; Paddock et al 2011; Wells et al., 2017).

18. Ionophores (e.g. monesin). The results of individual studies are variable (Callaway, 2010; Paddock et al 2011). It has been proposed that the effect of ionphores on STEC O157 is dependent upon cattle diet (Callaway, 2010).

19. Seaweed. The seaweed *Ascophyllum nodosum* (Tasco-14) is marketed as a supplement for cattle feed. It has been reported to reduce faecal and hide prevalence of STEC O157 when added to corn feed (Braden et al., 2004).

20. Direct Feed Microbials. This approach involves feeding animals with viable microorganisms which are antagonistic toward pathogens, either by modifying environmental factors in the gut or producing antimicrobial compounds. There is evidence that specific direct feed microbial treatments can reduce STEC O157 shedding by cattle (Wisner et al., 2015).

21. Sodium chlorate. Sodium chlorate is reduced to growth inhibitory chlorite by Enterobacteriaceae (Smith et al., 2009). Reduction in STEC O157 shedding by cattle and sheep following the addition of chlorate to drinking water or feed has been reported (Callaway et al., 2002; Edrington et al., 2003).

Bacteriophage.

22. A cocktail of phage strains is required to effectively target strains of even a single STEC serotype, as bacteriophage specifically target bacterial strains presenting specific receptors. Bacteriophage treatment of cattle can transiently reduce the numbers of STEC O157 shed by cattle (Wang et al., 2017).

Vaccination

23. Faecal shedding of STEC may be decreased using vaccines, e.g. Type III secreted protein (TTSP), SRP protein-based (Snedeker, 2011), Stx toxoid-based vaccines (Schmidt, 2018, Martorelli et al 2015), C-terminal 280 amino acids of intimin γ and EspB (Vilte et al 2011) .

Good management practices at farm

24. The following good management practices for animals are recommend to minimise STEC shedding and hide contamination on animals presented for slaughter. Of particular concern is preventing the formation of heavy tag on animal hides, as this can interfere with hygienic skinning and evisceration.

- Avoid non-natural stressful situations, e.g. poor animal husbandry or rough handling, because increased stress increases shedding of pathogens.
- Try to avoid the entry of or contact with new animals from other cattle raising farms to avoid or reduce horizontal transmission of EHEC among animals on the same farm or in the same pen (Calloway, 2010)
- In the same farm, keep animals in the same herd grouping and avoid sharing water troughs to avoid cross contamination during pathogen shedding periods.
- Clean and dry bedding. This may reduce heavy soiling of the brisket, reducing the potential for contamination during carcass dressing.

- Drinking water is an important route of STEC transmission in dairy cattle because of faecal contamination of water troughs, as indicated by detection of *E. coli* O157:H7 in trough water and sediments (Faith et al, 1996, Jackson et al 1998, Lejeune 2001). Ensure water is of a microbiological quality that minimises animal contamination and, if there is doubt, treat the water. Frequent cleaning of water troughs has been recommended to reduce replication and/or survival of these foodborne pathogens (Lejeune et al 2001). The position of water troughs on the farm also can affect STEC prevalence (Lejeune, 2001). Materials used in water troughs should also be considered; metal troughs had lower *E. coli* O157 counts compared with troughs that were manufactured from concrete or plastic (Lejeune, 2001).

- Specific Control Measures for Transport to Slaughterhouse and lairage

25. Increased hide contamination and/or shedding of STEC and other enteric pathogens by cattle. Transportation and lairage can be major contributors to the increasing occurrence of pathogens in animals. Contributing factors include mixing of animals of different origin, stress, extended duration of transportation and lairage, and dirtiness of transport vehicles and lairage pens (Norrung et al., 2008; Dewell et al., 2008a and 2008b).

- Specific Control measures at Transportation

26. Cross contamination among animals from different farms during transportation to the slaughter facility and at lairage (holding pens) can be an important source of hide contamination. Therefore, appropriate controls should be in place to minimize hide contamination.

27. Transportation practices should ensure that the animals arrive in as good a condition as when they left to prevent any disease, injury or other issues that could affect contamination of the meat. Control measures implemented prior to travel include:

• mustering and handling animals so that they are not unduly stressed; following the *Code of Hygienic Practice for Meat* (CXC 58-2005), which specifies that journey distance and time to be as short as possible and that rest and water should be provided.

• ensuring animals are as clean as possible. Dirty animals may increase the likelihood of pathogen contamination onto carcasses or hides during the slaughter and dressing processes. The likelihood of STEC contaminating the meat increases where levels of faecal contamination on the hide are high.

• loading the animals onto clean vehicles; and not overcrowding the vehicle.

- Specific Control measures at Receive and Unload

28. In this stage the hygiene condition of the animals must be evaluated, animals should be as clean as possible to minimize the initial load count of microorganisms on their hide.

29. Spraying chlorinated water under appropriate pressure can be used as a corrective action at the time of animals unloading in order to reduce faecal contamination on the hide.

30. The unloading should be carried out in a way that minimizes the stress caused by the action that could increase shedding of STEC, with adequate training of the operators on procedures that can minimize stress.

- Specific Control measures at Lairage

31. The lairage area should be cleaned as much as possible for each lot of animals, with the removal of residues and application of chlorinated water under pressure on the floor.

32. In this step, water spray or washing can be used to reduce residues on the animal's hide, reducing the initial count of microorganisms. Washing the live animal, specifically, washing of the hide significantly reduces the load of *E. coli* O157: H7 that enters the plant, which is closely related to the final levels of contamination of the carcasses (Arthur et al., 2007 and Arthur et al., 2010, Callaway, 2011, LeJeune and Wetzel, 2012)

33. It is preferable at lairage, maintaining cattle in closed herds to reduce social stress and prevent cross contamination between herds. Reducing stress may also help to reduce faecal shedding of *E. coli* O157:H7.

6. PROCESSING

- Specific Control Measures at Processing

34. Interventions at the slaughterhouse include physical, chemical or biological interventions that can be applied alone or in combination. These are more likely to reduce the number of STEC microorganisms to an acceptable level when applied with in the presence of strict hygiene practices and good manufacturing practices at slaughtering. Particular focus should be given to ensuring best practice in the course of the opera-

tions of dehiding, head removal, bunging and evisceration, as these operations are the initial sources of microbiota transfer to meat surfaces (Gill and Gill, 2012).

35. Targeted removal of visible contamination by trimming, washing or hot water/steam vacuum cleaning may be applied to carcasses, but the disadvantage of this manual methods is potential cross-contamination from dirty knives, aprons, mesh gloves, and waste. Also, even though effective at removing visible defects the effectiveness of these practices to reduce pathogen contamination is highly limited. There is no relationship between visible soiling and microbiological contamination, and removal of visible soiling has minimal impact on the contamination of the carcass (Gill and Landers, 2004; Gill and Baker et al 1998).

36. The specific control measures during this stage are intervention techniques aimed at removing STEC from the surface of beef carcasses, but stress tolerance to heat, salt and acid has been observed in many STEC strains and should be considered when devising interventions in food processing.

37. Specific control measures should be safe and feasible along the production process and should not change the organoleptic properties of beef meat.

38. The following interventions may reduce the level of microbiota, including STEC, on carcasses and meat surfaces. Many operations can be performed manually or with automated equipment. Automation offers the advantage of greater consistency of application (Signorini et al., 2018).

- *Carcass washing*, which may remove visible soiling and reduce overall bacterial counts on beef carcasses by up to 1 log unit (Gill and Landers, 2003).
- *Carcass washing with antimicrobial agents*, such as organic acids (e.g.; citric acid, lactic acid, acetic acid), oxidising agents (e.g. chlorine, peroxides, ozone) or other antimicrobial agents permitted by regulation (Gill and Gill, 2012). Such antimicrobial treatments may be applied with hot water to have a combined thermal impact. Factors determining the effectiveness of such treatments include the concentration of the agent, uniformity of surface coverage, the temperature of solution, and the contact period. Individual STEC strains may vary in their sensitivity to such treatments (Berry and Cutter, 2000; Gill et al., 2019). Organic acids alone can reduce the counts but not completely eliminate STEC O157 (Hussein and Sakuma, 2005).
- *Carcass surface pasteurisation*. This form of treatment is most commonly applied to carcass sides at the end of dressing. Water at >85 °C may be applied as a spray, a sheet or as steam (Gill and Bryant, 2000; Retzlaff et al., 2005). Treatment is most effective when applied to clean, dry carcass sides as large drops or sheets of water; when applied under such conditions the treatment can achieve >2 log reductions in total *E. coli* in commercial slaughter operations (Gill and Jones, 2006).
- *Steam and vacuum*. The carcasses are sprayed with steam and then an aspiration is performed, which fulfils a double function of eliminating and / or inactivating surface contamination. The manual device includes a vacuum tube with a hot water spray nozzle (which delivers water at approximately 82-88 ° C on the surface of the carcass. The process is effective in removing visible contamination in the carcasses without generating a loss in the weight of the carcass. (Huffman, 2002, Dorsa et al. 1996,1997, Koohmaraie, 2005, Kochevar et al.1997, M. Koohmaraie et al. / Meat Science 71 2005)

39. A range of non-thermal preservation technologies (e.g., pulsed light, natural bio- preservatives, high hydrostatic pressure, ionizing radiation) and thermal preservation technologies (e.g., microwave and radiofrequency tunnels, Ohmic heating or steam pasteurization) have been investigated for meat decontamination either during processing or after final packaging. The utility of these methods is dependent upon the impact on the organoleptic properties of the meat and the final use. For example, high pressure processing cannot be applied to bone-in meat cuts because it results in changes in the texture and appearance of raw red meats that are generally unacceptable to consumers, but beef patties treated with high pressure are marketed for institutional or commercial food preparation (Meat+Poultry, 2011). Factors determining the effectiveness of such treatments include the sensitivity of the microorganism, intrinsic characteristic of the environment (, temperature) and the intrinsic characteristics of the food (fat content, salt, additives, pH, etc.) (Aymerich et al., 2008; Gill and Gill, 2012).

- Specific control measures at Mechanical Tenderization

40. Processes such as marinating, brine injection, and mechanical tenderisation in which blades or needles penetrate the muscle surface present the potential for increased food safety risks due to the transfer of pathogens from the surface to the interior (resulting in internalization of STEC during marinating previously intact raw fresh beef products (Johns et al. 2011; CDC 2010; Lewis et al 2013). Such products should be considered as “non-intact” beef products, and appropriate consumer guidance may be required (USDA FSIS 2019; Health Canada 2019).

7. DISTRIBUTION/ RETAIL

- Specific Control measures at distribution and retail

41. Packaging conditions (to be developed)

8. CONSUMERS

9. VALIDATION OF CONTROL MEASURES

Please refer to general section.

10. MONITORING OF CONTROL MEASURES

42. Monitoring data are used to measure the effectiveness of any control measure put in place and to establish alternative or improved measures, and to identify trends and emerging STEC hazards, food vehicles, and food chain practices (FAO/WHO STEC Expert Report 2018).

43. A microbiological monitoring programme should be designed and implemented at farm and processing level.

44. The utility of testing for STEC presence/absence as part of monitoring programmes for food safety assurance in processing is limited by the typically low levels and prevalence of STEC in food. Process performance monitoring may be accomplished more effectively and efficiently by quantitatively monitoring sanitary and hygiene indicator organisms. These indicator organisms do not indicate pathogen presence; instead they provide a quantitative measure of the control of microbial contamination in the product and processing environment. Periodic testing for high risk STEC can also be conducted for verification of process performance. (FAO/WHO STEC Expert Report 2018).

11. VERIFICATION OF CONTROL MEASURES AND REVIEW OF CONTROL MEASURES

45. Since STEC is generally present at very low levels and is characterised by heterogeneous distribution (minced products excluded), making it difficult to detect STEC, frequent verification is necessary to ensure that interventions are functioning as intended. Appropriate faecal contamination indicators can be used for verification purposes.

46. It is recommended to use countable hygiene criteria to measure the effectiveness of control measures (E.g.; microorganism indicating faecal contamination), and to steer the hygiene conditions when manufacturing. The speed in detecting a loss of control of manufacturing hygiene increases with the verification frequency.

12. LABORATORY ANALYSIS CRITERIA FOR DETECTION OF STEC IN BEEF

47. Meat contains a high proportion of water and protein. All fresh meat has internal water activities (aw) of >0.99 which provides a suitable environment for microbial growth (ICMSF, 2005). Having into account that, STEC on the carcass can be transferred to meat cuts as the animal is further processed and can also be transferred between animals via meat processing equipment (ICMSF, 2005). Some meat cuts will need more control measures and monitoring than others (e.g. minced, ground, trim)

ANNEX 2. FRESH LEAFY GREEN VEGETABLES

INTRODUCTION

1. Fresh leafy green vegetables are grown, processed and consumed throughout the world. They are grown on farms of varying size; distributed and marketed locally and globally, providing year-round availability to consumers; and sold as fresh, fresh-cut, pre-cut or other ready-to-eat (RTE) products such as pre-packaged salads.

2. Outbreaks of illness caused by a broad range of microbial pathogens, including Shiga toxin-producing *Escherichia coli* (STEC), have been linked to the consumption of fresh leafy green vegetables. Epidemiological evidence, outbreak investigations and risk assessments have identified a number of areas of risk for STEC contamination of fresh leafy green vegetables, including from water, animals, workers and manure-based soil amendments. Fresh leafy green vegetables are typically grown and harvested in large volumes, increasingly in places where harvesting and distributing fresh leafy green vegetables is efficient, rapid and centralized. Fresh leafy green vegetables are packed in diverse ways, including: field packed direct for market; field cored and prepared for later processing; and as pre-cut leafy green vegetable mixtures and blends with other vegetables. As fresh leafy green vegetables move through the supply chain, there is also the potential for the introduction and growth of pathogens, including STEC. There is no further processing treatment applied that would eliminate or inactivate STEC. Examples of field level control measures are illustrative only and their use and approval may vary by country.

3. It is recognized that some of the provisions in this Annex may be difficult to implement in areas where primary production is conducted in small holdings, whether in developed or developing countries, and in areas where traditional farming is practiced. The Annex is therefore, by necessity, a flexible one, to allow for different systems of control and prevention of contamination for different cultural practices and growing conditions.

1. OBJECTIVE

4. The objective of this Annex is to provide guidance to reduce, during their production, harvesting, packing, processing, storage, distribution, marketing and consumer use, the risk of foodborne illness from STEC associated with fresh leafy green vegetables intended for human consumption without cooking. Figure 1 provides a flow diagram illustrating key production steps that are addressed by this Annex. Steps may not occur in all operations (as shown with dotted lines) and may not occur in the order presented in the flow diagram.

2. SCOPE AND DEFINITIONS

2.1 Scope

5. This Annex covers specific guidance for control of STEC related to fresh leafy green vegetables that are intended to be consumed without further lethality steps. Fresh leafy green vegetables for the purposes of this Annex include all vegetables of a leafy nature where the leaf is intended for consumption, and include, but are not limited to, all varieties of lettuce, spinach, cabbage, chicory, endive, kale, radicchio, and fresh herbs such as coriander, cilantro, basil, curry leaf, colocasia leaves and parsley. The Annex is applicable to fresh leafy green vegetables grown in open fields or in fully or partially protected facilities (hydroponic systems, greenhouses/controlled environments, tunnels etc.).

2.2 Definitions

6. Refer to the *General Principles of Food Hygiene* (CXC 1-1969) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003), including Annex I for Ready-to-Eat Fresh, Pre-cut Fruits and Vegetables and Annex III for Fresh Leafy Vegetables.

[Question: Are there any other terms that need definitions? We will add terms used multiple times here; if a term that needs a definition is used once, it will be included at the point the term is used.]

3. PRIMARY PRODUCTION

7. Refer to the *General Principles of Food Hygiene* (CXC 1-1969) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).

8. Most contamination of leafy green vegetables with STEC is thought to occur during primary production. Leafy green vegetables are grown and harvested under a diverse range of climatic and geographical

conditions. They can be grown in production sites indoors (e.g., greenhouses) and outdoors, harvested and either field-packed or transported to a packing establishment, using various agricultural inputs and technologies, and on farms of varying sizes. In each primary production area, it is necessary to consider the agricultural practices and procedures that minimize the potential for contamination of leafy green vegetables with STEC, considering the conditions specific to the primary production area, type of products, and growing and harvesting methods used.

3.1 Environmental Conditions

9. As far as possible, potential sources of STEC contamination should be identified prior to primary production activities. Where possible, growers should evaluate present and previous uses of both indoor and outdoor fresh leafy green vegetable primary production sites and the adjoining land (e.g. feed lot, animal production, sewage treatment site) in order to identify potential sources of STEC. The assessment of environmental conditions is particularly important because subsequent steps may not be adequate to remove STEC contamination that occurs during primary production, and in some cases conditions may enable the growth of STEC, thereby increasing the risk.

10. If the environment presents a risk of contamination of the primary production site with STEC, measures should be implemented to minimize the contamination of fresh leafy green vegetables at the site. When such risks cannot be minimized, the production site should not be used for fresh leafy green vegetable production.

11. The effects of some environmental events cannot be controlled. For example, heavy rains may increase the exposure of fresh leafy green vegetables to STEC if soil contaminated with STEC splashes onto them. When heavy rains occur, growers should evaluate the need to postpone harvesting fresh leafy green vegetables for direct consumption and/or to subject them to a treatment that will minimize the risk from STEC. If fresh leafy green vegetables that contact flood waters are not submitted to any measure to mitigate risks, they should not be eaten raw. This does not include flood irrigation, where the source of water is of known and appropriate quality.

3.1.1 Location of the Production Site

12. Animal primary production facilities can pose a significant risk for contamination production fields or water sources with STEC. Growers should evaluate the potential for such contamination and take measures to mitigate the risk of STEC contamination associated with runoff and flooding (e.g. terracing, digging a shallow ditch to prevent runoff from entering the field).

3.1.2 Animal activity

13. some wild and domestic animals present in the primary production environment are known to be potential carriers of STEC. Wild animals represent a particularly difficult risk to manage because their presence is intermittent. The following are particularly important to minimize the potential for animal contamination of fresh leafy green vegetables with STEC:

- Appropriate methods should be used in order to exclude animals from the primary production and handling areas to the extent practicable. Possible methods include the use of physical barriers (e.g. fences) and active deterrents (e.g. noise makers, scarecrows, images of owls, foil strips).
- Primary production and handling areas should be properly designed and maintained to reduce the likelihood of attracting animals that can contaminate fresh leafy green vegetables with STEC. Possible methods include minimizing standing water in fields, restricting animal access to water sources, and maintaining production sites and handling areas free of waste and clutter.
- Fresh leafy green primary production areas should be evaluated for evidence of the presence of wildlife or domestic animal activity (e.g. presence of animal faeces, bird nests, hairs/fur, large areas of animal tracks, burrowing, decomposing remains, crop damage from grazing), particularly near harvesting. Where such evidence exists, growers should evaluate the risks to determine whether the fresh leafy green vegetables in the affected area of the production site should be harvested for direct consumption.

3.2 Hygienic growing of fresh leafy green vegetables

3.2.1 Water for primary production

14. Several parameters may influence the risk of microbial contamination of fresh leafy green vegetables with STEC: the type of irrigation (e.g. drip, sprinkler, overhead), the source of water, whether the edi-

ble portions of fresh leafy green vegetables have direct contact with irrigation water, the timing of irrigation in relation to harvesting and, most importantly, the occurrence of STEC in the irrigation water. Growers should evaluate the sources of water used on the farm for the risk of contamination with STEC and identify corrective actions to prevent or minimize STEC contamination (e.g. from livestock, wildlife, sewage treatment, human habitation, manure and composting operations, or other intermittent or temporary environmental contamination, such as heavy rain or flooding). (Refer to section 3.2.1.1 of the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).)

15. Where necessary, growers should have the water they use tested for STEC or appropriate indicator organisms, according to the risk associated with the production. The frequency of testing will depend on the water source (i.e. lower for adequately maintained deep wells, higher for surface waters), the risks of environmental contamination, including intermittent or temporary contamination (e.g., heavy rain, flooding), or the implementation of a new water treatment process by growers. If the water source is found to have unacceptable levels of indicator organisms or is contaminated with STEC, corrective actions should be taken to ensure that the water is suitable for its intended use. Possible corrective actions to prevent or minimize contamination of water for primary production may include the installation of fencing to prevent large animal contact, the proper maintenance of wells, water filtering, chemical water treatment, the prevention of the stirring of the sediment when drawing water, the construction of settling or holding ponds or water treatment facilities. The effectiveness of corrective actions should be verified by regular testing. Where possible, growers should have a contingency plan in place that identifies an alternative source of water.

16. It is especially critical in hydroponic operations to maintain the quality of water used to irrigate fresh leafy green vegetables so as to reduce the risk of contamination and survival of STEC; the nutrient solution used may enhance the survival or growth of STEC. (Refer to section 3.2.1.1.3 of the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).)

3.2.1.2 Manure, biosolids and other natural fertilizers

17. The use of manure, biosolids and other natural fertilizers in the production of fresh leafy green vegetables should be managed to limit the potential for contamination with STEC, which can persist in manure, biosolids and other natural fertilizers for weeks or even months, if the treatment of these materials is inadequate. Treatment methods should be validated to inactivate STEC. Refer to section 3.2.1.2 of the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) for practices to minimize microbial pathogens such as STEC in manure, biosolids and other natural fertilizers.

3.2.3 Personnel health, hygiene and sanitary facilities

18. Hygiene and health requirements should be followed to ensure that personnel who come into direct contact with fresh leafy green vegetables during or after harvesting are not likely to contaminate them with STEC. Having adequate hygienic and sanitary facilities, including adequate means for hygienically washing and drying hands, is critical to minimize the potential for workers to contaminate fresh leafy green vegetables. People suffering from illness due to STEC should not be allowed to enter any area handling leafy green vegetables, including the harvest area. Refer to section 3.2.3 of the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) for practices to minimize microbial pathogens such as STEC.

3.2.4 Harvesting

19. The field should be evaluated for animal intrusion, the presence of faecal deposits, or other sources of STEC contamination prior to harvest to determine if the field or portions thereof should not be harvested. Growers should avoid moving harvesting equipment across fields where manure or compost was applied. Harvesting equipment should be cleaned and disinfected seasonally or as needed to avoid the contamination of fresh leafy green vegetables (e.g., if the equipment runs over an area with heavy animal intrusion and faecal deposits). Containers stored outside should be cleaned and, as appropriate, disinfected before being used to transport fresh leafy green vegetables.

3.2.5 Field packing

20. When packing fresh leafy green vegetables in the field, care should be taken to avoid contaminating containers or bins by exposure to manure or other contamination sources. When fresh leafy green vegetables are trimmed or cored in the field, knives and cutting edges should be cleaned and disinfected frequently to minimize the potential for cross-contamination with STEC.

3.2.6 Storage and transport from the field to the packing or processing facility

21. Fresh leafy green vegetables should be stored and transported under conditions that will minimize the potential for STEC contamination and/or growth. Fresh leafy green vegetables should not be transported in vehicles previously used to carry animal manure or biosolids.

4. PACKING OPERATIONS

22. Refer to the *General Principles of Food Hygiene* (CXC 1-1969) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).

4.1 Time and temperature control

23. Refer to the *General Principles of Food Hygiene* (CXC 1-1969). Temperature control during packing and storage is essential to prevent growth of any STEC that may be present, since an increase in numbers will increase the risk of illness.

4.2 Cooling fresh leafy green vegetables

24. The cooling of fresh leafy green vegetables should take place as rapidly as possible and in a manner that does not contribute to contamination of product with STEC. For example, fresh leafy green vegetables can be cooled immediately after harvest by using ice (for parsley), forced-air cooling, vacuum cooling (for iceberg lettuce), hydrocooling or spray-vacuum (hydro vac) cooling.

25. If water used for cooling enters into direct contact with the fresh leafy green vegetables and is recirculated, it should be controlled, monitored and recorded to ensure that biocides are sufficient to reduce the potential risk of cross-contamination.

4.3 Washing fresh leafy green vegetables

26. Packers washing fresh leafy green vegetables should follow good hygienic practices (GHPs) to prevent or minimize the potential for the introduction or spread of STEC in fresh leafy green vegetable wash water. Biocides should be used as per GHPs and where necessary to minimize post-harvest cross-contamination with STEC, with their levels monitored, controlled and recorded to ensure the maintenance of effective concentrations. Where appropriate, the characteristics of post-harvest water that may impact the efficacy of the biocidal treatments (e.g. the pH, turbidity and water hardness) should be controlled, monitored and recorded.

5. PROCESSING OPERATIONS

27. Refer to the *General Principles of Food Hygiene* (CXC 1-1969) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003), including Annex III on Fresh Leafy Vegetables and Annex I on Ready-to-Eat, Fresh, Pre-Cut Fruits and Vegetables.

28. Where feasible, raw material-handling areas should be physically separated from processing areas to minimize contamination with STEC. Processing cannot guarantee the elimination of STEC that may have occurred during primary production of fresh leafy green vegetables. Processors should ensure that growers, harvesters, packers and distributors have implemented measures to minimize the contamination of the fresh leafy green vegetables to be processed during primary production and subsequent handling in accordance with the provisions in the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).

5.1 Time and temperature control

29. Refer to the *General Principles of Food Hygiene* (CXC 1-1969). Temperature control during pre-processing storage, processing and post-processing storage is essential to prevent growth of any STEC that may be present, since an increase in numbers will increase the risk of illness.

5.2 Trimming, coring, cutting and shredding of fresh leafy green vegetables

30. Cutting knives and other cutting tools and equipment should be cleaned and disinfected frequently to minimize the potential for transfer of STEC.

5.3 Washing and dewatering/drying cut fresh leafy green vegetables

31. Washing and drying are important steps in the control of STEC for cut fresh leafy green vegetables. See Section 4.3 above and section 5.2.2.5.1 of Annex I on Ready-to-Eat, Fresh, Pre-Cut Fruits and Vegetables of the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003),

5.4 Cold storage

32. Fresh leafy green vegetables should be maintained at appropriate temperatures after cooling to minimize growth of any STEC that may be present. The temperature of the cold storage should be controlled, monitored and recorded.

5.5 Microbiological and other specifications

33. Microbiological testing for STEC can be a useful tool to evaluate and verify the safety and effectiveness of practices and to provide information about an environment, a process or even a specific product lot when sampling plans and testing methodology are properly designed and performed. Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

5.6 Documentation and records

34. Where appropriate, processing, production and distribution records should be retained long enough to facilitate a recall and STEC illness investigation if needed. This period may significantly exceed the shelf-life of fresh leafy green vegetables. Refer to section 5.7 of the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) for the types of records that should be maintained by growers, harvesters and packers that may be important when investigating outbreaks of foodborne illness due to STEC.

6. ESTABLISHMENT: MAINTENANCE AND SANITATION

35. Refer to the *General Principles of Food Hygiene* (CXC 1-1969) the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).

7. ESTABLISHMENT: PERSONAL HYGIENE

36. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

8. TRANSPORTATION

37. Refer to the *General Principles of Food Hygiene* (CXC 1-1969), the *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-Packed Food* (CXC 47-2001) and the *Code of Practice for the Packaging and Transport of Fresh Fruits and Vegetables* (CXC 44-1995).

9. PRODUCT INFORMATION AND CONSUMER AWARENESS

9.1 Lot identification

38. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

9.2 Product information

39. Refer to the *General Principles of Food Hygiene* (CXC 1-1969).

9.3 Labelling

40. Refer to the *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).

9.4 Consumer education

41. Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).

10. TRAINING

42. Refer to the *General Principles of Food Hygiene* (CXC 1-1969) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).

11. RETAIL AND FOODSERVICE

43. Fresh leafy green vegetables (intact and pre-cut) should be held at a temperature that prevents growth of STEC. Cross-contamination from or to other food items should be prevented. Food business operators serving fresh leafy green vegetables for direct consumption to consumers should take appropriate measures to

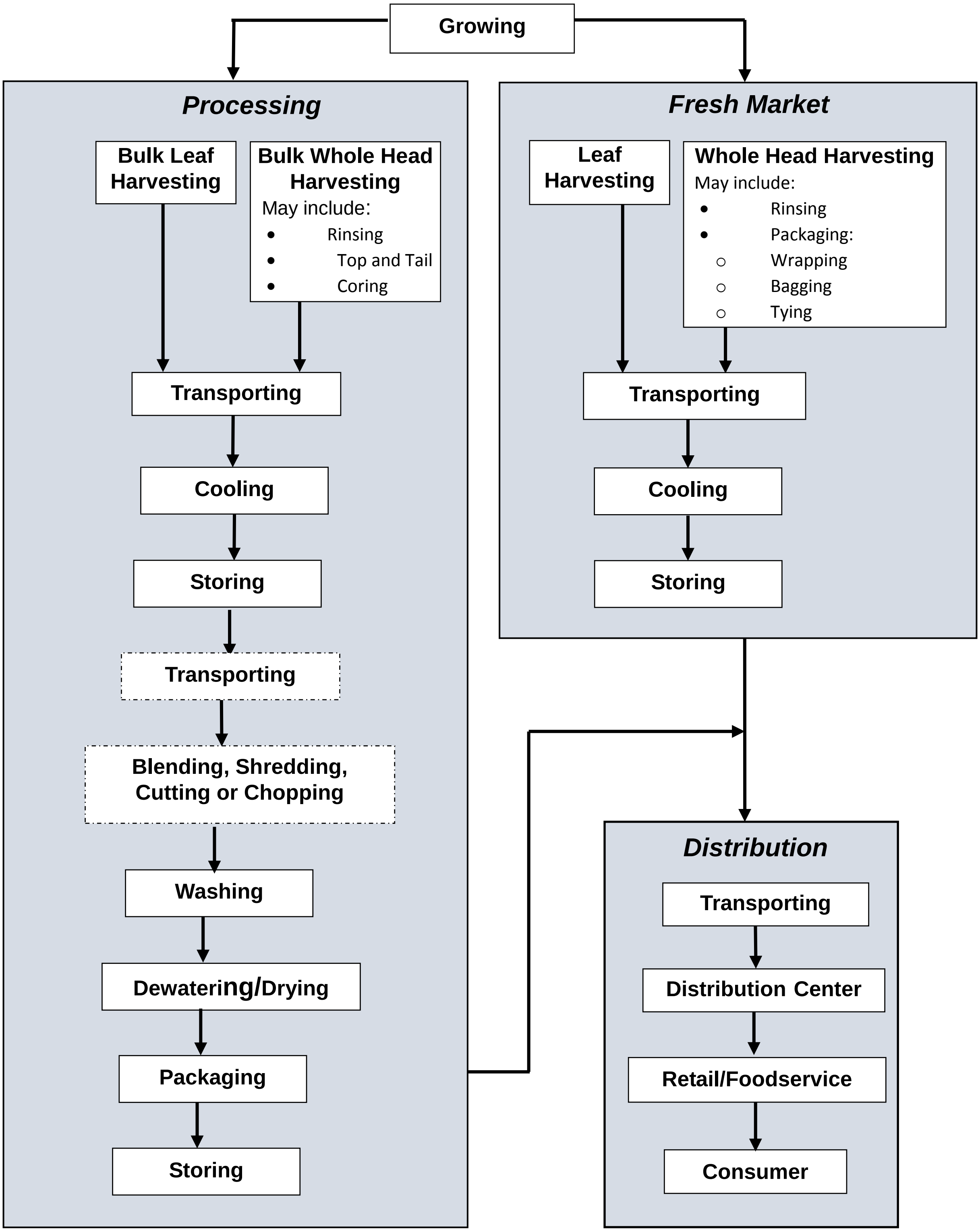
- prevent cross-contamination,

- maintain appropriate storage temperature, and
- ensure proper cleaning.

12. CONSUMER

44. See section 9.4 in the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).

Figure1: Fresh Leafy Green Vegetables Flow Diagram[17]



[17] Stippled boxes indicate steps that may not be included, depending in part on the commodity

APPENDIX II

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