

CODEx ALIMENTARIUS COMMISSION



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Agenda item 8 CX/FH 19/51/8-Add.1

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE

Fifty-first Session

Cleveland, Ohio, United States of America, 4 - 8 November 2019

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

Comments at Step 3 in reply to CL 2019/72-FH

Comments of Argentina, Brazil, Canada, Chile, Colombia, Gambia, Honduras, India, Iraq, Japan, Morocco, New Zealand, Nicaragua, Panama, Peru, Sri Lanka, Thailand, Uruguay, the United States of America, Collagen Casings Trade Association (CCTA), International Dairy Federation (IDF/FIL)

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2019/72-FH issued in September 2019. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

2. The comments submitted through the OCS are hereby attached as **Annex I** and are presented in table format.

ANNEX I

GENERAL COMMENT	MEMBER/OBSERVER						
<p>In the entire Spanish-language document:</p> <ul style="list-style-type: none"> - “La <i>Escherichia coli</i> productora de toxina Shiga” should be replaced with “<i>Escherichia coli</i> productor de toxina Shiga.” - The “la” in “la ECTS” should be removed. <p>“Seguimiento” should be replaced with “monitoreo.”</p>	Argentina						
<p>Canada recognizes the significant amount of work undertaken by the co-chairs on this document, and was mindful to focus on providing technical rather than editorial comments at this point. We believe that significant editing of the text still needs to occur, e.g., flow adjustments between the different annexes and the general guidance, review of the whole text to complete the unfinished sentences in several places, and shortening of sections 1,2 and 3 of the general document to improve readability (many statements are repeated or paraphrase text and concepts already covered in other documents - referencing these documents with a short summary sentence should suffice).</p> <p>We also note that the content/style in Annex 1 and 2 are very different and may need to be standardized.</p>	Canada						
<p>Chile suggest that the annex 1 on beef meat should continue ts developing after the report of the expert meeting on specific control measures.</p>	Chile						
<p>agree with you about guidelines , and we have no comments.</p>	Iraq						
<p>The current draft of Annex 2 has an overlap with CXC 53 and does not provide specific guidance for control of STEC. If CCFH continues this work, it will be helpful and useful to request scientific advice from JEMRA effective interventions to prevent STEC contamination in leafy vegetables. It will be necessary to consider whether a new STEC specific guidance should be developed or CXC-53 should be revised, in case that available data is mostly regarding indicator organisms or not specific to STEC.</p>	Japan						
<p>New Zealand would like to thank the Co-Chairs Chile and the United States of America, and the e-WG for the work to-date on these draft guidelines. We believe that there is considerable work still to be done on this document and its annexes, and have provided some general comments for consideration by the plenary.</p> <p>General comments:</p> <p>NZ would like to see more of the useful format used in previous Codex Guidelines such as the Salmonella beef and pork Guidelines (CAC/GL 87-2016) and as discussed by CCFH 50, with appropriate GHP-based and Hazard-based measures clearly and separately identified and relevant for a process step in a commercial setting. The introductory table previously used in other Guidelines, under Availability of control measures at specific process flow steps addressed in these Guidelines (see Page 10 of Annex 1 and page 25 of Annex II of CAC/GL 87-2016), showing availability of any GHP-based or hazard-based control measures at specific steps in the process flow is particularly useful. Risk-based measures should only be considered if available and validated for a specific process step in a commercial setting.</p> <p>Scope for beef: New Zealand would like to see the scope focus on beef meat that is particularly causing concern in relation to STEC in some countries; i.e. ground raw /undercooked beef.</p> <p>OIE: the development of the Guidelines should be done in conjunction with relevant information from the OIE Terrestrial Animal Health Code, the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004) and the Code of Hygienic Practice for Meat (CAC/RCP 58-2005).</p> <p>The key to STEC control in raw beef is to maintain consistent hygienic dressing techniques (refer Code of Hygienic Practice for Meat (CAC/RCP 58-2005).</p> <p>Hazard-based measures included in the text should be validated in a commercial setting. FAO/WHO may need to be requested to do this as was done for earlier Guidelines developed this way. (CAC/GL 78-2011).</p> <p>Consumers: validated hazard – based measures should be included for cooking of raw beef particularly in relation to the form known to cause most concern for STEC, i.e. ground beef.</p> <p>Specific comments on the draft text presented</p> <table border="1" data-bbox="136 1372 630 1440"> <thead> <tr> <th>Paragraph</th> <th>Comment</th> <th>Rationale</th> </tr> </thead> <tbody> <tr> <td>Introduction</td> <td></td> <td></td> </tr> </tbody> </table>	Paragraph	Comment	Rationale	Introduction			New Zealand
Paragraph	Comment	Rationale					
Introduction							

<p>Para 8 Examples of control measures Where is the rigorous scientific evaluation?</p> <p>Para 10 format The bulleted points don't appear to have been followed within the Annex</p> <p>Para 13 The primary focus is to provide information on practices that may be used to prevent, reduce, or eliminate STEC in raw beef meat6, leafy greens, raw milk and cheese produced from raw milk, and sprouts Typo. Superscript?</p> <p>Para 17 Delete paragraph here and include within Annex I not Annex IIOIE only relevant to animals, therefore not across all commodities</p> <p>Para 18</p> <p>4th Sentence Examples of hazard - based control measures are limited to those that have been scientifically demonstrated as effective in a commercial setting. Clarity around application necessary in a commercial setting</p> <p>Annex 1</p> <p>Scope This guidance applies to control of STEC in fresh beef meat, including cuts such as steaks and particularly ground meat products.</p> <p>Para 5</p> <p>2nd sentence While control in the primary production phase can decrease the number of animals carrying and/or shedding STEC, controls after primary production are important to prevent minimise the contamination and cross-contamination of carcasses and meat productsAlways some contamination likely. The main aim is to minimise contamination</p> <p>Para 6 and others Delete external references that are not Codex related</p> <p>Interventions to control enteric pathogens should always be seen as part of an integrated food safety system that includes all the stages from primary production to consumption "farm to fork." Replace with words consistent with text elsewhere describing "primary production to consumption"</p> <p>No specific process step table for control measures This is needed</p> <p>5. Primary Production Need to involve OIE</p> <p>Consumers Validated hazard-based measures needed around cooking Insert advice on hazard-based measures to properly cook ground beef in particular.</p>	
<p>Nicaragua thanks Chile, the United States, and the members of the eWG for drafting the document.</p>	<p>Nicaragua</p>
<p>In general, Thailand agrees with the current structure of the general section which explains different types of control measures, GHP-based, Hazard-based and Risk-based in the Annexes.</p>	<p>Thailand</p>
<p>The United States supports this work to provide comprehensive measures to control STEC, which is a significant public health problem worldwide. The United States co-chaired the development of this first draft. We appreciate all the input received from the electronic working group members and we look forward to country comments that can improve the text. We want to emphasize that, as noted in paragraph 18, the measures identified in this document need to be limited to those demonstrated to be effective; references are being included so JEMRA can evaluate the measures to ensure that those included have been shown scientifically to be effective in reducing the risk from STEC.</p> <p>This document uses the term "beef meat." "Beef" means meat from cattle, so the term is redundant. We suggest that the term "raw beef" be used instead of beef meat, as we think this is the intent of the document. We also suggest using the term "fresh leafy vegetables" instead of "leafy greens" to be consistent with the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003). "Leafy green vegetables" would also be acceptable; "leafy greens" is colloquial.</p> <p>Our comments here are primarily for clarification of the text and to provide input on those areas where we see gaps or problems. We note that some of the text is copied from a document on control of Salmonella. This text will need to be reviewed to ensure it is relevant to STEC and this document structure. We are aware of a number of typographical errors that will be fixed later and have generally not included them in our comments.</p>	<p>USA</p>

SPECIFIC COMMENTS	MEMBER / OBSERVER AND RATIONALE
DRAFT GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING E. COLI (STEC)	Argentina

IN RAW BEEF, FRESH LEAFY GREENS, RAW MILK AND CHEESE PRODUCED FROM RAW MILK, AND SPROUTS	<ul style="list-style-type: none"> - The scope and Annex I establish that the present guidelines apply to “raw beef.” - The scope of Annex II establishes that the present guidelines apply to “fresh leafy greens.” <p>Comment on application to the entire document: “Leafy greens” should be replaced with “fresh leafy greens,” and “beef” should be replaced with “raw beef.”</p>
GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING <i>E. COLI</i> (STEC) IN BEEF MEAT, LEAFY GREENS, RAW DRINKING MILK AND CHEESE PRODUCED FROM RAW MILK, AND SPROUTS	<p>IDF/FIL Add “drinking” in between “raw” and “milk” These Guidelines are not intended to address STEC in raw milk that is heat treated during manufacture, but only raw milk consumed directly by the consumer. The scope relates to dairy products made from raw milk that has not undergone heat treatment which includes:</p> <ul style="list-style-type: none"> • Raw drinking milk • Cheeses made from raw milk (raw milk cheeses) <p>Raw milk is used as the primary input in the production of dairy products. STEC is normally controlled by heat treatment of the raw milk and subsequent application of other control measures. Consequential changes are needed throughout the document. See also our comment to definitions (section 4)</p>
GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING <i>E. COLI</i> (STEC) IN BEEF MEAT, LEAFY GREENS, RAW MILK AND CHEESE PRODUCED FROM RAW MILK, AND SPROUTS<u>SPROUTS AND FRESH LEAFY VEGETABLES</u>	<p>Japan To be consistent with the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003), the order of annexes and the term “leafy green” should be changed.</p>
GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING <i>E. COLI</i> (STEC) IN BEEF, LEAFY GREENS, RAW MILK AND RAW MILK-BASED CHEESE, AND SPROUTS RAW BEEF, LEAFY GREENS, RAW MILK AND CHEESE PRODUCED FROM RAW MILK, AND SPROUTS	<p>Honduras</p>
GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING <i>E. COLI</i> (STEC) IN BEEF RAW BEEF, LEAFY GREENS, RAW MILK AND RAW MILK-BASED CHEESE, AND SPROUTS	<p>Uruguay Uruguay suggests incorporating a section on consumers, which would include information on products and on raising consumer awareness, both in the document overall and in the corresponding annexes. Uruguay suggests changing “beef meat” to “raw beef meat” in the title of the document and throughout.</p>
(Request for comments at Step 3 via CL 2019/72-FH)	<p>Colombia Make sure all citation numbers are superscripts.</p>
1. INTRODUCTION	
The Shiga toxin-producing <i>E. Coli</i> (STEC) ¹ are increasingly recognized as foodborne pathogens of concern, causing human illnesses with a range of mild to severe gastrointestinal presentations, occasionally leading to severe haemolytic uremic syndrome with kidney failure and death. The burden of the disease and the cost of control measures are significant; the pathogen has been associated with diverse commodities, and these associations appear to be regional, and thus STEC have the potential to disrupt trade between countries.	<p>Honduras We suggest adding the STEC abbreviation since this will be more familiar for the Spanish-language document.</p>
The Shiga toxin-producing <i>E. Coli</i> (STEC) ¹ are increasingly recognized as foodborne pathogens of concern, causing human illnesses with a range of mild to severe gastrointestinal presentations, occasionally leading to severe haemolytic uremic syndrome with kidney failure	<p>Colombia It is important to discuss <i>E. coli</i> in general terms in the introduction and then focus the text on STEC.</p>

<p>and death. The burden of the disease and the cost of control measures are significant; the pathogen has been associated with diverse commodities, and these associations appear to be regional, and thus STEC have the potential to disrupt trade between countries.</p> <p><u>Escherichia coli</u> <u>Strains of <i>E. coli</i> that are pathogenic to humans can be classified into specific groups according to their virulence, pathogenicity mechanism, and clinical symptoms. These categories include Enteropathogenic <i>Escherichia coli</i> (EPEC), Enterotoxigenic <i>Escherichia coli</i> (ETEC), Enteroinvasive <i>Escherichia coli</i> (EIEC), Diffusely Adherent <i>E. coli</i> (DAEC), Enteroaggregative <i>Escherichia coli</i> (EAEC), and Enterohemorrhagic <i>E. coli</i> (EHEC). The EHEC group includes a subgroup of Shiga toxin-producing <i>E. coli</i> (STEC), which includes <i>E. coli</i> strains that cause hemorrhagic diarrhea. STEC organisms produce one or two of the phage-encoded toxins: Shiga toxin 1 (Stx1) and Shiga toxin 2 (Stx2). However, the production of Stx alone may not be sufficient to cause the illness. Some strains of EHEC also contain genes that encode the ability to adhere to and damage intestinal tract cells, causing what are commonly known as “attaching and effacing” lesions. For a detailed review of the pathogenesis of EHEC and other STEC organisms, interested readers can consult the following recent publications: Paton and Paton (1998) and Nataro and Kaper (1998).</u></p>	<p>Taken from: “DISCUSSION DOCUMENT ON THE RISK PROFILE FOR ENTEROHEMORRHAGIC <i>E. COLI</i>, INCLUDING IDENTIFICATION OF BASIC PRODUCTS OF INTEREST, SUCH AS SPROUTS AND GROUND BEEF AND PORK” 1. COMBINATION OR COMBINATIONS OF PATHOGENS AND PRODUCTS OF INTEREST, pg. 13 http://www.fao.org/tempref/codex/Meetings/CCFH/ccfh36/fh0410bs.pdf</p>
<p>Most clinical symptoms of the disease in humans arise as a consequence of the production of Shiga-toxin type 1 (<i>stx1</i>), type 2 (<i>stx2</i>) or a combination of these genes. An adherence gene, Intimin, encoded by <i>eae</i> and a plasmid-encoded enterohemolysin (<i>ehxA</i>) has been used as a possible epidemiological marker for pathogenic STEC. These virulence genes and the O157:H7 specific single-nucleotide polymorphism (SNP) at position +93 of the <i>uidA</i> housekeeping gene (+93 <i>uidA</i>) have been related to assess the potential pathogenicity of STEC isolates. It must be pointed out that additional adherence genes such as <i>aggR</i> have been identified as associated with causing illness. These genes are mobile and can be transmitted to related organisms or be lost. Symptoms and their severity are determined by the variability in these genes. Because STEC are primarily a genotype-based hazard, this has implications for hazard identification and characterization, which will be discussed in this Guidance document. The utility of genotyping, serotyping and culture-based detection in hazard identification and characterization will also be discussed in this document.</p>	<p>IDF/FIL The definition mentioning that “virulence genes and the O157:H7 specific single-nucleotide polymorphism (SNP) at position +93 of the <i>uidA</i> housekeeping gene (+93 <i>uidA</i>) is too accurate and unusual. Instead of focusing on O157:H7 it could be mentioned that many different O:H serotypes of strains have been identified in STEC infections, they belong to different phylogenetic lineages but share a similar set of virulence determinants.</p>
<p>Most clinical symptoms of the disease in humans arise as a consequence of the production of Shiga-toxin type 1 (<i>stx1</i>), type 2 (<i>stx2</i>) or a combination of these genes. An adherence gene, Intimin, encoded by <i>eae</i> and a plasmid-encoded enterohemolysin (<i>ehxA</i>) has been used as a possible epidemiological marker for pathogenic STEC. These virulence genes and the O157:H7 specific single-nucleotide polymorphism (SNP) at position +93 of the <i>uidA</i> housekeeping gene (+93 <i>uidA</i>) have been related to assess the potential pathogenicity of STEC isolates. It must be pointed out that additional adherence genes such as <i>aggR</i> have been identified as associated with causing illness. These genes are mobile and can be transmitted to related organisms or be lost. Symptoms and their severity are determined by the variability in these genes. Because STEC are primarily a genotype-based hazard, this has implications for hazard identification and characterization, which will be discussed in this Guidance guidance document. The utility of genotyping, serotyping and culture-based detection in hazard identification and characterization will also be discussed in this document.</p>	<p>Japan</p>
<p>Most clinical symptoms of the disease in humans arise as a consequence of the production of Shiga-toxin type 1 (<i>stx1</i>), type 2 (<i>stx2</i>) or a combination of these genes. An adherence gene, Intimin, encoded by <i>eae</i> and a plasmid-encoded enterohemolysin (<i>ehxA</i>) has been used as a possible epidemiological marker for pathogenic STEC. These virulence genes and the O157:H7</p>	<p>Brazil Rationale: The virulence factor described was identified in <i>E. coli</i> O157:H7, as the scope of the document is to identify virulence factors for STEC in general and the virulence factor cited does not fit into the</p>

<p>specific single-nucleotide polymorphism (SNP) at position +93 of the It must be pointed out that additional adherence genes such as <i>uidA</i> housekeeping gene (+93 <i>uidA</i>) have been related to assess the potential pathogenicity of STEC isolates. It must be pointed out that additional adherence genes such as <i>aggR</i> have been identified as associated with causing illness. These genes are mobile and can be transmitted to related organisms or be lost. Symptoms and their severity are determined by the variability in these genes. Because STEC are primarily a genotype-based hazard, this has implications for hazard identification and characterization, which will be discussed in this Guidance document. The utility of genotyping, serotyping and culture-based detection in hazard identification and characterization will also be discussed in this document.</p>	<p>FAO/WHO monitoring recommendation, we suggest that it be taken from the introduction.</p>
<p>Most clinical symptoms of the disease in humans arise as a consequence of the production of Shiga-toxin type 1 (<i>stx1</i>), type 2 (<i>stx2</i>) or a combination of these genes. An adherence gene, Intimin, encoded by <i>eae</i> and a plasmid-encoded enterohemolysin (<i>ehxA</i>) has been used as a possible epidemiological marker for pathogenic STEC. These virulence genes and the O157:H7 specific single-nucleotide polymorphism (SNP) at position +93 of the <i>uidA</i> housekeeping gene (+93 <i>uidA</i>) have been related to assess the potential pathogenicity of STEC isolates. It must be pointed out that additional adherence genes such as <i>aggR</i> have been identified as associated with causing illness. These genes are mobile and can be transmitted to related organisms or be lost. Symptoms and their severity are determined by the variability in these genes, among other factors, e.g. dose, host susceptibility, and age. Because STEC are primarily a genotype-based hazard, this has implications for hazard identification and characterization, which will be discussed in this Guidance document. The utility of genotyping, serotyping and culture-based detection in hazard identification and characterization will also be discussed in this document.</p>	<p>USA It is not just the genes that determine symptoms and their severity.</p>
<p>Most clinical symptoms of the disease in humans arise as a consequence of the production of Shiga-toxin type 1 (<i>stx1</i>), type 2 (<i>stx2</i>) or a combination of these genes. An adherence gene, Intimin, encoded by <i>eae</i> and a plasmid-encoded enterohemolysin (<i>ehxA</i>) has been used as a possible epidemiological marker for pathogenic STEC. These virulence genes and the O157:H7 specific single-nucleotide polymorphism (SNP) at position +93 of the <i>uidA</i> (+93 <i>uidA</i>) have been related to assess the potential pathogenicity of STEC isolates. It must be pointed out that additional adherence genes such as <i>aggR</i> have been identified as associated with causing illness. These genes are mobile and can be transmitted to related microorganisms or be lost. Symptoms and their severity are determined by the variability in these genes. Because STEC are primarily a genotype-based hazard, this has implications for hazard identification and characterization, which will be discussed in this Guidance document. The utility of genotyping, serotyping and culture-based detection in hazard identification and characterization will also be discussed in this document.</p>	<p>Honduras</p>
<p>Most clinical symptoms of the disease in humans arise as a consequence of the production of Shiga-toxin type 1 (<i>stx1</i>), type 2 (<i>stx2</i>) or a combination of these genes. An adherence gene, Intimin, encoded by <i>eae</i> and a plasmid-encoded enterohemolysin (<i>ehxA</i>) has been used as a possible epidemiological marker for pathogenic STEC. These virulence genes and the O157:H7 specific single-nucleotide polymorphism (SNP) at position +93 of the <i>uidA</i> (+93 <i>uidA</i>) have been related to assess the potential pathogenicity of STEC isolates. It must be pointed out that additional adherence genes such as <i>aggR</i> have been identified as associated with causing illness. These genes are mobile and can be transmitted to related organisms or be lost. Symptoms and their severity are determined by the variability in these genes. Because STEC are primarily a genotype-based hazard, this has implications for hazard identification and characterization, which will be discussed in this Guidance document. The utility of genotyping,</p>	<p>Uruguay “Most clinical symptoms of the disease in humans arise as a consequence of the production of Shiga-toxin type 1 (<i>stx1</i>), type 2 (<i>stx2</i>) or a combination of these genes.” Uruguay believes this sentence could cause confusion because the abbreviation used for the term Shiga-toxin is “Stx,” and “stx” is used to refer to the gene of the toxin. We suggest “...the production of Shiga-toxin type 1 (Stx1) or Shiga-toxin type 2 (Stx2) or a combination of them, encoded by the <i>stx1</i> and <i>stx2</i> genes respectively.”</p>

<p>serotyping and culture-based detection in hazard identification and characterization will also be discussed in this document.</p>	
<p>Most clinical symptoms of the disease in humans arise as a consequence of the production of Shiga-toxin type 1 (<i>stx1</i>), type 2 (<i>stx2</i>) or a combination of these genes. An adherence gene, Intimin, encoded by <i>eae</i> and a plasmid-encoded enterohemolysin (<i>ehxA</i>) has been used as a possible epidemiological marker for pathogenic STEC. These virulence genes and the O157:H7 specific single-nucleotide polymorphism (SNP) at position +93 of the <i>uidA</i> (+93 <i>uidA</i>) have been related to assess the potential pathogenicity of STEC isolates. It must be pointed out that additional adherence genes such as <i>aggR</i> have been identified as associated with causing illness. These genes are mobile and can be transmitted to related organisms or be lost. Symptoms and their severity are determined by the variability in these genes <u>and their ability to be expressed</u>. Because STEC are primarily a genotype-based hazard, this has implications for hazard identification and characterization, which will be discussed in this Guidance document. The utility of genotyping, serotyping and culture-based detection in hazard identification and characterization will also be discussed in this document.</p>	<p>Panama</p>
<p>The Guidelines build on general food hygiene provisions already established in the Codex system and propose potential control measures specific for STEC strains of public health relevance in raw beef meat, fresh leafy greens, raw milk and cheese produced from raw milk, and sprouts.</p> <p>[Potential control measures for application at single or multiple steps of the food chain are presented in the following categories:</p> <ul style="list-style-type: none"> • Good hygienic practice (GHP) based: They are generally qualitative in nature and are based on empirical scientific knowledge and experience. They are usually prescriptive and may differ among countries. • Hazard based: They are developed from scientific knowledge of the likely level of control of a hazard at a step (or series of steps) in a food chain. They are based on a quantitative base estimate of the prevalence or concentration of STEC and can be validated as to their efficacy in hazard control at a specific step. The benefit of a hazard based measure cannot be exactly determined without a specific risk assessment; however, any significant reduction in pathogen prevalence or concentration is expected to provide a certain level of human health benefit.] 	<p>Argentina Rationale: Thus far, the control measures have not been classified into these categories in this document.</p>
<p>While historically <u>Historically</u>, STEC illnesses have been linked to the consumption of undercooked beef products; <u>however</u>, leafy greens, sprouts, and dairy products have been increasingly recognized as at-risk commodities. Sources of STEC in these foods can vary, as does the ability of the organism to persist, survive and <u>multiple</u> multiply within them. This guidance document will identify commodity-specific practices for source attribution in these different foods, and practices for monitoring STEC in perishable and shelf-stable products and the utility of indicators. STEC illnesses have also been linked to flour, seafood and vine-stalk vegetables. It is not yet clear whether these foods are significant emergent sources of individual illnesses or outbreaks. The association of specific food categories with STEC illness reflects the historical and current practices of food production, distribution and consumption. Changes in food production, distribution and consumption can cause changes in STEC exposure. Consequently, microbial risk management should be informed by an awareness of current local sources of STEC exposure.</p>	<p>IDF/FIL The first sentence does not read correctly. Please see suggestion.</p>
<p>While historically STEC illnesses have been linked to the consumption of undercooked beef products, leafy greens, sprouts, and dairy products have been increasingly recognized as at-risk commodities. Sources of STEC in these foods can vary, as does the ability of the organism to</p>	<p>USA Clarify what is meant by “practices for source attribution” in the following sentence:</p>

<p>persist, survive and multiply within them. This guidance document will identify commodity-specific practices for source attribution in these different foods, and practices for monitoring STEC in perishable and shelf-stable products and the utility of indicators. STEC illnesses have also been linked to flour, seafood and vine-stalk vegetables. It is not yet clear whether these foods are significant emergent sources of individual illnesses or outbreaks. The association of specific food categories with STEC illness reflects the historical and current practices of food production, distribution and consumption. Changes in food production, distribution and consumption can cause changes in STEC exposure. Consequently, microbial risk management should be informed by an awareness of current local sources of STEC exposure.</p>	<p>This guidance document will identify commodity-specific practices for source attribution in these different foods, and practices for monitoring STEC in perishable and shelf-stable products and the utility of indicators.</p>
<p>It is generally accepted that animals, in particular ruminants, are the primary source of STEC. STEC-positive ruminants are typically asymptomatic. Contamination with intestinal content or feces is the likeliest ultimate source of STEC in most foods. STEC outbreaks associated with field-grown leafy greens have been linked to contaminated irrigation water. Raw milk is most commonly contaminated as a result of soiled udders and teats as well as poor hygiene at processing. [Note to EWG – this paragraph needs to be expanded on sources and to include the other commodities.]</p>	<p>Brazil Consideration: Brazil points out that when including other commodities, care should be taken to include those identified as risk, i.e., with a history of involvement in outbreaks.</p>
<p>It is generally accepted that animals, in particular ruminants, are the primary source of STEC. STEC-positive ruminants are typically asymptomatic. Contamination with intestinal content or feces is the likeliest ultimate source of STEC in most foods. STEC outbreaks associated with field-grown leafy greens have been linked to contaminated irrigation water. Raw milk is most commonly contaminated as a result of soiled udders and teats as well as poor hygiene at processing. [Note to EWG – this paragraph needs to be expanded on sources and to include the other commodities.]</p>	<p>USA Provide additional general information about the source of contamination of sprouts, as this commodity was not mentioned in the paragraph.</p>
<p>The Guidelines build on general food hygiene provisions already established in the Codex system and propose potential control measures specific for STEC strains of public health relevance in raw beef meat, leafy greens, raw-raw drinking milk and cheese produced from raw milk, and sprouts. In this context, the Codex Alimentarius Commission (CAC) is committed to develop standards that are based on sound science². Potential control measures for application at single or multiple steps of the food chain are presented in the following categories:</p>	<p>IDF/FIL</p>
<p><u>Good hygienic practice (GHP) – based</u>: They are generally qualitative in nature and are based on empirical scientific knowledge and experience. They are usually prescriptive and may differ among countries.</p>	<p>Panama Panama believes that the guidelines do not indicate to countries the obligation to have implemented the HACCP plans within the establishments, including primary production, and the compulsory requirement to reevaluate their HACCP plans if they have had E. coli O157:H7 events at any point in the production chain.</p>
<p><u>Hazard – based</u>: They are developed from scientific knowledge of the likely level of control of a hazard at a step (or series of steps) in a food chain. They are based on a quantitative base estimate in the prevalence and/or concentration of STEC and can be validated as to their efficacy in hazard control at a specific stepstep or specific steps. The benefit of a hazard-based measure cannot be exactly determined without a specific risk assessment; however, any significant reduction in pathogen prevalence and / or concentration is expected to provide a certain level of human health benefit.</p>	<p>IDF/FIL Add “or specific steps” to accommodate for hurdle technology</p>
<p><u>Hazard – based</u>: They are developed from scientific knowledge of the likely level of control of a hazard at a step (or series of steps) in a food chain. They are based on a quantitative base estimate in the prevalence and/or concentration of STEC and can be validated as to their efficacy in hazard control at a specific step. The benefit of a hazard-based measure cannot be exactly determined without a specific risk assessment; however, any significant reduction in</p>	<p>India Hazards present in the food even at lesser concentration shall not give any health benefit.</p>

pathogen prevalence and / or concentration is expected to provide a certain appropriate level of human health benefit protection/Food Safety.	
Examples [Examples of control measures in each commodity specific annex that are based on quantitative levels of hazard control have been subjected to a rigorous scientific evaluation in development of the Guidelines. Such examples are illustrative only and their use and approval may vary amongst member countries. Their inclusion in the Guidelines illustrates the value of a quantitative approach to hazard reduction throughout the food chain.]	USA It is not clear at this point whether there will be examples of control measures that are based on a quantitative level of hazard control.
Highlights data gaps in terms of scientific justification / validation for control measures. [Translator's note: the change in the Spanish does not affect the English version.]	Colombia We propose to change the Spanish wording to make the idea clearer.
<ul style="list-style-type: none"> Assists in judging the equivalence⁵ of control measures for raw beef meat, fresh leafy greens, raw milk and cheese produced from raw milk, and sprouts applied in different countries. 	Argentina
Assists in judging the equivalence ³ of control measures for beef meat, leafy greens, raw drinking milk and cheese produced from raw milk, and sprouts applied in different countries.	IDF/FIL
In doing so, the Guidelines provide flexibility for use at the national (and individual processing) level. [Translator's note: the change in the Spanish does not affect the English version.]	Colombia We propose adding the word "de" in Spanish for clarity's sake.
2. OBJECTIVES	
11. These Guidelines provide information to governments and industry on the control of STEC in raw beef meat, fresh leafy greens, raw milk and cheese produced from raw milk, and sprouts that aim to reduce foodborne disease whilst ensuring fair practices in the international food trade. In addition, the Guidelines provide a scientifically sound international tool for robust application of GHP- and hazard-based approaches for control of STEC in raw beef meat, fresh leafy greens, raw milk and cheese produced from raw milk, and sprouts according to national risk management decisions. The control measures that are selected can vary between countries and production systems.	Argentina
These Guidelines provide information to governments and industry on the control of STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts that aim to reduce foodborne disease whilst ensuring fair practices in the international food trade. The Guidelines provide a scientifically sound international tool for robust application of GHP- and hazard-based approaches for control of STEC in raw beef meat, leafy greens, raw drinking milk and cheese produced from raw milk, and sprouts according to national risk management decisions. The control measures that are selected can vary between countries and production systems.	IDF/FIL
These Guidelines provide information to governments and industry on the control of STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts that aim to reduce foodborne disease whilst ensuring fair practices in the international food trade. The Guidelines provide a scientifically sound international scientific tool for robust application of GHP- and hazard-based approaches for control of STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts according to national risk management decisions. The control measures that are selected can vary between countries and production systems.	Gambia All Codex standards and related texts are based on sound international tool for robust application and does not need to be emphasized in the document
These Guidelines provide information to governments and industry on the control of STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts that aim to reduce foodborne disease whilst ensuring fair practices in the international food trade. The Guidelines provide a scientifically sound international tool for robust application of GHP- and hazard-based approaches for control of STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts according to national risk management decisions. The control measures that are selected can vary between countries and production systems.	Morocco Morocco recommends rephrasing the second sentence as follows: "The Guidelines provide a scientific tool for effective application of GHPs and a hazard-based approach" for national risk management oversight. Rationale: All Codex standards and related texts are based on a sound

	international tool for effective application and do not need to be emphasized in the document.
12. The Guidelines do not set quantitative limits for STEC in raw beef meat, fresh leafy greens, raw milk and cheese produced from raw milk, and sprouts in international trade. Rather, the Guidelines follow the examples of the overarching <i>Code of Hygienic Practice for Meat</i> (CXC 58-2005) and <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i> (CXC 53-2003) and provide an “enabling” framework which countries can utilize to establish control measures appropriate to their national situation.	Argentina
The Guidelines do not set quantitative limits for STEC in raw beef meat, leafy greens, raw drinking milk and cheese produced from raw milk, and sprouts in international trade. Rather, the Guidelines follow the examples of the overarching <i>Code of Hygienic Practice for Meat</i> (CXC 58-2005) and <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i> (CXC 53-2003) and provide an “enabling” framework which countries can utilize to establish control measures appropriate to their national situation.	IDF/FIL
The Guidelines do not set quantitative limits for STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts in international trade. Rather, the Guidelines follow the examples of the overarching <i>Code of Hygienic Practice for Meat</i> (CXC 58-2005 and 58-2005), <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i> (CXC 53-2003) and <i>Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004)</i> ” and provide an “enabling” framework which countries can utilize to establish control measures appropriate to their national situation.	India To also include milk and milk products.
The Guidelines do not set quantitative limits for STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts in international trade. Rather, the Guidelines follow the examples of the overarching <i>Code of Hygienic Practice for Meat</i> (CXC 58-2005) and <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i> (CXC 53-2003) and provide an an “enabling” framework which countries can utilize to establish control measures appropriate to their national situation.	USA It is not clear what is meant by the term, and it is not needed.
The Guidelines do not set quantitative limits for STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts in international trade. Rather, the Guidelines follow the examples of the overarching <i>Code of Hygienic Practice for Meat</i> (CXC 58-2005) and <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i> (CXC 53-2003 53-2003), and <i>Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004)</i> ,” and provide an “enabling” framework which countries can utilize to establish control measures appropriate to their national situation.	Uruguay “The Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004)” needs to be added.
The Guidelines do not set quantitative limits for STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts in international trade. Rather, the Guidelines follow the examples of the overarching <i>Code of Hygienic Practice for Meat</i> (CXC 58-2005) and <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i> (CXC 53-2003) and provide a “enabling” reference framework which countries can utilize to establish control measures appropriate to their national situation.	Colombia The standards of the Codex Alimentarius are international reference frameworks based on scientific evidence, so we consider it appropriate to use this word instead of enabling, which does not give much clarity to the paragraph and is not defined.
The Guidelines do not set quantitative limits for STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts in international trade. Rather, the Guidelines follow the examples of the overarching <i>Code of Hygienic Practice for Meat</i> (CXC 58-2005) and <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i> (CXC 53-2003) and provide an “enabling” framework which countries can utilize to establish control measures appropriate to their national situation. [Translator’s note: the change in the Spanish does not affect the English version.]	Panama Panama believes the guidelines should include an annex with examples for the other categories such as sprouts, raw milk and cheese, which have been involved in important foodborne illnesses internationally.

3.1. Scope	
13. The Guidelines do not set quantitative limits for STEC in raw beef meat, fresh leafy greens, raw milk and cheese produced from raw milk, and sprouts in international trade. The primary focus is to provide information on practices that may be used to prevent, reduce, or eliminate STEC in raw beef meat, fresh leafy greens, raw milk and cheese produced from raw milk, and sprouts. Other measures, in addition to those described here, may be needed to control STEC in offal.	Argentina Rationale: We propose eliminating the last sentence because offal is beyond the scope of this document. In the FAO/WHO 2018 report “Shiga toxin producing Escherichia coli (STEC) and food: attribution, characterization, and the monitoring the risk,” there is no information on offal.
These Guidelines are applicable to public health relevance STEC that may contaminate raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts and cause foodborne disease. The primary focus is to provide information on practices that may be used to prevent, reduce, or eliminate STEC in raw beef meat ⁴ , leafy greens, raw milk and cheese produced from raw milk, and sprouts. Other measures, in addition to those described here, may be needed to control STEC in offal. Other measures, in addition to those described here, may be needed to control STEC in offal.	Chile there is no reference to offal on the annex 1, neither is considered to be part of the scope, since offal are rarely consume undercook, and also not all offals are relevants for public health since some of them are used for pet food.
(...) The primary focus is to provide information on practices that may be used to prevent, reduce, or eliminate STEC in raw beef , fresh leafy greens, raw milk and cheese produced from raw milk, and sprouts...	Argentina Definition of raw beef: fresh beef, ground or separated mechanically, in accordance with the Code of Hygienic Practice for Meat (CAC/RCP 58/2005) Code of Hygienic Practice for Meat. Thus, offal should not be included in the scope. Our suggestion is to address this in a separate document as edible entrails. According to the content of the text and the proposed flow chart, the foods addressed are those that are subjected to primary processing as well as to the form of sale and numerals 22 through 32 of the document, related to packaging operations.
These Guidelines are applicable to public health relevance STEC that may contaminate raw beef meat, leafy greens, raw drinking milk and cheese produced from raw milk, and sprouts and cause foodborne disease. The primary focus is to provide information on practices that may be used to prevent, reduce, or eliminate STEC in raw beef meat ⁴ , leafy greens, raw drinking milk and cheese produced from raw milk, and sprouts. Other measures, in addition to those described here, may be needed to control STEC in offal.	IDF/FIL
These Guidelines are applicable to public health relevance STEC that may contaminate raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts and cause foodborne disease. The primary focus is to provide information on practices that may be used to prevent, reduce, or eliminate STEC in raw beef meat ⁴ , leafy greens, raw milk and cheese produced from raw milk, and sprouts. Other measures, in addition to those described here, may be needed to control STEC in offal.	Brazil Rationale: STEC monitoring should be performed on raw material intended for the production of ground beef or non intact beef products. In the sentence it seems that the monitoring of STEC in the offal should be more rigorous, which is not justifiable because the offal is marketed intact and not ground.
These Guidelines are applicable to public health relevance STEC that may contaminate raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts and cause foodborne disease. The primary focus is to provide information on practices that may be used to prevent, reduce, or eliminate STEC in raw beef meat ⁴ , leafy greens, raw milk and cheese produced from raw milk, and sprouts. Other measures, in addition to those described here, may be needed to control STEC in offal.	USA We think the focus of the document is skeletal muscle meat and not “variety meat” or organ meat. Including this statement in the scope suggests that offal is included. We are not aware of any STEC issues from these meats, as they are generally well-cooked.
These Guidelines are applicable to public health relevance STEC that may contaminate raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts and cause foodborne disease. The primary focus is to provide information on practices that may be used to prevent, reduce, or eliminate STEC in raw beef meat ⁴ , leafy greens, raw milk and cheese	Nicaragua Nicaragua believes that there should be a benchmark for determining public health relevance STEC, and therefore proposes that they be evaluated by JEMRA.

produced from raw milk, and sprouts. Other measures, in addition to those described here, may be needed to control STEC in offal.	In the same vein, Nicaragua proposes that the measures to be applied be scientifically validated for efficiency and STEC reduction.
These Guidelines are applicable to public health relevance STEC that may contaminate raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts and cause foodborne disease. The primary focus is to provide information on practices that may be used to prevent, reduce, or eliminate STEC in raw beef meat ⁴ , leafy greens, raw milk and cheese produced from raw milk, and sprouts. Other measures, in addition to those described here, may be needed to control STEC in offal.	Uruguay Suggests deleting the sentence "Other measures, in addition to those described here, may be needed to control STEC in offal." as it could lead to confusion. We understand that it must be clear that offal is not part of the scope of this document.
These Guidelines in conjunction with the relevant OIE (World Organisation for Animal Health) standards can apply from primary production-to consumption for raw beef meat, leafy greens, raw <u>drinking</u> milk and cheese produced from raw milk, and sprouts produced in commercial production systems.	IDF/FIL
These Guidelines in conjunction with the relevant OIE (World Organisation for Animal Health) standards can apply from primary production-to consumption for raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts produced in commercial production systems.	Uruguay The OIE standards only apply to beef meat.
These Guidelines in conjunction with the relevant OIE (World Organisation for Animal Health) standards can apply from primary production-to consumption for raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts produced in commercial production systems.	Panama The OIE standards only apply to beef meat.
3.2. Use	
15. The Guidelines provide specific guidance for control of STEC in raw beef meat, fresh leafy greens, raw milk and cheese produced from raw milk, and sprouts according to a primary production-to-consumption food chain approach, with potential control measures being considered at each step, or group of steps, in the process flow.	Argentina
The Guidelines provide specific guidance for control of STEC in raw beef meat, leafy greens, raw <u>drinking</u> milk and cheese produced from raw milk, and sprouts according to a primary production-to-consumption food chain approach, with potential control measures being considered at each step, or group of steps, in the process flow. The Guidelines are supplementary to and should be used in conjunction with the General Principles of Food Hygiene (CXC 1-1969), the Code of Hygienic Practice for Meat (CXC 58-2005), the Code of Practice on Good Animal Feeding (CXC 54-2004), Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003), Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004), and the Guidelines for the Validation of Food Safety Control Measures (CXG 69-2008).	IDF/FIL
The primary production section of these Guidelines is supplementary to and should be used in conjunction with relevant chapters of the <i>OIE Terrestrial Animal Health Code</i> ⁵ . [OIE has indicated they will take up work in this area in conjunction with this work]	Uruguay The OIE standards only apply to beef meat.
Several hazard-based control measures as presented in these Guidelines are based on the use of physical, chemical and biological decontaminants-decontamination processes to reduce the prevalence of STEC-positive carcasses and/or their concentration on positive carcasses from slaughtered-cattle STE C . The use of these control measures is subject to approval by the competent authority, where appropriate, and varies based upon the type of product being produced. Also, these Guidelines do not preclude the choice of any other hazard-based control measure that is not included in the examples provided herein, and that may have been scientifically validated as being effective in a commercial setting.	USA This is the general section of the document. This sentence should be more generic, as it is applicable to multiple commodities.
Several hazard-based control measures as presented in these Guidelines are based on the use of physical, chemical and biological decontaminants to reduce the prevalence of STEC-positive	Uruguay Uruguay suggests including control measures in all the other sources.

carcasses and/or their concentration on positive carcasses from slaughtered cattle. The use of these control measures is subject to approval by the competent authority, where appropriate, and varies based upon the type of product being produced. Also, these Guidelines do not preclude the choice of any other hazard-based control measure that is not included in the examples provided herein, and that may have been scientifically validated as being effective in a commercial setting.	
The Guidelines should be useful when comparing, or judging equivalence of, different food safety measures for raw beef meat, fresh leafy greens, raw milk and cheese produced from raw milk, and sprouts in different countries.	Argentina
The Guidelines should be useful when comparing, or judging equivalence of, different food safety measures for beef meat, leafy greens, raw drinking milk and cheese produced from raw milk, and sprouts in different countries.	IDF/FIL
4. DEFINITIONS	Uruguay Suggests adding the definition of Raw beef meat, going beyond what is provided in Annex I, as was done for the definition of “Leafy Green Vegetables”.
Cattle Beef Cattle : Animals of the species of <i>Bos indicus</i> , <i>Bos taurus</i> , and <i>Bubalus bubalis</i> .	Nicaragua Nicaragua suggests that this definition be limited to Beef cattle.
Cattle: Animals of the species of <i>Bos indicus</i> , <i>Bos taurus</i> , and <i>Bubalus bubalis</i> .	CCTA In Spanish, the term “Cattle” can mean Bovine, Ovine, Porcine, etc. We need to specify that the translation of the English term “Cattle” is “Bovine Cattle” or “Beef Cattle.”
Cattle Beef Cattle : Animals of the species of <i>Bos indicus</i> , <i>Bos taurus</i> , and <i>Bubalus bubalis</i> .	CCTA
Fresh Leafy Green Vegetables: Vegetables of a leafy nature where the leaf is intended for consumption without further microbiocidal steps. (CXC 53-2003, Annex III, 2.1 Scope) OR Fresh Leafy Green Vegetables: Vegetables of a leafy nature where the leaf is intended for consumption without cooking (CXC 53-2003, Annex III, 1 Objective)	Argentina
Leafy Greens vegetables : Vegetables of a leafy nature where the leaf is intended for consumption consumption without further microbiocidal steps.	Japan vegetables: To be consistent with the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003), the term “fresh leafy vegetable” is preferred. without further microbiocidal steps: To be consistent with the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003), Annex 3, Section 2.1.
Raw Milk: Milk which has not been pasteurized by heating beyond 40°C or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level. Raw Drinking Milk: Raw milk which is offered to the consumer for direct consumption.	IDF/FIL In order to differentiate raw milk from raw drinking milk, we suggest a separate definition for “raw drinking milk” See comment to the title of this document
Raw Milk: Milk which has not been pasteurized by heating heated beyond 40°C or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level.	IDF/FIL
Raw Milk: Milk (as defined in Codex General Standard for the Use of Dairy Terms) which has not been pasteurized by heating beyond 40°C or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level.	IDF/FIL The definition should be aligned with the definition of milk in CAC-RCP 57 (the Milk Hygiene Code): Milk (as defined in Codex General Standard for the Use of Dairy Terms) which has not been heated beyond 40°C or undergone any treatment that has an equivalent effect

	The additional phrase “to reduce pathogens to an acceptable level” is not part of this definition but can stay in
Raw Milk: Milk (as defined in the General Standard for the Use of Dairy Terms (CODEX STAN 206-1999)) which has not been pasteurized by heating heated beyond 40°C 40°C or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level effect.	India We propose to align the definition with that given in the General Standard for the Use of Dairy Terms (CODEX STAN 206-1999). The proposed definition in the discussion paper is contradictory to Pasteurization definition mentioned in the Appendix B of Microbiocidal control measures, Section 1 of Code of Hygienic practice for milk and milk products (CXC 57-2004).
Raw Milk: Milk which has not been pasteurized by heating beyond 40°C or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level.	Gambia The requirement for pasteurization by heating beyond 40°C is unclear and does not meet the standard condition for pasteurization
Raw Milk: Milk <u>It is a normal mammary secretion of milking animals</u> which has not been pasteurized by heating beyond 40°C or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level.	Brazil Rationale: Remove the 40°C parameter as it is expressed in the definition without any time delay. What makes thermal processing efficient is the combination of the temperature x time binomial, leaving only the temperature of 40 °C in the definition can create confusion, does not help in understanding this definition.
Raw milk: Milk which has not been pasteurized by heating beyond 40°C or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level.	Morocco Morocco recommends amending the definition as follows: “Milk that has not undergone treatment that has an equivalent effect to reduce pathogens to an acceptable level. Rationale: The requirement of pasteurization by heating beyond 40°C is unclear and does not meet standard conditions for acceptable level pasteurization.
Raw Milk: – Milk (as defined by the General Standard for The Use of Dairy Terms) which has not been pasteurized by heating heated beyond 40°C or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level ”	Uruguay Suggests the definition provided in the Code of Hygienic Practice for Milk and Milk Products
Raw Milk: Milk which has not been pasteurized by heating beyond 40°C or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level.	Uruguay We believe that the definition provided by the Code of Hygienic Practice for Milk and Milk Products does not apply to the scope of this document, and could lead to confusion that heat treatment of milk at, for example, 42°C does not ensure the elimination of pathogens and would nevertheless fall outside the scope of the document.
Raw Milk: Milk which has not been pasteurized by heating beyond 40°C 72°C or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level.	Colombia
Raw Milk: Milk which has not been pasteurized by heating beyond 40°C–72°C for 15 seconds (Continuous Flow Pasteurization) or 63°C for 30 minutes (discontinuous pasteurization) or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level.	Panama
<i>Shiga Toxin-Producing E. coli (STEC)</i> : A large, highly diverse group of bacterial strains that are demonstrated to carry <u>stx gene(s)</u> and produce Shiga toxin (Stx), pathogenesis–pathogenic to humans by entry into the human gut, attachment to the intestinal epithelial cells and production of Stx ⁷ .	India
<i>Shiga Toxin-Producing E. coli (STEC)</i> : A large, highly diverse group of bacterial strains that are demonstrated to carry <u>the gene for stx–Shiga toxin (stx)</u> , and produce Shiga toxin (Stx), pathogenesis–that are pathogenic to humans by entry into the human gut, attachment to the	USA To make clear that stx refers to the gene and Stx to the toxin.

intestinal epithelial cells and production of Stx ⁷ .	
<i>Shiga-like toxin producing E. coli (STEC):</i> A large, highly diverse group of bacterial strains that are demonstrated to carry stx and produce Shiga toxin (Stx), pathogenesis to humans by entry into the human gut, attachment to the intestinal epithelial cells and production of Stx⁷.	Panama
<i>Sprouts:</i> Germinated seeds used for human food.	Nicaragua Nicaragua suggests revising the definition of sprouts, as the current definition [in Spanish] is redundant.
<i>Sprouts:</i> Germinated seeds used for human food.	Honduras suggests revising the definition of sprouts suggests revising the definition of sprouts
<i>Sprouts:</i> Germinated seeds used for human food.	Panama The term “brotes de semilla” [seed shoots] could be used perfectly in place of “semillas germinadas” [germinated seeds]
5. PRINCIPLES APPLYING TO CONTROL OF STEC IN RAW BEEF MEAT, FRESH LEAFY GREENS, RAW MILK AND CHEESE PRODUCED FROM RAW MILK, AND SPROUTS	Argentina
5. PRINCIPLES APPLYING TO CONTROL OF STEC IN BEEF MEAT, LEAFY GREENS, RAW DRINKING MILK AND CHEESE PRODUCED FROM RAW MILK, AND SPROUTS	IDF/FIL
5. PRINCIPLES APPLYING TO CONTROL OF STEC IN RAW BEEF MEAT, LEAFY GREENS, RAW MILK AND CHEESE PRODUCED FROM RAW MILK AND SPROUTS, LEAFY GREENS, RAW MILK AND CHEESE PRODUCED FROM RAW MILK AND SPROUTS	Honduras
Overarching principles for good hygienic practice for meat production are presented in the Code of Hygienic Practice for Meat (CXC 58-2005), Section 4: General Principles of Meat Hygiene. For fresh and fresh pre-cut leafy greens are presented in the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003), Annex I For Ready-To-Eat Fresh Pre-Cut Fruits and Vegetables, and Annex III on Fresh Leafy Vegetables—, “Code of Hygienic Practice for Milk and Milk Products” as well as Annex II on Sprouts from the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003) Two principles that have particularly been taken into account in these Guidelines are:	Uruguay We suggest also including the “Code of Hygienic Practice for Milk and Milk Products” as well as Annex II on Sprouts of the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003).
a) The principles of food safety risk analysis should be incorporated wherever possible and appropriate in the control of STEC in raw beef meat, fresh leafy greens, raw milk and cheese produced from raw milk, and sprouts from primary production-to-consumption.	Argentina
a) The principles of food safety risk analysis should be incorporated wherever possible and appropriate in the control of STEC in raw beef meat, leafy greens, raw drinking milk and cheese produced from raw milk, and sprouts from primary production-to-consumption.	IDF/FIL
a) The principles of food safety risk analysis should be incorporated wherever possible and appropriate in the control of STEC in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts from primary production-to-consumption.	Nicaragua
b) Wherever possible and practical, competent authorities should formulate risk management metrics so as to objectively express the level of control of STEC in raw beef meat, fresh leafy greens, raw milk and cheese produced from raw milk, and sprouts that is required to meet public health goals.	Argentina
b) Wherever possible and practical, competent authorities should formulate risk management metrics ⁸ so as to objectively express the level of control of STEC in raw beef meat, leafy greens, raw drinking milk and cheese produced from raw milk, and sprouts that is required to meet public health goals.	IDF/FIL
b) Wherever possible and practical, competent The competent authorities should formulate risk management metrics so as to objectively express the level of control of STEC in raw beef meat,	Nicaragua

leafy greens, raw milk and cheese produced from raw milk, and sprouts that is required to meet public health goals.	
7. PRIMARY PRODUCTION CONTROL MEASURES	Panama Panama believes that Good Agricultural Practices (GAP) concepts related to water, worker hygiene, appropriate use of fertilizers and biosolids, appropriate handling during transport, temperature control, and contact surfaces should be included.
24. Controls in the primary production phase of the process flow can decrease the number of animals from carrying and/or shedding STEC as well as plants being contaminated with STEC on the farm. [Translator's note: the change in the Spanish does not affect the English version.]	Argentina
Controls in the primary production phase of the process flow can are focused on decrease decreasing the number of animals from carrying and/or shedding STEC as well as plants being contaminated with STEC on the farm.	Colombia
8. PROCESSING CONTROL MEASURES	
STEC controls during processing are important to prevent the and/or reduce contamination and to avoid cross contamination of commodities during processing.	USA Controls cannot always prevent contamination, but reduction of contamination can also have a positive impact on public health.
9. DISTRIBUTION CHANNEL CONTROL MEASURES	
26. STEC control measures during distribution are important to ensure product is stored at an appropriate temperature to prevent growth of microorganisms beyond a detectable level to minimize cross contamination, and provide consumers with the necessary product information to know the potential risk associated with the product and how to properly prepare the product for safety.	Argentina
STEC control measures during distribution are important to ensure product is stored at an appropriate temperature to prevent growth beyond a detectable level, minimize cross contamination, and provide consumers with the necessary product information to know the potential risk associated with the product and how to properly prepare the product for safety.	Brazil Rationale: Remove from this item and include in specific topic of product or consumer information.
Specific control measures for STEC are described in each commodity-specific annex where appropriate. The raw beef meat specific control measures are found in Annex I; the leafy green are found in Annex II, the raw drinking milk and cheese produced from raw milk are found in Annex III, and the sprouts are found in Annex IV.	IDF/FIL
Specific control measures for STEC are described in each commodity-specific annex where appropriate. The raw beef meat specific control measures are found in Annex I; the leafy green are found in Annex II, the raw milk and cheese produced from raw milk are found in Annex III, and the sprouts are found in Annex IV.	India Annexures III & IV is missing in the document
10. CONTROL MEASURES	
GHPs provide the foundation for most food safety control systems. Where possible and practicable, food safety control measures for STEC should incorporate hazard based control measures and risk assessment based on hazard analysis . Identification and implementation of risk-based control measures based on risk assessment can be elaborated by application of a risk management framework (RMF) process as advocated in the <i>Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CXG 63-2007)</i> .	IDF/FIL As this guidance is intended for FBOs, the term hazard analysis should be used instead. Risk management is a governmental responsibility
29. While these Guidelines provide generic guidance on development of GHP-based and hazard-based control measures for STEC, development of risk-based control measures for application at a single or at multiple steps in the food chain are primarily the domain of competent authorities at the national level. Industry may derive select the risk-based measures to implement to facilitate application of process control systems and comply with the	Argentina

requirements of the competent authority.	
While these Guidelines provide generic guidance on development of GHP-based and hazard-based control measures for STEC	Peru CXG 63-2007 “Principles and Guidelines for the Conduct of Microbiological Risk Management “Relationship between Various Risk Management Metrics. “ (...) management of food safety issues has moved from a hazard-based approach to a risk-based approach (...)”
10. CONTROL MEASURES and 10.1 Development of risk-based control measures These two (2) items should appear before item 7	Peru Location suggested to allow better comprehension of the text.
11.1 Prior to Validation	
Identification of the specific measure or measures to be validated. This would include consideration analysis of any measures agreed to by the competent authority and whether any measure has already been validated in a way that is applicable and appropriate to specific commercial use, such that further validation is not necessary.	Honduras
Identification of the specific measure or measures to be validated. This would include consideration of any measures agreed to by the competent authority and whether any measure has already been validated in a way that is applicable and appropriate to specific commercial use, such that further validation is not necessary. <u>Identification of the specific measure or measures to be validated. This would include analysis of any measures agreed to by the competent authority and whether any measure has already been validated in a way that is applicable and appropriate to specific commercial use, such that further validation is not necessary.</u>	Honduras
Identification of any existing food safety outcome or target, established by the competent authority or industry. Industry may set stricter targets than those set by the competent authority.	Gambia Rationale: “Targets” have already been addressed in the first sentence of para 35. The last sentence is a duplication and should be deleted. “Targets” have already been addressed in the first sentence of para 35. The last sentence is a duplication and should be deleted.
11.2 Validation	
Validation of measures may be carried out by industry and/or the competent authority.	Brazil Rationale: We suggest rewriting the paragraph to align with the validation paragraph of the HACCP annex (Paragraph 165).
11.3.1 Industry	
Industry has the primary responsibility for implementing, documenting, applying and supervising process control systems to ensure the safety and suitability of raw beef meat, leafy greens, raw drinking milk and cheese produced from raw milk, and sprouts, and these should incorporate GHP and hazard-based measures for control of STEC as appropriate to national government requirements and industry’s specific circumstances.	IDF/FIL
Industry has the primary responsibility for implementing, documenting, applying and supervising process control systems to ensure the safety and suitability of raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts, and these . <u>These</u> should incorporate GHP and hazard-based measures for control of STEC as appropriate to national government requirements and industry’s specific circumstances, <u>and where applicable the measures should be applied in accordance with manufacturer’s instructions.</u>	USA It is important that a manufacturer’s instructions be followed when control measures involve manufactured products.
Industry has the primary responsibility for implementing, documenting, applying and supervising process control systems to ensure the safety and suitability of raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts, and these should incorporate GHP and	Panama Panama believes that we should include annexes that describe preventive measures for products of plant origin that cause major

hazard-based measures for control of STEC as appropriate to national government requirements and industry's specific circumstances.	foodborne outbreaks of STEC For example: outbreaks in unpasteurized juices and lack of labeling. We believe that it is advisable to include annexes that describe preventive measures for products produced from raw milk and unpasteurized cheeses, major foodborne outbreaks of STEC caused by these foods
The documented process control systems should must describe the activities applied including any sampling procedures, specified targets (e.g. performance objectives or performance criteria) set for STEC, industry verification activities, and corrective and preventive actions.	Colombia
11.3.2 Regulatory systems	
The competent authority should must provide guidelines and other implementation tools to industry as appropriate, for the development of the process control systems.	Colombia
The competent authority may assess the documented process control systems to ensure they are science based and establish verification frequencies. Microbiological testing programmes should must be established for verification of HACCP systems where specific targets for control of STEC have been identified.	Colombia
11.4 Verification of control measures	
Refer to Section 9.2 of the <i>Code of Hygienic Practice for Meat</i> (CXC 58-2005), <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i> (CXC 53-2003) , <i>Code of Hygienic Practice for Milk and Milk Products</i> (CXC 57-2004), and Section IV of the Guidelines for the Validation of Food Safety Control Measures (CXG 69 -2008).	Japan Verification of control measures is not mentioned in CXC 53-2003.
11.4.1 Industry	
Industry verification should verify that all control measures for STEC have been implemented as intended. Verification should include observation of monitoring activities such as a program for employee observing the monitor perform monitoring procedures at a specified frequency, documentary verification by reviewing monitoring and verification records, and sampling for STEC and other microbiological testing as appropriate.	IDF/FIL Linguistically wrong wording
Industry verification should verify that all control measures for STEC have been implemented as intended. Verification should include observation of monitoring activities such as a program employee observing the monitor perform monitoring procedures at a specified frequency, documentary verification by reviewing monitoring and verification records, and sampling for STEC and other microbiological testing as appropriate.	India
Industry verification should verify that all control measures for STEC have been implemented as intended. Verification should include observation of monitoring activities such as a program employee observing the monitor perform monitoring procedures at a specified frequency, documentary verification by reviewing monitoring and verification records, and sampling for STEC and other microbiological testing as appropriate.	USA
Industry verification should verify ensure that all control measures for STEC have been implemented as intended. Verification should include observation of monitoring activities such as a program employee by the person responsible for monitoring in order to observe the monitor perform monitoring procedures at a specified frequency, documentary verification by reviewing monitoring and verification records, and sampling for STEC and other microbiological testing as appropriate.	Honduras
Industry verification should verify must demonstrate that all control measures for STEC have been implemented as intended. Verification should must include observation of monitoring activities such as a program employee observing the monitor perform monitoring procedures at a specified frequency, documentary verification by reviewing monitoring and verification records,	Colombia

and sampling for STEC and other microbiological testing as appropriate.	
Verification frequency should must vary according to the operational aspects of process control, the historical performance of the establishment and the results of verification itself.	Colombia
11.4.2 Regulatory systems	
The competent authority and/or competent body should must verify that all regulatory control measures implemented by industry comply with regulatory requirements, as appropriate, for control of STEC.	Colombia
12. MONITORING AND REVIEW	
12. MONITORING AND REVIEW	Argentina Global comment for the entire Spanish document: In the Spanish document, the word “seguimiento” should be replaced by “monitoreo”.
Monitoring and review of food safety control systems is an essential component of application of a riskmanagement risk management framework (RMF) ¹² . It contributes to verification of process control and demonstrating progress towards achievement of public health goals.	IDF/FIL RM is conducted by governments whereas HACCP is conducted by industry.
12.1 Monitoring	
Monitoring should be carried out at appropriate steps throughout the food chain using a validated diagnostic test and randomized or targeted sampling as appropriate ⁴³ .	USA Delete footnote related to the OIE manual and Code as it is not applicable for STEC at this time.
Monitoring should be carried out at appropriate steps throughout the food chain using a validated diagnostic test and randomized or targeted sampling as appropriate ⁴³ .	Uruguay Note 13 refers only to raw beef meat.
For instance, the monitoring systems for STEC and/or indicator organisms, where appropriate, in raw beef meat, leafy greens, raw drinking milk and cheese produced from raw milk, and sprouts may include testing at the farm, animal level, in the slaughter and processing establishments, and the retail distribution chains where appropriate.	IDF/FIL
For instance, the monitoring systems for STEC and/or indicator micro organisms, where appropriate, in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts may include testing at the farm, animal level, in the slaughter and processing establishments, and the retail distribution chains where appropriate.	Honduras We suggest clarifying what is meant by farm.
For instance, the monitoring systems for STEC and/or indicator organisms, where appropriate, in raw beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts may include testing at the farm, animal level, in the slaughter and processing establishments, and the retail distribution chains where appropriate.	Panama We believe it would be advisable to carry out analyses of indicator organisms in primary production processes and throughout the production chain, along with tests for STEC in positive cases.
Regulatory monitoring programmes should be designed in consultation with relevant stakeholders, taking into account the most cost-efficient resourcing option for collection and testing of samples. Given the importance of monitoring data for risk management activities, sampling and testing components should be standardized on a national basis and be subject to quality assurance.	USA Clarify whether the regulatory monitoring programs are conducted by competent authorities or food business operators.
The type of samples and data collected in monitoring systems should be appropriate for the outcomes sought. Enumeration and sub-typing-characterization of microorganisms generally provides more information for risk management purposes than presence or absence testing.	Honduras
However, due to typically low levels and low prevalence of STEC in food, enumerative monitoring of STEC is impractical and the utility of presence/absence testing in monitoring process performance is also limited (FAO/WHO 2018). Consequently, for process Process performance monitoring enumeration of may be accomplished more effectively and efficiently by quantitatively monitoring sanitary and hygiene indicator organisms. These indicator organisms may do not indicate pathogen presence; instead they provide a more efficient and effective quantitative measure of controlling the control of microbial contamination, including STEC,	Canada This paragraph suggests a correlation between STEC contamination and indicator presence, which is misleading. We suggest using similar wording as in paragraph 44 of Section 10 of Annex 1 (beef) instead.

<p><u>contamination</u> in the product and processing environment. Indicator monitoring can be supplemented by periodic testing for STEC.</p>	
<p>However, due to typically low levels and low prevalence of STEC in food, enumerative monitoring of STEC is impractical and the utility of presence/absence testing in monitoring process performance is also limited (FAO/WHO 2018). Consequently, for process performance monitoring enumeration of sanitary and hygiene indicator organisms may provide a more efficient and effective measure of controlling microbial contamination, including STEC, in the product and processing environment. Indicator monitoring can be supplemented by periodic testing for STEC.</p>	USA
<p>However, due to typically low levels and low prevalence of STEC in food, enumerative monitoring of STEC is impractical and the utility of presence/absence testing in monitoring process performance is also limited (FAO/WHO 2018). Consequently, for process performance monitoring enumeration of sanitary and hygiene indicator <u>micro</u>organisms may provide a more efficient and effective measure of controlling microbial contamination, including STEC, in the product and processing environment. Indicator monitoring can be supplemented by periodic testing for STEC.</p>	Honduras
<p>54. However, due to typically low levels and low prevalence of STEC in food, enumerative monitoring quantitative monitoring of STEC is impractical and the utility of presence/absence testing in monitoring process performance is also limited (FAO/WHO 2018). Consequently, for process performance monitoring enumeration of sanitary and hygiene indicator <u>micro</u>organisms may provide a more efficient and effective measure of controlling microbial contamination, including STEC, in the product and processing environment. Indicator monitoring can be supplemented by periodic testing for STEC.</p>	Argentina
<p>Surveillance of clinical illness from STEC in humans</p>	<p>Panama We believe that the guide should include symptoms experienced by people after ingesting STEC bacteria, according to STEC bacteria type. What actions should be taken by people who have been diagnosed with a STEC infection, especially if they work in daycares, nursing homes, cafeterias, food processing facilities, how much time needs to pass before they can begin working again in these areas. We believe that the guide should include preventive actions for consumers, such as hygiene practices, taking precautions in environments associated with STEC, such as: raising animals, zoos, swimming in ponds, or farms where they come into contact with animals or animal waste.</p>
12.2 LABORATORY ANALYSIS CRITERIA FOR DETECTION OF STEC	
	<p>Sri Lanka the molecular detection test for virulent gene is quite expensive for developing countries like sri lanka. Sri Lanka recommends Applying control measure based on surveillance data both on clinical and STEC common serotypes which is more cost effective.</p>
	<p>Brazil Consideration: Brazil supports the adoption of risk criteria based on the combination of virulence genes for STEC, as recommended in the document prepared by FAO/WHO.</p>
<p>The risk of severe illness from STEC infections is best predicted based on virulence factors (encoded by genes) identified for an STEC strain and should be used as an analysis criterion for</p>	Argentina

<p>detection of STEC in food samples. Based on current scientific knowledge, STEC strains with <i>stx2a</i> and adherence genes, <i>eae</i> or <i>aggR</i>, have the strongest potential to cause diarrhoea, bloody diarrhoea (BD), and haemolytic uremic syndrome (HUS). Strains of STEC with other <i>stx</i> subtypes may cause diarrhoea but their association with HUS is less certain and can be highly variable. Thus, to appropriately manage the risk of STEC in beef meat foods, tests that detect virulence factors such as these should be used. The risk of severe illness may also depend on virulence gene combinations and gene expression, the dose ingested, and the susceptibility of the human host, so a risk management framework should also be applied when laboratory methodologies for STEC detection are selected by countries.</p>	
<p>The risk of severe illness from STEC infections is best predicted based on virulence factors (encoded by genes) identified for an STEC strain and should be used as an analysis criterion for detection of STEC in food samples. Based on current scientific knowledge, STEC strains with <i>stx2a</i> and adherence genes, <i>eae</i> or <i>aggR</i><i>aggR</i>, have the strongest potential to cause diarrhoea, bloody diarrhoea (BD), and haemolytic uremic syndrome (HUS). Strains of STEC with other <i>stx</i> subtypes may cause diarrhoea but their association with HUS is less certain and can be highly variable. Thus, to appropriately manage the risk of STEC in beef meat, tests that detect virulence factors such as these should be used. The risk of severe illness may also depend on virulence gene combinations and gene expression, the dose ingested, and the susceptibility of the human host, so a risk management framework should also be applied when laboratory methodologies for STEC detection are selected by countries.</p>	<p>Chile The <i>aggR</i> gene is not a virulence factor for STEC pathotype, it is a virulence marker for EAEC. Other virulence markers such as <i>saa</i> gene should be considered since it has been described in association with human illness on LEE negative</p>
<p>The risk of severe illness from STEC infections is best predicted based on virulence factors (encoded by genes) identified for an STEC strain and should be used as an analysis criterion for detection of STEC in food samples. Based on current scientific knowledge, STEC strains with <i>stx2a</i> and adherence genes, <i>eae</i> or <i>aggR</i>, have the strongest potential to cause diarrhoea, bloody diarrhoea (BD), and haemolytic uremic syndrome (HUS). Strains of STEC with other <i>stx</i> subtypes may cause diarrhoea but their association with HUS is less certain and can be highly variable. Thus, to appropriately manage the risk of STEC in beef meat, tests that detect virulence factors such as these should be used. The risk of severe illness may also depend on virulence gene combinations and gene expression, the dose ingested, and the susceptibility of the human host, so a risk management framework should also be applied when laboratory methodologies for STEC detection are selected by countries.</p> <p><u>60. The determination of virulence and other salient marker genes may be achieved using validated polymerase chain reaction methods or whole genome sequencing analysis. Special consideration should be given to the efficacy of enrichment culture techniques used to recover STEC from foods, as this is a broad family with diverse growth characteristics which preclude the use of "universal" selective approaches allowing for detection of all STEC strains of public health concern.</u></p>	<p>Canada The selection on methodology should include a statement about which types of analytical technologies are considered suitable for the determination of virulence genes.</p>
<p>The risk of severe illness from STEC infections is best predicted based on virulence factors (encoded by genes) identified for an STEC strain and should be used as an analysis criterion for detection of STEC in food samples. Based on current scientific knowledge, STEC strains with <i>stx2a</i> and adherence genes, <i>eae</i> or <i>aggR</i>, have the strongest potential to cause diarrhoea, bloody diarrhoea (BD), and haemolytic uremic syndrome (HUS). Strains of STEC with other <i>stx</i> subtypes may cause diarrhoea but their association with HUS is less certain and can be highly variable. Thus, to appropriately manage the risk of STEC in beef meat food, tests that detect virulence factors such as these should be used. The risk of severe illness may also depend on virulence gene combinations and gene expression, the dose ingested, and the susceptibility of the human host, so a risk management framework should also be applied when laboratory</p>	<p>Canada Recommend removing "beef meat" as this is still in the general section and the sentence applies to all commodities.</p>

methodologies for STEC detection are selected by countries.	
<p>The risk of severe illness from STEC infections is best predicted based on virulence factors (encoded by genes) identified for an STEC strain and should be used as an analysis criterion for detection of STEC in food samples. Based on current scientific knowledge, STEC strains with <i>stx2a</i> and adherence genes, <i>eae</i> or <i>aggR</i>, have the strongest potential to cause diarrhoea, bloody diarrhoea (BD), and haemolytic uremic syndrome (HUS). Strains of STEC with other <i>stx</i> subtypes may cause diarrhoea but their association with HUS is less certain and can be highly variable. Thus, to appropriately manage the risk of STEC in beef meat STEC, tests that detect virulence factors such as these should be used. The risk of severe illness may also depend on virulence gene combinations and gene expression, the dose ingested, and the susceptibility of the human host, so a risk management framework should also be applied when laboratory methodologies for STEC detection are selected by countries.</p>	<p>USA This is the general section of the document. This sentence should be more generic, as it is applicable to multiple commodities.</p>
<p>A recommendation of a set of criteria that includes 5 risk levels (highest to lowest) based on virulence gene combinations identified in an isolated strain of STEC, which can be used to identify risk management goals for STEC and the testing regimes that would be needed to monitor achievement of those goals is presented in the FAO/WHO Shiga toxin-producing <i>Escherichia coli</i> (STEC) and food: attribution, characterization, and monitoring expert report (FAO/WHO 2018).</p>	<p>Argentina</p>
<p>A recommendation of a set of criteria that includes 5 risk levels (highest to lowest) based on virulence gene combinations, which can be used to identify risk management goals for STEC and the testing regimes that would be needed to monitor achievement of those goals is presented in the FAO/WHO Shiga toxin-producing <i>Escherichia coli</i> (STEC) and food: attribution, characterization, and monitoring expert report (FAO/WHO 2018).</p>	<p>USA Provide additional context around the table from the 2018 FAO/WHO report. The table in this document gives the impression that isolation of Stx2d alone may lead to HUS, BD or D, but the report notes that “Using the criteria described at the other levels (2, 3 and 4) may further reduce the risk of HUS, but will require additional strain characterization.” The FAO/WHO report also concludes that presence of an attachment factor is essential for pathogenicity.</p>
<p>12.4 Public health goals</p>	<p>Honduras We suggest examining the use of the term “goals” throughout the document. It might be more appropriate to use “objectives.”</p>
ANNEX 1: SPECIFIC CONTROL MEASURES FOR RAW BEEF MEAT	
	<p>Canada Canada suggests that there should be a discussion around which type of control measures should be provided in the Annex for raw beef meat. For example, control measures supported by robust scientific evidence only or should potential interventions that might be developed into commercial use in the future also be included.</p>
	<p>Thailand The structure of Annex 1 Specific Control Measures for Raw Beef Meat should be based on the format of Guidelines for the Control of Nontyphoidal Salmonella spp. In Beef and Pork Meat (CXG 87-2016). The control measures in Annex 1 should be designated based on the steps in flow diagram, and identified as GHP-based, Hazard-based or Risk-based so that the similar measures from CXG 87-2016 can be referred to and the specific control for STEC is highlighted.</p>
<p>ANNEX 1: SPECIFIC CONTROL MEASURES FOR RAW BEEF BEEF MEAT</p>	<p>Uruguay</p>

	<p>Suggests correcting the [Spanish] title here to “Carne bovina cruda” (raw beef meat), as well as in the rest of the document where applicable.</p>
<p>1. Foodborne outbreaks of Shiga toxin-producing <i>Escherichia coli</i> (STEC) have historically been linked to meat products, in particular, beef meat, and more specifically to preparations such as ground raw or undercooked beef. STEC are commonly carried by cattle, with reported prevalence in faeces ranging from 0.3% to 27.8% of animals for STEC O157 and 3.6% to 19.4 % of animals for all STEC (Hussein and Bollinger, 2005). STEC shedding by individual cattle is transient and episodic (Williams et al., 2014; Williams et al., 2015), thus it appears that almost all cattle will carry and shed STEC at some time during their life. In addition, STEC are widespread within the farm environment, so it should be expected that a significant proportion of cattle arriving for slaughter will have hides contaminated to some extent with STEC. As with faecal prevalence, the prevalence of STEC on animal hides varies greatly among studies, with prevalence greater than 70% having been reported in some studies (Stromberg et al 2018).</p>	<p>Canada We propose to replace the sentence with the following text to provide more recent and comprehensive information on STEC prevalence in cattle. Associated references: Hussein, H.S., and Bolinger, L.M. 2005. Prevalence of Shiga toxin-producing <i>Escherichia coli</i> in beef cattle. <i>Journal of Food Protection</i>. 68(10):2224-2241. Kolenda, R., Burdukiewicz, M., and Schierack, P. 2015. A systematic review and meta-analysis of the epidemiology of pathogenic <i>Escherichia coli</i> of calves and the role of calves as reservoirs for human pathogenic <i>E. coli</i>. <i>Front. Cell. Infect. Microbiol.</i> 5: 23.</p>
<p>1. Foodborne outbreaks of Shiga toxin-producing <i>Escherichia coli</i> (STEC) have historically been linked to meat products, in particular, beef meat, and more specifically to preparations such as ground raw or undercooked beef. STEC are commonly carried by cattle. <u>A systematic review of reports of STEC prevalence in calves, with reported between 1989 and 2013, found an average prevalence in faeces-healthy calves of 19.4% for eae negative STEC, and 10.7% of eae positive STEC (Kolenda et al., 2015). However, the prevalence of STEC in specific cattle herds can vary considerably, one review of reports of STEC prevalence in beef cattle feces, noted prevalence rates for STEC O157 ranging from 0.3%-2 to 27.8% of animals for STEC O157 and 3non-O157 STEC 2.6%-1 to 1970.4 % of animals for all STEC-1% (Hussein and Bollinger, 2005).</u> STEC shedding by individual cattle is transient and episodic (Williams et al., 2014; Williams et al., 2015), thus it appears that almost all cattle will carry and shed STEC at some time during their life. In addition, STEC are widespread within the farm environment, so it should be expected that a significant proportion of cattle arriving for slaughter will have hides contaminated to some extent with STEC. As with faecal prevalence, the prevalence of STEC on animal hides varies greatly among studies, with prevalence greater than 70% having been reported in some studies (Stromberg et al 2018).</p>	<p>Canada</p>
<p>1. Foodborne outbreaks of Shiga toxin-producing <i>Escherichia coli</i> (STEC) have historically been linked to meat products, in particular, beef meat, and more specifically to preparations such as ground raw or undercooked beef. STEC are commonly carried by cattle, with reported prevalence in faeces ranging from 0.3% to 27.8% of animals for STEC O157 and 3.6% to 19.4 % of animals for all STEC (Hussein and Bollinger, 2005). STEC shedding by individual cattle is transient and episodic (Williams et al., 2014; Williams et al., 2015), thus it appears that almost all cattle will carry and shed STEC at some time during their life. <u>However, animal age, season or herd type are associated with an increase in STEC prevalence.</u> In addition, STEC are widespread within the farm environment, so it should be expected that a significant proportion of cattle arriving for slaughter will have hides contaminated to some extent with STEC. As with faecal prevalence, the prevalence of STEC on animal hides varies greatly among studies, with prevalence greater than 70% having been reported in some studies (Stromberg et al 2018).</p>	<p>IDF/FIL Additionnal information that may be relevant.</p>
<p>1. Foodborne outbreaks of Shiga toxin-producing <i>Escherichia coli</i> (STEC) have historically been linked to meat products, in particular, beef meat, and more specifically to preparations such as ground raw or undercooked beef. STEC are commonly carried by cattle, with reported prevalence in faeces <u>ranging from 0.3% to 27.8% of animals for STEC O157-varying greatly</u></p>	<p>USA Rather than including a variety of prevalence percentages, we recommend a simple statement about prevalence. We believe the prevalence numbers are so highly varied as to be meaningless. It is</p>

<p>depending on animal factors, geographic location, and 3.6% to 19.4 % of animals for all STEC production type (Hussein and Bollinger, 2005). STEC shedding by individual cattle is transient and episodic (Williams et al., 2014; Williams et al., 2015), thus it appears that almost all cattle will carry and shed STEC at some time during their life. In addition, STEC are widespread within the farm environment, so it should be expected that a significant proportion of cattle arriving for slaughter will have hides contaminated to some extent with STEC. As with faecal prevalence, the prevalence of STEC on animal hides varies greatly among studies, with prevalence greater than 70% having been reported in some studies (Stromberg et al 2018).</p>	<p>unclear how representative these numbers are worldwide.</p>
<p>2. Zoonotic pathogens such as STEC carried by cattle could be spread to carcasses during slaughter. The muscle tissue of healthy cattle is essentially sterile, with microbiota, potentially including STEC, transferred to carcass surfaces from the contents of the gastrointestinal tract or hide during the operations of dehiding, head removal, bunning and evisceration (Gill and Gill, 2012). STEC contamination of meat also potentially occurs during further processing, if the product comes into contact with contaminated surfaces. Generally, contamination is confined to the carcass surface and is not found in deep muscle tissues of intact beef.</p>	<p>USA Reflects the actual source of the contamination.</p>
<p>1. SCOPE</p>	
<p>4. This guidance applies to control of STEC in <u>raw</u> fresh beef meat, including cuts such as steaks and ground meat products.</p>	<p>Argentina Justification: We should use the term "raw beef meat" in order to be consistent with the title and the general part of the document.</p>
<p>4. This guidance applies to control of STEC in fresh beef meat, including cuts such as steaks and ground meat products.</p>	<p>Honduras We suggest using the term "raw beef meat"</p>
<p>DEFINITIONS</p>	
	<p>USA Delete definitions not used more than once in the annex. Consider whether to refer to the definitions in the Code of Hygienic Practice for Meat (CXC 58-2005) rather than repeating those definitions here. Codex practice is to only list definitions that are used multiple times in a document. If only used once, a definition can be provided when the word is used. Referring to the definitions in another code minimizes the need to find all the places a specific definition is used if it is changed.</p>
<p><i>Beef meat:</i> All the muscle tissue <u>All parts surrounding the skeleton</u> of a cattle that are intended for, or have been judged as safe and suitable for, human consumption.</p>	<p>Chile</p>
<p><i>Beef meat:</i> All parts of a cattle <u>cattle/bovines</u> that are intended for, or have been judged as safe and suitable for, human consumption.</p>	<p>India The definition should be aligned with that given in Codex Standard for Corned Beef (CXS 88-1981).</p>
<p><i>Fresh Meat:</i> Meat that apart from refrigeration <u>refrigeration, and maintain at a temperature between 0° and 7°C,</u> has not been treated for the purpose of preservation other than through protective packaging and which retains its natural characteristics.</p>	<p>Chile</p>
<p><i>Manufactured Meat Products:</i> resulting from the processing of raw meat or from the further processing of such processed products, so that when cut, the cut surface shows that the product no longer has the characteristics of fresh meat.</p>	<p>India Clarity is needed in these two definitions" Manufactured Meat Products" and "Meat Preparations"). The difference in these two terms is not clear, whether they include cooked, dried, fermented meat products etc.</p>
<p><i>Meat:</i> All parts <u>the muscle tissue surrounding the skeleton</u> of an animal <u>animal</u>, that <u>has been matured that</u> are intended for, or have been judged as safe and suitable for, human consumption.</p>	<p>Chile</p>

<p><i>Meat hygiene:</i> All conditions and measures necessary to ensure the safety and suitability of meat at all stages of the food chain. <i>Meat preparation</i> <i>Meat preparation:</i> Raw meat which has had foodstuffs, seasonings or additives added to it.</p>	<p>Uruguay The definition of “Meat preparation” appeared within the definition of Meat hygiene.</p>
<p><i>Raw meat:</i> Fresh meat, <u>raw</u> minced meat or <u>raw</u> mechanically separated meat.</p>	<p>India</p>
<p><i>Raw meat:</i> Fresh meat<u>All parts of an animal that are intended for, minced meat or mechanically separated meat</u>have been judged as safe and suitable for, human consumption without heat treatment.</p>	<p>Brazil Rationale: The definition only gives examples of raw meat, not the definition itself.</p>
<p>3. PRIMARY PRODUCTION-TO-CONSUMPTION APPROACH TO CONTROL MEASURES</p>	
<p>6. STEC have a wide range of potential hosts (Persad and LeJeune, 2014), and STEC cells can potentially persist for over a year in the environment (Jang et al., 2017; Nyberg et al., 2019). These features of the ecology of STEC indicate that control strategies based on denying STEC access to hosts or habitat will be highly challenging to implement in a manner which reliably prevents exposure of cattle to STEC.</p>	<p>USA Clarify “environment” in the first sentence: STEC have a wide range of potential hosts (Persad and LeJeune, 2014), and STEC cells can potentially persist for over a year in the environment (Jang et al., 2017; Nyberg et al., 2019). It is important to clarify that these studies refer to the natural environment rather than the plant environment. It would be helpful to include information on where in the environment STEC have been found.</p>
<p>7. Interventions to control enteric pathogens should always be seen as part of an integrated food safety system that includes all the stages from “farm to fork.” Measures to reduce STEC shedding or hide contamination prior to harvest have the potential to reduce environmental exposure to STEC and may improve beef meat safety, but they cannot prevent STEC contamination or compensate for poor hygiene practices during slaughter, processing and distribution. Conversely, there is evidence that the adoption of the best hygienic practices during slaughter and processing can minimise contamination with STEC and other enteric pathogens (Brichta-Harhay et al., 2008; Pollari et al., 2016). Consequently, the adoption of best practices for preharvest management of cattle should be promoted as a support to hygienic slaughter and processing.</p>	<p>USA The document is about STEC.</p>
<p>Process Flow Diagram: Primary Production to Consumption of Beef (from CXG 087)</p>	<p>Thailand Process flow diagram 1: Primary Production-to-Consumption – Beef ‘Spinal cord removing’ should be added between Step13 Evisceration and Step14 Splitting. Rationale: To complete the Process Step of beef production.</p>
<p>Process Flow Diagram: Primary production to consumption beef (from CXG 087) of beef (from CXG 087)</p>	<p>Honduras</p>
<p>Process Flow Diagram: Primary Production to Consumption of Beef (from CXG 087)</p>	<p>Uruguay Copy the flow diagram for beef given in the DRAFT GUIDELINES FOR THE CONTROL OF NONTYPHOIDAL SALMONELLA SPP. IN BEEF AND PORK MEAT (CAC/GL 87-2016).</p>
<p>5. PRIMARY PRODUCTION</p>	
	<p>Japan [General comment] Control measures in all stages (from primary production to consumption) should be discussed in CCFH after a scientific advice from JEMRA is available.</p>
<p>10. Control measures to reduce the carriage of STEC in ruminants prior to slaughter that have the potential to reduce the prevalence of STEC are described in this section.</p>	<p>Canada The following applies to paragraphs 10 and 11: It is suggested that robust lot testing (for example n=60) for E. coli O157 in beef that will be further processed into ground beef be mentioned as a risk</p>

	management control measure as it has resulted, along with other actions, in an important decrease in foodborne illness cases caused by E. coli O157 over the past 10 years in Canada.
Specific Control measures at farm level	Nicaragua Nicaragua suggests that only scientifically proven measures be included, since the research that is mentioned provides contradictory results.
Specific Control measures at farm level for primary production	USA There are variations in practices worldwide and in the terminology for where the animals are raised prior to slaughter.
Diet	USA Delete all paragraphs from 14-23 for interventions that have not shown efficacy against STEC or the use described is not consistent with manufacturer's instructions. The information in these paragraphs has been helpful in understanding the types of interventions that have been explored for controlling STEC at primary production. However, it does not appear that these interventions can be supported by science as being effective in reducing shedding of STEC such that they can be implemented as management strategies to reduce STEC. Additional information for our rationale is provided below under the "Feed Additives" section.
14. A wide variety of cattle diets have been investigated for their impact on STEC O157 prevalence and/or shedding, including hay, barley, distillers and brewers grains, sage brush, millet, alfalfa, (Callaway et al., 2009). Both STEC O157 and generic E. coli populations have been demonstrated to respond to changes in diet, but replication of results indicating STEC O157 reduction has been poor and no dietary composition has been identified that reliably reduces STEC O157. Some diets that have been proposed increase STEC O157 shedding (Thomas and Elliott, 2013).	Uruguay We suggest improving the Spanish translation.
14. A wide variety of cattle diets have been investigated for their impact on STEC O157 prevalence and/or shedding, including hay, barley, distillers and brewers grains, sage brush, millet, alfalfa, (Callaway et al., 2009).	Argentina
Feed Additives	USA Delete all paragraphs from 14-23 for interventions that have not shown efficacy against STEC or the use described is not consistent with manufacturer's instructions. The information in these paragraphs has been helpful in understanding the types of interventions that have been explored for controlling STEC at primary production. However, it does not appear that these interventions can be supported by science as being effective in reducing shedding of STEC such that they can be implemented as management strategies to reduce STEC. For example, the studies cited in paragraph 17 provide evidence that ractopamine does not have a significant impact on STEC. A white paper on "Pre-harvest Control of E. coli O157:H7" by T. R. Callaway (a preeminent USDA researcher in this area) prepared for the National Cattlemen's Beef Association in 2010 concluded that the results of

	<p>studies as a whole indicate that the effects of β-agonist (e.g., ractopamine) feeding are minimal or non-existent on E. coli O157. Paragraph 18 indicates that studies on ionophores such as monensin have been variable. In fact, monensin targets Gram-positive bacteria and it has been postulated that inclusion in the diet could promote survival of STEC in the digestive tract of cattle, and thereby increase shedding. (However, a study by McAllister et al. (Journal of Food Protection 69:2075-2083. 2006) on shedding of E. coli O157:H7 by cattle fed diets containing monensin or tylosin found these compounds did not increase shedding of O157 or its persistence in the environment.) A Paddock et al. study (Journal of Animal Science 89:2829-2835. 2011) investigated the effect of monensin, urea, and ractopamine on fecal shedding of E. coli O157:H7 in cattle fed diets supplemented with distillers grains, which have been reported to increase fecal E. coli O157 prevalence in cattle. The inclusion of urea or ractopamine in these diets had no effect on fecal prevalence of E. coli O157:H7. Cattle fed higher levels of monensin (44 mg/kg feed) in these diets had a lower fecal prevalence of fecal E. coli O157:H7 than cattle fed lower levels (33 mg/kg), but the authors indicated further study was needed to confirm the results, since prior studies on monensin at 33 mg/kg had shown no effect on E. coli O157:H7 in cattle. Thus, the compounds in paragraphs 17 and 18 have not been scientifically demonstrated as effective The efficacy of other interventions in these paragraphs is also not proven at this time. We also note that the use described for some of these compounds is not consistent with manufacturer's instructions.</p>
<p>17. β-adrenergic agonists (e.g. ractopamine, zilpaterol). An early study reported reduced prevalence of STEC O157 in cattle treated with ractopamine (Edrington et al. 2006). Subsequent studies have not reported any significant impact on STEC prevalence or shedding levels (Edrington et al. 2009; Paddock et al 2011; Wells et al., 2017).</p>	<p>Thailand Some listed feed additives, are not specifically designed for controlling and reduction of the STEC. Specifying these agents as feed additive might lead to misuse and antimicrobial resistance.</p>
<p>18. Ionophores (e.g. Monesin Monensin). The results of individual studies are variable (Callaway, 2010; Paddock et al 2011). 2011). It has been proposed that the effect of ionphores on STEC O157 is dependent upon cattle diet (Callaway, 2010).</p>	<p>Uruguay suggests changing Monesin to Monensin</p>
<p>18. Ionophores (e.g. monesin). The results of individual studies are variable (Callaway, 2010; Paddock et al 2011). It has been proposed that the effect of ionphores on STEC O157 is dependent upon cattle diet (Callaway, 2010).</p>	<p>Thailand In addition, the use of these feed additives and the residue limit should refer to the Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for Residues of Veterinary Drugs in Foods (CXM 2) from CCRVDF. Also, the specified result stated in paras 17 and 18 is still inconclusive and varied depending on various factors. Thus, it should not be shown as a part of control measures for primary production.</p>
<p>Bacteriophage.</p>	<p>USA Delete all paragraphs from 14-23 for interventions that have not shown efficacy against STEC or the use described is not consistent with manufacturer's instructions. The information in these paragraphs has been helpful in understanding</p>

	<p>the types of interventions that have been explored for controlling STEC at primary production. However, it does not appear that these interventions can be supported by science as being effective in reducing shedding of STEC such that they can be implemented as management strategies to reduce STEC.</p> <p>Additional information for our rationale is provided above under the "Feed Additives" section.</p>
Vaccination	<p>USA</p> <p>Delete all paragraphs from 14-23 for interventions that have not shown efficacy against STEC or the use described is not consistent with manufacturer's instructions.</p> <p>The information in these paragraphs has been helpful in understanding the types of interventions that have been explored for controlling STEC at primary production. However, it does not appear that these interventions can be supported by science as being effective in reducing shedding of STEC such that they can be implemented as management strategies to reduce STEC. Additional information for our rationale is provided above under the "Feed Additives" section.</p>
24. The following good management practices for animals are recommend to minimise STEC shedding and hide contamination on animals presented for slaughter. Of particular concern is preventing the formation of heavy tag on animal hides, as this can interfere with hygienic skinning and evisceration.	<p>Uruguay</p> <p>suggests improving the Spanish translation.</p>
Avoid non-natural stressful situations Where possible, e.g. poor animal husbandry or rough handling, stressful situations should be minimized because increased stress increases shedding of pathogens.	<p>USA</p> <p>Makes the bullet more practical.</p>
Try to avoid Minimize the entry of or contact with new animals from other cattle raising farms to avoid or reduce horizontal transmission of EHEC-STE C among animals on the same farm or in the same pen (Calloway, 2010)	<p>USA</p> <p>Makes the bullet more practical.</p>
In the same farm, keep where possible, animals should be kept in the same herd grouping and avoid sharing water troughs to avoid cross contamination during pathogen shedding periods contamination.	<p>USA</p> <p>Makes the bullet more practical. With respect to bullet #3, it is difficult to know when pathogen shedding occurs.</p>
Clean and dry bedding —This, where appropriate, may reduce heavy soiling of the brisket, reducing the potential for contamination during carcass dressing.	<p>USA</p> <p>Makes the bullet more practical.</p>
Drinking water is an important route of STEC transmission in dairy cattle because of faecal contamination of water troughs, as indicated by detection of E. coli O157:H7 in trough water and sediments (Faith et al, 1996, Jackson et al 1998, Lejeune 2001). Ensure water is of a microbiological quality that minimises animal contamination and, if there is doubt, treat the water. Frequent cleaning of water troughs has been recommended to reduce replication and/or survival of these foodborne pathogens (Lejeune et al 2001). The position of water troughs on the farm also can affect STEC prevalence (Lejeune, 2001). Materials used in water troughs should also be considered; metal troughs had lower E. coli O157 counts compared with troughs that were manufactured from concrete or plastic (Lejeune, 2001).	<p>Honduras</p> <p>suggests reconsidering the use of the term "drinking water" since the presence of fecal contamination is mentioned.</p>
Drinking water Water is an important route of STEC transmission in dairy cattle because of faecal contamination of water troughs, as indicated by detection of E. coli O157:H7 in trough water and sediments (Faith et al, 1996, Jackson et al 1998, Lejeune 2001). Ensure water is of a microbiological quality that minimises animal contamination and, if there is doubt, treat the water. Frequent cleaning of water troughs has been recommended to reduce replication and/or survival	<p>Nicaragua</p> <p>Nicaragua suggests deleting the term to avoid confusion.</p>

of these foodborne pathogens (Lejeune et al 2001). The position of water troughs on the farm also can affect STEC prevalence (Lejeune, 2001). Materials used in water troughs should also be considered; metal troughs had lower E. coli O157 counts compared with troughs that were manufactured from concrete or plastic (Lejeune, 2001).	
25. Increased hide contamination and/or shedding of STEC and other enteric pathogens by cattle. Transportation and lairage can be major contributors to the increasing occurrence of pathogens in animals. Contributing factors include mixing of animals of different origin, stress, extended duration of transportation and lairage, and dirtyness cleanliness of transport vehicles and lairage pens (Norrung et al., 2008; Dewell et al., 2008a and 2008b).	USA The first statement is an incomplete sentence and is not needed. "Cleanliness" is a better term to use than "dirtyness."
Specific Control measures at Transportation	USA Transportation is covered by the previous subheader.
27. Transportation practices should <u>aim to</u> ensure that the animals arrive in as good a condition as when they left <u>primary production</u> to prevent any disease, injury or other issues conditions that could affect contamination of the meat. Control measures implemented prior to travel include:	USA Focus on what is practical and important for STEC control and to remove provisions that are out of scope in this document.
• mustering and handling animals so that they are not unduly stressed; following the Code of Hygienic Practice for Meat (CXC 58-2005), which specifies that journey distance and time to be as short as possible and that rest and water should be provided.	USA
• ensuring animals are as clean as <u>possible</u> . Dirty animals may increase possible to decrease the likelihood of opportunity for pathogen contamination onto carcasses or hides during the slaughter and dressing processes. The likelihood of STEC contaminating the meat increases where levels of faecal contamination on the hide are high.	USA
• loading the animals onto clean vehicles; and not overcrowding the vehicle.	USA
Specific Control measures at Receive and Unload	USA Paragraph numbering seems to have started again from 1 below.
Spraying chlorinated water under appropriate pressure can be used as a corrective action at the time of animals unloading in order to reduce faecal contamination on the hide.	Nicaragua Nicaragua suggests indicating the concentration of chlorine to use, taking animal welfare into account.
Spraying chlorinated water under appropriate pressure can be used as a corrective action at the time of animals unloading in order to reduce faecal contamination on the hide <u>hide as a whole</u> .	Brazil Rationale: The spraying step should be able to reduce fecal contamination of the hide as a whole. Care should be taken when using equipment that only performs localized cleaning and often concentrates fecal contamination in the ventral region of cattle.
Spraying chlorinated water under appropriate pressure can be used as a corrective action at the time of animals unloading in order to reduce faecal contamination on the hide.	USA We suggest deletion of the paragraph as we have concerns that this could stress animals and could be impractical under certain weather conditions. It is likely to spread contamination. No reference was provided to show data that this reduces STEC.
In this step, water spray or washing can be used to reduce residues on the animal's hide, reducing the initial count of microorganisms. Washing the live animal, specifically, washing of the hide significantly reduces the load of E. coli O157: H7 that enters the plant, which is closely related to the final levels of contamination of the carcasses (Arthur et al., 2007 and Arthur et al., 2010, Callaway, 2011, LeJeune and Wetzel, 2012)	Honduras Review the recommendation, whether the live animal is washed or not We suggest considering water pressure a relevant factor in washing hides.
It is preferable at <u>lairage, maintaining lairage to maintain</u> cattle in closed herds to reduce social stress and prevent cross contamination between herds. Reducing stress may also help to reduce faecal shedding of E. coli O157:H7.	USA The last point is not needed as it has been said in other places.
PROCESSING	Uruguay

<p>[Translator’s note: the change in the Spanish version does not affect the English version.]</p>	<p>suggests replacing the term “Elaboración” with “Procesamiento” [in the Spanish]</p>
<p>6. PROCESSING</p>	
<p>Specific Control Measures at Processing <u>Stunning: In access to the stunning box the animals can be conducted with water jets at appropriate pressure aiming the hygiene of the rectum during the course due to the possible elimination of faces and shedding STECs by the stress in the conduction to slaughter. The stunning box should be preserved clean as much as possible to avoid contamination of the animal’s hide in the fall after the stunning process.</u> <u>Dehiding: The rinsing of the rectum and disinfection of the perianal hide should be performed in order to reduce or eliminate contamination prior to dehiding. The dehiding operation should be performed with a dehiding of the entire perianal region and bending the hide, making it stay above the tail, in order to avoid contact of the hide with the part of carcass that is already dehided. This contact could happens mainly after the dehiding of the first leg, especially in the first exchange of hang to dehide the other leg which occurs normally when the dehiding is performed in the median region of the perineum. Those measures prevents tail flapping of, when hide pullers are used and also avoid contamination of the rectum occlusion bag directly on the hide, that can result in a cross-contamination to de carcass dehided. Severing or removing the switch on the tail when using hide pullers to minimize the possibility that contaminations become airborne from splattering or flapping of the hide.</u> <u>Bunging: The rectum occlusion should be performed hygienically in order to avoid carcass and tools contamination, either with the gastrointestinal content or, if the dehide was not already done, even with the contact of the hide still present in the carcass (In Brazil occlusion of the rectum occurs prior to complete removal of the hide). The extravagation of the gastrointestinal contents to the pelvic region of the carcass is the source of contamination in tenderloin.</u> <u>Evisceration: In this stage the operators have to be efficiently trained to performed the operation without the cut of the gastrointestinal tract resulting in a consequent overflow of content.</u></p>	<p>Brazil Rationale: Brazil suggests the inclusion of measures adopted in stunning, dehiding, bunging and evisceration, as described below, as these measures can significantly reduce fecal contamination, thus reducing the risk of STEC contamination (Paragraph 34).</p>
<p>Targeted removal of visible contamination by trimming, washing or hot water/steam vacuum cleaning may be applied to carcasses, but the disadvantage of this manual methods is potential cross-contamination from dirty knives, aprons, mesh gloves, and waste. <u>The temperature use in the water should not affect the color or quality of the meat.</u> Also, even though effective at removing visible defects the effectiveness of these practices to reduce pathogen contamination is highly limited. There is no relationship between visible soiling and microbiological contamination, and removal of visible soiling has minimal impact on the contamination of the carcass (Gill and Landers, 2004; Gill and Baker et al 1998). <u>When organic acids are use in the washing procedure, hot water should be avoid, since increase the volatization of the organic acids.</u></p>	<p>Chile</p>
<p>Targeted removal of visible contamination by trimming, washing or hot water/steam vacuum cleaning may be applied to carcasses, but the disadvantage of this manual methods is potential cross-contamination from dirty knivesknives (if not using a knife switching disinfection protocol in between cuts), aprons, mesh gloves, and waste. Also, even though effective at removing visible defectsdefects, the effectiveness of these practices to reduce pathogen contamination is highly limited. There is no relationship between visible soiling and microbiological contamination, and removalRemoval of visible soiling has minimal impact on the contamination of the carcass (Gill and Landers, 2004; Gill and Baker et al 1998).</p>	<p>USA</p>
<p><i>Carcass washing</i>, which may remove visible soiling and reduce overall bacterial counts on beef carcasses by up to 1 log unit (Gill and Landers, 2003).</p>	<p>Honduras suggests including information on the type of water to use for washing</p>

	(e.g. drinking water, clean water).
<i>Carcass washing with antimicrobial agents</i> , such as organic acids (e.g.; citric acid, lactic acid, acetic acid), oxidising agents (e.g. chlorine, peroxides, ozone) or other antimicrobial agents permitted by regulation (Gill and Gill, 2012). Such antimicrobial treatments may be applied with hot water to have a combined thermal impact. Factors determining the effectiveness of such treatments include the concentration of the agent, uniformity of surface coverage, the temperature of solution, and the contact period. Individual STEC strains may vary in their sensitivity to such treatments (Berry and Cutter, 2000; Gill et al., 2019). Organic acids alone can reduce the counts but not completely eliminate STEC O157 (Hussein and Sakuma, 2005).	Honduras suggests including a temperature recommendation for the hot water
<i>Carcass washing with antimicrobial agents</i> , such as organic acids (e.g.; citric acid, lactic acid, acetic acid), oxidising agents (e.g. chlorine, peroxides, ozone) or other antimicrobial agents permitted by regulation (Gill and Gill, 2012). Such antimicrobial treatments may be applied with hot water to have a combined thermal impact. Factors determining the effectiveness of such treatments include the concentration of the agent, uniformity of surface coverage, the temperature of solution, and the contact period. Individual STEC strains may vary in their sensitivity to such treatments (Berry and Cutter, 2000; Gill et al., 2019). Organic acids alone can reduce the counts but not completely eliminate STEC O157 (Hussein and Sakuma, 2005).	Nicaragua Nicaragua suggests indicating the recommended dosage.
<i>Carcass surface pasteurisation</i> . This form of treatment is most commonly applied to carcass sides at the end of dressing. Water at >85 °C may be applied as a spray, a sheet or as steam (Gill and Bryant, 2000; Retzlaff et al., 2005). Treatment is most effective when applied to clean, dry carcass sides as large drops or sheets of water; when applied under such conditions the treatment can achieve >2 log reductions in total E. coli in commercial slaughter operations (Gill and Jones, 2006).	Nicaragua Nicaragua suggests indicating the recommended dosage.
Processes such as marinating, brine injection, and mechanical tenderisation in which blades or needles penetrate the muscle surface present the potential for increased food safety risks due to the transfer of pathogens from the surface to the interior (resulting in internalization of STEC during marinating-tenderization previously intact raw fresh beef products (Johns et al. 2011; CDC 2010; Lewis et al 2013). Such products should be considered as “non-intact” beef products, and appropriate consumer guidance may be required (USDA FSIS 2019; Health Canada 2019).	Chile
Processes such as marinating, in combination with knife scoring, proteolytic enzymes, or vacuum brine injection, and mechanical tenderisation in which blades or needles penetrate the muscle surface present the potential for increased food safety risks due to the transfer of pathogens from the surface to the interior (resulting in internalization of STEC during marinating into previously intact raw fresh beef products (Johns et al. 2011; CDC 2010; Lewis et al 2013). Such products should be considered as “non-intact” beef products, and appropriate consumer guidance may be required (USDA FSIS 2019; Health Canada 2019).	USA Marinating alone (soaking without injection or vacuum) does not result in increased risk from internalized STEC similar to brine injection of marinade or mechanical tenderization.
8. CONSUMERS	
	USA Add information about consumer handling such as proper cooking, hand washing after handling raw meat, and cleaning counters and meat drip. Consumers have an important role in minimizing the risk of illness from STEC in raw meat in the home.
10. MONITORING OF CONTROL MEASURES	
The utility of testing for STEC presence/absence as part of monitoring programmes for food safety assurance in processing is limited by the typically low levels and prevalence of STEC in food. Process performance monitoring may be accomplished more effectively and efficiently by	Honduras

<p>quantitatively monitoring sanitary and hygiene indicator microorganisms. These indicator microorganisms do not indicate pathogen presence; instead they provide a quantitative measure of the control of microbial contamination in the product and processing environment. Periodic testing for high risk STEC can also be conducted for verification of process performance. (FAO/WHO STEC Expert Report 2018).</p>	
<p>The utility of testing for STEC presence/absence as part of monitoring programmes for food safety assurance in processing is limited by the typically low levels and prevalence of STEC in food. Process performance monitoring may be accomplished more effectively and efficiently by quantitatively monitoring sanitary and hygiene indicator organisms. These indicator organisms do not indicate pathogen presence; instead they provide a quantitative measure of the control of microbial contamination in the product and processing environment. Periodic testing for high risk STEC can also be conducted for verification of process performance. (FAO/WHO STEC Expert Report 2018).</p>	<p>Canada Remove (or reword) first sentence in paragraph 44. Further to our previous comment : While testing for indicator bacteria is more appropriate for day to day process control monitoring, there is still significant utility to conduct total lot testing for E. coli O157 in raw beef that is intended for further processing into ground beef. This testing contributes to directly reducing contamination rates in retail ground beef and promoting continuous process improvement.</p>
<p>11. VERIFICATION OF CONTROL MEASURES AND REVIEW OF CONTROL MEASURES</p>	
<p>It is recommended to use countable hygiene criteria to measure the effectiveness of control measures (E(e.g.; microorganism indicating faecal contamination), contamination) and to steer adjust the hygiene conditions when manufacturing. The speed in detecting a loss of control of manufacturing hygiene increases with the verification frequency.</p>	<p>USA</p>
<p>12. LABORATORY ANALYSIS CRITERIA FOR DETECTION OF STEC IN BEEF</p>	
<p>LABORATORY ANALYSIS CRITERIA FOR DETECTION OF STEC IN BEEF This section does not appear complete and need more details to be added as per its title.</p>	<p>India This section does not appear complete and need more details to be added as per its title.</p>
<p>Meat contains a high proportion of water and protein. All fresh meat has internal water activities (aw) of >0.99 which provides a suitable environment for microbial growth (ICMSF, 2005). Having into account that, STEC on the carcass can be transferred to meat cuts as the animal is further processed and can also be transferred between animals via meat processing equipment (ICMSF, 2005). Some meat cuts will need more control measures and monitoring than others (e.g. minced, ground, trim)</p>	<p>Canada Paragraph 47 seems out of place under section 12 "laboratory analysis criteria for detection of STEC in beef".</p>
<p>Meat contains a high proportion of water and protein. All fresh meat has internal water activities (aw) of >0.99 which provides a suitable environment for microbial growth (ICMSF, 2005). Having into account that, STEC on the carcass can be transferred to meat cuts as the animal is further processed and can also be transferred between animals via meat processing equipment (ICMSF, 2005). Some meat cuts will need more control measures and monitoring than others (e.g. minced, ground, trim)</p>	<p>Brazil Consideration: STEC monitoring should be performed on raw materials intended for the production of ground beef or products composed of pieces of raw beef that will be consumed raw. Intact beef, when contaminated with STEC, has very low numbers of the microorganism, requiring a large sample size to recover the pathogen. Unlike ground beef, the insides of these intact raw products are considered pathogen free. Accordingly, the usual cooking of such products is expected to deactivate any STEC that may be present on the surface. Intact primary and subprime cuts used for purposes other than the manufacture of finished raw ground beef products do not present the same level of risk as ground beef and therefore should not require microbiological testing for STEC (i.e.: steaks). Meat trimmings are small pieces of meat collected from primals during boning when carcasses are cut into several intact cuts of meat. These trimmings are used for the production of ground beef. Consequently, this material is more likely to contain STEC as it represents a large number of carcasses/animals. Paragraph 47 should be developed to clarify this understanding and to establish the categories of raw meat that should</p>

	necessarily be searched for STEC, such as, ground beef and non-intact beef products that will be consumed raw.
Meat contains a high proportion of water and protein. All fresh meat has internal water activities (aw) of >0.99 which provides a suitable environment for microbial growth (ICMSF, 2005). Having into account that, STEC on the carcass can be transferred to meat cuts as the animal is further processed and can also be transferred between animals via meat processing equipment (ICMSF, 2005). Some meat cuts will need more control measures and monitoring than others (e.g. minced, ground, trim)	USA This paragraph is not relevant to laboratory analysis.
ANNEX 2. FRESH LEAFY GREEN VEGETABLES	
ANNEX 2. FRESH FRESH LEAFY GREEN VEGETABLES	Uruguay suggests changing the title of the document to Fresh Leafy Vegetables, here and in the rest of the document where applicable. Our proposed name would include all leafy vegetables whose leaves are intended for consumption.
	Canada We suggest using the expression "fresh leafy vegetables" throughout instead of "leafy greens" or "fresh leafy green vegetables" for consistency with the terminology used in the Code of Practice for fresh fruits and vegetables and its annex III on "fresh leafy vegetables."
ANNEX 2. FRESH LEAFY GREEN-VEGETABLES	Canada Canada noted that some information in Annex 2 is similar to the Code of Practice for Fresh Fruits and Vegetables. We suggest focusing on control measures that are specific to STEC, if available
ANNEX 2. FRESH LEAFY GREEN-VEGETABLES	Japan To be consistent with the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003), the term "fresh leafy vegetable" is preferred.
	Thailand The structure of Annex 2 Fresh Leafy Green Vegetables should be based on Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003) in order to facilitate the implementation of FBOs who are more familiar with only GHP based control measure in accordance with CXC 53-2003. Most of control measures in this Annex are not specific for STEC. If the detail is not much different from the control measures of CXC 53-2003 and CXC 1-1969. CXC 53-2003 and CXC 1-1969 should be referred to, instead of repetition. Only specific control measures for reducing STEC should be added.
INTRODUCTION	
1. Fresh leafy green vegetables are grown, processed and consumed throughout the world. They are grown on farms of varying size; distributed and marketed locally and globally, providing year-round availability to consumers; and sold as fresh, fresh-cut, pre-cut or other ready-to-eat (RTE) products such as pre-packaged salads.	Gambia The Gambia supports the use of the term "fresh leafy green vegetables" rather than "leafy greens" and "leafy green vegetable" as proposed by the Chairs of EWG
1. OBJECTIVE	
4. The objective of this Annex is to provide guidance to reduce, during their production, harvesting, packing, processing, storage, distribution, marketing and consumer use, the risk of foodborne illness from STEC associated with fresh leafy green vegetables intended for human	Japan To be consistent with the beef annex.

<p>consumption without cooking. Figure 1 provides a flow diagram illustrating key production steps that are addressed by this Annex <u>process of fresh leafy vegetables</u>. 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.</p>	
<p>2.1 Scope</p>	
<p>5. This Annex covers specific guidance for control of STEC related to fresh leafy green vegetables that are intended to be consumed without further lethality steps. Fresh leafy green vegetables for the purposes of this Annex include all vegetables of a leafy nature where the leaf is intended for consumption <u>consumption and has been indicated as a relevant source of STEC in cases of human illnesses</u>, and include, but are not limited to, all varieties of lettuce, spinach, cabbage, chicory, endive, kale, radicchio, and fresh herbs such as coriander, cilantro, basil, curry leaf, colocasia leaves and parsley. The Annex is applicable to fresh leafy green vegetables grown in open fields or in fully or partially protected facilities (hydroponic systems, greenhouses/controlled environments, tunnels etc.).</p>	<p>Chile</p>
<p>3.1 Environmental Conditions</p>	
<p>9. As far as possible, it is recommended that potential sources of STEC contamination should be identified prior to primary pro-duction activities. Where possible, growers should evaluate present and previous uses of both indoor and outdoor fresh leafy green vegetable primary production sites and the adjoining land (e.g. feed lot, animal production, sewage treatment site) in order to identify potential sources of STEC. The assessment of environmental conditions is particularly important because subsequent steps may not be adequate to remove STEC contamination that occurs during primary production, and in some cases conditions may enable the growth of STEC, thereby increasing the risk.</p>	<p>Uruguay</p>
<p>11. The effects of some environmental events cannot be controlled. For example, heavy rains may increase the exposure of fresh leafy green vegetables to STEC if soil contaminated with STEC splashes onto them. When heavy rains occur, growers should evaluate the need to postpone harvesting fresh leafy green vegetables for direct consumption and/or to subject them to a treatment that will minimize the risk from STEC. If fresh leafy green vegetables that contact flood waters are not submitted to any measure to mitigate risks, they should not be eaten raw. This does not include flood irrigation, where the source of water is of known and appropriate quality.</p>	<p>Uruguay suggests removing the following sentence from Paragraph 11: “This does not include flood irrigation, where the source of water is of known and appropriate quality” since section 3 .2 .1 Water for Primary Production emphasizes the importance of knowing the quality of irrigation water.</p>
<p>3.1.2 Animal activity</p>	
<p>13. some <u>Some</u> wild and domestic animals present in the primary production environment are known to be potential carriers of STEC. Wild animals represent a particularly difficult risk to manage because their presence is intermittent. The following are particularly important to minimize the potential for animal contamination of fresh leafy green vegetables with STEC:</p>	<p>Japan</p>
<p>3.2 Hygienic growing Factors to consider in the production of fresh leafy green STEC-free fresh leafy green vegetables</p>	
<p>14. Several parameters may influence the risk-likelihood of microbial contamination of fresh leafy green vegetables with STEC: the type of irrigation (e.g. drip, sprinkler, overhead), the source of water, whether the edible portions of fresh leafy green vegetables have direct contact with irrigation water, the timing of irrigation in relation to harvesting and, most importantly, the occurrence of STEC in the irrigation water. Growers should evaluate the sources of water used on the farm for the risk-likelihood of contamination with STEC and identify corrective actions to prevent or minimize STEC contamination (e.g. from livestock, wildlife, sewage treatment, human</p>	<p>Uruguay suggests changing the title from “Hygienic growing of fresh leafy green vegetables” to “Factors to consider in the production of STEC-free fresh leafy green vegetables”.</p> <p>Japan To avoid use of “risk” for different meaning from the one in the Codex definition</p>

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 <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i> (CXC 53-2003).)	
15. Where necessary, it is suggested that growers should have the water they use tested for STEC or appropriate indicator organisms, according to the risk associated with the production. The frequency of testing will depend on the water source (i.e. lower for adequately maintained deep wells, higher for surface waters), the risks of environmental contamination, including intermittent or temporary contamination (e.g., heavy rain, flooding), or the implementation of a new water treatment process by growers. If the water source is found to have unacceptable levels of indicator organisms or is contaminated with STEC, corrective actions should be taken to ensure that the water is suitable for its intended use. Possible corrective actions to prevent or minimize contamination of water for primary production may include the installation of fencing to prevent large animal contact, the proper maintenance of wells, water filtering, chemical water treatment, the prevention of the stirring of the sediment when drawing water, the construction of settling or holding ponds or water treatment facilities. The effectiveness of corrective actions should be verified by regular testing. Where possible, growers should have a contingency plan in place that identifies an alternative source of water.	Uruguay
15. Where necessary, growers should have test the water they use tested for STEC or appropriate indicator organisms, according to the risk associated with the production. The frequency of testing will depend on the water source (i.e. lower for adequately maintained deep wells, higher for surface waters), the risks of environmental contamination, including intermittent or temporary contamination (e.g., heavy rain, flooding), or the implementation of a new water treatment process by growers. If the water source is found to have unacceptable levels of indicator organisms or is contaminated with STEC, corrective actions should be taken to ensure that the water is suitable for its intended use. Possible corrective actions to prevent or minimize contamination of water for primary production may include the installation of fencing to prevent large animal contact, the proper maintenance of wells, water filtering, chemical water treatment, the prevention of the stirring of the sediment when drawing water, the construction of settling or holding ponds or water treatment facilities. The effectiveness of corrective actions should be verified by regular testing. Where possible, growers should have a contingency plan in place that identifies an alternative source of water.	Japan
3.2.3 Personnel health, hygiene and sanitary facilities	
18. Hygiene and health requirements should be followed to ensure that personnel who come into direct contact with fresh leafy green vegetables during or after harvesting are not likely to contaminate them with STEC. Having adequate hygienic and sanitary facilities, including adequate means for hygienically washing and drying hands, is critical to minimize the potential for workers to contaminate fresh leafy green vegetables. People who are known or suspected to be carriers of suffering from illness due to STEC or others, likely transmissible by fresh fruits and vegetables or that are carriers, should not be allowed to enter any area where foods are handled, including the harvest area, if it is possible that they might contaminate the fresh fruits and vegetables. All affected persons should immediately inform the company's head office of their illness and/or their symptoms. Refer to section 3.2.3 of the <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i> (CXC 53-2003) for practices to minimize microbial pathogens such as STEC.	Uruguay
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	Uruguay suggests adding the following to this item (Paragraph 19): "Avoid

<p>should not be harvested. Growers should avoid moving harvesting equipment across fields where manure or compost was applied. Harvesting equipment should be cleaned and disinfected seasonally or as needed to avoid the contamination of fresh leafy green vegetables (e.g., if the equipment runs over an area with heavy animal intrusion and faecal deposits). Containers stored outside should be cleaned and, as appropriate, disinfected before being used to transport fresh leafy green vegetables. <u>Avoid performing this task during times of high temperatures or excessive humidity</u></p>	<p>performing this task during times of high temperatures or excessive humidity.”</p>
<p>3.2.6 Storage and transport from the field to the packing or processing facility</p>	
<p>21. Fresh leafy green vegetables should be stored and transported under conditions that will minimize the potential for STEC contamination and/or growth. Fresh leafy green vegetables should not be transported in vehicles previously used to carry animal manure or biosolids.</p>	<p>Uruguay</p>
<p>4.2 Cooling fresh leafy green vegetables</p>	
<p>24. The cooling of fresh leafy green vegetables should take place as rapidly as possible and in a manner that does not contribute to contamination–multiplication of product with STEC. For example, fresh leafy green vegetables can be cooled immediately after harvest by using ice (for parsley), forced-air cooling, vacuum cooling (for iceberg lettuce), hydrocooling or spray-vacuum (hydro vac) cooling.</p>	<p>Brazil Rationale: Cooling will prevent bacterial multiplication</p>
<p>4.3 Washing fresh leafy green vegetables</p>	
<p>26. Packers washing fresh leafy green vegetables should follow good hygienic practices (GHPs) to prevent or minimize the potential for the introduction or spread of STEC in fresh leafy green vegetable wash water. Biocides should be used as per GHPs and where necessary to minimize post-harvest cross-contamination with STEC, with their levels monitored, controlled and recorded to ensure the maintenance of effective concentrations. <u>Where appropriate, it is suggested that</u> 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.</p>	<p>Uruguay</p>
<p>5. PROCESSING OPERATIONS</p>	
<p>28. Where feasible, It is recommended that fresh raw material-handling areas should be physically separated from processing areas to minimize contamination with STEC. Processing cannot guarantee the elimination of STEC that may have occurred during primary production of fresh leafy green vegetables. Processors should ensure that growers, harvesters, packers and distributors have implemented measures to minimize the contamination of the fresh leafy green vegetables to be processed during primary production and subsequent handling in accordance with the provisions in the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003).</p>	<p>Uruguay</p>
<p>5.1 Time and temperature control</p>	
<p>29. Refer to the <i>General Principles of Food Hygiene</i> (CXC 1-1969). Temperature–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 illness.</p>	<p>Japan To be consistent with the section title.</p>
<p>5.5 Microbiological and other specifications</p>	
<p>33. Microbiological testing for STEC can be a useful tool to evaluate and verify the safety and effectiveness of practices and to provide information about an environment, a process or even a specific product lot when sampling plans and testing methodology are properly designed and performed. Refer to the <i>Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods</i> (CXG 21-1997).</p>	<p>Canada The messaging in this paragraph somewhat differs from that in the general text and the annex for beef (i.e., paragraph 54 and 44 respectively). It should be adjusted to provide consistent advice. We think that using hygiene indicator organisms for monitoring the performance of control measures, with periodic testing for high risk</p>

	STEC for verification purposes, would be a more efficient and effective approach for leafy greens.
33. Microbiological testing for STEC can be a useful tool to evaluate and verify the safety and effectiveness of practices and to provide information about an environment, a process or even a specific product lot when sampling plans and testing methodology are properly designed and performed. Refer to the <i>Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods (CXG 21-1997)</i> .	Japan Testing for STEC: how about the use of other indicator organisms e.g. Enterobacteriaceae?
Figure1: Fresh Leafy Green Vegetables Flow Diagram¹⁵	Uruguay suggests including a reference to the production phase, including the steps of pegging, transplant, and crop management at the production site. The suggestion is based on the justification given in the analyzed document: Paragraph 8 "...Most contamination of leafy green vegetables with STEC is thought to occur during primary production..."
Figure1: Fresh Leafy Green Vegetables Flow Diagram¹⁵	Japan [General Comment]The flow diagram should be developed along with the guidance. The current draft has the section of primary production, therefore, the flow diagram should start with primary production.
Figure1: Fresh Leafy Green Vegetables Flow Diagram¹⁵	Japan To be consistent with the beef annex, the title of Figure 1 should be changed.
Stippled boxes indicate steps that may not be included, depending in part on the commodity	Uruguay Suggests changing the term "Elaboración" to "Procesamiento" here and in the rest of the [Spanish] document where applicable.