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Agenda Item 9 **CX/FH 18/50/9**

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Control of Shiga Toxin-Producing *Escherichia coli* (STEC) in Beef, Unpasteurized Milk and Cheese produced from Unpasteurized Milk, Leafy Greens, and Sprouts

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Introduction

1. Strains of pathogenic *Escherichia coli* that are characterized by their ability to produce Shiga toxins are referred to as Shiga toxin-producing *E. coli* (STEC). STEC are an important cause of foodborne disease and infections have been associated with a wide range of human clinical illnesses ranging from mild non-bloody diarrhoea to bloody diarrhoea (BD) and haemolytic uremic syndrome (HUS), which often includes kidney failure. A high proportion of patients are hospitalized, some develop end-stage renal disease (ESRD) and some die. Some STEC strains that express Shiga toxin (Stx) and adherence virulence genes pose a significant risk of severe infection upon exposure to a single cell. This pathogenic group of *E. coli* has been referred to using multiple terms and acronyms. Some of these, e.g. verotoxin-producing *E. coli* (VTEC) and Shiga toxin-producing *E. coli* (STEC), are synonymous and refer to toxin-producing capability of the organism. Another, non-O157 STEC, refers to the STEC group aside from serotype O157:H7. STEC is used here to apply broadly to all strains that produce Shiga toxin; however, not all strains of STEC are pathogenic.

2. The Codex Committee on Food Hygiene (CCFH) has discussed the issue of STEC in foods since its 45th Session, and at the 47th Session (November 2015), it was agreed that it was an important issue to be addressed[1]. To commence this work, CCFH47 requested the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to develop a report compiling and synthesizing available relevant information, using existing reviews where possible, on STEC. A Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) panel of experts was created and a report entitled Shiga Toxin-Producing *Escherichia coli* (STEC) and Food: Attribution, Characterization, and Monitoring[2] was published in June 2018 (hereafter the "JEMRA review" and referenced as FAO/WHO, 2018).

3. In 2015, WHO published the first estimates of the global burden of foodborne disease, which estimated that in 2010 more than 600 million people fell ill from foodborne disease caused by 31 microbiological and chemical agents (including STEC), resulting in 420,000 deaths and 33 million Disability Adjusted Life Years (DALYs). The Foodborne Disease Burden Epidemiology Reference Group (FERG)[3], which conducted the work for WHO, estimated that foodborne STEC caused more than 1 million illnesses, resulting in more than 100 deaths and nearly 13,000 DALYs. Although, of the microbiological hazards considered by FERG, STEC ranked towards the lower end in terms of burden, the expert group concluded that STEC is indeed a global problem. After considering additional data on human STEC illness from both FAO and WHO member countries and the peer reviewed and grey literature (e.g. reports or other information not available through traditional commercial or academic publishing and distribution channels), the JEMRA review noted that human STEC illnesses have been found in most countries. In addition, STEC poses an economic impact in terms of disease prevention and treatment and has implications for domestic and international trade. Because of international trade, STEC has the potential to become a risk management priority in countries in which it is not currently a public health priority (FAO/WHO, 2018).

[1]Report of the 47th Session of the CCFH Rep 16/FH available http://www.fao.org/fao-whocodexalimentarius/download/report/931/REP16_FHe.pdf
[2] http://www.fao.org/3/ca0032en/CA0032EN.pdf
[3]The Foodborne Disease Burden Epidemiology Reference Group (FERG) was established in 2007 by the World Health Organization (WHO) to estimate the global burden of diseases commonly transmitted through food.

4. STEC are comprised of a large, highly diverse group of strains, common only in the fact that they produce Stx and share a common theme of pathogenesis, namely entry into the human gut (often via ingestion), attachment to the intestinal epithelial cells, and elaboration of Stx. It has been postulated that the production of Stx alone without adherence is deemed to be insufficient for STEC to cause severe infections. As a result, Stx and the ability to adhere to intestinal epithelial cells are the critical characteristics of STEC in determining the course of infections and are regarded as major STEC virulence traits (FAO/WHO, 2018).

5. Ever since the emergence of STEC serotype O157:H7 as an important foodborne pathogen, serotype data have been used as a factor for identifying STEC strains that have the potential to cause severe human diseases. This focus on serotypes continued as non-O157 STEC strains were implicated in outbreaks and other serotypes became targeted as being of health concern. There are hundreds of STEC serotypes; however, based on the evidence gathered in the JEMRA review, the serotype of the STEC strain is not a virulence criterion. All STEC strains with the same serotype should not be assumed to carry the same virulence genes and to pose the same risk, as many STEC virulence genes are mobile and can be lost or transferred to other bacteria. Serotype can be useful in epidemiological investigations but is not very reliable for risk assessment. The risk of severe illness from STEC infections is best predicted based on virulence factors (encoded by genes) identified for an STEC strain (FAO/WHO, 2018). There are two major Stx gene families, Stx1 and Stx2, both of which include many subtypes and variants (Scheutz et al. 2012). Based on present scientific knowledge, STEC strains with stx2a and adherence genes, eae or aggR have the strongest potential to cause diarrhoea, BD and HUS. Strains of STEC with other stx subtypes may cause diarrhoea, but their association with HUS is less certain and can be highly variable. The risk of severe illness may also depend on virulence gene combinations and gene expression, the number of microorganisms ingested, and the susceptibility of the human host. A set of criteria for categorizing the potential risk of severity of illness associated with STEC in food was recommended by JEMRA based on evidence of virulence gene profiles and associations with clinical severity. The criteria could be applied by risk managers in a risk-based management approach to the control of STEC in food. The criteria could also be used in interpretation of the potential risk associated with an STEC strain detected in a food. The set of criteria includes five 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 these goals (FAO/WHO,2018).

6. In most countries, half of STEC illnesses in humans are estimated to be foodborne, with warm-blooded animals being the reservoir associated with transmitting the bacteria into the human food chain. Climate, human and animal densities, land use, farming practices, food harvesting and processing technologies and consumer habits are some of the factors resulting in different epidemiological patterns in different parts of the world (FAO/WHO, 2018).

Sources of STEC in Foods

7. According to the data compiled in the JEMRA review, the most important sources of STEC estimated globally are produce (attribution proportion of 13%), beef (11%), and dairy products (7%). More than half of the outbreaks globally could not be attributed to any source (60%).

8. Cattle have been identified as an important reservoir for pathogens, including STEC. The intestinal tract, mouth, hide, and hooves of cattle can contain these pathogens. STEC illnesses historically have been associated with non-intact beef products since the customary preparation of raw ground beef and non-intact steaks (i.e., cooking to a rare or medium state) does not destroy STEC throughout the product or render the product safe. (Non-intact beef steaks have been subjected to processes that cause significant pathogen penetration such that customary cooking practices do not attain a time and temperature combination sufficient to destroy this pathogen throughout the product and render the product safe. Non-intact products in addition to ground beef include, among others, beef products that have been mechanically tenderized, injected by pumping, vacuum tumbled, or beef that has proteolytic enzymes applied.) E. coli O157:H7 was first identified as the etiologic agent causing hemorrhagic colitis from hamburger patties in two United States outbreaks in 1982 (Riley et al., 1983). E. coli O157:H7 in beef continues to be a source of illnesses; a recent outbreak associated with E. coli O157:H7 occurred in the United States where contaminated ground beef caused 11 illnesses in which 7 patients were hospitalized and 1 patient developed HUS (CDC, 2016). However, non-O157 STEC illnesses from meat are increasingly being recognized. Worldwide between 1994 and 2010, eight confirmed outbreaks of non-O157 STEC illness due to consumption of ruminant meat have occurred in Australia, Denmark, France, Germany, Italy, Norway, and the United States. Six of these outbreaks involved beef products. These eight outbreaks resulted in 228 confirmed cases, including 45 cases of HUS and 3 deaths. In five of these outbreaks, the pathogen caused HUS as well as other severe illness. In all of these outbreaks, the Shiga toxin gene or product was detected. Intimin (eae) was detected in all but one of these outbreaks when researchers screened for it (FSIS, 2012). In the Southeast Asian region where beef makes up less of the overall meat consumed, meat from small ruminants (e.g. sheep, goats) was significant (FAO/WHO, 2018).

9. The dairy products proportion is largely attributed to the consumption of raw milk and cheese produced from raw milk. STEC present in the feces of cows and other animals used for milk production (e.g. goats, sheep) can contaminate the udder and teats, and in turn contaminate raw milk. Insanitary or inadequate processing conditions can also result in the contamination of raw milk or products made from raw milk. Studies investigating the prevalence of STEC in raw cow's milk use different methodologies for detection, and often have a small number of samples. A review of data primarily from the United States and Europe yielded prevalence rates of 0 to 3.8% (Farrokh, et al., 2013). Studies conducted in other counties have reported a higher occurrence, e.g. 4.5-7% in India (Das, et al., 2005; Pandey, et al., 2015), 17.5% in Iran (Mohammadi, et al., 2013). A summary of international studies investigating the prevalence of E. coli O157:H7 and STEC in cheese made from unpasteurized milk showed a range of 0-13% (Farrokh, et al., 2013). The consumption of unpasteurized milk and cheese made from unpasteurized milk have led to outbreaks attributed to STEC. Thirteen outbreaks of STEC due to the consumption of unpasteurized milk occurred in the United States between 2007-2012; 28% of these illnesses were in children aged 1-4 (Mungai, et al., 2015). Outbreaks due to the consumption of unpasteurized milk and cheese made from unpasteurized milk have also been recorded in Canada and Europe. To date E. coli O157:H7 has been the serotype most frequently associated with these outbreaks (Farrokh, et al., 2013).

10. While beef was identified as the most important food category in the African, European and Eastern Mediterranean regions and the Americas, analysis of the outbreak data indicated that fresh produce (i.e., fruits/vegetables) was almost as important as a source in North America and Europe. Outbreak data in North America and Europe show that leafy greens and sprouts form the majority of outbreaks (FAO/WHO 2018). (Examples of leafy greens include iceberg lettuce, romaine lettuce, green leaf lettuce, red leaf lettuce, butter lettuce, baby leaf lettuce, escarole, endive, spring mix, and spinach.) Collectively across the United States from 1998-2016, according to the Centers for Disease Control's National Outbreak Reporting System (NORS), there were 45 confirmed STEC outbreaks linked to vegetable row crops and 44 (98%) were from leafy greens (CDC, 2018). As an example, spinach contaminated with STEC O157:H7 caused 199 illnesses in the United States in 2006, with more than half of the cases being hospitalized; there were 3 deaths (CDC, 2006). More recently in 2018 there was an outbreak of STEC O157:H7 in romaine lettuce in the United States that resulted in 210 illnesses, 96 hospitalizations and 5 deaths (CDC, 2018).

11. Sprouts represent a special food safety concern because the conditions under which sprouts are produced (time, temperature, water activity, pH and available nutrients) are also ideal for the growth of pathogens if they are present. In the United States, sprouts (e.g. alfalfa and clover) outbreaks have been caused by STEC O157, e.g. alfalfa sprouts in 2016 (CDC, 2016) and by other serotypes, e.g. STEC O121 in clover sprouts (CDC, 2014). In 2011 sprouts contaminated with STEC O104:H4 resulted in over 3,000 cases of illness in Europe (EFSA, 2011). Since leafy greens and sprouts are produced using distinctive practices and conditions, they will be discussed in separate sections of the guidance, even though both are produce.

STEC Infectious Dose

12. Factors such as genetic variations among bacterial strains, age and health status of the host, portal of entry and chemical nature of the food-vehicle will influence the infectious dose. Beef products are common food vehicles of STEC in many countries. Most STECs trains that are pathogenic to humans produce little clinical disease in animals used for meat production. Detection of STEC-infected animals must therefore be based on bacteriological or virulence factor analyses. STEC contamination can pass from the colonized intestinal tracts of these warm-blooded animals into the human meat supply and produce grown in proximity to warm-blooded animals (or grown in fields fertilized with uncomposted manure), exposing consumers to STEC. Limited information is available on the dose-response of STEC. The risk of life threatening illness in humans and the absence of an animal model that replicates human pathology preclude experimental determination of STEC dose-response. Estimates of dose-response have been made for STEC O157:H7 based on concentration of the pathogen in food and patient consumption data from outbreaks. It is thought that exposure to less than 100 cells of STEC O157:H7 is sufficient to cause infection. Exposure estimates have been reported from three outbreaks where the concentration of STEC O157:H7 in the food at consumption could be determined; 2 to 45 cells in salami (Tilden et al., 1996), less than 700 cells in beef patties (Tuttle et al. 1999) and 31 to 35 cells in pumpkin salad with seafood sauce (Teunis, Takumi, & Shinagawa, 2004). These estimates are reinforced by reports of STEC O157:H7 concentration, expressed either as Colony Forming Units (CFU) or Most Probable Number (MPN), in a variety of foods involved in outbreaks, e.g. in raw milk cheeses, 5-10 CFU/g (Strachan, Fenlon and Ogden 2001) and 0.0037 to 0.0095 MPN/g (Gill and Oudit, 2015) and in beef patties 1.45 MPN/g (Hara-Kudo and Takatori, 2011) and 0.022 MPN/g (Gill and Huszczynski, 2016). The probability of infection on exposure to a single viable cell of STEC O157 is significant. In one foodborne outbreak a median value of 25% was estimated for children, and a median value of 17% was estimated for adults (Teuniset al., 2004). It is not currently possible to identify STEC strains that have a higher probability of causing infection than STEC O157:H7. An investigation of an STEC outbreak involving serotypes O145:H28 and O26:H11 in ice cream found concentrations of 2.4 MPN/g for O145 and 0.03 MPN/g for O26 (Buvens et al., 2011). In an outbreak of STEC O111:H- associated with fermented

sausage, the estimated exposure dose was 1 cell per 10 g (Paton et al.,1996). This indicates that the probability of infection upon exposure to other STEC strains may approach that of O157:H7. In addition to STEC strain factors, host factors very likely affect dose-response relationships as well as disease outcome. Individuals with a weakened immune system, such as the frail, elderly, and individuals that lack acquired immunity, such as young children, have the highest rate of illness and HUS (Havelaar and Swart, 2014).

Development of Guidelines for Reduction of Risk from STEC

13. As noted above, cattle are an important reservoir for STEC, with the pathogens being found in the intestinal tract and mouth and on the hide and hooves of cattle. STEC is a foodborne concern in beef, since contamination can be transferred to the carcass during the slaughter process. The processing of beef, including veal, from live animal to the packaged product requires multiple steps. Each step has a potential for contamination of STEC in processed meat. Thus, including controls at slaughter and during further processing to ensure that STEC has been reduced below detectable limits on non-intact raw beef products and intact raw beef intended for non-intact raw beef products is important. Much research has been done on many of these steps on measures that would have potential for the reduction of STEC. Many of the steps have known interventions that are supported by scientific literature; in addition to cattle, these interventions can have application to small ruminants, which are consumed in greater numbers in some countries.

14. In many countries, it is a requirement for food processors, including slaughterhouses and meat processing establishments, to implement food safety programs. Many countries routinely use enumeration of hygiene indicator bacteria in food and processing environments, and measurements of critical processing parameters at critical control points to monitor process performance. Periodic process performance verification testing is conducted for STEC in products. In countries where a regulation requires the absence of STEC in a food (e.g. absence of *E. coli* O157 in ground beef and precursors), testing for STEC (or certain STEC strains) is usually required, together with hygiene indicators. Where a country is exporting food to another country that has a domestic regulatory requirement for the absence of STEC in that food, the exporter may be required to meet these requirements even if there is no such requirement in its domestic market. This is common for beef-exporting countries that have monitoring programs for STEC in export slaughter establishments only for international market access purposes.

15. Raw milk is the source of STEC in dairy products. Guidelines to reduce STEC in raw milk and for the production of cheese made from raw milk are needed to reduce risk from STEC in these products.

16. Adoption of a risk-based approach to risk reduction is important for produce to prioritize those products of high risk and to establish risk-based controls, since the individual produce items are very diverse. Existing data show that leafy greens and sprouts present the greatest risk. Sprouts are given special consideration in many countries. In the EU, a regulatory microbiological criterion has been established for sprouts for the absence of specific STEC strains with the highest potential risk of severe illness, while in other countries testing for specific STEC strains may be required during processing as a process performance measure (FAO/WHO, 2018).

17. Based on the information presented above, it is proposed that the guidelines focus on controlling STEC in beef meat (indicating those practices for beef that would have benefits for controlling STEC in small ruminants), unpasteurized milk and cheese made from unpasteurized milk, leafy greens, and sprouts.

18. If accepted as new work by CCFH, the beef slaughter process (including applicable information for small ruminants) can be further detailed with guidelines to include interventions at each major step. Intervention options are applicable to various establishments depending on size and production volume. An example of an intervention for STEC would be to use a hot water carcass wash[4] or acid sprays[5].

19. Similarly, the leafy greens and sprouts annexes in the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) should be assessed to determine whether there is information on interventions specific to STEC appropriate for steps in the production of these commodities. Packaged fresh-cut lettuce has gained broad market acceptance for its convenience and fresh nutritional value but has been increasingly associated with foodborne illness outbreaks. Although contamination of leafy greens can occur at any point in the farm-to-plate continuum, exposure to irrigation water, soil, soil amendments, animals, handling by field workers and equipment make the field production stage particularly high risk for STEC contamination. Leafy green trimming and coring in field are relatively recent industry developments and require additional human handling and exposing the internal leaf tissues to potential contamination (Yang et. al. 2013). A washing step with a commercial wash solution could be a potential intervention for reduction of E. coli O157:H7 (Getty et. al 2013). There are various sources of contamination of sprouts; contaminated seeds have been the source of

[4]https://www.fsis.usda.gov/wps/wcm/connect/a70bb780-e1ff-4a35-9a9a-3fb40c8fe584/HACCP_Systems_Validation.pdf?MOD=AJPERES pg. 49
[5]https://www.fsis.usda.gov/wps/wcm/connect/a70bb780-e1ff-4a35-9a9a-3fb40c8fe584/HACCP_Systems_Validation.pdf?MOD=AJPERES pg. 53

most sprout-associated foodborne illnesses and are considered to be the most common source of contamination. Recent studies have employed physical treatments, such as dry heat/hot water, high hydrostatic pressure, irradiation, and super critical carbon dioxide treatment to reduce or eliminate foodborne pathogens on seeds or sprouts. Combinations of treatment such a heat and chemicals or heat and irradiation may reduce STEC O157:H7 (Bari et. al. 2009). Assessing which interventions are scientifically valid for control of STEC on produce could enhance the existing guidance.

Conclusion

20. This discussion paper presents the need for a new Codex guideline for the control of STEC in beef meat, unpasteurized milk and cheese produced from unpasteurized milk, leafy greens, and sprouts. For meat, the outcome would be a companion guideline to the existing *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011) and *Guidelines for the Control of Nontyphoidal Salmonella sppin Beef and Pork Meat* (CXG 87-2016) recently developed by CCFH. For produce, including sprouts, the outcome would be information specific to control of STEC supplemental to the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003). For unpasteurized milk and cheese produced from unpasteurized milk, the outcome would be information specific to control of STEC supplemental to the *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004). It is clear that reduction and prevention of STEC illnesses in humans is a world-wide priority. CCFH would contribute greatly towards preventing and reducing this public health problem by developing guidance based on the JEMRA review compiling and synthesizing the available relevant information on STEC. The JEMRA review has informed this discussion paper and will be a key resource in the development of a guidance document. Annex 1 is a project document requesting CCFH to begin new work to develop Guidelines for the Control of Shiga Toxin Producing Escherichia coli in Beef Meat, Unpasteurized Milk and Cheese Produced from Unpasteurized Milk, Leafy Greens, and Sprouts.

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Annex 1

PROJECT DOCUMENT

Development of Guidelines for the Control of Shiga Toxin-Producing *Escherichia coli* (STEC) in Beef Meat, Unpasteurized Milk and Cheese Produced from Unpasteurized Milk, Leafy Greens, and Sprouts

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

1. The purposes and scope of the Standard

The purpose and scope of the work is to draft guidelines for the control of STEC in beef meat, unpasteurized milk and cheese produced from unpasteurized milk, leafy greens, and sprouts.

2. Its relevance and timeliness

Strains of pathogenic *Escherichia coli* that are characterized by their ability to produce Shiga toxins are referred to as Shiga toxin-producing *E. coli* (STEC). STEC are an important cause of foodborne disease, and infections have been associated with a wide range of human clinical illnesses ranging from mild non-bloody diarrhoea to bloody diarrhoea (BD) and haemolytic uremic syndrome (HUS), which often includes kidney failure. A high proportion of patients are hospitalized, some develop end-stage renal disease (ESRD) and some die.

This pathogenic group of *E. coli* has been referred to using multiple terms and acronyms. Some of these, e.g. verotoxin-producing *E. coli* (VTEC) and Shiga toxin-producing *E. coli* (STEC), are synonymous and refer to toxin producing capability of the organism. Another, non-O157 STEC, refers to the STEC group aside from serotype O157:H7. STEC is becoming the most common term to apply broadly to all strains that produce Shiga toxin; however, not all strains of STEC are pathogenic.

The Codex Committee on Food Hygiene (CCFH) has discussed the issue of STEC in foods since its 45th Session and at the 47th Session (November 2015), it was agreed that it was an important issue to be addressed[6]. To commence this work, the CCFH requested the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to develop a report compiling and synthesizing available relevant information, using existing reviews where possible, on STEC. A Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) panel of experts was created and a report entitled *Shiga Toxin-Producing Escherichia coli (STEC) and Food: Attribution, Characterization, and Monitoring*, was published in June 2018.

In 2015, WHO published the first estimates of the global burden of foodborne disease, which estimated that in 2010 more than 600 million people fell ill from foodborne disease caused by 31 microbiological and chemical agents (including STEC), resulting in 420,000 deaths and 33 million Disability Adjusted Life Years (DALYs). The Foodborne Disease Burden Epidemiology Reference Group (FERG), which conducted the work for WHO, estimated that foodborne STEC caused more than 1 million illnesses, resulting in more than 100 deaths and nearly 13,000 DALYs.

Of the microbiological hazards considered by FERG, STEC ranked towards the lower end in terms of burden; however, the expert group concluded that STEC is indeed a global problem. After considering additional data on human STEC illness from both FAO and WHO member countries and the peer reviewed and grey literature, it was noted that human STEC illnesses have been found in most countries. In addition, STEC poses an economic impact in terms of disease prevention and treatment and has implications for domestic and international trade. Because of international trade, STEC has the potential to become a risk management priority in countries in which it is not currently a public health priority.

Rapidly evolving international trade demands associated with the need to mitigate the risk of international outbreaks and the severe human consequences and potential trade embargoes that could result from emergence of STEC in less developed areas suggest that all countries should have the ability to detect and monitor STEC in foods destined for domestic or international consumption. In terms of international food standards developed by the Codex Alimentarius, which serve as the benchmark for the safety and quality of foods traded internationally, it was also noted that STEC is one of the few foodborne pathogens that was considered in FERG's global burden on foodborne disease work for which Codex has not as yet developed explicit risk management guidance.

According to the data compiled by the JEMRA expert panel, the most important sources of STEC estimated globally are produce (attribution proportion of 13%), beef (11%), and dairy products (7%). More than half of the outbreaks globally could not be attributed to any source (60%). The dairy products proportion is largely attributed to the consumption of raw milk and cheese produced from raw milk. While beef was identified as the most important food category in the African, European and Eastern Mediterranean regions and the Americas,

[6]Report of the 47th Session of the CCFH Rep 16/FH available http://www.fao.org/fao-whocodexalimentarius/download/report/931/REP16_FHe.pdf)

analysis of the outbreak data indicated that fresh produce (i.e., fruits/vegetables) was almost as important as a source of outbreaks in North America and Europe. In the Southeast Asian region where beef makes up less of the overall meat consumed, meat from small ruminants was significant. Outbreak data in North America and Europe indicate that leafy greens (e.g. lettuce, spring mix, spinach) and sprouts caused the majority of outbreaks. Sprouts represent a special food safety concern because the conditions under which sprouts are produced (time, temperature, water activity, pH and available nutrients) are also ideal for the growth of pathogens if they are present. Since leafy greens and sprouts are produced using distinctive practices and conditions, they will be discussed in separate sections even though both are produce. Based on these data, it is proposed that the guidelines focus on controlling STEC in beef meat (indicating those practices that would have benefits for controlling STEC in small ruminants such as sheep and goats), unpasteurized milk and cheese made from unpasteurized milk, leafy greens, and sprouts.

3. The main aspects to be covered

It is not the intention of the Guidelines to set quantitative limits for STEC in beef meat, unpasteurized milk and cheese produced from unpasteurized milk, leafy greens, and sprouts in international trade. Rather, the Guidelines will follow the examples of the overarching *Code of Hygienic Practice for Meat* (CXC 58-2005)[7], *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003)[8], and *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004)[9], to provide an "enabling" framework that countries can use to establish control measures appropriate to their national situation.

The projected format will follow the *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011)[10]and *Guidelines for the Control of Nontyphoidal Salmonella spp. In Beef and Pork Meat* (CXG 87-2016)[11]The proposed structure is as follows;

Part 1: General guidelines for the control of Shiga Toxin-Producing *Escherichia coli* (STEC) in beef, unpasteurized milk and cheese produced from unpasteurized milk, leafy greens and sprouts.

Part 2: Specific control measures for beef (indicating practices that may be applicable to small ruminants)

Part 3: Specific control measures for unpasteurized milk and cheese produced from unpasteurized milk

Part 4: Specific control measures for leafy greens

Part 5: Specific control measures for sprouts

Parts 2-5 would include (similar to the previously mentioned guidelines) for each food type, as applicable:

- Control measures for primary production (work with OIE for beef)
- Control measures for processing
- Control measures for distribution channels
- Validation of control measures
- Verification of control measures
- Laboratory Analysis Detection Criteria for control of STEC in food (based on the recommendations made in the JEMRA review (Shiga toxin-producing *Escherichia coli* (STEC) and food: attribution, characterization, and monitoring)
- Monitoring and review of control measures

[7]http://www.fao.org/fao-who-codexalimentarius/sh-proxy/ru/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BRCP%2B58-2005%252FCXP_058e.pdf
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4. An assessment against the *Criteria for establishment of work priorities*

The guidelines need to be developed in order to meet the General criterion: Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed work is directed primarily at the control of STEC, a microbial hazard that is a public health problem world-wide. This document will provide guidance to all countries on the control of STEC in the production of beef meat, unpasteurized milk and cheese produced from unpasteurized milk, leafy greens, and sprouts.

Also under the Criteria applicable to general subjects, the guidelines are needed in consideration of the global magnitude of the problem or issue.

STEC related illnesses have been reported in most parts of the world, thus making this a global concern. In addition, to the burden of disease, STEC also poses an economic impact in terms of disease prevention and treatment, and has implications for domestic and international trade. STEC is the sole remaining foodborne hazard considered by FERG for which risk management guidance has not been developed by Codex.

5. Relevance to the Codex strategic objectives

The proposed work directly relates to several Codex strategic goals from the Codex Strategic Plan: 2014-2019.

- Strategic Goal 1: Establish international food standards that address current and emerging food issues:

  These Guidelines would establish a new Codex standard in response to needs identified by Members and in response to factors that affect food safety and fair practices in the foods trade. As noted previously, control of STEC is currently an issue world-wide.

- Strategic Goal 2: Ensure the application of risk analysis principles in the development of Codex standards

  The development of the Guidelines will be consistent with the use of scientific advice and risk analysis principles in the articulation of the control measures. Scientific advice from the FAO/WHO expert bodies, particularly JEMRA, and scientific input from all countries will be solicited.

- Strategic Goal 3: Facilitate the effective participation of all Codex Members

  The development of these Guidelines will be open to all Codex Members to participate and provide useful and meaningful contributions.

- Strategic Goal 4: Implement effective and efficient work management systems and practices

  It is expected that the working group efforts will be effective, efficient, transparent, and consensus-based for a timely adoption of these Guidelines. The process would likely begin with initial discussions at the ad hoc working group on new work at CCFH50 and in plenary, followed by an electronic working group (EWG) to establish the initial framework. CCFH could then explore whether having a physical working group (with translation) would be useful, perhaps in conjunction with the next year's meeting of the CCFH. This would encourage more participation.

6. Information on the relation between the proposal and other existing Codex documents

The proposed Guidelines will follow the example of the overarching *Code of Hygienic Practice for Meat* (CXC 58-2005), the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) and *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004) to provide an "enabling" framework which countries can utilize to establish control measures appropriate to their national situation.

The projected format will follow the *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011) and *Guidelines for the Control of Nontyphoidal Salmonella spp. In Beef and Pork Meat* (CXG 87-2016) and include only provisions of particular importance for the safety of beef meat, unpasteurized milk and cheese produced from unpasteurized milk, leafy greens, and sprouts.

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

To commence this work, the CCFH requested FAO and WHO to develop a report compiling and synthesizing available relevant information, using existing reviews where possible, on STEC that would be the basis for the guidelines development.[12] We anticipate that there may be a need for additional scientific advice from

[12]Report of the 47th Session of the CCFH Rep 16/FH available http://www.fao.org/fao-whocodexalimentarius/download/report/931/REP16_FHe.pdf)

FAO's/WHO's expert body JEMRA on the scientific and practical soundness of the proposed control measures and their validation, verification, and review activities. This activity would likely be reaching out to the JEMRA expert panel that developed the report entitled *Shiga Toxin-Producing Escherichia coli (STEC) and Food: Attribution, Characterization, and Monitoring the Risk* published in June 2018.

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

Since the OIE's Working Group on Animal Production Food Safety has been discussing the issue of STEC in food-producing animals, particularly for pre-harvest (production level, farm level) controls, OIE should be notified and cooperation encouraged. At CCFH49, OIE indicated it would consider new work on STEC if CCFH also initiated work on STEC.

9. The proposed time-line for completion of the new work

A four-year timeline is proposed for the completion of the guidelines. The shorter than usual timeframe may be applicable, as this effort will closely follow the format of the existing *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011) *and Guidelines for the Control of Nontyphoidal Salmonella spp. In Beef and Pork Meat* (CXG 87-2016), thus facilitating the development of this proposed document. The shorter timeframe is also applicable since the Codex has already sought the expert advice of JEMRA and a report has been developed by the expert contributors. Assuming approval of this new work by the Codex Alimentarius Commission (CAC) in 2019 at CAC42, a proposed draft document would be projected for initial discussion by CCFH51 in 2019 at Step 3, with a projected date for a recommendation for adoption at Step 5 in 2020 at CCFH52 (possibly Step 5/8) and subsequent adoption at Step 5 by CAC44 in 2021. Recommendation for adoption at Step 8 is proposed to take place at CCFH53 in 2021, followed by adoption by CAC45 in 2022.