CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda Item 5 **CRD03**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Fifty-fourth Session

Nairobi, Kenya

11 - 15 March 2024

REPORT OF THE PHYSICAL WORKING GROUP ON THE PROPOSED DRAFT GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING ESCHERICHIA COLI (STEC) IN RAW BEEF, FRESH LEAFY VEGETABLES, RAW MILK AND RAW MILK CHEESES, AND SPROUTS

(Prepared by Chile, New Zealand and the United States of America)

Background

1. A physical working group (PWG) was held on 10 March 2024 in Nairobi, Kenya immediately prior to CCFH54 chaired by Chile and co-chaired by New Zealand and the United States of America to discuss the Proposed Draft Guidelines for the Control of Shiga Toxin-Producing *Escherichia coli* (STEC) In Raw Beef, Fresh Leafy Vegetables, Raw Milk and Raw Milk Cheeses, and Sprouts.

2. The Chair began the session by focusing on two issues for resolution: definitions of fresh leafy vegetables and sprouts and whether microgreens would be addressed in the Sprouts Annex or the Fresh Leafy Vegetables Annex.

3. The Chairs presented a revised version the Annex II on Fresh Leafy Vegetables and Annex IV on Sprouts, which had been amended based on comments provided in CX/FH 24/54/5 Add.1, CX/FH 24/54/6 Add.1, and various CRDs. Many editorial changes were made to the document, as well as several substantive changes. The PWG reviewed the substantive changes in the document, considered the proposed revision and making additional changes as appropriate.

Summary of Discussions

4. The following changes were made in the documents at the PWG:

Fresh Leafy Vegetables Annex:

5. The PWG made the following changes:

- Paragraph 3 – for clarity, the PWG agreed to modify the paragraph and add “although internalization of STEC in leaves may reduce the effectiveness of such treatments.”
- Paragraph 14– agreed to clarifying language that the competent authority should require a risk assessment to identify necessary measures to ensure safety of the fresh leafy vegetables.
- paragraph 17– agreed to clarifying language on indicator organisms to include additional flexibility.
- paragraph 18 – cochairs proposed, and the PWG agreed to language on when water testing would be appropriate to verify a corrective action.
- paragraph 21– cochairs proposed, and the PWG agreed to clarifying language on adequate access to, and use of, hygienic and sanitary facilities including means to effectively clean and dry hands.
- Based on feedback from JEMRA, throughout the document, statements that fresh leafy vegetables should be cooled to <7°C have been removed, and where appropriate in the document, have been changed to fresh leafy vegetables should be cooled to appropriate refrigeration temperatures. The corresponding footnotes have been changed to “*E. coli* O157:H7 and other STEC are unlikely to grow on fresh leafy vegetables at temperatures lower than 7°C, based on available scientific evidence.”
- paragraph 28– agreed to clarifying language on biocides to prevent microbial growth in processing water.

- paragraph 34 – agreed to clarifying language in 33. The co-chairs were asked to provide additional language on the design of equipment, knives and other cutting tools, and any other contact surfaces to minimize the potential for harborage or transfer of STEC.
- paragraph 37 – on the language on microbiological testing of fresh leafy vegetables and water a phrase to refer to the possibility of not detecting STEC even when is present was added.
- New paragraph 39 – the co-chairs were asked to provide wording on the trend analysis. This new language was agreed upon in the PWG.

Sprouts Annex

6. The PWG made the following changes:

- Paragraph 7 – for consistency with Annex II of fresh leafy vegetables, agreed to change “for human consumption without cooking or other microbicidal treatment” to “that are intended to be consumed raw.”
- Paragraph 9 – added reference to CXG100-2023.
- Paragraph 12 – added for clarity “particularly those located uphill or downstream” and “of seed contamination”.
- Paragraph 19 – added “analysis of microorganism test results over time may help growers identify emerging issues”.
- Paragraph 20 - added reference to CXG100-2023.
- Paragraph 22 – removed reference to section 3.2.2.1.2 of CXC53-2003 to avoid the need for updating should the CXC change during realignment.
- Paragraph 23 – replace “the time period between the application, and the planting and harvesting of seed should be maximized” with “the time period before harvesting of seed should be maximized”
- Paragraph 25 -- for consistency with Annex II of fresh leafy vegetables, agreed on language on clean and dry hands.
- Paragraph 27 – removed reference to section 3.2.3 and section 6 of CXC1-1969 to avoid the need for updating should the CXC change during realignment. Added reference to CXC53-2003.
- New paragraph 34 (old 33, 35, and 36) – all paragraphs were related to storage containers for seeds. The pWG agreed with the cochairs proposal to rearrange to content for clarity and to reduce duplication. No substantive content was deleted.
- Paragraph 49 – removed references to non-Codex documents.
- Paragraph 50 – removed references to non-Codex documents.
- Paragraph 57 – for consistency with Annex II of fresh leafy vegetables, included footnote relating to temperature. Consolidation of old paragraphs 62 - 70 –The pWG agreed with the cochairs proposal to rearrange the content for clarity and to reduce duplication. No substantive content was deleted.
- Paragraph 77 – for consistency with Annex II of fresh leafy vegetables, included footnote relating to temperature.

Recommendations for the plenary of the 54th session of CCFH:

7. Consider the revised proposed draft annex to the Guidelines Appendix I to this report as the basis for discussion during the plenary session.

8. Consider the revised version of Annex II and Annex IV to be move forward in the Codex Step procedure

PROPOSED DRAFT ANNEX II ON FRESH LEAFY VEGETABLES

INTRODUCTION

1. Fresh leafy vegetables are grown, processed, and consumed throughout the world. They are grown on open fields or in fully or partially protected facilities ~~farms~~ of varying sizes; distributed and marketed locally and globally, providing year-round availability to consumers; and sold as fresh whole, fresh 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 vegetables. Epidemiological evidence, outbreak investigations, research, and risk assessments have identified several possible contamination sources of fresh leafy vegetables with STEC, including water, domestic and wild animals, workers, and improperly treated manure-based soil amendments[1]. ~~Fresh leafy vegetables are typically grown and harvested in large volumes, increasingly in locations where harvest and distribution of fresh leafy vegetables is efficient and rapid~~. Fresh leafy vegetables are packed in diverse ways, including field packed for direct transport to ~~for~~ market; field cored and prepared for later processing; and as pre-cut fresh leafy vegetable mixtures and blends with other vegetables.

~~2.~~3. Control measures such as antimicrobial treatments to minimize cross-contamination may be applied prior to packaging and/or shipment to market, although internalization of STEC in leaves may reduce the effectiveness of such treatments. As fresh leafy vegetables move through the supply chain, there is also the potential for the introduction and growth of pathogens, including STEC. The increasing worldwide use of pre-packaged fresh-cut leafy vegetables to expand the supply chain might increase the potential for the presence of contaminated product in the marketplace through cross-contamination with STEC, and STEC replication during processing, distribution and storage if fresh-cut leafy vegetables are improperly handled. There is no processing treatment applied to fresh leafy vegetables that would eliminate or inactivate STEC, although contamination can be reduced by measures and treatments such as washing in water that may contain, biocides. Examples of field level control measures provided in this document are illustrative only and their use and approval by competent authorities may vary by country.

~~3.~~4. 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 countries with developed or developing economies, and in areas where traditional farming is practiced. The Annex is, therefore, a flexible one, to allow for diverse systems of control and prevention of contamination for different cultural practices and growing conditions. Figure 1 provides a flow diagram illustrating a generalized process flow for fresh leafy vegetables. This flow diagram is for illustrative purposes only. Steps may not occur in all operations (as shown with dotted lines) and may not occur in the order presented in the flow diagram.

1. OBJECTIVE

~~4.~~5. The objective of this Annex is to provide guidance to reduce the risk of foodborne illness from STEC associated with fresh leafy vegetables intended for human consumption without cooking~~.~~, during primary production, harvesting, packing, processing, storage, distribution, marketing, and for consumer awareness.

2. SCOPE, USE AND DEFINITIONS

2.1 Scope

~~5.~~6. This Annex covers specific guidance for the control of STEC related to fresh leafy vegetables that are intended to be consumed raw. The Annex is applicable to fresh leafy vegetables grown in open fields or in fully or partially protected facilities (hydroponic systems, greenhouses/controlled environments, tunnels, etc.).

2.2 Use

~~6.~~7. This Annex should be used in conjunction with the *General Principles of Food Hygiene* (CXC 1-1969), the Guidelines for the Safe Use and Reuse of Water in Food Production, Annex I Fresh Produce (CXG 100-2023). and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).

2.3 Definitions

[1] "Soil amendments" are fertilizers soil improvers, conditioners, or other material added to a soil to improve nutrients or the soil's physical properties, such as water retention, permeability, water infiltration, and drainage.

~~7.~~8. 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 Scope of Annex III for Fresh Leafy Vegetables.

- **Fresh leafy vegetables** - Vegetables of a leafy nature where the leaf is intended for consumption raw, including, but 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, among other local products for foliar consumption.

3. PRIMARY PRODUCTION

~~8.~~9. 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). As noted in CXC 1-1969, some of the principles of HACCP can be applied at primary production and may be incorporated into Good Agricultural Practices for the production of fresh leafy vegetables to minimize contamination with STEC.

~~9.~~10. ~~Most contamination of fresh leafy vegetables with STEC is thought to occur during primary production. Fresh leafy 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 could minimize the potential for contamination of fresh leafy vegetables with STEC, taking into account the conditions specific to the primary production area, type of products, and types of methods used in growing, including irrigation source and use of organic fertilization and harvesting.

3.1 Location of the Production Site

~~10.~~11. Potential sources of STEC contamination should be identified prior to commencement of primary production activities and periodically evaluated for changes. Where possible, growers should evaluate present and previous uses of both indoor and outdoor fresh leafy vegetable primary production sites and the nearby and adjacent land (e.g., animal production, sewage treatment site) in order to identify potential sources of STEC. The assessment of potential sources of contamination ~~environmental conditions~~ is particularly important because subsequent interventions would not be sufficient to fully remove STEC contamination that occurs during primary production, and in some cases, conditions may enable the growth of STEC, thereby increasing the risk of illness for consumers.

3.1.1 Neighbouring animal farms

~~11.~~12. Animal production facilities located in proximity to sites where fresh leafy vegetables are grown and access to the growing site by wildlife can pose a significant likelihood of contamination of production fields or water sources with STEC. Concentrated animal feeding operations, dairy farms and cattle grazing lands present a significant risk of contamination of fresh leafy vegetables in the field; although guidelines exist for the distance between fields and nearby animal operations, the safe distance depends on factors that can increase or decrease the risk of contamination, such as topography of the land and opportunity for water runoff through or from such operations. 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 Environmental conditions

~~12.~~13. If the environment presents a likelihood of contamination of the primary production site with STEC, measures should be implemented to minimize the potential for contamination of fresh leafy vegetables at the site. When the likelihood of contamination cannot be managed or minimized, the production site should not be used for fresh leafy vegetable production.

14. The effects of some environmental events cannot be controlled and may need to be evaluated. For example, heavy rains or flood events may increase the exposure of fresh leafy vegetables to STEC. When heavy rains occur, growers should evaluate the need to postpone harvesting fresh leafy vegetables for consumption. Fresh leafy vegetables that contact flood waters should not be consumed unless approved by the competent authority. In doing so, the competent authority should require a risk assessment to identify necessary measures to ensure safety of the fresh leafy vegetables. This does not include flooding of furrows for irrigation purposes, where the source of water is known and of appropriate quality and is not the result of a weather event.

3.1.3 Animal activity

~~13.~~15. 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 activity to contaminate fresh leafy 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 vegetables with STEC. Possible methods include minimizing standing water in fields, restricting animal access to water sources from use in production (e.g. irrigation and washing), and maintaining production sites and handling areas free of waste and clutter.
- Fresh leafy vegetable primary production areas should be regularly checked 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 the time of harvesting. Where such evidence exists, growers should evaluate the risks to determine whether the fresh leafy vegetables in the affected area of the production site should be harvested for consumption~~.without~~ further processing that eliminate STEC (e.g. cooking).~~cooking~~.

3.2 Hygienic primary production of fresh leafy vegetables

3.2.1 Water for primary production

~~14.~~16. Several parameters may influence the likelihood of contamination of fresh leafy vegetables with STEC from water: the source of water used for irrigation and the application of fertilizers and pesticides, the type of irrigation (e.g. drip, furrow, sprinkler, overhead), whether the edible portions of fresh leafy vegetables have direct contact with irrigation or other water, the timing of final irrigation in relation to harvesting and, most importantly, the occurrence of STEC in the water used for irrigation or application of pesticides or fertilizers. Growers should identify and evaluate the sources of water used on the farm for the likelihood of contamination with STEC and ~~-~~identify measures 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 *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) and the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023), including Annex 1 “Fresh Produce”.

17. Depending on the water source and guidelines of the competent authority, growers should assess~~-~~ the microbiological quality of water and its suitability for the intended use by testing the water. for ~~-~~indicator microorganisms and, ~~-~~where necessary, STEC. 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.

~~15.~~18. If the intended water source is found to contain unacceptable levels of indicator microorganisms 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 immediate water testing and then periodically thereafter where appropriate. Where possible, growers should have a contingency plan in place that identifies an alternative source of water fit for purpose. Refer to the *Guidelines for the Safe Use and Reuse of Water in Food Production and Processing* (CXG 100-2023), including Annex 1 “Fresh Produce”.

~~16.~~19. It is especially critical in hydroponic operations to maintain the microbiological quality of water used as the growth medium for fresh leafy vegetables to reduce the likelihood of contamination and survival of STEC; the nutrient solution used may enhance the survival or growth of STEC. (Refer of the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003).)

3.2.2 Manure, biosolids and other natural fertilizers

~~17.~~20. The use of manure, biosolids and other natural fertilizers in the production of fresh leafy vegetables should be managed to limit the potential for contamination with STEC. STEC can persist in manure, biosolids and other natural fertilizers for weeks or even months, if treatment of these materials is inadequate.~~STEC can persist in these materials for weeks or even months, if treatment is inadequate~~. Composting can be effective in controlling STEC in manure, depending on factors that include time, temperature, indigenous microorganisms, moisture, composition of the compost, pile size, and turning of the pile. Another manure treatment method involves anaerobic digestion. Treatment methods should be validated to inactivate STEC. Refer to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) for practices to minimize contamination of fresh leafy vegetables with microbial pathogens such as STEC in manure, biosolids and other natural fertilizers.

3.2.3 Personnel health, hygiene, and sanitary facilities

~~18.~~21. Hygiene and health requirements should be followed to ensure that personnel who come into direct contact with fresh leafy vegetables prior to, during or after harvesting will not contaminate them with STEC. Adequate access to, and use of, hygienic and sanitary facilities, including means to effectively clean and dry hands, are critical to minimize the potential for workers to contaminate fresh leafy vegetables. People known or suspected to be suffering from gastrointestinal illness should not be allowed to enter any area where handling fresh leafy vegetables occurs, including the harvest area. Refer to 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.~~22. 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 has been applied. Harvesting equipment should be designed and constructed to ensure that, when necessary, it can be cleaned, disinfected, and maintained to avoid the contamination of fresh leafy vegetables (e.g., if the equipment runs over an area with animal intrusion and faecal deposits). Containers stored outside and field containers to be re-used should be cleaned and, as appropriate, disinfected before being used to transport fresh leafy vegetables.

3.2.5 Field packing

~~20.~~23. When packing fresh leafy vegetables in ~~the~~ the field ~~noting that containers are often open-topped and stacked~~, care should be taken to avoid contaminating containers or bins by exposure to manure or other contamination sources, noting that containers are often open-topped and stacked.. When fresh leafy 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.~~24. Fresh leafy vegetables should be stored and transported under conditions that will minimize the potential for STEC contamination and/or growth and noting that containers are often open-topped and stacked. Fresh leafy vegetables should not be transported in vehicles previously used to carry potentially contaminated materials (e.g., heavily soiled root vegetables, live animals, animal manure, compost, or biosolids). When vehicle receptacles or containers have been used for the transport of products other than fresh leafy vegetables, effective cleaning and disinfection should be carried out between loads to avoid cross-contamination.

4. PACKING OPERATIONS

~~22.~~25. 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.~~26. Refer to the *General Principles of Food Hygiene* (CXC 1-1969). Time and temperature control during packing and storage is essential to prevent growth of any STEC that may be present, since an increase in numbers of STEC will increase the risk of illness.

4.2 Cooling fresh leafy vegetables

~~24.~~27. The cooling of fresh leafy vegetables should take place as rapidly as possible to minimize growth of any STEC that may be present, and in a manner that does not contribute to contamination of product with STEC. For example, fresh leafy vegetables can be cooled immediately after harvest by using ice (e.g., for parsley), forced-air cooling, vacuum cooling (e.g., for iceberg lettuce), hydrocooling or spray-vacuum (hydro-vac) cooling. When cold damage is not a concern, fresh leafy vegetables should be cooled to

appropriate refrigeration temperatures[2] to prevent the growth of STEC. For fresh leafy vegetables susceptible to quality damage at refrigeration temperatures, the growth of STEC should be minimized by cooling to temperatures as low as possible while avoiding quality damage.

~~25.~~28. If water, including ice, used for cooling comes into direct contact with fresh leafy vegetables, it should be fit for purpose to minimize the likelihood of cross-contamination. When biocides are used, the concentration and other appropriate parameters (e.g., pH and temperature) in this water should be controlled, monitored, and recorded to ensure that biocides are sufficient to prevent microbial growth in the processing water, reducing the potential for cross-contamination.

4.3 Washing fresh leafy vegetables.

~~26.~~29. The washing of fresh leafy vegetables should follow good hygienic practices (GHPs) to prevent or minimize the potential for the introduction or spread of STEC in wash water. ~~.~~ All water used for cooling and washing fresh leafy vegetables should be fit for purpose. If necessary ~~When washing fresh leafy vegetables,~~ biocides should be added, ~~when identified as necessary, should be added~~ to wash water as per GHPs, with their levels monitored, controlled and recorded regularly during production to ensure the maintenance of effective concentrations. 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.~~30. 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.~~31. It is recommended that unprocessed fresh leafy vegetable handling areas be physically separated from processing areas to minimize contamination with STEC. Processing, with some exceptions (e.g., cooking) cannot fully eliminate STEC contamination that may have occurred during primary production or packing of fresh leafy vegetables. Processors should ensure that growers, harvesters, packers, and distributors have implemented measures to minimize the contamination during primary production and packing of the fresh leafy vegetables and also during 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.~~32. Refer to the *General Principles of Food Hygiene* (CXC 1-1969). Time and 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 of the STEC population will increase the risk of consumer illnesses.

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

~~30.~~33. Equipment, knives and other cutting tools, and any other contact surfaces, should be cleaned and disinfected frequently to minimize the potential for harbourage or transfer of STEC.

~~31.~~34. The design of equipment, knives and other cutting tools, and any other contact surfaces should allow for effective cleaning and disinfection to minimize the potential for harbourage or transfer of STEC to fresh leafy vegetables.

5.3 Washing and removal of water/drying cut fresh leafy vegetables.

~~32.~~35. Washing and removal of water/drying are important steps in the control of STEC in~~for~~ fresh-cut leafy vegetables. Refer to ~~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

~~33.~~36. It is recommended that fresh leafy vegetables be maintained at appropriate refrigeration temperatures (see footnote 2) after cooling to minimize growth of any STEC that may be present.. For fresh leafy vegetables susceptible to quality damage at refrigeration temperatures, the growth of STEC should be minimized by cooling to temperatures as low as possible while avoiding quality damage. The temperature of the cold storage should be controlled, monitored, and recorded.

[2] *E. coli* O157:H7 and other STEC are unlikely to grow on fresh leafy vegetables at temperatures lower than 7°C, based on available scientific evidence.

6. MICROBIOLOGICAL TESTING

34.37. Microbiological testing of fresh leafy vegetables and of water for primary production for STEC is currently of limited use due to difficulty in detecting STEC because of low and sporadic prevalence and when present, low numbers of the organism in fresh leafy vegetables and in water. This may lead to STEC not being detected even when present. Testing of fresh leafy vegetables for indicator microorganisms, supplemented, where appropriate, by testing for STEC strains considered to be a country's highest priority (e.g., those strains with virulence factors capable of causing severe illness or considered to cause significant illness in that country), can be a useful tool to evaluate and verify the safety of the product, the effectiveness of the control measures, 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. Measures to be undertaken in case of positive results for STEC (or when indicator microorganisms reach a pre-defined threshold) need to be established and defined. Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997) and *Principles and Guidelines for the conduct of microbiological risk management (MRM) (CXG 63-2007)*.

7. DOCUMENTATION AND RECORDS

38. It is recommended that primary production, harvesting, processing, storage, and distribution records be retained according to the requirements of the competent authority or long enough to facilitate STEC illness investigation and recalls if needed. This period may significantly exceed the shelf-life of fresh leafy vegetables. Refer to 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 foodborne illness outbreaks due to STEC.

35.39. Microbiological test results should be retained for an appropriate period to allow for trend analysis. Increases, often small, in the population of indicator microorganisms over time may suggest that there is an emerging issue (or issues) in the production process which may require remediation.

86. ESTABLISHMENT: MAINTENANCE AND SANITATION

36.40. 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).

97. ESTABLISHMENT: PERSONAL HYGIENE

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

8. TRANSPORTATION

38.42. 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

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

9.2 Product information

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

9.3 Labelling

41.45. 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 awareness

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

10. TRAINING

43.47. 43. 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

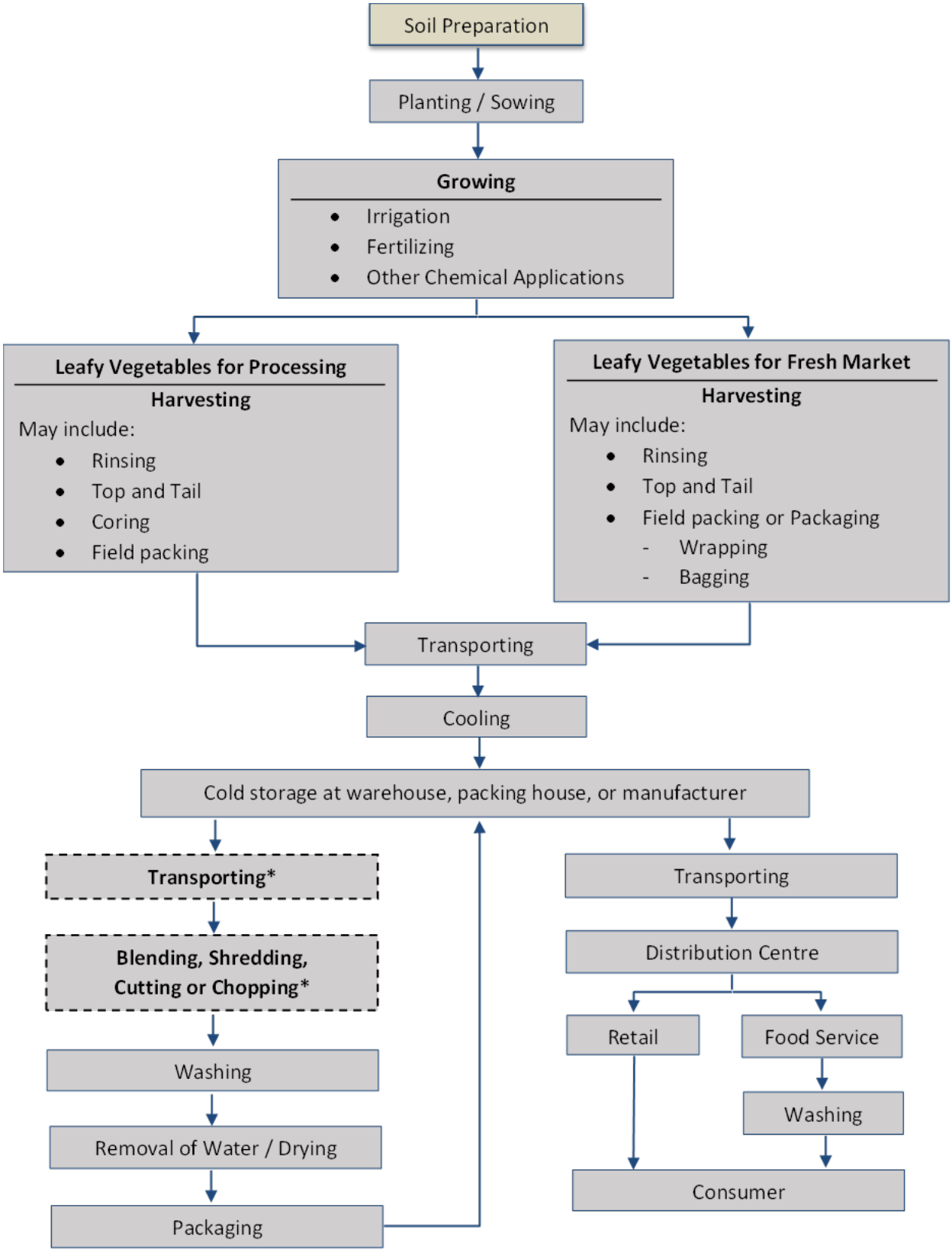
44.48. Fresh leafy vegetables (intact and pre-cut) should be held at an appropriate temperature to minimize growth of STEC. Cross-contamination from or to other food items should be prevented. Food business

operators serving fresh leafy vegetables for consumption without cooking to consumers should take appropriate measures to

- prevent cross-contamination,
- maintain appropriate holding and storage temperature,
- thoroughly wash fresh leafy vegetables in accordance with section 4.3 prior to use when appropriate, and
- ensure proper cleaning of tools and surfaces that may come in contact with these products.

~~45.~~49. When cold damage is not a concern, fresh leafy vegetables should be cooled to appropriate refrigeration temperatures (see footnote 2) to prevent the growth of STEC. For fresh leafy vegetables susceptible to quality damage at refrigeration temperatures, the growth of STEC should be minimized by cooling to temperatures as low as possible while avoiding quality damage.

Figure1: Process Flow for Fresh Leafy Vegetables[3]



[3] The diagram illustrates a generalised process flow for fresh leafy vegetables for illustrative purposes only. Steps may not occur in all operations and may not occur in the order presented in the flow diagram.
*Boxes with broken lines indicate steps that may not be included, depending in part on the commodity.

ANNEX IV SPROUTS

1. INTRODUCTION

1. Sprouts are commonly consumed raw and sometimes ~~often~~ without a processing ~~application of a kill~~ step that would eliminate microbial pathogens, prior to consumption. Consequently, it is necessary to ensure safe production of sprouts by preventing or minimizing contamination of incoming seeds, in the production environment and in the finished products. While no single step will reliably eliminate all pathogenic microorganisms that may survive on sprouts, using a series of preventive and risk-reduction steps (i.e. a multi-hurdle approach) can greatly reduce the food safety risks that may be associated with sprouts.

2. Sprouts have different food safety concerns from other fresh fruits and vegetables because the conditions for seeds to sprout (e.g. time, temperature, water activity, pH, and available nutrients) also support the growth of foodborne bacterial pathogens if present.

3. Contaminated seeds have historically been identified as the likely source of most sprout-related outbreaks, particularly those attributed to Shiga toxin-producing *Escherichia coli* (STEC) contamination and continues to be the most common source of sprout contamination[1] (NACMCF, 1999; EFSA, 2011; Ferguson et. al., 2005, FAO/WHO, 2022). Bacterial pathogens that may be present at low levels on seeds can multiply to very high levels during the sprouting process. Sprout contamination could also be caused by poor hygienic practices and contamination in production environments[1].

4. Figure 1 provides a flow diagram illustrating a generalized process flow to produce sprouts. This flow diagram is for illustrative purposes only. All steps may not occur in all operations or may not occur in the order presented in the flow diagram. Sprouts are grown in production environments that vary based in size and resources of the operation, seed type, available equipment, etc.

5. During seed production, conditioning, storage, and distribution for sprouting, the application of Good Agricultural Practices (GAPs) and Good Hygienic Practices (GHPs) should aim to prevent the contamination of seeds by microbial pathogens such as STEC. During sprout production, any step for the microbiological decontamination of seeds is aimed at reducing potential contaminants, while GHPs are aimed at preventing the introduction of microbial pathogens and minimizing their potential growth. The degree of control in these two areas has a significant impact on the safety of sprouts.

2. OBJECTIVE

6. The objective of this Annex is to provide guidance to reduce the risk of foodborne illness from STEC associated with sprouts intended for human consumption without cooking, during production, harvesting, packing, processing, storage, distribution, and marketing as well as addressing consumer awareness.

3. SCOPE, USE, AND DEFINITIONS

3.1 Scope

7. This Annex covers specific guidance for the control of STEC related to sprouts that are intended to be consumed raw.

8. Home-sprouting, and shoots, cress, and microgreens[2] where the seed is not kept in the final product are outside the scope of this document.

3.2 Use

9. This Annex should be used in conjunction with the *General Principles of Food Hygiene* (CXC 1-1969), the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003), including Annex II for Sprout Production and the Guidelines for the Safe Use and Reuse of Water in Food Production and Processing (CXG 100-2023), including Annex 1 “Fresh Produce”.

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[1] FAO/WHO. 2022. Microbiological Risk Assessment Series 43: *Prevention and control of microbiological hazards in fresh fruits and vegetables – sprouts.*

[2] Shoots are grown hydroponically, and true leaves are developed. The shoots and the leaves are cut during harvest and the final product does not include the seed and roots. Cress is grown with substrate and true leaves are developed; as with shoots grown hydroponically, the cut shoots and leaves do not include the seed and roots. For microgreens, plants reach a later stage of growth than sprouts, typically associated with the emergence of “true” leaves. They can be grown in soil or substrate and are harvested above the soil or substrate line; they Include both shoots and cress (FAO/WHO, 2022).

3.3 Definitions

Sprouts - Sprouted seeds or beans harvested when the cotyledons (or seed leaves) are still un- or underdeveloped and true leaves have not begun to emerge. They can be grown in water, soil or substrate and can be harvested with or without the root (cut sprouts)[3]

Seeds for sprouting – Seeds or beans used to produce sprouts for human consumption.[4]

4. PRIMARY PRODUCTION OF SEEDS FOR SPROUT PRODUCTION

4.1. Control measures for seed production and handling

~~9.~~10. Interventions aimed at reducing the risk from seed-borne contamination should focus on controlling contamination of seeds from animal and human activities and ensuring proper use and application of manure, biosolids, other natural fertilizers, and agricultural water.

4.1.1. Animal and human activities

~~10.~~11. Grazing of domestic animals should not occur in fields while crops are actively being grown for use in sprouted seed/bean production. History of the growing area regarding previous uses for grazing domestic animals should also be considered, as STEC have been shown to survive for several weeks in bovine feces.

~~11.~~12. In addition, nearby fields with livestock, particularly those located uphill or upstream, can increase the likelihood of STEC contamination. Livestock should be located as far as feasibly possible from fields growing seeds for sprout production, because the risk of seed contamination decreases as the distance to livestock increases (Berry et al., 2015, 2019).

~~12.~~13. During the growing season the areas used for growing seeds for sprouting should be assessed for evidence of potential contamination of seeds from domesticated or wild animals (e.g., observation of animals or animal activity, animal excreta, crop destruction).

~~13.~~14. When evidence of potential contamination is found (e.g., the plant or seed is visibly contaminated with animal excreta), growers should evaluate whether the seed should not be harvested due to the potential for contamination with pathogens such as STEC. Growers should then take measures to label (or otherwise indicated) ~~identify~~ contaminated seed and/or the contaminated area (e.g., mark the affected area) so that such seed will not subsequently be harvested in the event weather conditions, or other occurrences, make the evidence of potential contamination no longer visible.

~~14.~~15. Wild animals should be excluded from the production area to the extent possible. Possible methods include the use of physical barriers (e.g., fences) and active deterrents (e.g., noise makers, scarecrows, images of owls, foil strips).

~~15.~~16. The presence of nearby animal production facilities (e.g., animal feed operations, poultry farms, dairy farms) or other related factors such as slope of land, lack of runoff controls, and manure spreading that could lead to contamination of the seed or irrigation water with untreated manure, should be assessed and appropriate actions taken to prevent contamination of growing areas and seed with STEC.

4.1.2 Water for seed production

~~16.~~17. Water for irrigation and other applications should be fit for purpose and used in a manner to avoid the introduction of pathogens onto seeds.

~~17.~~18. Growers should evaluate the sources of water used on the farm for the likelihood of contamination with STEC (e.g., from livestock, wildlife, sewage treatment, human habitation). The following actions may prevent contamination of water supplies with STEC:

- installation of fencing around surface water supplies to prevent large animal contact,
- proper maintenance of wells,
- water filtration system or chemical water treatment,

[3] FAO/WHO. 2022. Microbiological Risk Assessment Series 43: *Prevention and control of microbiological hazards in fresh fruits and vegetables – sprouts.*

[4] References to “seeds” in this document include other things that are sprouted to produce sprouts for human consumption, such as beans.

- prevention of stirring of the sediment when drawing water, and
- construction of settling or holding ponds or water treatment facilities.

~~18.~~19. The effectiveness of these actions should be verified by periodic risk-based water testing. Where necessary, growers should test the water they use for appropriate indicator microorganisms and, where identified as necessary, STEC, according to the risk associated with the production. The frequency of testing will depend on the water source (e.g., 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. Analysis of indicator microorganism test results over time may help growers notice emerging issues.

~~19.~~20. Where possible, growers should be able to identify or have a contingency plan in place that identifies an alternative source of fit-for-purpose water if the primary water source is found to have unacceptable levels of indicator microorganisms or is contaminated with STEC. Refer to the Guidelines for the Safe Use and Reuse of Water in Food Production and Processing (CXG 100-2023), including Annex 1 “Fresh Produce”.

4.1.3 Manure, biosolids and other natural fertilizers

~~20.~~21. Growers who use biological soil amendments of animal origin (e.g., manure) on fields producing seeds for sprouting should only use them in such a way that they do not contaminate the seeds for sprouting. Manure, biosolids, and other natural fertilizers are potential sources of bacterial pathogens. Only properly composted manure/biosolids treated to reduce or eliminate STEC should be used during seed production to reduce the risk of seed contamination.

~~21.~~22. Refer to 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.

~~22.~~23. If untreated or partially-treated natural fertilizers are used, the time period before harvesting of seed should be maximized, as bacterial pathogens die off over time.

4.1.4 Personnel health, hygiene, and sanitary facilities

~~23.~~24. Worker hygiene and health requirements should be followed to ensure that personnel who have direct contact with seeds for sprouting prior to, during or after harvesting will not contaminate them with STEC.

~~24.~~25. Adequate access to, and use of, hygienic and sanitary facilities, including means for to effectively clean and dry hands , are critical to minimize the potential for workers to contaminate seeds for sprouting.

~~25.~~26. People known or suspected to be suffering from diarrheal illness should not be allowed to enter any area handling seeds destined for sprouting, including the growing and harvest area.

~~26.~~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) for more recommendations that may apply.

4.1.5 Equipment associated with growing and harvesting of seeds for sprouting.

~~27.~~28. Equipment should be designed for ease of cleaning and maintained to minimize soil intake and seed damage and prevent introduction of pathogens such as STEC onto seeds for sprouting.

~~28.~~29. Growers should avoid moving harvesting equipment across fields where improperly composted manure/biosolids have ~~manure or compost non – properly composted, has~~ been applied.

~~29.~~30. To avoid contamination of seeds destined for sprouting, harvesting equipment should be cleaned and disinfected prior to harvesting. In addition, in the event of circumstances that may result in contamination, e.g., equipment runs over an area with animal intrusion and faecal deposits, harvesting should cease, and equipment should be cleaned and disinfected prior to using the equipment for harvesting again.

4.1.6 Handling, storage, and transport of seeds for sprouting

~~30.~~31. Good hygiene practices (GHPs) should be implemented to avoid possible contamination of seeds during storage and transportation. When possible, temperature and humidity should be controlled.

~~31.~~32. Equipment used to transport the seeds should be clean and, where necessary, disinfected prior to use.

~~32.~~33. Packaging of seeds is recommended to minimize the potential for contamination. Growers should pack and hold seeds under sanitary conditions and pest controls should be implemented in storage facilities.

~~33.~~34. Seeds for sprouting should be held and stored in solid bags (e.g. new or recycled bags) or completely closed/covered containers, in a clean, dry area dedicated only to seed storage. Open weave bags or containers with holes or uncovered openings should not be used to store seeds.

~~34.~~35. Containers stored outdoors should be cleaned and, as appropriate, disinfected before being used to transport seeds for sprouting. Such containers should be positioned off the ground.

~~35.~~36. Each container should be marked to identify the source and lot and if the seed has been treated. This should be clearly indicated on the label.

~~36.~~37. Containers should not be stored on the floor or placed against walls to reduce the possibility of contamination with STEC by rodents or other pests and to facilitate regular monitoring for pest problems.

5. SPROUT PRODUCTION

38. HACCP principles should be applied to sprout production, with all the steps well documented and potential critical control points (e.g., decontamination of the seeds) identified and controlled. If a problem is identified (e.g., STEC contamination of sprouts), corrective actions should be taken and a critical review of all the steps should be performed to determine whether changes are needed.

~~37.~~39. Water used throughout sprouts production should be fit for purpose.

5.1 Sourcing and Receiving oft seeds for sprouting

~~38.~~40. Seeds should be obtained from suppliers, (producers or distributors) that follow GAPs and GHPs during production, storage, and distribution, ~~and commercialization~~ of the seeds for sprouting. When possible, microbiological testing/certificates of analysis or a letter of guarantee should be obtained from the supplier.

~~39.~~41. When seeds arrive at a sprout operation, they should be inspected for physical damage and signs of contamination (e.g., rodent/bird droppings, dirt, and other visible contamination).

~~42. Keeping seeds and sprouts from different batches separated can facilitate the identification of contaminated batches and help trace seeds back to the supplier~~. ~~Water used throughout sprouts production should be fit for purpose.~~

5.2 Storage of seeds for sprouting

42. Seeds should be stored and handled in conditions (e.g., temperature and relative humidity) that will prevent growth of microorganisms, such as STEC.

43. Seeds should also be stored and handled in a manner that will avoid damage and keep them protected from pests and other sources of STEC contamination.

~~40.~~44. Keeping seeds and sprouts from different batches separated can facilitate the identification of contaminated batches and help trace seeds back to the supplier.

5.3 Initial Rinse

~~41.~~45. Seeds should be rinsed thoroughly to remove dirt or debris before any ~~antimicrobial~~ treatment is applied.

~~42.~~46. Seeds should be rinsed and agitated in large volumes of fit for purpose water. Repeat the process with fit for purpose water until the dirt or debris are removed and rinse water remains clear.

~~43.~~47. The rinsing process should be designed to maximize surface contact of seeds with water (e.g., use large buckets of water and sieves).

5.4 Treatment and pre-germination soak of seeds for sprouting

~~44.~~48. Treatment of seeds to reduce the presence of pathogens such as STEC may be determined to be a critical control point. However, seed treatment can be challenging due to the low water activity of the seeds, and the need to preserve the viability of the seeds, including their ability to germinate. Treating seeds used for sprouting reduces the level of potential contamination but does not reliably eliminate pathogens, such as STEC, therefore treating seeds does not replace the importance of measures to prevent contamination of seeds and sprouts. Known seed treatment methods include those that work by chemical methods (liquid or gas), physical methods, or a combination of these. The use of certain seed treatments may be subject to approval by competent authorities.

~~45.~~49. The following chemicals, when used at appropriate concentrations, may be able to achieve at least a 3-log reduction of pathogens: calcium hydroxide, calcium hypochlorite, sodium hypochlorite, caprylic acid, gaseous acetic acid, hydrogen peroxide, lactic acid, monocaprylin, oxalic acid, and phytic acid. When authorized by competent authorities, the use of ~~using chemical~~ treatments, including the duration of treatment and the concentration of the chemical used should be accurately measured and recorded.

~~46.~~50. Physical treatments have been reported to achieve a 5-log or greater reduction in pathogens, including *E. coli* O157:H7, on seeds. Physical treatments, such as heat (dry heat or hot water), high pressure, and irradiation are reported to have better penetration characteristics for reaching bacteria on microscopically rough surfaces as well as the interior of the seed as compared to chemical treatments. Combinations of several p~~P~~hysical and/or chemical ~~combination~~ treatments have been reported to be the most effective for removing pathogens from seeds for sprouting. Combination treatments ~~methods~~ applied sequentially or simultaneously may be more effective than using a single treatment alone.

~~47.~~51. Where feasible, sprout growers should treat the seeds used for sprouting with a method validated to reduce microorganisms of public health significance such as STEC.

~~48.~~52. All steps involved in antimicrobial treatment for seeds should be carried out in an area separated from the germination and packaging areas.

5.5. Rinse after seed treatment

~~49.~~53. Seeds may need to be rinsed after a seed treatment (e.g., seeds treated with chemicals). Time duration of the rinse step should be adequate to limit potential microbial growth.

5.6. Germination and Growth of sprouts

~~50.~~54. Sprouts are grown hydroponically or in soil. Practices employed for germination, growth, harvest, and post-harvest washing vary depending on the operation and the type of sprout grown. Growing units include rotating drums, bins, beds, trays, and buckets.

~~51.~~55. Seeds for soil-grown sprouts are generally rinsed and soaked to allow for initial germination before sowing in soil in plastic trays. Water is sprayed over the trays daily. Sprouts such as alfalfa, broccoli, clover, and radish are grown hydroponically, at ambient or higher temperature, in rotating drums with frequent water sprays. Because of the relative high temperature, i~~I~~f present at the growing stage, microbial pathogens such as STEC can multiply, significantly increasing the risk for consumers~~illness~~.

5.7 Harvesting

~~52.~~56. Sprouts are harvested manually by removing them from growing units. Sprouts may be washed to remove hulls and/or to help lower the temperature of the sprouts and then spin-dried. Soil-grown sprouts are harvested by cutting them from the trays, prior to washing and packaging, or the sprout trays are sent to retailers and cut at the point of sale. GHPs should be applied to prevent these operations from being a source of contamination (e.g., if some of the sprouts are contaminated with STEC from the environment or from handlers).

5.8 Cold sprout storage

~~53.~~57. Sprouts should be maintained at appropriate refrigerated temperatures (see footnote 5) after cooling to minimize growth of any STEC that may be present. The temperature of cold storage should be controlled, monitored, and recorded.

5.9 Personal and environmental hygiene at sprout production

~~54.~~58. Proper storage, handling and disposal of waste, sanitation of equipment and tools, and effective pest control will minimize the risk of sprout contamination with pathogens such as STEC.

~~55.~~59. Facilities should be designed (e.g., differentiation between areas, hygienic zones, flow of operations and personnel) to prevent potential cross-contamination from raw materials to the finished sprouts.

5.10 Documentation and records

~~56.~~60. Documentation of key information for incoming seeds (e.g., supplier details, date of receipt, quantity, production batch/lot code etc.) should be maintained.

~~57.~~61. It is recommended that production, harvesting, packing, storage, and distribution records should be retained long enough to facilitate investigation of product recalls and any notified STEC illnesses, if needed. This period may significantly exceed the shelf-life of sprouts.

~~58.~~62. It may be appropriate to retain microbiological test results for a longer period since this data should be used for trend analyses. Increases, often small, in the population of indicator microorganisms over time may suggest that there is an emerging issue (or issues) in the production process which may require remediation.

~~59.~~63. 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 foodborne illness outbreaks due to STEC.

6. MICROBIOLOGICAL CRITERIA AND OTHER SPECIFICATIONS FOR LABORATORY TESTING

~~60.~~ Where appropriate and when possible, spent sprout irrigation water (SSIW) (or in-process sprouts), and possibly seeds, should be tested for the presence of pathogens such as STEC; in particular, strains demonstrated to be a country's highest priority due to their public health burden (e.g., those strains with virulence factors capable of causing severe illness or considered to cause significant illness in that country). The samples collected for testing should be representative of the production batch.

~~61.~~64. Testing for indicator microorganisms, can be a useful tool to evaluate and verify the safety of the product, the effectiveness of the control measures, 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. Measures to be undertaken in case of positive results for STEC (or when indicator microorganisms reach a pre-defined threshold) need to be established and defined. Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997) and *Principles and Guidelines for the conduct of microbiological risk management (MRM)* (CAC/GL 63-2007).

6.1 Testing of seed lots before entering production

~~62.~~65. Some seed producers or seed suppliers may opt to test their seed for pathogens to help identify contaminated lots before distribution. However, the likelihood of detecting the presence of pathogens such as STEC in seeds is low, due to the heterogeneous distribution and low numbers of STEC contaminating the seeds. A negative test does not assure the absence of STEC on the seeds.

~~63.~~

6.2 Testing of sprouts and/or spent sprout irrigation water (SSIW).

~~64.~~66. Microbial testing of SSIW (or in-process sprouts) is an important part of a multi-hurdle approach to ensure contaminated sprouts do not enter the marketplace. Testing SSIW (or in-process sprouts) for STEC from each production batch of sprouts is a much more reliable indicator than testing seed to determine whether the sprouts and potentially the seeds used to produce the batch, are contaminated with STEC. The highly perishable nature of sprouted seeds generally makes routine microbiological testing of finished sprouts impractical.

~~65.~~67. Samples of SSIW can be collected as early as 48 hours after the start of sprouting, although the optimal time for sample collection may vary depending on the type of sprouts and sprouting practices. If the seeds are pre-soaked (e.g., soaked in water for a short time and then transferred to growing units for sprouting), include the pre-soak time. Early results will allow sprout growers to take corrective actions sooner, thus ensuring that sprouts grown from that (those) lot(s) of seeds do not enter commerce, and to report positive test findings to the seed grower, distributor, supplier, or other relevant entity.

~~66.~~68. If testing SSIW is not practicable (for example, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water), each production batch of sprouts could be tested at the in-process stage (i.e., while sprouts are still growing).

7. DISTRIBUTION AND POINT-OF-SALE

~~67.~~69. STEC growth and contamination can occur during transport, distribution and at point-of-sale due to improper handling and poor personal hygiene, and contamination through comingling with other raw food commodities and animals/animal products, and exposure to unsanitary surfaces and/or water. Control measures should be applied during distribution and at point of sale to prevent contamination with STEC.

7.1 Transportation

~~68.~~70. Sprouts should be transported ~~Transportation should be done~~ in clean, enclosed, and refrigerated transport vehicles and the temperature in the refrigerated compartment of such transport vehicles, should be monitored.

8. PRODUCT INFORMATION AND CONSUMER AWARENESS

~~69.~~71. Producers should provide relevant information to the consumer to assure the safety of sprout~~sed seeds~~ during storage, handling, and preparation of the product. This information may include, but is not limited to: (1) recommended temperature of storage; (2) the date by which the sprouts should be consumed or discarded (e.g. use-by date); (3) ~~cooking or~~ washing instructions, which should be included on the label if the product is intended to be ~~consumed as non-RTE or cooked~~ washed before consumption.

~~70.~~72. Consumers should store sprouts at temperatures that will minimize the growth of pathogens such as STEC and adhere to any instructions provided on labeling (e.g., a use-by date or cooking instructions).

9. TRAINING

~~71.~~73. All personnel involved in the production and handling of seeds for sprouting or sprouts across the supply chain should receive training on the principles of food hygiene and food safety, in particular the high risk nature of sprouts and the illness associated with them, as well as personal health and hygiene requirements.

~~72.~~74. Seed producers, handlers, distributors, and processors should be aware of GAPs, GHPs and their role and responsibility in protecting seeds intended for sprouting from STEC contamination.

~~73.~~75. Control measures ~~Interventions~~ designed to reduce microbiological hazards in sprouts can be highly technical and difficult to implement. Specific training related to seed sourcing and storage, seed treatment, cleaning and disinfecting, sampling and microbiological testing, and record keeping should be done to ensure successful implementation.

10. RETAIL AND FOODSERVICE

~~74.~~76. Sprouts for retail sale should be held at an appropriate refrigeration temperature[5] to minimize growth of STEC. Temperatures should be monitored.

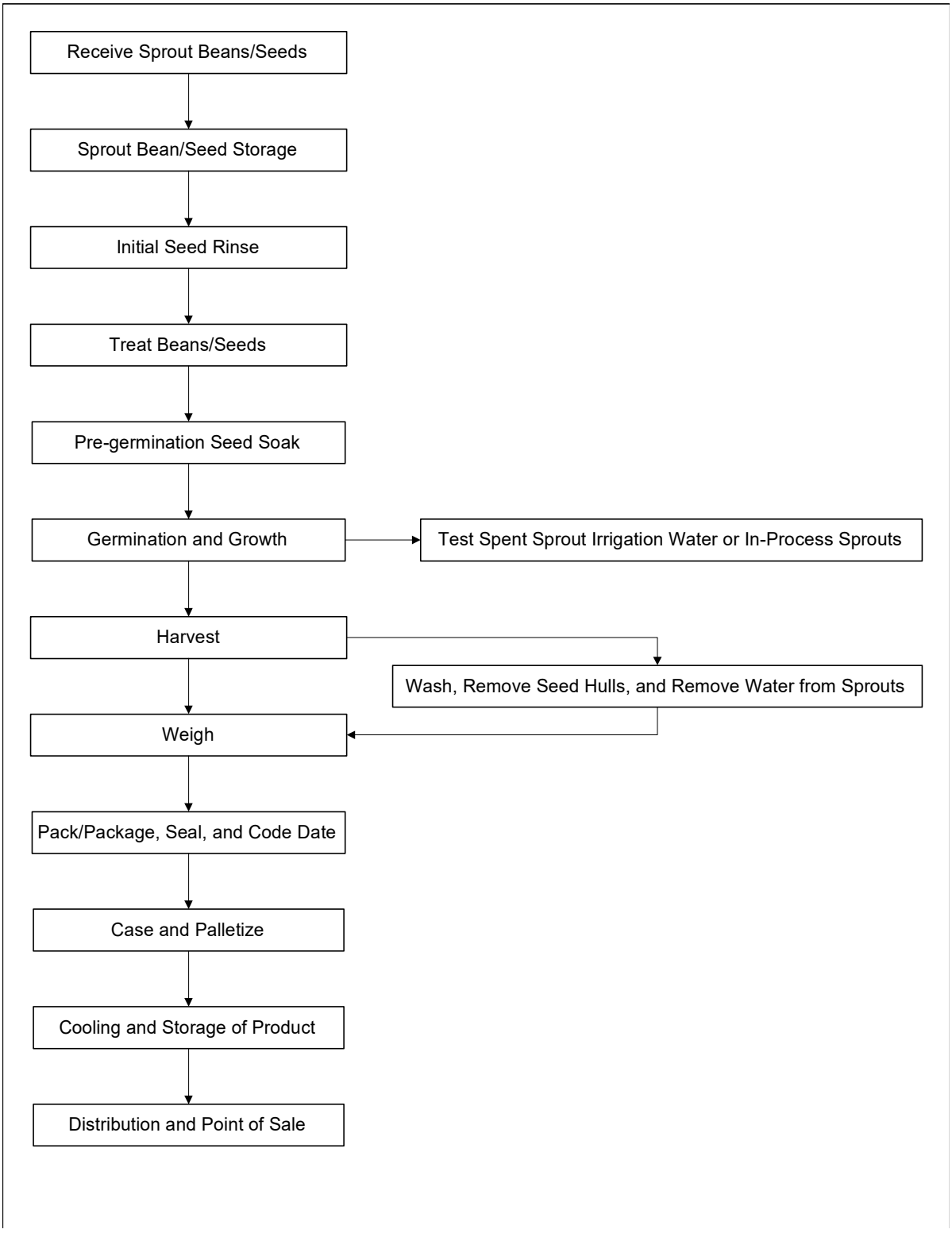
~~75.~~77. Food business operators serving sprouts for consumption without cooking to consumers should take appropriate measures to:

- prevent cross-contamination,
- discard any sprouts that are past the date on their label for which they can be consumed,
- maintain sprouts at an appropriate storage temperature to minimize growth of STEC that may be present, and
- ensure proper cleaning of tools and surfaces that may come in contact with these products.

~~76.~~78. For in-restaurant sprouting, control measures ~~interventions~~ recommended for sprout operations to minimize the potential for STEC should be considered, including seed sourcing programs, seed treatment (if appropriate), prevention of cross-contamination, sampling, and testing of spent sprout irrigation water (samples to be tested by contract laboratories), as well as cleaning and disinfecting food contact surfaces.

[5] E. coli O157:H7 and other STEC are unlikely to grow on fresh leafy vegetables at temperatures lower than 7°C, based on available scientific evidence.

Figure1: Sprouts Flow Diagram[6]



[6] The diagram illustrates a generalised process flow to produce sprouts for illustrative purposes only. Steps may not occur in all operations and may not occur in the order presented in the flow diagram and the germination time may be different.