INTRODUCTION

1. Fresh leafy 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 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 (Bottichio et al., 2019; CDC, 2006, 2012, 2020; Gobin et al., 2018; Herman et al., 2015; Kintz et al., 2019; Kinnula et al., 2018; Marden et al., 2014; Sharapov et al., 2006). 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 manure-based soil amendments1 (Berry et al., 2015; Gelting et al., 2011; Islam et al., 2004; Jay-Russell et al., 2014; Jongman and Korsten, 2018; Olaimat and Hoolley, 2012; Soderstrom et al. 2008). Fresh leafy vegetables are typically grown and harvested in large volumes, increasingly in places where harvest and distribution of fresh leafy vegetables is efficient and rapid. Fresh leafy vegetables are packed in diverse ways, including: field packed direct for market; field cored and prepared for later processing; and as pre-cut fresh leafy vegetable mixtures and blends with other vegetables. Control measures such as antimicrobial washes to minimize cross-contamination may be applied prior to packaging and/or shipment to market. 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 distribution and storage if fresh-cut leafy vegetables are improperly handled. There is no processing treatment applied that would eliminate or inactivate STEC, although contamination can be reduced by washing in water containing antimicrobials. Examples of field level control measures provided in this document 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 smallholdings, whether in developed or developing countries, 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. The objective of this Annex is to provide guidance to reduce, during production, harvesting, packing, processing, storage, distribution, marketing and consumer use, the risk of foodborne illness from STEC associated with fresh leafy vegetables intended for human consumption without cooking.

2. SCOPE AND DEFINITIONS

2.1 Scope

5. This Annex covers specific guidance for the control of STEC related to fresh leafy vegetables that are intended to be consumed without cooking. 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 Definitions

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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.

Fresh leafy vegetables - Vegetables of a leafy nature where the leaf is intended for consumption without cooking, including, but not limited to, all varieties of lettuce, spinach, cabbage, chicory, endive, kale, radicchio, and fresh herbs such as coriander, cilantro, curry leaf, colocasia leaves and parsley, among other local products for foliar consumption.

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). 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.

8. Most contamination of fresh leafy vegetables with STEC is thought to occur during primary production (FAO/WHO, 2008; Julien-Javaux, 2019; Mogren et al., 2018; Monaghan et al., 2016). 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 growing (including irrigating) and harvesting methods used.

3.1 Environmental Conditions

9. 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 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 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.

10. 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.

11. 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 if soil contaminated with STEC splashes onto them. When heavy rains occur, growers should evaluate the need to postpone harvesting fresh leafy vegetables for consumption without cooking and/or to subject them to a treatment that will minimize consumer exposure to STEC. If fresh leafy vegetables that contact flood waters are not subjected to any measure to mitigate risks from STEC to consumers, they should not be consumed raw. This does not include flooding of furrows for irrigation purposes, where the source of water is known and appropriate quality and is not the result of a weather event.

3.1.1 Location of the Production Site

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 and cattle grazing lands present a significant risk of contamination of leafy greens in the field (FDA, 2020; Berry et al., 2015; Yamamula et al, 2011); although guidelines exist for the distance between fields and nearby animal operations (California Leafy Green Products Handler Marketing Agreement (CA-LGMA), 2019), 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 (CA-LGMA, 2019). 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 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, 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 cooking (Wells et al., 2019).

3.2 Hygienic primary production of fresh leafy vegetables

3.2.1 Water for primary production

14. Several parameters may influence the likelihood of contamination of fresh leafy vegetables with STEC: the source of water used for irrigation and the application of fertilizers, the type of irrigation (e.g. drip, sprinkler, overhead), whether the edible portions of fresh leafy vegetables have direct contact with irrigation or other water, the timing of 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 evaluate the sources of water used on the farm for the likelihood 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 test the water they use for appropriate indicator microorganisms and, where necessary, STEC, 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 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 periodic water testing. Where possible, growers should have a contingency plan in place that identifies an alternative source of water fit for purpose.

16. It is especially critical in hydroponic operations to maintain the quality of water used as a 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 to section 3.2.1.1.3 of the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003).)

3.2.2 Manure, biosolids and other natural fertilizers

17. 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, which can persist in manure, biosolids and other natural fertilizers for weeks or even months, if the treatment of these materials is inadequate (Shepherd et al. 2007; Gurtler et al., 2018). 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 (Jiang et al., 2003; Shepherd et al., 2007; Gurtler et al., 2018, Gonçalves and Marin, 2007; Rigobelo et al., 2016). Another manure treatment method involves anaerobic digestion (Alegbeleye and Sant’Ana, 2020; Martens and Böhm, 2009). 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 vegetables prior to, during or after harvesting will not contaminate them with STEC. Adequate
access to, and use of, hygienic and sanitary facilities, including adequate means for hygienically washing and drying hands, are critical to minimize the potential for workers to contaminate fresh leafy vegetables. People known or suspected to be suffering from illness due to STEC should not be allowed to enter any area handling leafy 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 as needed 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 should be cleaned and, as appropriate, disinfected before being used to transport fresh leafy vegetables.

3.2.5 Field packing
20. When packing fresh leafy 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 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 vegetables should be stored and transported under conditions that will minimize the potential for STEC contamination and/or growth. Fresh leafy vegetables should not be transported in vehicles previously used to carry 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 should be carried out between loads to avoid the risk of contamination.

4. PACKING OPERATIONS

4.1 Time and temperature control
23. 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. As far as possible, 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.

25. If water used for cooling comes into direct contact with the fresh leafy vegetables, it should be controlled, monitored and recorded to ensure that the concentration of biocides is sufficient to minimize the likelihood of cross-contamination.

4.3 Washing fresh leafy vegetables
26. Packers washing 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. Where used, biocides 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 (Zhang, et al. 2009; Nou et al., 2011; Lou et al., 2012; López-Gálvez et al., 2019; Tudela et al., 2019(a), 2019(b)). 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 (Gombas, et al. 2017).

5. PROCESSING OPERATIONS
28. 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 of fresh leafy vegetables. Processors should ensure that growers, harvesters, packers and distributors have implemented measures to minimize the contamination during primary production 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. 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 will increase the risk of consumer illnesses. A temperature of 7°C or below will prevent growth of STEC and is appropriate for those fresh leafy vegetables that are not subject to cold injury.

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

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

5.3 Washing and dewatering/drying cut fresh leafy vegetables

31. Washing and drying are important steps in the control of STEC for fresh-cut leafy 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 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 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 prevalence and low numbers of the organism in fresh leafy vegetables and in water. Testing of fresh leafy vegetables for indicator microorganisms, supplemented, where appropriate, by periodic testing for STEC, can be a useful tool to evaluate and verify the safety of the product and 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).

5.6 Documentation and records

34. It is recommended that harvesting, processing, production and distribution records should be retained 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 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. ESTABLISHMENT: MAINTENANCE AND SANITATION


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**


**9.4 Consumer education**


**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 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 storage temperature,
- thoroughly wash fresh leafy vegetables prior to use, and
- ensure proper cleaning of tools and surfaces that may come in contact with these products.

**12. CONSUMER**

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.

2 Blue boxes indicate steps that may not be included, depending in part on the commodity.