CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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Agenda item 7 **CX/FH 22/52/7 Add.1**

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

Codex Committee on Food Hygiene

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GUIDELINES FOR THE CONTROL OF STEC IN RAW BEEF, FRESH LEAFY VEGETABLES, RAW MILK AND RAW MILK CHEESES AND SPROUTS

Comments in reply to CL 2021/63-FH

Comments of Canada, Colombia, Cuba, Ecuador, Egypt, European Union, India, Iran, Iraq, Japan, Malaysia, Norway, Republic of Korea, Saudi Arabia, Somalia, Thailand, Uruguay, USA and IDF/FIL, IFT

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2021/63-FH issued in December 2021. 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 COMMENTS	MEMBER / OBSERVER
Cuba agrees with the contents of this document, which provide theoretical considerations to be taken into account when implementing control measures for this hazard.	**Cuba**
This guideline contains valuable information, but it is defective by lengthening and repeating the sentences.	**Egypt**
While Shiga toxin-producing Escherichia coli (STEC) is considered to indicate that generic E. Coli or other organisms are present or concentrated, an indicator in raw milk does not suggest the presence of STEC. For this reason, our country suggests more specific analyses in cases of food alerts. However, given the low STEC contamination rate, implementing these techniques does not warrant genotype and PCR studies given their high cost and low incidence. Since the document points out that STEC is very rarely found in beef, milk, cheese, and vegetables, we do not think conducting a study to quantify STEC is the most viable option.	**Ecuador**
The EUMS consider that further improvement is possible and the Annex on STEC in sprouts has not been developed. It is therefore proposed to maintain the draft at step 3.	**European Union**
Agree with guidelines.	**Iraq**
A general remark would be that we prefer not repeating text or definitions from the main document in the annexes. Furthermore, we would like to suggest that main issues are adressed in the general part and only provide specific guidelines in the annexes, only if necessary and if particular to the commodities in question.	**Norway**
Uruguay believes this document is ready for the next step in the process.	**Uruguay**
The United States is providing some General Comments for clarification on the General Section. With these changes, we think this document is ready to progress in the Step process. We are also providing General and Specific comments further down in the document on the annexes.	**USA**
It should be explained why a hazard-based approach to define control measures should be used instead of a classical risk-based approach, as recommended by Codex Alimentarius. We understand that the hazard-based control measures should be validated based on the proof that they are able to reduce significantly the prevalence/concentration, in the raw material, in the finished products. Risk-based control measures (i.e. control measures can also be based on their efficiency to reduce significantly the risk of illness for the consumer) are also largely addressed in the whole text, so we suggest to modify as "GHP-, hazard- and risk-based approaches". IDF recommends the progress of the document to the next step.	**IDF/FIL**
SPECIFIC COMMENTS	
INTRODUCTION	
Par. 2 Clinical symptoms of the disease in humans arise as a consequence of consuming food contaminated with *E. coli* that produces protein ~~toxins Shiga-toxin~~ toxins, Shiga toxin type 1 (Stx-1) (encoded by the gene *stx*~~1), Shiga-toxin~~ 1) and/or Shiga toxin type 2 (Stx-2, encoded by the	**Canada**

gene *stx*~~2) or protein toxins from a combination of these genes~~2). Historically, the term verotoxin has also been used for the Shiga toxins of *E. coli* and the term verotoxigenic *E. coli* (VTEC) used as synonymous with STEC. In this document, the term Shiga toxin (Stx) is used to indicate the protein toxin, *stx* to indicate the toxin gene, and STEC to indicate the *E. coli* strains demonstrated to carry *stx* or produce Stx. STEC are pathogenic to humans by entry into the human gut and attachment to ~~the~~ intestinal epithelial cells where production of Stx occurs. Attachment to intestinal epithelial cells is the result of other genes, including the locus of enterocyte effacement, which includes a principal adherence gene ~~for a protein, Intimin, encoded by~~ which encodes the protein intimin~~*eae*~~. Suggest to modify the sentence because as written before it was suggesting that production of chimeric toxins when both proteins are produced. Also remove the hyphen in Shiga toxin as in the rest of the text. Intimin does not function as an attachment factor alone but as part of suite of genes, the locus of enterocyte effacement (LEE).	
Paragraph 3: Historically STEC illnesses have been linked to the consumption of undercooked or raw ground/minced or tenderized beef; We would like to include the term “raw.” Paragraph 4: Contamination with intestinal content, skin, or feces is the likeliest ultimate source of STEC in most foods. We would like to include skin as it is reportedly a highly relevant source of transmission. Paragraphs 9 and new 10: 9. The Guidelines provide flexibility for use at the national (and individual processing) level. 10. Transmission of STEC infection mainly occurs through eating or handling contaminated food and contact with infected animals. Food can also be contaminated from infected humans handling it. Further person-to-person transmission is possible among close contacts (families, childcare centres, nursing homes, etc). Source: https://www.efsa.europa.eu/es/topics/topic/shiga-toxin-producing-e-coli-outbreaks 10. Sampling plans can be carried out at various processing steps and used as part of a quantitative risk assessment, simulating meat processing scenarios which reduce risks. Subsequently, existing controls can be implemented or improved. [Translator’s Note: This paper is not publicly available, so it was impossible to obtain the exact quote] (Smith, 2013) We suggest making this addition as paragraph 10 (Smith, J. L., Fratamico, P. M., & Gunther, N. W. (2014). Shiga toxin-producing escherichia coli. In Advances in Applied Microbiology (1st ed., Vol. 86). https://doi.org/10.1016/B978-0-12-800262-9.00003-2. This would be a paragraph before section 2. OBJECTIVES	**Colombia**
Par. 2 “…….from a combination of these genes……” Does this mean that this combination is from the two genes (stx1, stx2) or from a group of genes (which mentioned later)? Par. 3 “…….Changes in food production, distribution and consumption can cause changes in STEC exposure. ……..” Please explain with an example	**Egypt**
~~These genes, in addition to~~ The presence if these genes ~~encoding Stx,~~ are ~~considered predictors~~ an aggravating factor for the prediction of pathogenicity, already causes by the ~~pathogenicity~~ presence of ~~strains~~Stx genes in their own. Par 2, Introduction, sixth sentence: the EUMS propose to replace the sentence “These genes, in addition to genes encoding Stx, are considered predictors of pathogenicity of strains” by “The presence if these genes are an aggravating factor for the prediction of pathogenicity, already causes	**European Union**

by the presence of Stx genes in their own." Stx genes are the predictors of pathogenicity while the presence of the eae and aggR genes are aggravating factors, not predictors of pathogenicity (See 2020 EFSA Opinion)	
Par. 2 (This document provides a Table showing combinations of virulence genes and their association with disease severity that can be used for risk management ~~purposes~~purposes (Table1).) Rationale: For easy identification	**India**
Par. 1 The most well-known STEC pathogen is *E. coli* O157:H7, and STEC strains with genomic and pathogenic features similar to *E. coli* O157:H7 may be referred to as enterohemorrhagic E. coli (EHEC). Although the group is quite diverse, *E. coli* O157:H7 is considered the most well-documented. STEC strains are a diverse group which can cause disease in humans. These strains may be referred to as enterohemorrhagic *E. coli* (EHEC). The most well-studied and documented STEC strain is *E. coli* O157:H7. Re-order and re-word these sentences for clarity and accuracy Par. 2 Clinical symptoms of the disease in humans arise as a consequence of consuming food contaminated with *E. coli* that produces **either a single Shiga-**toxin type 1 (Stx-1) (encoded by the gene *stx1*), **or** Shiga-toxin type 2 (Stx-2, encoded by the gene *stx2*) or **both of these toxins.** The gene name should be in full italics ie *stx1* or *stx2* Don't need to say "protein" so deleted. In all cases were "protein toxin" is mentioned, delete protein as it is not necessary to say. Also, the last part of the sentence is not accurate. The two genes produce individual toxins even when both genes are in the genome. Par. 2 Attachment to intestinal epithelial cells is the result of other **proteins**, including the principal adherence protein, **intimin**, encoded by *eae.* Reword for accuracy. As written the statement is about the proteins not the genes ie the process of attachment. Initimin should not have a capital letter Par. 2 The aggregative adherence fimbriae adhesins, commonly **associated with enteroaggregative *E. coli,* regulated by the *aggR* gene, when found with the *stx* have also been linked severe illness and have been used as predictors of pathogenicity.** Reworded for accuracy. As written, it implied that all *aggR* encoding strains were also STEC which is not the case. EaggEC are a sub-group of diarrhoeagenic *E. coli* and a sub-group of these have acquired a number of genes including *stx.* Par. 2 (~~This document provides a~~ Table 1 show<u>s</u> ~~ing~~ combinations of virulence genes and their association with disease severity that can be used for risk management purposes.) For clarity add reference to Table 1. Given distance from this clause, maybe reference the clause number as well.	**New Zealand**
Par. 5 In practice, this means that there is no "one size fits all" solution, and different production systems may require different approaches to control the various ~~serovars~~ <u>serotypes</u> of STEC. This is terminology mostly used, also by JEMRA	**Norway**

Par.2 STEC are pathogenic to humans by entry into the human gut and attachment (colonises) to the intestinal epithelial cells where production of Stx occurs. Par. 3 Historically STEC illnesses have been linked to the consumption of undercooked ground/minced or tenderized beef; however fresh leafy vegetables, sprouts, and dairy products (in particular raw milk and raw milk cheeses) (cheeses made from raw milk) have been increasingly recognized as commodities that pose a risk of illness from STEC. … This guidance document will identify commodity-specific intervention practices based on known source attribution in these different foods, and practices for monitoring STEC in food products, including the utility (presence) of indicator microorganisms. Par. 6 The Guidelines build on general food hygiene provisions already established in the Codex system and propose potential control measures specific for STEC strains in raw beef, fresh leafy vegetables, raw milk and raw milk ~~cheeses,~~ cheeses(cheeses from raw milk) and sprouts.	**Somalia**
Paragraph 6: Uruguay suggests maintaining the paragraph as it was in the previous version: 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 cheeses produced from raw milk, and sprouts. Should we incorporate this paragraph, we suggest adding a definition of "public health relevance."	**Uruguay**
Par. 4 It is generally accepted that animals, in particular ruminants, are the primary reservoir/source of STEC. STEC-positive ruminants are typically asymptomatic. Contamination with intestinal content or feces is the ~~likeliest ultimate~~ most likely initial source of STEC in most foods.	**USA**
Par. 3 Historically STEC illnesses have been linked to the consumption of undercooked ground/minced or tenderized beef; however fresh leafy vegetables, sprouts, and dairy products ~~(in particular raw~~ (raw milk and raw milk cheeses) have been increasingly recognized as commodities that pose a risk of illness from STEC. Par. 5 The large degree of variation exhibited by STEC in their biological properties, host preferences, and environmental survival presents a challenge for ~~controlling~~ managing the presence of STEC in animal and plant production.	**IDF/FIL**
2. OBJECTIVES	
Par. 10. The Guidelines provide a scientific tool for the effective application ~~of GHP- and hazard-based approaches~~ for control of STEC in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts according to national risk management decisions. This should be modify for consistency with the Annexes where GHP-based and Hazard-based control measures were deleted.	**Japan**
Par. 10.The Guidelines provide a scientific tool for the effective application of GHP- and ~~hazard-based approaches for~~ risk-based hazard identification and control of STEC in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts according to national risk management decisions. It should be explained why a hazard-based approach to define control measures should be used instead of a classical risk-based approach, as recommended by Codex Alimentarius. We understand that the hazard-based control measures should be validated based on the proof that they are able to reduce significantly the prevalence/concentration, in the raw material, in the finished products. Risk-based control measures (i.e. control measures can also be based on their efficiency to reduce significantly the risk of illness for the consumer) are also largely addressed in the whole text, so we suggest to modify as "GHP-, hazard- and risk-based approaches"	**IDF/FIL**

This comment also applies elsewhere in the text.	
3. SCOPE AND USE OF THE GUIDELINES	
Par. 12 "……..The primary focus is to provide information on scientifically validated practices that may be used to prevent, reduce, or eliminate STEC contamination of raw beef, ……..." Egypt prefers to cross out the word "reduce". And read the sentence as follow: "……..The primary focus is to provide information on scientifically validated practices that may be used to prevent or eliminate STEC contamination of raw beef, ……."	**Egypt**
Par 13: Use: It seems relevant to refer also to the Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (CXG 63-2007) as referred to several times in the text. It can be questioned if a reference to the Code of Practice on Good Animal Feeding (CXC 54-2004) is very relevant since feed is not considered as a source of STEC and paragraphs dealing with feed (e.g. 13 to 16 in Annex I) are not examples of good feeding practices.	**European Union**
Par. 14. The Guidelines present a number of ~~GHP-based~~ control measures. ~~GHPs are prerequisites to making choices on hazard-based~~ These control ~~measures. Hazard-based control~~ measures will likely vary at the national level and therefore these Guidelines only provide examples of ~~hazard-based controls~~them. Examples of ~~hazard-based~~ control measures are limited to those that have been scientifically demonstrated as effective in a commercial setting. … Government and industry can use choices on ~~hazard-based~~ control measures to inform decisions on critical control points (CCPs) when applying HACCP principles to a particular food process. This paragraph should be modify for consistency with the Annexes where GHP-based and Hazard-based control measures were deleted. Par. 15. Several ~~hazard-based~~ control measures as presented in these Guidelines are based on the use of physical, … 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. This paragraph should be modify for consistency with the Annexes where GHP-based and Hazard-based control measures were deleted.	**Japan**
Par. 14.The Guidelines present ~~a number of GHP-based~~ several Good Hygiene Practices (GHP)-based control measures. … The quantifiable outcomes reported for control measures are specific to the conditions of ~~particular~~ studies and the control measures would need to be validated under local commercial conditions to provide an estimate of hazard reduction[2] based on risk. Reference 2 should be updated to WHO; FAO -- Microbiological Risk Assessment Series 2021 36". reference should also be done the report recently published by JEMRA Microbiological risk assessment: guidance for food.	**IDF/FIL**
4. DEFINITIONS	
Par. 20 [Indicator microorganisms - microorganisms used as a sign of quality or hygienic status in food, water, or the environment, ~~often~~ commonly used to ~~signify~~ suggest the potential presence of pathogens, a lapse in sanitation or a process failure. Common indicator microorganisms include total bacterial counts, coliform or faecal coliform counts, total *E. coli* counts and counts of Enterobacteriaceae.] Suggest to retain the second definition. The use of the term "safety" and use of indicators to validate control measures, may create confusion. It muddles the definition. This second definition is clearer.	**Canada**

Paragraph 19: Fresh leafy vegetables – Vegetables of a leafy nature [where the leaf is intended for consumption] [that may be consumed] without cooking, including, but not limited to, all varieties of lettuce, spinach, cabbage, chicory, escarole, kale, radicchio, and fresh herbs such as coriander, cilantro, basil, curry leaf, colocasia leaves and parsley, among other local products for foliar consumption. "[Where the leaf is intended for consumption]": We support this phrase. Paragraph 20: We support the following definition of Indicator microorganisms - microorganisms used as a sign of quality or hygienic status in food, water, or the environment, often used to indicate the potential presence of pathogens, a lapse in sanitation or a process failure. Some hygiene indicator microorganisms are total bacterial counts, coliform or faecal coliform counts, total E. coli counts and counts of Enterobacteriaceae.	**Colombia**
Par. 20 Egypt recommends crossing out the last line in the paragraph No. (20) "Common indicator microorganisms include total bacterial counts, coliform or faecal coliform counts, total E. coli counts and counts of Enterobacteriaceae.]" because it is repeated in the fourth line. Par. 22 Egypt recommends to review the following sentence in third line in paragraph No. 22 "….beyond 40 ºC. and , can be supply or any additive which lead to a decrease in ……"	**Egypt**
Par 19: Definition of fresh leafy greens: the EUMS prefer the second option: "Vegetables of a leafy nature that may be consumed without cooking, …" Par. 20: Definition of indicator microorganism: the EUMS prefer the second option: "- microorganisms used as a sign of quality or hygienic status in food, water, or the environment, often used to signify the potential presence of pathogens, a lapse in sanitation or a process failure. Common indicator microorganisms include total bacterial counts, coliform or faecal coliform counts, total E. coli counts and counts of Enterobacteriaceae." Par. 21: Definition of raw beef: It should be clarified if meat preparations (meat tenderized with injection of brine, etc.) are included in the scope/definition. It is included in the scope (Annex I, 2) but is not mentioned in the definition.	**European Union**
Par. 19. Fresh leafy vegetables - Vegetables of a leafy nature ~~[where~~ where the leaf is intended for ~~consumption] [that may be consumed]~~ consumption without cooking… Japan supports the former definition since it is close to a description on CXC53 "…fresh leafy vegetables intended for human consumption without cooking." Par. 20~~. [Indicator~~ .Indicator microorganisms - microorganisms that are used to evaluate the microbiological status of food production and food control systems, including the evaluation of the quality or safety of raw or processed food products and the validation of the efficacy of microbiological control measures. Some hygiene indicator microorganisms are total bacterial counts, coliform or faecal coliform counts, total *E. coli* counts and counts of Enterobacteriaceae.~~] [Indicator microorganisms - microorganisms used as a sign of quality or hygienic status in food, water, or the environment, often used to signify the potential presence of pathogens, a lapse in sanitation or a process failure. Common indicator microorganisms include total bacterial counts, coliform or faecal coliform counts, total *E. coli* counts and counts of Enterobacteriaceae.]~~ Japan supports the former definition since the scope of the former definition is broader which covers the status of food control system. 25. Sprouts: Products obtained from the germination of seeds collected before the development of true leaves. The final product contains the ~~seed~~seed to be consumed without cooking.	**Japan**

The scope of sprouts should clearly state that they are intended to be consumed without cooking since, in Japan, a kind of sprout called “Moyashi” (e.g. mung bean sprout) is basically cooked before consumption, and producers are producing them, with the intention that they are cooked before consumption.	
Par. 19. Fresh leafy vegetables - Vegetables of a leafy nature [**where the leaf is intended for consumption**] ~~[that may be consumed]~~ ;… Fresh leafy vegetables - Vegetables of a leafy nature [where the leaf is intended for consumption] [that may be consumed] The first option is better and is also consistent with CXC 53-2003 the Code of Hygienic Practice for Fresh Fruits and Vegetables Par. 20. Indicator microorganisms Indicator microorganisms – microorganisms used **as an indication of the** ~~as a sign of~~ quality or hygienic status **of** ~~in~~ food, water, or the processing environment, often used to signify the potential presence of pathogens, a lapse in process **hygiene** ~~sanitation~~ or a process failure. Examples of ~~common~~ indicators ~~microorganisms include~~ are total bacterial counts, coliform or faecal coliform counts, total *E. coli* counts and counts of *Enterobacteriaceae*. Preference for the second option with amendments. Suggest changing for consistency. Par. 25 Support the definition of sprouts as drafted. If raised, we believe that microgreens could be addressed and covered by the definition and annex addressing fresh leafy vegetables rather than sprouts.	**New Zealand**
Par. 19. Fresh leafy vegetables - Vegetables of a leafy nature ~~[where~~ where the leaf is intended for ~~consumption] [that may be consumed]~~ consumption without cooking… We support the wording «Fresh leafy vegetables - Vegetables of a leafy nature where the leaf is intended for consumption without cooking ……» This expresses that the product was grown intentionally to be consumed as it is. (See also our comment on Annex 2: Fresh Leafy Vegetables, para 6). However for us both definitions will work. Par. 20. [Indicator microorganisms - microorganisms that are used to evaluate the microbiological status of food production and food control systems, including the evaluation of the quality or safety of raw or processed food products and the validation of the efficacy of microbiological control measures. Some hygiene indicator microorganisms are total bacterial counts, coliform or faecal coliform counts, total *E. coli* counts and counts of Enterobacteriaceae.] ~~[Indicator microorganisms - microorganisms used as a sign of quality or hygienic status in food, water, or the environment, often used to signify the potential presence of pathogens, a lapse in sanitation or a process failure. Common indicator microorganisms include total bacterial counts, coliform or faecal coliform counts, total *E. coli* counts and counts of Enterobacteriaceae.]~~ We would prefer alternative 1 as this, in our view, better explains the intent in paragraph 49.	**Norway**
Par. 19. Fresh leafy vegetables - Vegetables of a leafy nature **[where the leaf is intended for consumption]** It is stated in the art.7 of Food Sanitation Act (Korean Law) that raw food material is determined for human consumption based on the evidence to determine whether it is edible, and has no toxicity and side effects. Therefore, the Republic of Korea suggests using the first phrase [where the leaf is intended for consumption] for the definition of Fresh leafy vegetables. In the case of leafy vegetables production, the second definition is more comprehensive than the first one since the level of microbial contamination of environmental factors such as water, soil can be measured indirectly by the indicator microorganisms.	**Republic of Korea**

Par. 20 [Indicator microorganisms - microorganisms used as a sign of quality or hygienic status in food, water, or the environment~~, often used to~~ , (most proply) signify the potential presence of pathogens, a lapse in sanitation or a process failure. Common indicator microorganisms include total bacterial counts, coliform or faecal coliform counts, total *E. coli* counts and counts of Enterobacteriaceae.]	**Somalia**
Par. 19. Fresh leafy vegetables - Vegetables of a leafy nature [where the leaf is intended for ~~consumption] [that may be consumed]~~ consumption] without cooking... - For fresh leafy vegetable, we prefer the first phrase as follows: Fresh leafy vegetable: Vegetables of a leafy nature [where the leaf is intended for consumption] without cooking, including, but not limited to,… Rationale: The vegetables defined in this standard should be specific to those to be consumed without further microbiocidal steps. Par. 20~~. [Indicator microorganisms - microorganisms that are used to evaluate the microbiological status of food production and food control systems, including the evaluation of the quality or safety of raw or processed food products and the validation of the efficacy of microbiological control measures. Some hygiene indicator microorganisms are total bacterial counts, coliform or faecal coliform counts, total .*E. coli* counts and counts of Enterobacteriaceae.]~~ [Indicator microorganisms - microorganisms used as a sign of quality or hygienic status in food, water, or the environment, often used to signify the potential presence of pathogens, a lapse in sanitation or a process failure. Common indicator microorganisms include total bacterial counts, coliform or faecal coliform counts, total *E. coli* counts and counts of Enterobacteriaceae.] - For indicator microorganisms, we prefer the latter sentence as follows: Indicator microorganisms - microorganisms used as a sign of quality or hygienic status in food, water, or the environment, often used to signify the potential presence of pathogens, a lapse in sanitation or a process failure. Common indicator microorganisms include total bacterial counts, coliform or faecal coliform counts, total E. coli counts and counts of Enterobacteriaceae. Rationale: This definition of indicator microorganisms is more appropriate and inclusive. Par. 21. Raw beef – Skeletal muscle meat from **slaughtered** cattle, including primal cuts[3], sub-primal cuts, and trimmings. - For raw beef, we would like to propose the amendment to definition of raw beef as follows: Raw Beef - Skeletal muscle meat from slaughtered cattle, including primal cuts, sub-primal cuts, and trimmings. Rationale: The definition of raw beef in general section should be consistent with the definition in the annex for raw beef.	**Thailand**
Paragraph 19. Fresh Leafy Vegetables: Vegetables of a leafy nature [where the leaf is intended for consumption] **[that may be consumed]** without cooking [Translator's Note: This change affects the Spanish version only, not the English version] Uruguay believes this definition is more accurate. Paragraph 20. Uruguay suggests the following definition: Indicator microorganisms - microorganisms used to assess quality or hygienic status in food, water, or the environment, often used to signify the potential presence of pathogens, a lapse in sanitation or a process failure. Some hygiene indicator microorganisms are total mesophilic aerobes counts, coliform or faecal coliform counts, total E. coli counts and counts of Enterobacteriaceae.	**Uruguay**

Par. 19. Fresh leafy vegetables - Vegetables of a leafy nature ~~[where the leaf is intended for consumption] [that~~ that may be ~~consumed]~~ consumed without cooking,… The United States prefers the second text in brackets, as this is more accurate; for many leafy vegetables, the stalk as well as the leaf will be consumed. The key point is that the focus should be on leafy vegetables that may be consumed without cooking and not the part of the vegetable that is eaten. 20~~. [Indicator microorganisms - microorganisms that are used to evaluate the microbiological status of food production and food control systems, including the evaluation of the quality or safety of raw or processed food products and the validation of the efficacy of microbiological control measures. Some hygiene indicator microorganisms are total bacterial counts, coliform or faecal coliform counts, total .*E. coli* counts and counts of Enterobacteriaceae.] [Indicator~~ Indicator microorganisms - microorganisms used as a ~~sign~~ measure of ~~quality~~ quality, process efficacy, or hygienic status in food, water, or the environment, often used in food production systems to ~~signify~~ verify the ~~potential presence~~ effectiveness of ~~pathogens, a lapse in~~ sanitation procedures or a process ~~failure~~step, or to assess overall hygienic conditions. Common indicator microorganisms include total bacterial counts, coliform or faecal coliform counts, total *E. coli* counts and counts of Enterobacteriaceae.~~]~~ Par. 22 This definition excludes processing techniques used for microbiological control (e.g. heat treatment above 40 °C~~, as well as~~ , microfiltration and ~~bactofugation which lead to a decrease in the microbiota equivalent to heating~~bactofugation.) Neither microfiltration not bactofugation can reach a log reduction to meet the safety level of pasteurization. This is especially true for bacofugation, which is mostly used to remove spores from milk, and is only able to reduce mesophilic microflora by 1-2 logs. Both microfiltration and bactofugation involve heating above 40 °C (e.g., 50-55°C.) and thus would be excluded from the definition. References: 1) Effect of milk bactofugation on the counts and diversity of thermoduric bacteria https://doi.org/10.3168/jds.2020-18591; 2) Use of Microfiltration to Improve Fluid Milk Quality https://doi.org/10.3168/jds.S0022-0302(06)72361-X.	**USA**
Par. 20. [Indicator microorganisms - microorganisms that are not human pathogens but with characteristics similar to associated human pathogens and used to evaluate the microbiological ~~status~~ safety of food production and food control systems, including the evaluation of the quality or safety of raw or processed food products and the validation of the efficacy of microbiological control measures. Some hygiene indicator microorganisms are ~~total bacterial counts,~~ coliform or faecal coliform counts, total *E. coli* counts and counts of Enterobacteriaceae.] ~~[Indicator microorganisms - microorganisms used as a sign of quality or hygienic status in food, water, or the environment, often used to signify the potential presence of pathogens, a lapse in sanitation or a process failure. Common indicator microorganisms include total bacterial counts, coliform or faecal coliform counts, total *E. coli* counts and counts of Enterobacteriaceae.]~~ Total bacterial counts are not indicator micro-organisms as they are too general. Par. 22. This definition excludes product that have been subjected to processing techniques used for microbiological control (e.g. heat treatment above 40 °C, as well as microfiltration and bactofugation which lead to a decrease in the microbiota equivalent to heating.)	**IDF/FIL**
5. PRINCIPLES APPLYING TO CONTROL OF STEC IN RAW BEEF, FRESH LEAFY VEGETABLES, RAW MILK AND RAW MILK CHEESES, AND SPROUTS	
Paragraph 26: We suggest replacing “risks” with “hazards.”	**Colombia**
6. PRIMARY PRODUCTION-TO-CONSUMPTION APPROACH TO CONTROL MEASURES	
Sub-section 6.1: We suggest replacing “Development” with “Definition.”	**Colombia**

Par. 30 to 33: Development of risk-based control measures: These paragraphs do not contain any specific information related to the control of STEC. The EUMS therefore proposes to delete or replace by a cross-reference to the Principles and Guidelines for the conduct of Microbiological Risk Management (MRM) (CXG 63-2007).	**European Union**
Par. 32 Very limited quantitative examples are included in beef and milk annex. Japan proposes to ask JEMRA to provide more quantitative examples based on quick literature review published after the last JEMRA meeting.	**Japan**
Par. 28.GHPs provide the foundation for most food safety control systems. Where possible and practicable, food safety control measures for STEC should incorporate risk-based hazard analysis activities and ~~hazard-based~~ associated control measures. Par. 29 When no microbiological criterion or food safety objectives has been established by competent authorities, industry is also able to propose control measures based on risk assessment. Validation should be performed based on the capacity of the control measures to decrease the risk for public health. Par. 30 The STEC control measures need to include competent authorities working with their impacted food sectors which will be much more effective in driving a more positive outcome in the reduction of STEC in food sectors. Par. 31 Risk modelling tools can be very enlightening for both risk managers and industry. We suggest the following formulation: "Risk modelling tools can be developed to assess the impact of control measures to on the reduction or elimination of the hazard. Capability and limitations should be clearly specified."	**IDF/FIL**
7. PRIMARY PRODUCTION CONTROL MEASURES	
~~7. PRIMARY PRODUCTION~~7. PRIMARY MEASURES FOR PRODUCTION CONTROL ~~CONTROL MEASURES~~ This refers to the step	**Colombia**
Par. 34 Egypt recommends to it is enough to write: apply GAPs.	**Egypt**
8. PROCESSING CONTROL MEASURES	
~~8. PROCESSING CONTROL MEASURES~~ 8. PROCESSING CONTROL MEASURES [Translator's Note: This does not affect the English version] This refers to the step. We propose the following wording: Paragraph 35: We suggest "maintain the initial load" as this depends on the type of microorganism found in this initial load. Also, in certain foods, some microorganisms are naturally present while others can be the result of contamination, warranting removal due to the associated hazards.	**Colombia**
9. DISTRIBUTION CHANNEL CONTROL MEASURES	
~~9. DISTRIBUTION CHANNEL CONTROL MEASURES~~9. DISTRIBUTION CONTROL MEASURES This refers to the step	**Colombia**
9. FOOD DISTRIBUTION ~~CHANNEL~~ CONTROL MEASURES	**IDF/FIL**

10. IMPLEMENTATION OF CONTROL MEASURES	
Par. 43 Canada prefers keeping the word "primary". Par. 45.The competent authority ~~[should] [could]~~ may … Canada has another suggestion: The competent authority [may] provide guidelines. Rationale: The type of wording is used in the following paragraph (no.46.) “Should” has a mandatory tone that could leave authorities in a bind should they not wish to provide guidelines or other tools to industry according to their particular legislation. “Could” seems strange.	**Canada**
Paragraph 40: We suggest removing “or the competent authority.” That is not what competent authorities do; they provide guidelines, standards, and verification. Paragraph 45: We prefer “could.” ~~Paragraph 48:~~ Verification should include observation of monitoring activities, document verification, and sampling verification (and sampling and testing for indicator organisms and STEC where appropriate) Analysis of results, ISO 22000 section 8.8.2.	**Colombia**
Par. 43 Industry responsibility: The EUMS would prefer to delete the word “primary”, as FBO have the responsibility of marketing safe food. Par. 45 Regulatory systems: The EUMS prefer the word “could”. Par 48. Industry may use testing information on indicator microorganisms for verification of STEC control measures due to the high cost of testing for detection of ~~STEC~~STEC and its low prevalence in food. Industry testing: Testing by the industry is not only quite inefficient due to the cost of testing but also to the low prevalence, making it necessary to take a lot of samples to verify the presence of STEC. The EUMS therefore propose the following addition at the end of the first sentence: “ … due to the high cost of testing for detection of STEC and its low prevalence in food.”	**European Union**

Par. 43.Industry has the ~~[primary]~~ primary … Japan supports to include “primary” because CXG82-2013 describes “Food business operators have the primary role and responsibility for managing the food safety of their products and for complying with requirements relating to those aspects of food under their control.” Par. 45.The competent authority ~~[should] [could]~~ should … Japan supports “should.” Par. 48. … document verification by reviewing ~~monitoring~~ monitoring, corrective action and verification records, and sampling and testing for ~~indictor organisms~~ indicator microorganisms and STEC where appropriate. (Substantive) Japan proposes to add "corrective action records" for reviewing, it is important to review it as a verification activity. (Editorial) indicator Par. 49…. Examples of potential hygiene ~~indicators~~ indicator microorganisms include total bacterial (mesophilic aerobes) counts, counts of coliforms or fecal coliforms, counts of total *E. coli,* and counts of Enterobacteriaceae. An increase in the numbers of the selected indicator microorganism indicates ~~decreasing~~ loosing control and the need for corrective action. Additionally, with the increase in the frequency of verification, there is also an increase in the speed of detecting a loss of control of manufacturing hygiene. Verification at multiple points in the processing chain can assist in rapid identification of the specific process step where .. Japan proposes to replace "decreasing" with "loosing". step: (rationale) improve readability	**Japan**
Par. 43 Malaysia is of the view that there is no necessity to include the word “primary” in the sentence because the activity listed is under the purview of the industry and they should be responsible for the control of STEC in the production and its safety at all time. Par. 45 Malaysia agrees with the word “should” to be used in the sentence as it shows that it is the “must” for the competent authority to provide guidelines and other implementation tools to industry, as appropriate, for the development of the process control system.	**Malaysia**
Par. 45 The competent authority **~~[should][could]~~ may** provide guidelines and other implementation tools to industry. The competent authority may provide Par. 46 Microbiological testing programmes should be established **to verify** ~~for verification of~~ the effectiveness of control measures ~~**HACCP systems where specific targets**~~ for ~~control of~~ STEC ~~have been identified~~. Question whether this is needed as the establishment of monitoring programmes is one of the HACCP principles. Also, if STEC are controlled through GHP or other pre-requisite programmes then there is not a CCP and therefore not a HACCP system. Par. 48 Verification should include observation of monitoring activities (such as having a**n** ~~program~~ employee with overall responsibility for monitoring activities observe the person conducting a monitoring activity ~~perform monitoring procedures~~ at a specified frequency) document verification by reviewing monitoring and verification records, sampling and testing for indicator **micro**organisms and STEC where appropriate. This sentence refers to internal verification or operator verification activities that are undertaken to show that verification and monitoring procedures are effective. Tried to simplify the wording and ensure consistency with the definitions. Par. 49 …STEC in food, ~~enumerative~~ **quantitative** monitoring of STEC is impractical… Replace enumerative with quantitative as the usual terminology	**New Zealand**

43. Industry has the ~~[primary]~~ responsibility … Delete text in square brackets to be clear on the fact that it is the responsibility of the establishments. Par. 45. The competent authority ~~[should] [could]~~ could … Food business operators also develop guidelines to good practice for their sectors.	**Norway**
Par. 43 The Republic of Korea supports keeping the word [primary] in the paragraph. Par. 45 The Republic of Korea suggests [should] be included in the sentence.	**Republic of Korea**
Paragraph 43: Uruguay is in favor of including "primary." Paragraph 45: Uruguay believes "could" is the best option. Paragraph 49: Uruguay believes the definition should be "total mesophilic aerobes count." Uruguay believes a more adequate definition would be: "An increase in the numbers of the selected indicator microorganism above established control values indicates decreasing control and the need for corrective action."	**Uruguay**
Par. 43. Industry has the ~~[primary]~~ … Rationale: These are industry responsibilities. Par. 45. The competent authority ~~[should] [could]~~ should, where feasible, provide guidelines and other implementation tools to industry, as appropriate, for the development of the process control systems. Rationale: While competent authorities should provide guidance to industry on how to comply with requirements, this insertion provides flexibility. Par. 49 Examples of potential hygiene indicators include counts of total ~~bacterial~~ bacteria (mesophilic ~~aerobes) counts~~aerobes), ~~counts of~~ coliforms or fecal coliforms, ~~counts of~~ total *E. coli,* and ~~counts of~~ Enterobacteriaceae Rationale: Editorial, less wordy.	**USA**
Par. 43 IDF supports adding 'primary' in the first line. Par. 44. The documented ~~process~~ control ~~systems~~ measures should describe … Par. 45. The competent authority ~~[should] [could]~~ professional organizations or both working together need to provide guidelines and other implementation tools to industry, as appropriate, for the development of the process control systems. 46. The competent authority may assess the documented process control systems to ensure they are science based and establish verification frequencies. Microbiological testing programmes should be established for verification of ~~HACCP~~ hazard control systems when specific targets for control of STEC have been identified. **~~10~~7.4.1 Industry**	**IDF/FIL**

Par. 48. … Industry monitoring and verification activities should verify that all control measures for STEC have been implemented as intended ... document verification by reviewing operational monitoring and ~~verification~~ related records, ~~and~~ including sampling and testing results for indictor organisms and STEC where appropriate. Par. 49. Due to typically low levels and low prevalence of STEC in food, enumerative monitoring of STEC is ~~impractical and~~ usually ineffective as the only hazard control measure, as well as the utility of presence/absence testing in monitoring process performance is also limited (FAO/WHO 2018)…. The environmental hygiene …~~Verification~~ Monitoring and verification at multiple points ... STEC testing can contribute to the overall hazard control effort to reducing contamination rates improved food safety and promoting continuous process improvement, if testing results are linked to requirements for corrective action. Testing alone cannot contribute to reducing contamination rates. Par. 50 ~~Verification frequency could vary according to the operational aspects of process control, the historical performance of the establishment,~~ 50. Monitoring and ~~the results of verification activity itself.~~verification frequency could vary according to the operational aspects of process control, the historical performance of the establishment, and the results of verification activity itself.	
Par. 38 IFT believes it would be useful in paragraph 38 to add the words "including parameters and values" after the words "implementation plan", in order to clarify the details of the implementation plan that should be included. Par. 40 IFT believes in paragraph 43, point 10.3.1, that the wording should be modified to include "verifying" in the list of Industry responsibilities. Par. 49 IFT agrees with paragraph 49 under point 10.4.1 on enumerative monitoring, but believes it should be placed into the "Monitoring and Review" section 11 after Paragraph 53	**IFT**
11. MONITORING AND REVIEW	
Par. 61 Par. 61 Monitoring: The paragraph seems to be purely repetitive of paragraph 60. The EUMS propose to delete. Par. 62-68 Laboratory Analysis Criteria for Detection of STEC (general): The EUMS highly appreciate these paragraphs, in particular the consideration of virulence genes. Such consideration is of core interest in the appropriate management of STEC in food commodities, in particular in the consideration of corrective actions. It is the main reason why analysis for virulence genes is considered necessary in these guidelines. The EUMS consider therefore that it is necessary to develop this more in a separate paragraph. The paragraph should better explain how virulence genes can be taken into account in corrective actions, considering in addition other elements such as whether food is ready to-eat (raw milk and raw dairy products!), eating/cooking habits, … Par. 63 …Based on current scientific knowledge, all STEC strains are pathogenic for humans and capable of causing severe illness. However, STEC strains with *stx2a* and adherence genes, *eae* or *aggR* have the greatest association with ~~diarrhoea,~~ severe illness such as bloody diarrhoea (BD), ~~and~~ haemolytic uremic syndrome ~~(HUS)~~(HUS) and hospitalisations. ~~Strains of STEC with other *stx* subtypes may cause diarrhoea, but their association with HUS is less certain and can be highly variable.~~ Laboratory Analysis Criteria for Detection of STEC (specific): the EUMS propose the following change to better reflect the current scientific knowledge : “Based on current scientific knowledge, all STEC strains are pathogenic for humans and capable of causing severe illness. However, STEC strains with stx2a and adherence genes eae or aggR have the greatest association with severe illness such as bloody diarrhoea (BD), haemolytic uremic syndrome (HUS) and hospitalisations."	**European Union**

Par. 69-71: Review: These paragraphs do not contain any specific information related to the control of STEC. The EUMS therefore proposes to delete or replace by a cross-reference to the Principles and Guidelines for the conduct of Microbiological Risk Management (MRM) (CXG 63-2007).	
Par. 64.The determination of virulence and other salient marker genes for testing purposes may be achieved by ~~using~~ using, for example, polymerase chain reaction methods or whole genome sequencing analysis To clarify PCR and WGS analysis are examples since other methods to determine virulence are introduced on JEMRA report "Shiga toxin-producing Escherichia coli (STEC) and food: attribution, characterization, and monitoring (MRA31)."	**Japan**
Par. 56 For instance, the monitoring ~~systems~~ **programmes** for STEC… Par. 57 Competent authority regulatory monitoring programmes should be designed in consultation with relevant stakeholders, where appropriate, and **should consider** ~~taking into account~~ the sample plan including the number, ~~of most cost-effective resourcing option for~~ location, collection and testing of samples, and resource constraints. The monitoring programme should consider all elements of the sampling plan such as number, location, method of collection and the testing of samples. Par. 60 Monitoring information **collected** from **throughout** the food chain should be used… Improve the clarity of the sentence Par. 61 Activities that may provide new information to consider in the monitoring **programme** include: Missing a word Par. 64 The determination of virulence and other salient marker genes for testing purposes may be achieved by using polymerase chain reaction **(PCR)** methods or whole genome sequencing **(WGS)** analysis. Added the abbreviation as this is used later in the text. Par. 65 In addition, bacteria other than STEC may contain ~~harbor~~ the same virulence genes and the detection of **these** genes alone… Additional clarification and emphasis Par. 66 …, it could be sent to a reference centre / **laboratory**. Added laboratory for clarity.	**New Zealand**
Uruguay believes "verification" should be replaced with "monitoring."	**Uruguay**
Par. 70.Information gained from monitoring in the food chain should be integrated with human ~~health~~ foodborne disease surveillance, food source attribution data, and withdrawal and recall data, where available to evaluate and review the effectiveness of control measures from primary production to consumption. Rationale: more relevant and precise term	**USA**

Par. 54. Information on the level of control of STEC at appropriate points in the food chain can be used for several purposes, e.g. to validate and/or verify outcomes of food control measures, to monitor compliance with ~~hazard-based and~~ risk-based ~~regulatory~~ hazard control goals, and to help prioritize regulatory efforts to reduce foodborne illness. Par. 55. Effective monitoring includes the effectiveness of STEC control processes throughout the food chain as well as during processing, packaging and distribution. Monitoring via sampling and testing should be carried out at appropriate steps throughout the food chain using a validated diagnostic test and randomized or targeted sampling as appropriate. Par. 61 Surveillance of clinical illness from STEC in humans ~~and~~and host animals, as well as Par. 63 • controls to meet market access requirements; and Need a scientific reference for all of the information in the statement in the second sentence. Par. 65 Need a scientific reference for all of the information in the last sentence. Par. 68. Include the specific JEMRA reference or other scientific source for this information and the table.	**IDF/FIL**
Par. 63 In paragraph 63, IFT would suggest adding clarification on the frequency of doing testing for virulence factors and whether these should be a routine procedure	**IFT**
ANNEX 1: RAW BEEF	
GENERAL COMMENTS	
Canada would consider Annex 1 to be complete, with no significant additional content required. The structure and format of the annexes is acceptable.	**Canada**
We have no objections to the structure and format of the annexes; we do not believe a single format is needed for all the annexes, since the products and processes are varied. In several places, statements are made that there is limited evidence that listed control measures have a specific impact on STEC. For example, see paragraph 47, where for the control measures at rodding "insufficient evidence was found specifically for their effects on STEC" and paragraph 57, where for carcass splitting "the effectiveness of these practices to reduce pathogen contamination, including STEC, is limited." The United States recognizes that it can be quite difficult to get good enough research data specific to STEC to be able to definitively make statements about certain measures applied to control microbial pathogens. This does not mean the practice won't have positive effects on STEC control. The Committee should consider whether to retain sections of the document for which control measures have not been demonstrated to reduce STEC contamination when the practices are known to help prevent fecal contamination.	**USA**
1. INTRODUCTION	
Paragraph 4: We propose the following wording: Zoonotic pathogens ... Head removal, anus bunging, removal and cut, and evisceration ...	**Colombia**
General comment: most of the practices included (apart from the ones at primary production) are not specific for the control of STEC and are also included in the Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork Meat (CAC/GL 87-2016). It might be useful to include a cross-reference. More general, it can be questioned if it is opportune to maintain two sets of guidelines covering the same control measures.	**European Union**

Par. 4 Par. 4 Introduction: Since the scope also covers ground/minced beef, it might be appropriate to add at the end of the paragraph a sentence of the presence of STEC in such meat.	
Par. 2 STEC are a part of the **normal** intestinal microbiota of cattle, with For wording accuracy, delete common and replace with “normal”. The term for a bacterial species found in a host where it does not cause disease is “normal flora” Par. 2 …STEC **are known to be** widespread within the farm environment **and it is therefore likely** that the majority of cattle arriving for **slaughter have STEC on their hides** Reword for clarity and simplification of the meaning Most operators would assume that STEC are likely to be present on the hides and process them accordingly. Par. 2 Individual studies of **feedlot cattle** have reported the prevalence of STEC O157 on cattle hides presenting for slaughter as high as 94.5% (Arthur et al., 2007), and as high as 74.5% for other STEC (Stromberg et al., 2018). Added in “feedlot cattle” as cattle finished in these environments are known to have higher levels of STEC. Par. 3 The sporadic nature of STEC and common movement and comingling of cattle ~~prior to slaughter~~ **in** feedlots, lairage, and livestock markets prior to slaughter **allows** STEC to spread **between animals.** Could also add “for example” if needed Par. 3 or could be shedding STEC **in their faeces** Added for clarity, since in principle bacteria can be shed from the hide as well. Par. 4 ~~Zoonotic pathogens such as~~ STEC carried by cattle could be spread to carcasses during slaughter. Delete “Zoonotic pathogens such as” This has already been established in the general sections of the document and does not need to be repeated here. Par. 4 the muscle tissue of healthy cattle is ~~essentially~~ sterile Delete “essentially” Muscle tissue in healthy cattle is sterile. If there is known disease, then the animal should not be being presented for slaughter. Par. 4 Generally, contamination is confined to the carcass surface and is not found in deep muscle tissues of intact ~~raw beef~~ **carcasses** Not clear what is meant by “intact raw beef”. Changed to “carcasses” as this makes more sense that this is the case until boning out processes occur. Par. 5 STEC contamination has historically ~~occurred~~ **been detected** in raw **non-intact beef products** Change wording for clarity. The issue is raw ground or non-intact beef products. This is where contamination is normally detected and when undercooked is most likely to result in illness.	**New Zealand**
Par. 2. STEC ~~are a common~~ can be part of the intestinal microbiota of cattle, with the reported prevalence in cattle faeces varying greatly, depending on factors such as animal age, herd type, season, geographic location and production type (Hussein and Bollinger; 2005, Callaway et al	**USA**

2013). STEC shedding by individual cattle is transient and ~~episodic, with almost all cattle carrying and shedding STEC at some time during their life~~ episodic (Williams et al., 2014; Williams et al., 2015). In addition, STEC ~~are widespread~~ can be found within the farm environment. It should be expected that ~~the majority of~~ cattle arriving for slaughter could have hides contaminated to some extent with STEC… Rationale: More accurately reflects the science; there are insufficient data to state that almost all cattle will shed STEC as some time during their life (and this was not a conclusion of the cited studies) or that "the majority of cattle" arriving for slaughter could have contaminated hides. Terms like "common" and "widespread" are subjective. Par. 4. Zoonotic pathogens such as STEC carried by cattle could be spread to carcasses during slaughter. Prior to slaughter, the muscle tissue of healthy cattle is ~~essentially sterile~~free of STEC. STEC … Rationale: We think the original statement was somewhat misleading, since bacteria such as Salmonella can be present in the lymph system and hence can be closely associated with the muscle.	
Uruguay believes Annex 1: RAW BEEF is comprehensive	**Uruguay**
2. SCOPE	
Par. 6 including cuts such as steaks This guidance applies to control of STEC in raw beef, including ~~cuts such as steaks~~ non-intact products such as raw ground/minced or tenderized beef. Suggested deleting steaks and replacing with non-intact products such as ground/minced or tenderised beef products. Steaks may be a risk where they have been tenderised by needle or equivalent processes. The main risk beef products are those parts that are intended for grinding or tenderising.	**New Zealand**
3. DEFINITIONS	
Point 3 Definitions: as the definition of raw beef is already in the introduction, this part could be deleted, as redundant.	**European Union**
4. PRIMARY PRODUCTION-TO-CONSUMPTION APPROACH TO CONTROL MEASURES	
Par. 7 The systematic approach to the identification and evaluation of potential control measures allows consideration of the use of controls in the food chain and allows the application of ~~different combinations of~~ control measures individually or in combination ~~to be developed~~. Context of the sentence means that this sentence does not fit well. Provided clarification Par. 7 This is particularly important **among countries** where differences occur in primary production and processing systems. Sentence order changed to improve clarity and understanding Par. 8 **Control strategies based on preventing STEC infection of cattle or their environment would therefore be highly challenging to implement in a reliable manner** Reword for sense and flow.	**New Zealand**

Par. 9 …or compensate for ~~poor~~ un**hygienic** practices during slaughter, processing and distribution. Conversely, there is evidence that the adoption of ~~the best~~ **good** hygienic practices during slaughter and processing can minimise **carcass** contamination with STEC…. Consequently, the adoption of best practices for preharvest… Grammar. Word change Amended to remove reference to poor hygienic practice and best hygienic practice Par. 10 poor **un**hygiene practices Word change	
Paragraph 10: Uruguay suggests the following wording: Similarly, operations to decontaminate carcasses or raw beef cuts will be of limited effectiveness if the initial contamination load is high or if poor hygiene practices during subsequent processing and distribution permit recontamination.	**Uruguay**
4.1 GENERIC FLOW DIAGRAM FOR APPLICATION OF CONTROL MEASURES	
Par 11 Process flow diagram: The EUMS propose to replace the the flow diagram with the one included in Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork Meat (CAC/GL 87-2016), annex I, 6.1. (or just a cross-reference made), as it was already agreed and it is slightly different from the one included in the draft (for instance, the diagram in CAC/GL 87.2016 does not show the step "carcass washing", see also comments on paragraph 58).	**European Union**
Indicate/ Highlight the sections where contamination occurs (mild, moderate and heavy) and also sections to show where the sampling has to be made by color coding or any other means as appropriate. Rationale: For more clarity.	**India**
4.1 Generic flow diagram for application of control measure We are of the opinion that the process flow diagram used in this Proposed Draft should be in line with the Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork Meat (CXG 87-2016). In this relation, we would like to ask for a clarification that the step such as post-mortem inspection should be added or not. Rationale: The processing steps in the process flow diagram of this Draft annex should be consistent with the process flow diagram of primary production-to-consumption – Beef in CXG 87-2016. This consistency will facilitate the use of this Guidelines when adopted.	**Thailand**
On the process flow diagram, IFT would ask that consideration be given to the possibility of washing animals pre-slaughter (washing hide, etc.) as it is not clear if this can/should be done.	**IFT**
4.2 PRIMARY PRODUCTION	
Par. 17 The addition of viable microorganisms to feed should be assessed with respect to whether these microorganisms pose a risk for ~~emergence~~ the transmission of antimicrobial resistance ~~in~~ genes to pathogens ~~in the gut~~carried by cattle. Suggestion to improve the sentence. Par 19 … in beef following vaccination and the lack of farm-level incentives to cover additional ~~cost~~ costs associated with vaccines and their administration (JEMRA, 2020).	**Canada**

13. The prevalence of STEC shedding in a herd and each animal's shedding status for STEC is generally unpredictable, although factors have been identified that may influence STEC shedding. Interventions proposed to reduce the prevalence of STEC shedding or numbers of STEC shed by cattle include animal vaccination, dietary additives and adequate manipulation of animal feeds, animal welfare practices, and primary production practices. We are adding information for clarification and to emphasize animal welfare practices whose ability to reduce pathogen prevalence and concentration have been extensively proven by science.	**Colombia**
Par. 17 No evidence of antimicrobial resistance reported for use of common probiotics as food and feed. They usually inhibit adherence of pathogens to the GI epithelium and also activate the immune system. It is suggested to remove the last sentence. Par. 18 It is also recommended to addition of medicinal plants containing phenol compounds to the feed and/or silage. Par. 20 Stressful situations should be minimized wherever possible, because increased **stress increases shedding of pathogens** (e.g. poor animal husbandry, rough handling, dietary stress and food deprivation (Stein and Katz, 2017; Venegas-Vargas et al 2016)). Stress also attenuates the immune system. It is recommended to add it in this part.	**Iran**
Par. 12. Control measures should be discussed in CCFH after JEMRA report on STEC in beef/milk is available. Based on inputs from JEMRA, the potential measures supported by low degree of confidence should be deleted from this draft. (In the other words, control measures supported by high degree of confidence should be retained in this draft.) Therefore Japan proposes to ask FAO/WHO to publish the report as soon as possible. Par. 18. The seaweed *Ascophyllum nodosum* ~~(Tasco-14)~~ is marketed as a supplement for cattle feed. It has been reported to reduce faecal and hide prevalence of STEC O157:H7 when added to corn feed (Braden et al., 2004). The product name should be deleted.	**Japan**
Par. 11 This flow diagram is for illustrative purposes only. **The** process steps are generic, **and not** all the steps may occur <u>during processing, at the same establishment, -or in</u> the order <u>shown</u> ~~may be varied as appropriate; it should be noted that not all steps may be completed within the same establishment.~~ Grinding/mincing, for example, can be done at sites other that the slaughter or fabrication site. Re order sentences to improve understanding Some wording changes to improve grammar and flow. Par. 13 and primary production <u>management</u> practices Unclear what this means in terms of production and how this differs from the listed measures? Assume this means animal management within a production environment ie a farm? Have suggested adding "management" for clarity Par. 15, 16 and 17 Delete the word "serotype" where it occurs in this clause as not necessary and is not consistently used. Recommend checking whole document for consistent usage. Par. 17 Would these organisms have to be considered as GRAS? Note that it is unlikely that these types of probiotics would produce antimicrobials that would be used for the treatment of disease in animals or humans ie not an antibiotic.	**New Zealand**

Par. 20 These would be for cattle and beef production rather than generic animals given the studies referenced refer to cattle. And this annex is for raw beef only Section 4.3 Suggest that a comment is added to clause 22, 23 and 24 or as a separate clause in this section I	
Par. 20 Use materials in water troughs that facilitate the cleaning process~~; metal troughs had lower *E. coli* O157:H7 counts compared with troughs that were manufactured from concrete or plastic (Lejeune, 2001)~~. Good management practices at primary production In paragraph 20 (sub-bullet 4, under bullet 5), we would like to propose an amendment as follows: Use materials in water troughs that facilitate the cleaning process. ; metal troughs had lower E. coli O157:H7 counts compared with troughs that were manufactured from concrete or plastic (Lejeune, 2001). Rationale: Control measure should be objective driven without being too prescriptive.	**Thailand**
Par. 19 The use of vaccination in cattle has not been commercially adopted due <u>in part</u> to the lack of evidence to support the reduction of STEC in beef following vaccination ~~and the lack of farm-level incentives to cover additional cost associated with vaccines and their administration~~ (JEMRA, 2020). Rationale: To focus on the scientific aspects and not the economics. <u>Par. 20 To the extent possible, m</u>~~Maintain~~ <u>aintain</u> clean living conditions (e.g. clean holding areas, remove gross ~~contamination to the extent possible~~<u>contamination</u>, and maintain clean and dry bedding) to prevent <u>potential</u> transmission from the living environment (e.g. animals resting in STEC-contaminated materials). Rationale: to provide greater flexibility allow for diverse global production systems and unavoidable environmental and/or weather events such as monsoons or heavy snow fall that can make providing clean and dry bedding impossible.	**USA**
4.3 Transportation	
Par. 21 and 22 Change “animal” to “cattle” for consistency and for this annex on raw beef. Suggest checking document for consistent usage Par. 22 It is unclear what is meant by the term “visual controls” – Would be better to say “visual inspection” and then if they exceed the acceptable levels have an action or implement a routine control point. Par. 23 …miles doubled the risk of having **STEC** positive hides at slaughter Unclear if this was a reference to faecal contamination or STEC. Add in STEC for clarity if this is appropriate. Par. 23 It is not possible to ensure that animals are clean during transportation; there is no way to prevent defecation during transport or rubbing between animals Par. 24 and 25 Excessive repetition. Suggest combining 24 and 25 together into one statement. 4.4 Add dressing as this section also address carcass dressing as wel	**New Zealand**
Par. 22 Controls <u>can</u> include:	**USA**

Rationale: provide more flexibility. Changing truck design is a major economic undertaking, and often outside of the control of the cattle producer or beef processor. With the beef supply chain including livestock markets and other marketing channels, it may be impractical to separate lots of animals from different farms. Par. 22 When possible, s~~Separate~~ eparate lots of animals from different farms, use holding pens of an appropriate size for the number of animals, avoid overpopulation and stress of the animals. Rationale: provide more flexibility. Par. 23. Transportation practices should minimize any condition that could affect contamination of the meat. Control measures implemented prior to travel can include: Par. 23 As much as practical, m~~Minimize~~ inimize distance over which slaughter cattle should be transported~~. One study noted that transporting cattle more than 100 miles doubled~~ , as increased transportation distance can increase the risk of having positive hides at slaughter compared to cattle that ~~traveled~~ travel a shorter distance (Dewell et al, 2008). Rationale: Provide flexibility and eliminate results from a specific study. Other bullets do not contain detailed information on specific studies.	
Par. 22 In paragraph 22, IFT recommends adding an additional bullet point on the cleaning of transport vehicles and inspection thereafter.	**IFT**
4.4 SLAUGHTER	
Par. 40 To prevent transfer of contamination from the hide to the freshly exposed carcass, operators working at this stage should be ~~effectively~~ trained to perform this ~~operation~~operation to maximize hygiene. To improve the sentence. Par. 41. Slaughterhouses may ~~consider, when feasible,~~ consider a pre-hide removal carcass decontamination procedure to reduce visible hide contamination. Suggest to delete "when feasible", since the words "may" and "when feasible" are redundant in the sentence. Par. 49 "Incidental" should be deleted. Any leakage (incidental or not) needs to be avoided.	**Canada**
Par 45 Weasand meat: Since the recovery of weasand meat is not authorised for use in minced meat in all countries, the EUMS propose the following modification in the second sentence of paragraph 45: “In some countries, weasand meat may be recovered from the gastrointestinal tract for use in raw ground/minced beef production.	**European Union**
Par. 26 Interventions used **during primary processing** include physical Slaughterhouse is not a term commonly used, rather called primary processing or meat processing to encompass all parts of the process Par. 26 At this point in the process, this is a carcass rather than an animal Par. 26 Strict hygiene practices and good manufacturing practices. Good manufacturing practices Consider these two to be synonymous? Prefer to use GMP as refers to the processes Par. 26 dehiding, head removal, clipping **the weasand**, bunging and evisceration Important to precent ingesta from contaminating carcass	**New Zealand**

Par. 28 Tolerance to heat This is not proven to be an issue with STEC and is one of the most effective control measures available. Need to provide a reference if included Par. 28 The impact of interventions should be quantified by conducting experimental trials with surrogate organisms that have similar or greater resistance to individual treatments than STEC Delete from here or revise, use of surrogates is not necessarily equivalent to Wild type strains isolated at source. Careful consideration is needed when verifying suitable strains for validation of interventions. Par. 29 and **application** is feasible Add “application” as it is important that an intervention is applied using the validated conditions, particularly if applying a multiple hurdle intervention approach Par. 29 ~~control measures~~ **interventions** Need to use one terminology when referring to an application throughout the document for consistency. Par. 30 following **processing** steps Add for clarity Par. 30 ~~surfaces~~ **products**. Products is a more appropriate way of describing Par. 30 Automation of **intervention application** offers the advantage of greater consistency of application but needs proper adjustment (Signorini et al., 2018) Add wording to make this clearer in the section. Suggest similar modification is made to the previous section to make this clear that automation applies to intervention application and not beef carcass processing Par. 31 In this stage the hygiene condition of the animals should be evaluated; animals should be as clean as possible to minimize the initial load count of microorganisms, which potentially includes STEC, on their hide. **Animals should be as clean as possible, with no visible faecal material or dags present.** Reword. This section implies that visually clean animals are less of a microbial risk, but this is not the case. Dry dusty hides also harbour microbes that can easily be transferred to the carcass during slaughter and dehiding. Par. 31 **Where practical,** dirty or wet animals Need to have a proviso here, ie ‘where practical,..’. Par. 32 removal of gross contamination ~~and residues~~ with application of ~~chlorinated~~ water under pressure on the floor. Unclear what the residues are in lairage over and above gross contamination which will cover all things that are likely to appear in yards.	

Unclear why chlorinated water is better than water alone at removing gross contamination and washing of yards between cattle groups, this is not likely to make any significant difference in the presence or not of STEC Par. 33 ~~Tap~~ water Delete tap as all water in meat processing facilities is going to come from a tap. Does this water need to be clarified as either potable or clean water? Par. 34 When feasible, at lairage cattle should not be comingled with other herds ~~maintained in closed herds~~ to reduce social stress and prevent cross-contamination between herds. Delete as repetition of Clause 24 or reword for consistency Suggest including and say that cattle from different lots should not be comingled – terminology used elsewhere in Clauses 24, 21, 23 and 20 Par. 35 **In the access to the stunning box, or** following the stunning box, the animals can be treated with water jets at appropriate pressure, aiming at the hygiene of the rectum for possible elimination of faeces and STEC shed due to stress in leading the animal to slaughter. Following stunning, should faecal material have been released, a water wash can be applied the hind quarters of the animal to remove the gross contamination. Where this is applied, consideration should be given to removal of excess water prior to hanging of the carcass Reword this sentence for accuracy. This statement is contrary to the clauses re washing of animals. Minimal water should be applied to the animal pre and post stunning and only when faecal matter has been released during stunning. A small amount of water can be applied to the head area as required to facilitate stunning. Par. 36 The stunning box **and sticking table** should be kept as clean as possible to avoid contamination of the animal's hide in the fall after the stunning process Both of these areas need to be kept as clean as practical and both may become contaminated with faeces. Ideally a cold water wash should be followed by a hot water wash Par. 37 self-contained bolt, firearm, alternative Should electrical stunning be added here as this is the only halal method which is accepted? Par. 38 In slaughter **where there is no stunning**, special attention should be paid to avoid a delay in clipping the weasand to minimize contamination **of neck meat** with STEC. Delete this part as the assumption should be that the ingesta is contaminated rather than assume it is not. Clipping the weasand should be done as soon as practical in all situations, contamination of neck meat is likely during all during slaughter and bleeding, so would remove this as a special condition for one type of process. Par. 40 operators working at this stage should be ~~effectively~~ **appropriately** trained to perform this operation Reword for clarity. Unclear what “effectively” trained means in this context	

Par. 41 Slaughterhouses may consider, when feasible, a pre-hide removal carcass decontamination procedure to reduce ~~visible~~ hide contamination Delete “visible”. A pre-hide wash should be aimed at reduction of the microbial load on the hide rather than being limited to visible contamination. Par. 41 The excess liquid from the decontamination procedure should be **removed (eg vacuumed)** from the hide to avoid contamination of the carcass with liquid that could easily run onto the carcass when the hide is opened Any method that can be remove the liquid could be applied. Vacuum is one option. Par. 42 Rinsing of the rectum and disinfection of the perianal hide should be performed in order to reduce or eliminate contamination prior to dehiding. Hide-on carcass washes are frequently used for that purpose (Yang et al., 2015). New 43. To prevent transfer of contamination from the hide to the **carcass during hide opening (opening cuts),** techniques can include: **Worker rotations during the dehiding process should occur so as to minimise the risk of cross-contamination events of carcasses occurring** Split this clause into two as indicated as these are two separate processes 42 Anal washing 43 opening cuts Added additional wording to clarify this applies to hide opening cuts In the bullet points, need to consider worker rotations in the process of opening up the carcass as this can influence contamination. Par. 43 to avoid contact of the hide with **exposed parts of the** carcass that is already dehided Re word for clarity Par. 44 Measures should be taken to prevent tail flapping **and contacting the carcass** when hide pullers are used. **The tail should be trimmed pre and post hide puller use.** Removed splattering and added alternative wording for clarity. Also the switch should be docked, and the stump trimmed pre-post hide removal. Par. 46 to prevent **ingesta** movement Reword for consistency (see clause 45) Par. 46 Cleaning the weasand to minimize cross-contamination Can an example of how this is achieved be added here? Not something that I have seen being done so maybe if not common, delete? Par. 47 When appropriately applied, these techniques will reduce contamination with gut microorganisms **generally, and these** may include pathogens; however, insufficient evidence was found specifically for their effects on STEC. When appropriately applied, these techniques will reduce contamination with gut microorganisms, **which may include STEC**; however, insufficient evidence was found specifically for their effects on STEC. Delete “generally” as does not make sense where it is and reword to include STEC rather than general pathogens.	

Par. 49 ~~Rinsing or washing the bung area before cutting~~ Delete as this would be high risk of increase contamination of the carcass	
Par. 30 We would like to suggest a new point 30 bis: Operators should be effectively and appropriately trained to perform their operation in the slaughtering process. Rationale: Hygienic slaughtering requires trained personnel at several operations. Paragraph 4, third sentence states “STEC can be transferred to carcass surfaces from the contents of the gastrointestinal tract or hide during the operations of dehiding, head removal, bunging and evisceration (Gill and Gill, 2010).» In paragraph 40 and 54, the need for sufficient training of personel performing dehiding and eviceration is pointed out. The need for training applies to several other opterations, and should be highlighted	**Norway**
Par. 43 Agreed with keeping “primary” as the Industry has the responsibility of the safety and suitability for raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts. Par. 45 Agreed with “should “because the competent authority has to provide the guidelines to industries.	**Saudi Arabia**
Paragraph 26: Uruguay believes it should read “to eliminate ... entirely.” Paragraph 28: Uruguay believes that in the Spanish version, this sentence should be edited after “*similar o mayor que la de la ECTS*.” [similar or greater... than STEC] Paragraph 38: Uruguay suggests removing this sentence.	**Uruguay**
Par. 32. The lairage area should be cleaned as much as possible for each lot of animals, with the removal of gross contamination and residues with application of chlorinated water under <u>appropriate</u> pressure <u>and environmental conditions</u> on the floor. Cleaning and disinfection should be applied according to good hygiene practices and manufacturer’s instructions. Rationale: Provide more information about factors that need to be accounted for in such cleaning. Par. 45 – 47 This section (paragraphs 45-47) can be deleted, as it does not contain any specific control measures for STEC. If this section is retained, modify paragraph 47 as follows: Although, when appropriately applied, these techniques can reduce contamination with gut microorganisms generally, and these may include pathogens; there is insufficient evidence for specific effects on STEC.	**USA**
Par. 32 IFT would caution against the use of chlorinated water "under pressure" for the cleaning of the lairage area as it has the potential to aerosolize microbes. IFT would suggest use of low -pressure water for this purpose that cannot readily aerosolize microbes. IFT would recommend addition of a point that for good hygienic practice, employees involved in slaughter should be separate from employees involved in post-slaughter meat fabrication steps. Par. 46 IFT would add that a carcass with a punctured GI tract should be immediately separated from the other carcasses so as to avoid further cross-contamination. Par. 51 IFT again recommends the immediate separation of carcasses with perforated GI tracts from the others to minimize cross-contamination potential.	**IFT**
4.5 PROCESSING	

Par. 66 ~~[311]~~ Storing products to prevent the growth of STEC. Multiplication of STEC is inhibited below 7°C, but low temperatures would not significantly reduce STEC. Establishments need to control STEC, using adequate time/temperature combinations.	**Canada**
Par. 58. ~~After trimming, all carcasses should be washed to remove blood and bone dust.~~ Par 58 Carcass trimming: The EUMS consider that it should be emphasized that the best practice for removing visible contamination is trimming, and that abusive washing of carcasses which can lead to splashing and spread of contamination, should be avoided. Moreover, blood and bone dust are not sources of STEC, so washing for their removal does not contribute to the control of STEC (on the contrary). Therefore, the EUMS suggest deleting the last sentence of paragraph 58. Par 63 Meat tenderization: see comment on definition of “raw beef”. If these meat preparations are not included, this paragraph should be deleted.	**European Union**
Par. 54 For paragraph 54, IFT would add "trained employees" to the techniques listed. Par. 59 IFT would add to the sentence ending with "the contact period" the words "in line with label directions". Par. 64 IFT would add in the first sentence after "are cleaned", the words "and disinfected" prior to the words "regular basis" Par. 65 For paragraph 65, IFT believes it would be beneficial to add a technical reference regarding this point to allow deeper review. Par. 66 On the second bullet point for paragraph 66, IFT would add the words "and disinfecting" after the word "Cleaning" Par. 68 For Paragraph 68, IFT recommends adding the words "and consumer acceptability" after the words "organoleptic properties"	**IFT**
Par. 52 STEC on the carcass can be transferred to meat cuts as the **animal** is further processed and can also be transferred between meat cuts via meat processing equipment (ICMSF, 2005). STEC on the carcass can be **remain on or be transferred to other** meat cuts as the **carcass** is further processed and can also be transferred between meat cuts via meat processing equipment (ICMSF, 2005). Word change animal to carcass. Also query the transfer to meat products if already on the meat. Reword to cover presence and then transfer. Par. 54 If the gastrointestinal tract has been punctured causing a major contamination, no further work should be carried out on the carcass until it has been removed from the slaughter line. **A clean down of the environment, operators and tools being used at the time of the contamination event should be undertaken to prevent cross-contamination with leading and trailing carcasses as required** Inference is that by removing the carcass the issue is resolved. Have included an additional action that is required to be undertaken to limit cross-contamination on remaining carcasses Par. 56 Removing **visible carcass** defects that may contaminate the saw or cleaver Clarification Par. 56 Allowing adequate distance **between split half carcasses and between different** carcasses Clarification	**New Zealand**

Par. 57 Targeted removal of visible contamination **on carcasses** by trimming, but the disadvantage **trimming** is potential cross-contamination from dirty knives Reword sentence for sense. Remove manual methods and replace with “trimming” as not aware of an automated method for trimming off contamination Par. 58 After trimming, all carcasses should be washed to remove blood and bone dust This is not normal practice and would not be carried out unless using an anti-microbial wash, otherwise would result in spreading of microbial contamination. Re word or clarify if this is the intend but if not then recommend deletion of this recommendation Par. 60 The specific impact on STEC is not known. Hot water treatments reduced *E. coli* O157:H7 prevalence by 81%, on pre-evisceration beef carcasses. Delete/replace this statement. There is evidence in the literature around the efficacy of hot water on O157:H7. Other references are available – suggested statement is from the reference below J Food Prot 2006;69(8):1808-13. Treatments using hot water instead of lactic acid reduce levels of aerobic bacteria and Enterobacteriaceae and reduce the prevalence of Escherichia coil O157:H7 on preevisceration beef carcasses Joseph M Bosilevac Par. 61 The specific impact on STEC is not known. Delete/replace this statement as there are support evidence for e. coli and maybe O157 in the review below Food Res Int. 2017 Mar; 93:16-25 Meta-analysis on the effect of interventions used in cattle processing plants to reduce Escherichia coli contamination Samson Zhilyaev et al Par. 62 Rapid chilling minimizes the potential for **bacterial growth;** STEC, can only grow at temperatures of 7 °C and above. The potential for bacterial **growth** is also dependent upon the water activity at the carcass Change replicate to growth as this is the term more commonly used in this context Par. 64 Manufacturers should ensure that mechanical tenderizers and associated processing equipment are cleaned on a regular basis ~~to minimize the potential for translocating STEC from the exterior surface of the product to the interior and~~ Deleted this part of the sentence as it does not matter how much you clean the processing equipment for tenderization it will not change the transfer of any STEC on the surface to the interior of the meat. This is a function of the meat and what is on the meat surface. Can prevent cross-contamination so second point is fine Par. 65 Antimicrobial washes, such as lactic acid, peroxyacetic acid and acidified sodium chlorite have been shown to reduce **the concentration of** *E. coli* O157:H7 and other STEC on beef Re-ordered sentence to improve understanding	

Par. 66 ~~personal~~ hygiene practices in order to avoid ~~cross~~ contamination Not sure how personal hygiene practices will impact STEC cross contamination. Have taken out personal and cross out for sense purposes Par. 67 when handling ~~ground meat products~~ Added in ground meat products for clarity; as these are the products which represent the highest risk for consumers	
Par. 58 ~~After trimming, all carcasses should be washed to remove blood and bone dust.~~ We would like to suggest deleting the wording in the last sentence. Rationale: Such washing may spread contamination on the carcass and it is preferable to use as little water as possible on the carcass if the water is not heated to have an effect as decontamination. *Par. 58 Carcass washing with approved antimicrobial agents.* Par. 59. Carcass washing may remove visible soiling and reduce overall bacterial counts on beef carcasses by up to 1 log unit (Gill and Landers, 2003). Carcass washing with approved antimicrobial agents, such as organic acids … This will bring the wording in line with the wording in bullet point 4 in paragraph 66: Treating the outer surfaces of the meat with organic acid sprays or other approved treatments before grinding/mincing. We find it important to highlight that only approved antimicrobial agents can be used for carcass washing.	**Norway**
Par. 66. To minimize STEC contamination and/or the spread contamination of ground/minced beef with STEC, measures may include**, where appropriate**: 4.5 Processing 4.5.5 Specific control measure at tenderization, grinding/mincing Paragraph 66 bullet point 3, we would like to propose the following amendment. To minimize STEC contamination and/or the spread contamination of ground/minced beef with STEC, measures may include, where appropriate:… Rationale: To provide flexibility for the users of this Guidelines.	**Thailand**
Par. 58 Rationale: The sentence applies to all of the methods bulleted in section 4.5.3, not just carcass washing with antimicrobial agents. Par. 59. ~~Carcass washing may remove visible soiling and reduce overall bacterial counts on beef carcasses by up to 1 log unit (Gill and Landers, 2003).~~ Carcass washing with antimicrobial agents… Par. 66 ~~[311]~~ Storing products to prevent the growth of STEC. Multiplication of STEC is inhibited below 7°C, but low temperatures would not significantly reduce STEC. Establishments need to control STEC, using adequate time/temperature combinations.	**USA**
4.6. DISTRIBUTION / RETAIL	

Par. 73 Since not all tenderized products are readily distinguishable from non-tenderized products, labelling to state that the product is tenderized, along with validated cooking instructions, **should be provided to** consumers and food service workers the essential information to safely prepare the product (USDA FSIS, 2015). Think instructions should be provided for all at risk products. So change may to should	**New Zealand**
4.7 CONSUMERS	
Par. 75 The five keys should be mentioned on the labeling for the consumers, when packed raw beef is prepared.	**Iran**
Par. 75 IFT would add "and disinfected" after the word "clean" IFT would as that reference to recommended cooking temperatures be added here.	**IFT**
6. MONITORING OF CONTROL MEASURES	
Par. 78. Some raw beef products will need more control measures and monitoring than others (e.g. non- intact raw beef, ground/minced raw beef, trim).	**Canada**
Par. 77. Process performance monitoring may be accomplished more effectively and efficiently by quantitatively monitoring hygiene indicator ~~organisms~~microorganisms. These indicator ~~organisms~~ microorganisms do not indicate pathogen presence;	**Japan**
Uruguay believes “verification” should be replaced with “monitoring.”	**Uruguay**
7. VERIFICATION OF CONTROL MEASURES AND REVIEW OF CONTROL MEASURES	
Par 82 Intact raw beef cuts: The EUMS consider that it is often unpredictable whether or not “intact raw beef cuts” will not be used as “finished raw beef products” e.g. by the consumer. These wordings are in addition not defined and might be confusing. It is therefore proposed to delete this paragraph.	**European Union**
Par. 79. …Consequently, verification programs should also include quantitative monitoring of hygiene indicator ~~organisms~~microorganisms. Hygiene ~~indicators~~ indicator microorganisms used should be those that are the most informative for the specific processing environment. Examples of potential hygiene ~~indicators~~ indicator microorganisms include total bacterial counts, ~~counts of~~ coliform or faecal ~~coliforms~~coliform counts, ~~and counts of~~ total *E. coli*. counts and counts of Enterobacteriaceae. An increase in the numbers of the selected indicator microorganisms indicates decreasing control and corrective action should be taken. (Editorial) Japan proposes to modify the wording of indicator microorganisms in line with those in the definition in the General Section. (Technical) Japan proposes to add Enterobacteriaceae as an example since it is referred in the definition of indicator microorganisms in the General Section.	**Japan**
Par. 79 selected indicator indicates decreasing **process** control and corrective action should be taken Added “process” for clarity Par. 79 The speed in detecting a loss of control of **process** hygiene increases with the verification frequency. Changed “manufacturing” to “process” – more appropriate terminology as meat is processed not manufactured Par. 80 Lot testing is particularly important	**New Zealand**

Does not make sense as written, think this is what is meant	
Paragraph 79: Uruguay is considering including a reference to definition 10.4.1 in the General document.	**Uruguay**
IFT would recommend adding to section 7 that "observing employees performing control measures and reviewing records" be added to the list.	**IFT**
8. CONSIDERATIONS FOR LABORATORY TESTING FOR DETECTION OF STEC IN RAW BEEF	
Par. 82 Intact raw beef cuts used for purposes other than the manufacture of **ground** raw beef products Unclear as written what the difference is between intact and finished products. Added ground as this would make sense wrt to lower risk of STEC Par. 84 ~~Levels of STEC in non-intact and ground/ minced products are often higher than in intact beef because ground or disrupted tissue presents an environment that is more conducive for bacterial growth.~~ Delete statement. It is about STEC being distributed throughout the product combined with inadequate cooking, ie undercooked burgers and so on. Is there evidence to support this statement on growth? Par. 84 ~~In addition, many of the processing and post-processing interventions are more efficacious if the targeted pathogen is exposed on the surface of the meat as opposed to embedded within a tissue matrix.~~ Delete this statement or modify so it makes sense on its own Although this is true this is not an addition reason associated with the first statement. Any interventions applied to ground meat would be different to those applied to an intact carcass or muscle meat product Par. 85 in large scale processing plants, trim and ground / minced beef originate from the tissues of multiple carcasses, whereas **an intact raw beef product would be from a single carcass.** First part of the sentence is correct and the essence of the second part is also correct but not as written. Reword to improve clarity	**New Zealand**
Par. 85. ~~in large scale processing plants, trim~~ Trim and ground / minced beef can originate from the tissues of multiple carcasses… Rationale: The size of processing facility does not necessarily determine where trim and ground/minced beef originate. Deletion of this allows the document to apply to all size facilities while still maintaining the intent of the statement.	**USA**
ANNEX 2. FRESH LEAFY VEGETABLES	
GENERAL COMMENTS	
The Annex on Fresh Leafy Vegetables can be modified once it is determined if there is sufficient STEC-specific control information for an annex and if there is a decision on restructuring CXC 53-2003.	**Canada**
Japan suggests that CCFH should proceed with this Annex taking into consideration of the progress of work on the General section and other Annexes as well as JEMRA scientific advice.	**Japan**
The United States is open to the wishes of the Committee with respect to retaining Section 11 Retail and Food service and the Flow charts in Annex 2 on Fresh Leafy Vegetables.	**USA**

INTRODUCTION	
Paragraph 2: We are suggesting the following synonyms for the term “amendments”: “Fertilizers,” “improvers,” and “conditioners.” Paragraph 3: Include Figure 1. Or indicate the page number where it is located.	**Colombia**
Par. 2 …Control measures such as antimicrobial washes to minimize cross-contamination may be applied prior to packaging and/or shipment to market. As fresh leafy vegetables move through the supply chain, there is also the potential for the introduction and growth of pathogens, including STEC. The increasing worldwide use of pre-packaged fresh-cut leafy vegetables to expand the supply chain might increase the potential for contaminated product in the marketplace through cross-contamination with STEC, and their replication during distribution and ~~storage~~storage if improperly handled. … Rationale: Edit to the 5th sentence is to emphasize that the control provided by antimicrobial washes is for cross-contamination. Edit to the 7th sentence is for clarification--increased use of pre-packaged fresh-cut leafy vegetables does not per se increase cross-contamination and replication. Par. 6 Fresh leafy vegetables - Vegetables of a leafy nature ~~[where the leaf is intended for consumption] [that~~ that may be ~~consumed]~~ consumed without cooking… Rationale: Modify as indicated in the General Section to be clearer and more concise.	**USA**
Par. 2 IFT would suggest inserting to the sentence beginning "There is no processing treatment applied that would..." the word "completely" before "eliminate"	**IFT**
SCOPE AND DEFINITIONS	
Par. 6 Both options in the [ ] would work for the definition of fresh leafy vegetables, but the second option reads better.	**Canada**
Par. 6 Egypt recommends the definition of Fresh leafy vegetables is appropriate as the following: Vegetables of a leafy nature where the leaf is intended for consumption without cooking, including, but not limited to, all varieties of lettuce, spinach, cabbage, chicory, endive, kale, radicchio, and fresh herbs such as coriander, cilantro, basil, curry leaf, colocasia leaves and parsley, among other local products for foliar consumption.	**Egypt**
Par. 6 Par 6 Definitions: definition of “fresh leafy vegetables” is already in the introductions so it does not need to be repeated here.	**European Union**
Par. 6 Malaysia agrees with the phrase “where the leaf is intended for consumption” to be in-line with what has been described as Fresh Leafy Vegetables in the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53 – 2003). For consistency, the definition of Fresh Leafy Vegetables in Annex 2 of this document should also be the same.	**Malaysia**
~~Par. 6 Fresh leafy vegetables - Vegetables of a leafy nature [where the leaf is intended for consumption] [that may be consumed] without cooking, including, but not limited to, all varieties of lettuce, spinach, cabbage, chicory, endive, kale, radicchio, and fresh herbs such as coriander, cilantro, basil, curry leaf, colocasia leaves and parsley, among other local products for foliar consumption.~~ Does not need to be repeated here, if repeated see our comment on this definition already provided for in the introduction part.	**Norway**
Par. 6 The Republic of Korea supports the first phrase [where the leaf is intended for consumption] .	**Republic of Korea**

Paragraph 5: Uruguay suggests the following addition: “and parsley, among other products whose leaves are consumed.” Paragraph 6: Uruguay believes “that may be consumed” to be the better option.	**Uruguay**
Definition of vegetables of a leafy nature: Agreed with [that may be consumed]. Definitions of Indicator microorganisms agreed with [microorganisms that are used to evaluate the microbiological status of food production and food control systems, including the evaluation of the quality or safety of raw or processed food products and the validation of the efficacy of microbiological control measures. Some hygiene indicator microorganisms are total bacterial counts, coliform or faecal coliform counts, total E. coli counts and counts of Enterobacteriaceae]	**Saudi Arabia**
3. PRIMARY PRODUCTION	
Par. 15.Where necessary, growers should test the water they use for appropriate hygiene indicator organisms and, where necessary, STEC, according to the risk associated with the production… If the water source is found to contain unacceptable levels of hygiene indicator organisms or is contaminated with STEC.. For consistency within the document.	**Canada**
Par 14 to 16 Water for primary production: considering the development of specific “Guidelines for the safe use and re-use of water in food production”, including an Annex on fresh produce, the EUMS consider that those guidelines/recommendations should not be duplicated here. Therefore, these paragraphs should be replaced by a cross-reference to the guidelines on the use of water. Wording of the title of the guidelines and its references can be adapted later on if the STEC guidance is adopted before the water one. Par. 21 Fresh leafy vegetables should be stored and transported under conditions that will minimize the potential for STEC contamination and/or growth. Fresh leafy vegetables should not be transported in vehicles previously used to carry heavily soiled root vegetables, live animals, animal manure, compost, or biosolids. When vehicle receptacles or containers have been used for the transport of products other than foodstuffs or for the transport of different foodstuffs, effective cleaning should be carried out between loads to avoid the risk of contamination.Par 21 Storage and transport from the field to the packing or processing facility: The EUMS propose that the following sentence is added at the end of the paragraph to complete recommendations: “When vehicle receptacles or containers have been used for the transport of products other than foodstuffs or for the transport of different foodstuffs, effective cleaning should be carried out between loads to avoid the risk of contamination”.	**European Union**
Par. 15.Where necessary, growers should test the water they use for appropriate indicator ~~organisms~~ microorganisms and, where necessary, STEC, according to the risk associated with the production. The frequency of testing will depend on the water source (i.e. lower for adequately maintained deep wells, higher for surface waters), the risks of environmental contamination, including intermittent or temporary contamination (e.g. heavy rain, flooding), or the implementation of a new water treatment process by growers. If the water source is found to contain unacceptable levels of indicator ~~organisms~~ microorganisms or is …	**Japan**
Par. 10 When the likelihood of contamination cannot be managed or ~~such possibilities exist and cannot be~~ minimised, the production site should not be used for fresh leafy production. Wording change to improve clarity Par. 11 For example, heavy rains or flood events may increase the exposure of fresh leafy vegetables… Suggest adding flooding as a further example Par. 14 …, the occurrence of STEC in the ~~irrigation~~ water used for irrigation or application of pesticides or fertilisers.	**New Zealand**

Water is used for a number of purposes including the application of pesticides, fertilisers and other agrichemical additions Par. 15 If the intended water source is found to contain unacceptable levels of indicator microorganisms or is… It should be the intended water source, add micro to organism to ensure consistency with the definitions Par. 18 Hygiene and health requirements should be followed to ensure that personnel who come into direct contact with fresh leafy vegetables prior, during or after harvesting… There may be other occasions when workers need to come into direct contact with the crops, eg during thinning or weeding where this is performed by hand. Good hygiene will be required at this time too.	
Par. 11 IFT would recommend replacing "cannot be controlled" with "may need to be evaluated" Par. 15 IFT recommends adding to the phrase "the water is suitable for its intended use" that "Under no circumstances should contaminated water be used". Par. 18, IFT recommends adding a point around "sewage management" in this section. Par. 19 In section 3.2.4, IFT recommends adding something around the placement of a "buffer zone" around animal waste	**IFT**
4. PACKING OPERATIONS	
Par. 23.Refer to the *General Principles of Food Hygiene* (CXC 1-1969). ~~Time and temperature~~ Temperature [i.e., 7°C or below] control during packing and storage is essential to prevent growth of any STEC that may be present, since an increase in numbers of STEC will increase the risk of illness. Time is only relevant if trying to maintain the pathogen below a threshold level.	**Canada**
Par 26 Washing fresh leafy vegetables: considering the development of specific “Guidelines for the safe use and re-use of water in food production”, including an Annex on fresh produce, the EUMS consider that those guidelines/recommendations should not be duplicated here. Therefore, this paragraph should be replaced by a cross-reference to the guidelines on the use of water. Wording of the title of the guidelines and its references can be adapted later on if the STEC guidance is adopted before the water one.	**European Union**
Par. 23.Refer to the *General Principles of Food Hygiene* (CXC 1-1969). Time and ~~temperature [i.e., 7°C or below]~~ temperature control during packing and storage is essential to prevent growth of any STEC that may be present, since an increase in numbers of STEC will increase the risk of illness. In the abovementioned Sections, we would like to propose the amendments as follow: 4.1 Time and temperature control Refer to the General Principles of Food Hygiene (CXC 1-1969). Time and temperature control during packing… Rationale: The specification of the temperature at 7°C or below is not appropriate for fresh leafy vegetable from tropical area since the specified temperature may lead to chilling injury for vegetables such as basil, coriander.	**Thailand**
5. PROCESSING OPERATIONS	

Par. 29.Refer to the *General Principles of Food Hygiene* (CXC 1-1969). ~~Time and temperature~~ Temperature control during pre-processing storage, processing and post-processing storage is essential to prevent growth of any STEC that may be present, since an increase in numbers will increase the risk of consumer illnesses. Time is only relevant if trying to maintain the pathogen below a threshold level.	**Canada**
Par.32. ~~Fresh~~ When appropriate, fresh leafy vegetables should be maintained at appropriate temperatures [i.e., 7°C or below] after cooling to minimize growth of any STEC that may be present. The temperature of the cold storage should be controlled, monitored and recorded. To be consisted with Section 5.2.2.4 of CXC53 and to ensure feasibility for small productions. Par. 33. …Measures to be undertaken in case of positive results for STEC (or when indicator ~~organisms~~ microorganisms reach a pre-defined threshold) need to be established and defined. Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).	**Japan**
Par. 33 Indicator microorganisms Add micro to organisms in the paragraph on two occasions Comment The quality of the water is not considered as part of this annex, does it require a qualifier ie clean, potable or fit for purpose water?	**New Zealand**
Par. 32.Fresh leafy vegetables should be maintained at appropriate ~~temperatures [i.e., 7°C or below]~~ temperatures after cooling to minimize growth of any STEC that may be present. The temperature of the cold storage should be controlled, monitored and recorded. We would like to propose the amendments: Rationale: The specification of the temperature at 7°C or below is not appropriate for fresh leafy vegetable from tropical area since the specified temperature may lead to chilling injury for vegetables such as basil, coriander.	**Thailand**
Uruguay supports the new order, especially for this paragraph and its items. Item 5.1, Time and temperature control, does emphasize the importance of time and temperature control but does not define a benchmark in that regard. We suggest defining these benchmarks.	**Uruguay**
Par. 32.Fresh leafy vegetables should be maintained at appropriate temperatures ~~[~~ii.e., 7°C or ~~below]~~ below after cooling to minimize growth of any STEC that may be present. The temperature of the cold storage should be controlled, monitored and recorded. Rationale: The temperature is appropriate to prevent growth of STEC.	**USA**
11. RETAIL AND FOODSERVICE	
Keeping section 11 retail and foodservice is acceptable.	**Canada**
Section 11 retail and food service and flow charts addressed that food business operators serving fresh leafy vegetables for consumption without cooking to consumers should take appropriate measures to prevent cross-contamination, maintain appropriate storage temperature, and ensure proper cleaning of tools and surfaces that may come in contact with these products. However, Egypt recommends to give some examples of these measures	**Egypt**
Par 43 (Section 11) Retail and food service: the EUMS prefer to keep the section.	**European Union**

Par. 43.No mention is observed about cleaning of the vegetable itself. Addition of one bullet about cleaning and disinfection of fresh leafy vegetables by clean water or approved disinfectants is recommended.	**Iran**
We would like to propose inclusion of the detail related to retail and food service in Section 5 Control of Operation with sub-section providing control measure specifically for retail and food services. Rationale: This is to be in line with the structure of the General Principles of Food Hygiene (CXC 1-1969) and Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003). Par. 43.Fresh leafy vegetables (intact and pre-cut) should be held at a temperature that prevents growth of ~~STEC [i.e., 7°C or below].~~ STEC Cross-contamination from or to other food items should be prevented. … We would like to propose the amendments Rationale: The specification of the temperature at 7°C or below is not appropriate for fresh leafy vegetable from tropical area since the specified temperature may lead to chilling injury for vegetables such as basil, coriander.	**Thailand**
Par. 43.Fresh leafy vegetables (intact and pre-cut) should be held at a temperature that prevents growth of STEC ~~[~~i.e., 7°C or ~~below]~~below. Cross-contamination from or to other food items should be prevented. Food business operators serving fresh leafy vegetables for consumption without cooking to consumers should take appropriate measures to Rationale: The temperature is appropriate to prevent growth of STEC.	**USA**
12. CONSUMER	
Figure1: Fresh Leafy Vegetables Flow Diagram[14] Canada supports keeping the flow diagram.	**Canada**
Figure1: Fresh Leafy Vegetables Flow Diagram[14] Figure 1 Flow diagram: Consistently with other Annexes/guidelines, the EUMS consider the flow diagram useful and prefer to keep it.	**European Union**
Figure1: Fresh Leafy Vegetables Flow Diagram[14] Indicate/ Highlight the sections where contamination occurs (mild, moderate and heavy) and also sections to show where the sampling has to be made by color coding or any other means as appropriate. Rationale: For more clarity.	**India**
Figure1: Fresh Leafy Vegetables Flow Diagram[14] Japan supports the flow diagram should be retained with modification as below. (1) “Soil preparation” should be added before “Planting” since this step is relevant to control of pathogenic microorganisms and it is referred on JEMRA report MRA37. (2) Irrigation, Fertilizing and Other chemical Applications don’t flow one direction and therefore these are contained in a box named “Growing” like the below. ～～～ Growing May include:	**Japan**

・Irrigation ・Fertilizing ・Other chemical applications ～～～	
Figure1: Fresh Leafy Vegetables Flow Diagram[14] New footnote: **Figure 1 provides a flow diagram illustrating a generalised process flow for fresh leafy vegetables. This flow diagram is for illustrative purposes only. Steps may not occur in all operations (as shown with dotted lines) and may not occur in the order presented in the flow diagram.** Can the diagram include a footnote replicating the explanatory test in paragraph 3, so it can be used in isolation from the rest of the text. Suggest including a reference to sowing of seeds if this is different to planting ie placing of a plant in the growing substrate. Suggest replacing 'cold storing' with pack house or manufacturing as cold storage is a subset of the activities that occur here. It's unclear why there are 2 boxes (for processing and fresh market) at the harvest step, as the different activities are similar.	**New Zealand**
Figure1: Fresh Leafy Vegetables Flow Diagram[14] The Republic of Korea supports keeping the flow diagram in the annex as the overall process of the work can be seen at a glance and the it is easy to recognize the steps for safety management.	**Republic of Korea**
Figure1: Fresh Leafy Vegetables Flow Diagram[14] We propose to delete the Flow Diagram since the practices during primary production are varied depending on practices in different countries. Also, the proposed detail in various Sections and the flow diagram are not related. By following the structure of CXC 53-2003, there is no need for the Flow Diagram.	**Thailand**
Figure1: Fresh Leafy Vegetables Flow Diagram[14] Uruguay believes this Flow Diagram should remain in this Annex.	**Uruguay**
Figure1: Fresh Leafy Vegetables Flow Diagram[14] If the figure is kept, we recommend including as a footnote the caveat that is included in paragraph 3 of the introduction (i.e., that "the flow diagram illustrates a generalized process flow, with steps that may not occur in all operations, and may not occur in the same order").	**USA**
Figure1: Fresh Leafy Vegetables Flow Diagram[14] For washing, IFT recommends clarifying with "washing with an antimicrobial agent" IFT recommends adding to the Food Service section "washing with an antimicrobial agent"	**IFT**
ANNEX 3. RAW MILK AND RAW MILK CHEESES	
GENERAL COMMENTS	

We do not object the addition of 'Scientific knowledge' during the standard elaboration process. However, after the scientific detail is validated and reviewed by JEMRA, the recommended good hygiene practices should only be remained in the Draft annex so that it is consistent with the existing Codex standards.	**Thailand**
Uruguay considers the current format of this annex to be adequate for this step.	**Uruguay**
There was an error in the flow diagram (Figure 2) where a box labeled "Receive raw milk" should have been labeled "Set raw milk;" an updated version has been provided to the Secretariat. Par. 2 Raw milk and raw milk cheeses have been associated with foodborne infections ~~associated with~~ caused by Shiga toxin-…	**USA**
Concerning the format of Annex 3 on Raw Milk and Raw Milk Cheeses, it is important to recognize that the level of knowledge, food matrix and control measures all impact the control of STEC so while the structure of each annex should be the same, the content and control measures can be different. Mentioning technical and scientific knowledge before to present control measures allows a better understanding and acceptance of the measures by operators. We suggest keeping this structure for this annex	**IDF/FIL**
1. INTRODUCTION	
Although most milk for drinking is pasteurized or sterilized ~~UHT milk,~~ by ultra-high temperature (UHT) processing raw milk products are consumed in many countries. Raw milk cheeses are fermented products made from raw milk that are consumed in a variety of countries around the world. Cheeses are produced by both large manufacturers and small factories such as farm cheese producers, artisanal cheese producers or industrial cheese makers. Specific combinations of ingredients and technologies are used by manufacturers to obtain a wide variety of cheeses with desired characteristics and meet consumer expectations.	**Canada**
Concerning the format of Annex 3 on Raw Milk and Raw Milk Cheeses, it is important to recognize that the level of knowledge, food matrix and control measures all impact the control of STEC so while the structure of each annex should be the same, the content and control measures can be different. Mentioning technical and scientific knowledge before to present control measures allows a better understanding and acceptance of the measures by operators. We suggest keeping this structure for this annex. Par. 1 Although most milk for drinking is pasteurized or ~~sterilized~~ UHT milk, raw milk products … artisanal cheese producers or ~~industrial~~ large-scale cheese makers. Par. 2 … A comprehensive risk-based approach, considering all the aspects of raw milk and raw milk cheeses from production ~~and~~ to consumption, is necessary to reduce the presence of STEC in these products. Par. 4. … It is also important to emphasize that this document is intended for use by a variety of operators utilizing diverse ~~farming and~~ milk ~~product processing systems~~production system and cheese technologies. Par. 5. … Consequently, it will be up to competent authorities and to each operator (farmer and/or dairy) ~~and / or cheese industry~~ to define appropriate risk-based monitoring and control measures, considering relevant scientific and technical information.	**IDF/FIL**
2. OBJECTIVE	
Par. 6. The objective of this annex is to provide science-based guidance for the risk-based control of STEC related to raw drinking milk and raw milk cheeses. This guidance focuses on control of STEC during raw milk production (cows, buffaloes, goats and sheep), raw milk cheese making, storage, distribution and ~~consumer use of these products~~consumption.	**IDF/FIL**

3. SCOPE AND DEFINITIONS	
Par 8, last bullets Definitions: the EUMS propose to move the definitions of validation, monitoring and verifications to the general part as they are used in all annexes.	**European Union**
Par. 8 Raw milk - ….which has not been heated beyond 40ºC or undergone any treatment that has an equivalent effect.[16] This definition excludes processing techniques used for microbiological control (e.g. heat treatment above 40 °C, as well as microfiltration and bactofugation, which lead to a decrease in the microbiota equivalent which has not been heated beyond 40ºC or undergone any treatment that has an equivalent effect.[16] This definition **includes** processing techniques used for microbiological control (e.g. heat treatment above 40 °C, as well as microfiltration and bactofugation, which lead to a decrease in the microbiota equivalent The definition lists treatments that CANNOT be applied, which INCLUDES techniques used for microbiological control Par. 8 Footnote 18 There is no reference provided for footnote 18 at the end of the bullet points on monitoring and verification	**New Zealand**
Paragraph 8; Validation Monitoring Verification Uruguay believes these definitions should be in the general document.	**Uruguay**
Par. 8 Raw milk –Milk (as defined in *Codex General Standard for the Use of Dairy Terms* (CXS 206-1999)) that is intended for direct consumption or a primary input for dairy products and which has not been heated beyond 40ºC or undergone any treatment that has an equivalent effect.[16] This definition excludes processing techniques used for microbiological control (e.g. heat treatment above 40 °C, ~~as well as~~ microfiltration and bactofugation~~, which lead to a decrease in the microbiota equivalent to heating.)~~ .) Rationale: see Rationale in the General Section	**USA**
4. PRIMARY PRODUCTION-TO-CONSUMPTION APPROACH TO CONTROL MEASURES	
Paragraph 9: Include Figures 1 and 2. Or indicate the page number where it is located.	**Colombia**
5. PRIMARY PRODUCTION – MILK PRODUCTION AT DAIRY FARM	
Par. 12.… In addition, the introduction of ~~newly purchased~~ new animals ~~may be~~ to a ~~relevant introduction of a new~~ herd may introduce STEC ~~source~~ (Sanderson et al. 2006; Ellis-Iversen et al. 2008). Environmental transmission has also been demonstrated due to poor housing conditions or to ~~a long~~ the survival period of STEC (potentially more than a year) in effluent and the environment (soil, plants, crops, grain and water) (Jang et al., 2017; Nyberg et al., 2019; Haymaker et al., 2019). Pastures can also maintain bacterial circulation by ~~direct~~ faeces deposited onto the ground and/or spreading of effluent (Fremaux et al., 2008; Jang et al., 2017; Nyberg et al., 2019). ~~Risks for~~ Factors affecting STEC contamination on farm are varied and include ~~many factors such as~~ animal health status… To improve the readability of the sentences. Par. 14.STEC excretion by dairy ruminants: Ruminants are the main reservoir of STEC. A review (Hussein and Sakuma, 2005) has indicated a wide range of estimates for the prevalence of ~~healthy carriage of~~ STEC carriage in healthy dairy cattle. …	**Canada**

To clarify the meaning. **STEC during ~~prepping animals~~ preparation ofanimals for milking, milking, and then transfer of milk to bulk containers/tanks.** Suggest using "preparation" instead of "prepping". “prepping” is a contraction and informal speech according to both the Collins and Merriam dictionaries. Suggest to use the term “preparation” in keeping with the general voice of Codex documents. ***Specific control measures during ~~prepping~~ the preparation of animals for milking, milking, and then transfer of milk to bulk containers/tanks*** Suggest using "preparation" instead of "prepping". “prepping” is a contraction and informal speech according to both the Collins and Merriam dictionaries. Suggest to use the term “preparation” in keeping with the general voice of Codex documents.	
Paragraph 21: We recommend mentioning disinfection.	**Colombia**
Par 12-15 Scientific knowledge: The EUMS consider that the inclusion of such section is not appropriate in these kind of guidelines. The scientific information should just be used as a basis for developing recommendations for control measures or briefly mentioned in the introduction. These paragraphs should therefore be deleted.	**European Union**
Par 16-17 Control measures for STEC at the dairy farm: The EUMS would like to have a clarification why control measures included in Annex I, 4.2 primary production, are not mentioned here (Diet ingredients, microbials, feed additives, vaccination, good management practices at primary production).	
Par. 15 The point raised in the last sentence needs to be reviewed or verified: while the contamination in the cow's milk is sporadic, we notice that there is more often presence of STEC in the milk of small ruminants, because the lack of cleaning of udder before milking. Par. 16 New bullet Ensure hygienic measures are consistently applied to the udder and teats of the animal prior to the milking Par. 20 Udders and teats ~~should~~ must be properly cleaned before the milking process to minimize the risk of contamination of milk with STEC. Par. 20 In the case of manual milking, in addition to udder and teats, the operator's hands ~~should~~ need to be properly cleaned. Par 22 If necessary, carry out an acid treatment based on the milking ~~machine, possibly following or during disinfecting~~ machine after thorough cleaning and rinsing prior to disinfection of the equipment (Trząskowska et al. 2018; Sabillon et al, 2020).	**IDF/FIL**
Par. 21 Under paragraph 21, IFT recommends that wording be added after (Wang et al., 2012) "particularly if cleaning is not done effectively prior to the application of a sanitizer or if a sanitizer is used at sub-lethal concentrations Par. 22 IFT suggests deleting this paragraph unless more appropriate references can be included as these are related to beans and wheat. Application of acids is normally done to remove mineral salts prior to disinfecting.	**IFT**

Japan proposes to remove « scientific knowledge » parts from this annex to align with other Annexes Par. 16 Control measures should be discussed in CCFH after JEMRA report on STEC in beef/milk is available.. Based on inputs from JEMRA, the potential measures supported by low degree of confidence should be deleted from this draft. (In the other words, control measures supported by high degree of confidence should be retained in this draft.) Therefore Japan proposes to ask FAO/WHO to publish the report as soon as possible. Par. 21 … If recycled water is used, it should be treated and maintained under conditions ensuring that its use does not impact the safety of the milk (CXC 57-2004). Well water regularly tested for ~~indicators~~ indicator microorganisms and/or STEC could also be used.	**Japan**
Par. 12 Other wildlife or livestock, pests, and birds can also carry STEC and thus contribute to their circulation in **milking herds**. To separate livestock mentioned at the beginning of the sentence from milked animals Par. 14 Faecal contamination of sheep and goat milks exist but is less likely than for cows, **because of anatomical differences and** as their faeces tend to be more solid and thus are less likely to easily cross-contaminate An important factor is that in goats and sheep their udder is not close to the anus like in cows	**New Zealand**
Par. 12.… Risks for STEC contamination on farm are varied and include many factors such as animal health status, animal age, stage of lactation, geography, climate, exposure to wildlife, ~~farm practices~~ and farm practices… Par. 13.Feed and drinking water: ~~Contamination of feed with STEC is unusual (Berry~~ Feed and ~~Wells, 2010). Nevertheless,~~ water (surface water, roofing water, contaminated drinking water) can contribute to introduction or circulation of STEC, following direct or indirect contamination (Schets et al., 2005; Lascowski et al., 2013; Saxena et al., 2015). Rationale: The original 2001 reference cited by the Berry and Wells review is considered questionable. Dodd C. et al (2020) reported a 14.9% positive rate in the tested cattle feed samples, which is consistent with one stakeholder's past observation from working in the 3rd party testing industry. It is especially true for silage Reference: Dodd C. et al. (2020) Prevalence of Escherichia coli O157 in Cattle Feeds in Midwestern Feedlots. doi: 10.1128/AEM.69.9.5243-5247.2003 Par. 17 The presence of~~As previously noted, contamination of feed with~~ STEC ~~is uncommon. The presence~~ in feed can be minimized by application … Rationale: For consistency with the modification in paragraph 13. Par. 18 … This in turn soils the teats, and consequently the milk can be subsequently contaminated during the milking process. Therefore, limiting faecal contamination during milking is ~~a major~~ of key importance to manage STEC on the farm (Farrokh *et al*., 2013). Par. 19 The implementation of control measures aims primarily at avoiding contamination of the raw milk with STEC during milking and storage on the farm. For this it is important to apply good hygiene practices during milking, to keep animals clean, and most importantly, to ~~reduce cross-contamination~~ prevent contamination with faeces. Rationale: To emphasize the importance of preventing the most important source of STEC in raw milk (faeces). Par. 21… Studies have shown biofilm formation by O157:H7 STEC and non-O157 ~~strains~~ STEC with increased tolerance to sanitizers commonly used in the food processing environment (Wang *et al.,* 2012). … Rationale: Clarify that this refers to non-O157 STEC and not strains of other bacteria.	**USA**

6. CONTROLS DURING MILK COLLECTION, STORAGE AND TRANSPORTATION	
Paragraph 23: We suggest the following wording: If raw milk is processed immediately after milking, cooling is not necessary.	**Colombia**
Par. 24 Although not a standard practice, a full tanker **clean** once per 24 h, with the use of a between-load water rinse Amended to provide clarity Par. 25 Temperatures over **7°C**…. The temperature referenced elsewhere in the document is 7°C; should this be changed for consistency?	**New Zealand**
Par. 25.… Temperatures ~~≥~~ ≤ 6°C, extended storage of raw milk, and initial bacterial counts in raw milk during collection, storage and transportation have been associated with increased counts of *E. coli* in raw milk ... Sign to be corrected	**IDF/FIL**
Par. 25 …Temperatures ≥ 6°C, extended storage of raw milk, ~~and initial bacterial counts~~ in raw milk during collection, storage and transportation have been associated with increased counts of *E. coli* in raw milk. In contrast, deep cooling (2°C) significantly extended the storage life for quality… "High initial bacterial counts" is preferred.	**Iran**
Par.25. STEC can rapidly ~~multiply~~ replicate in raw milk if the milk is ~~at~~ above 7°C, the minimum temperature of STEC growth (Wang et al., 1997), so temperature control of the milk post-harvest is ~~crucial. Milk should be maintained cold~~ crucial including during its storage in the farm and throughout the collection route to prevent microbial growth (Wang et al~~.~~., 1997, Kim et al., 2014). ~~2014) to prevent microbial growth.~~ Temperatures ≥ 6°C, extended storage of raw milk, and initial bacterial counts in raw milk during collection, storage and transportation have been associated with increased counts of *E. coli* in raw milk. In contrast, ~~deep~~ cooling ~~(2°C)~~ to 2°C significantly extended the storage ~~life for quality~~life. Milk temperature should be monitored during storage and checked before it is unloaded, when possible. Suggestions to have wording similar to the other annexes and to improve readability.	**Canada**
7. CONTROL DURING PROCESSING	
Par. 30 What does "drying" mean in cheese making?!! Does it refer to separation of whey from curd? It is suggested to change it. Drying is not appropriate word here.	**Iran**
Section 7 Control during processing - References Seven references to Miszczycha et al, 2013 in Section 7 Miszczycha et al (2013) Behavior of Different Shiga Toxin-Producing Escherichia coli Serotypes in Various Experimentally Contaminated Raw-Milk Cheeses, AEM, 79(1), p.150-158 Not included in the Reference list Par. 27 Raw milk cheeses are made from raw milk by coagulating **the casein protein in milk and then separating the milk into solid curds and liquid whey. The liquid whey is drained away, and the curds are salted, shaped and left to ripen in a controlled environment.** ~~Then,~~	**New Zealand**

Different processing techniques can be applied to give the end-products. This results in very different cheese types, including ripened or unripened soft, semi-hard, hard, or extra-hard product, which may be coated or uncoated, blue-type cheeses, lactic cheeses, and white mould cheeses. Should include major steps that are common for all types of raw milk cheeses Cooked cheeses are, by the definition, not raw milk cheeses. Including hard, extra hard cheeses in the range has already covered presence of curd cooking during the cheesemaking for these cheeses Par. 30 During the ripening step, the microbial stability of cheeses is determined by the combined application of different hurdle factors (low pH, aw values, NaCl, non-dissociated lactic acid, starter cultures (such as lactic acid bacteria, *Penicillium* mould)). Consequently, the quality of raw milk used in cheese making is crucial to reduce the risk associated with the end products During the ripening step, the microbial stability of cheeses is determined by the combined application of different hurdle factors (low pH, aw values, NaCl, non-dissociated lactic acid, ~~starter~~ cultures (such as lactic acid bacteria, *Penicillium* mould)). Consequently, the microbiological quality of raw milk used in cheese making is crucial for reduction of the risk associated with the end products Starter cultures are applied during acidification, not at the ripening step There is a range of raw milk qualities that are very important for raw milk quality, but are not critical for its safety	
Par. 27. Raw milk cheeses are made from raw milk coagulating through the action of rennet or other suitable coagulating agents, and by partially draining the whey resulting from the coagulation, while adhering to the principle that cheese-making results in a concentration of milk protein. ~~Then~~Following this step, different processing techniques ~~can be~~ are applied to ~~give~~ generate the end-products. …	**USA**
Par. 28 … During the first hours of cheese-making (transition from milk to curd), an increase in STEC level by 1-3 log can be observed for some ~~cheese-making~~ cheese technologies. This increase in number is due to the multiplication of the cells in the liquid milk and then in the curd where cells are entrapped (Miszczycha et al., 2013; Peláez et al., 2019). Par. 30 … These hurdles ~~make the cheese become~~ create an increasingly challenging environment for STEC during the manufacturing process and ripening of aged cheeses (Montel et al., 2014)…. Par. 33.For example, testing ~~the~~ raw milk for the presence of STEC ~~can~~ is unlikely to be ~~established, as well as an audit program of milk suppliers~~ effective but needs to ~~assess their hygienic practices~~be utilized in combination with other control measures starting at the farm and continuing through to the consumer.	**IDF/FIL**
9. VALIDATION, MONITORING AND VERIFICATION OF CONTROL MEASURES	
Par. 36 It is unclear what is meant by “food alerts”. Suggest clarification or rewording this sentence. Par. 42**.** **Milk collection to the dairy establishment:** Routine surveillance of the quality of the raw milk received by the dairy establishment (indicators or/and STEC) can be based on samples collected periodically ~~regularly~~ or even for each load... Removal of a repetitive word.	**Canada**

Figure 1. Process Flow Diagram for Raw milk The structure and format of the annexes, in particular Annex 3 on Raw Milk and Raw Milk Cheeses is suitable and Egypt have some questions in the flow diagram. Why cooling not mentioned in any of the steps? **Figure 2: Making Cheese from Raw Milk** Why in the fourth step repeating a sentence “receive raw milk”?	**Egypt**
Par. 36.Even if they are useful hygienic markers of the quality of raw milk, the presence or concentration of generic *E. coli* or other indicator organisms in raw milk does not indicate presence of STEC. More specific analyses are needed in cases such as food alerts. Periodic testing for ~~“high risk”[18]~~ STEC <u>virulence genes</u> may also be conducted for verification of hygienic practices (FAO/WHO, 2018). Par 36, last sentence E coli enumeration and STEC testing: The EUMS propose the following change, in particular because all STEC are pathogenic and can cause severe illness in particular in ready-to-eat raw milk (products). Periodic testing for virulence genes is beneficial for such food: “Periodic testing for STEC virulence genes may also be conducted for verification of hygienic practices (FAO/WHO, 2018).” Par. 51 Fig 1 and 2: flow diagrams: the box “milk”, should replaced by “raw milk”. **Figure 2: Making Cheese from Raw Milk** Fig 1 and 2: flow diagrams: the box “milk”, should replaced by “raw milk”.	**European Union**

36. Even if they are useful hygienic markers of the quality of raw milk, the presence or concentration of generic *E. coli* or other indicator organisms in raw milk does not ~~indicate~~ prove the presence of STEC. More specific analyses are needed ~~in cases such as food alerts~~to identify and confirm the presence of STEC. Periodic testing for "high risk"[18] STEC may also be conducted for verification of hygienic practices (FAO/WHO, 2018). Par. 37. Control measures should be validated before being ~~implemented~~implemented and reviewed regularly. To limit the cost of this important step, it can be shared by several FBOs and a professional ~~association~~ organisation which may gather, analyse and interpret data in order to establish alternative or improved measures, for example by writing GHP guidelines adapted to the local context or to the traditional steps of processing. Par. 40. Enhanced monitoring should be implemented when STEC strains have been detected in milk or in ~~cheeses~~cheeses and production and sale of the products should be ceased. ... Par. 41. General hygiene audits can be useful to check periodically that the GHPs are effectively implemented at each farm where the milk is collected. They might be conducted by the ~~dairy establishment~~ dairies or by a local professional association. Par. 42**….** Collection of filters from the milking machine at the time of milking, could constituted a sample library at the cheese factory for use in any possible investigation according to the results of the analyses of the cheeses, customer complaints, or during enhanced surveillance Par. 46. When STEC are ~~accidentally~~ present in raw milk, it has been found at very low levels in cheeses (Strachan et al., 2001; Buvens et al., 2011; Miszczycha et al., 2013; Gill and Oudit, 2015). … Par. 47. The FBO defines its sampling plan in line with its own acceptable sanitary quality level. Par. 48. Enhanced surveillance can be put in place when STEC are detected in curds or in cheeses ~~or in the case of~~ which is a public health risk. For example, STEC can be screened in greater detail in other batches of cheeses to assess the magnitude of contamination. In addition, it is important to identify the remaining contaminated milk, if any, and stop using it. **Figure 1. Process Flow Diagram for Raw ~~milk~~milk production, distribution and sale** This diagram doesn't apply in all cases, for example, those where sale is directly from the farm to the consumer. **Figure 2: Making Cheese from Raw Milk** Receive raw milk is down twice. The second mention should be clarified or deleted. The term "Room temperature storage" is incorrect in this flow diagram as the raw milk subject to cold storage is then warmed to between 30°C – 37°C so this block should state, "Warming Raw Milk (30°C – 37°C)	**IDF/FIL**
Par. 42 IFT would question whether the evaluation for STEC in this surveillance wold be practical since the microbial testing results would likely not be available for 24 hours, long past when a decision on the use of the milk would need to be made. **Figure 1. Process Flow Diagram for Raw milk** IFT recommends that in this section that a warning statement about the potential health hazards of consuming raw milk (or derived products) be added. **Figure 2: Making Cheese from Raw Milk** Again, IFT recommends that a warning on packaging be placed on the label regarding the potential health hazards of consuming raw milk derived products.	**IFT**

Figure 1. Process Flow Diagram for Raw milk Indicate/ Highlight the sections where contamination occurs (mild, moderate and heavy) and also sections to show where the sampling has to be made by color coding or any other means as appropriate. Rationale: For more clarity	**India**
Par. 35. Although STEC can be isolated from raw milk and raw milk cheeses, STEC testing is uncommon and most sampling and testing protocols target indicator ~~organisms~~ microorganisms such as *E. coli*, whose level can be used as an indicator microorganisms of raw milk quality prior to raw milk cheeses production. Microbiological criteria (refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Relating to Food* (CXG 21-1997)) based on process and hygiene ~~indicators~~ indicator microorganisms (*E. coli* / Enterobacteriaceae) may also prove a useful tool for validation, monitoring and verification of control measures. Par. 36. Even if they are useful hygienic markers of the quality of raw milk, the presence or concentration of generic *E. coli* or other indicator ~~organisms~~ microorganisms in raw milk does not indicate presence of STEC. More specific analyses are needed in cases such as food alerts. Periodic testing for "high risk"[18] STEC may also be conducted for verification of hygienic practices (FAO/WHO, 2018). Par. 39. **At the dairy farm:** Indicator ~~organism~~ microorganism testing for faecal contamination can be implemented periodically using ~~indicators~~ indicator microorganisms of hygiene in milk. For example, routine analysis of milk at the point of production for ~~microbial quality indicators~~ indicator microorganisms (*E. coli*, coliform levels or total aerobic plate counts) can provide information on the hygiene of the operation. Nevertheless, low levels of ~~microbial quality indicators~~ indicator microorganisms do not confirm the absence of STEC nor other pathogens. Par. 42**. Milk collection to the dairy establishment:** Routine surveillance of the quality of the raw milk received by the dairy establishment ~~(indicators~~ (indicator microorganisms or/and STEC) can be based on samples collected periodically ~~regularly~~ or even for each load. Sampling milk filters may be a more suitable monitoring point for STEC than raw milk from the bulk tank, considering dilution due to pooling and sporadic contamination issues. If it is not necessary the word "regularly"、the word should be deleted. Par. 49. The published year is different from "Perrin F. et al. (2015)" at Thirteenth reference from the top on page 50. It should be corrected to the correct year. Par. 51 Japan suggests to move this paragraph after paragraph 5. of 1. INTRODUCTION.	**Japan**
Par. 40 This criterion should be based on experience and statistical evaluation of the historical microbiological **results**. Statistics cannot be done on analyses Par. 42 Routine surveillance of the quality of the raw milk (indicator microorganisms or/and STEC), conducted by the dairy establishment, can be based on samples collected periodically ~~regularly~~ or even for each load. (indicator microorganisms or/and STEC) are related to the organisms, not to the dairy establishments. Reworded to improve clarity	**New Zealand**
Figure 1. Process Flow Diagram for Raw milk	**Uruguay**

Packaged/Bottled Raw Milk Processing Flow Diagram

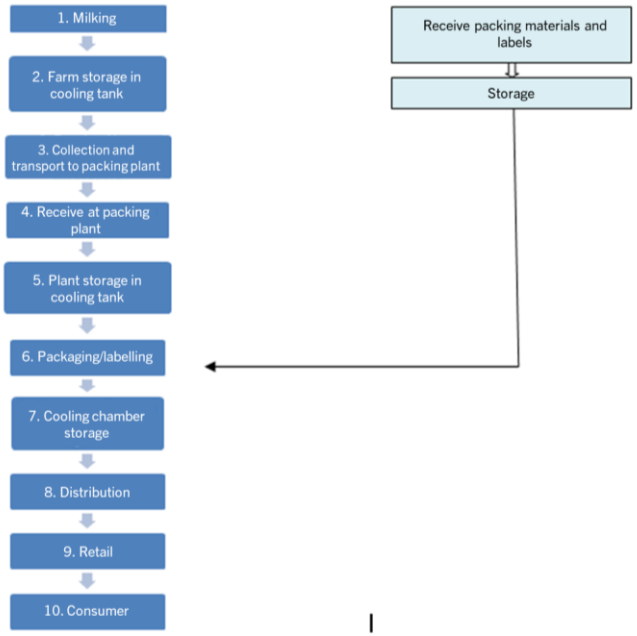
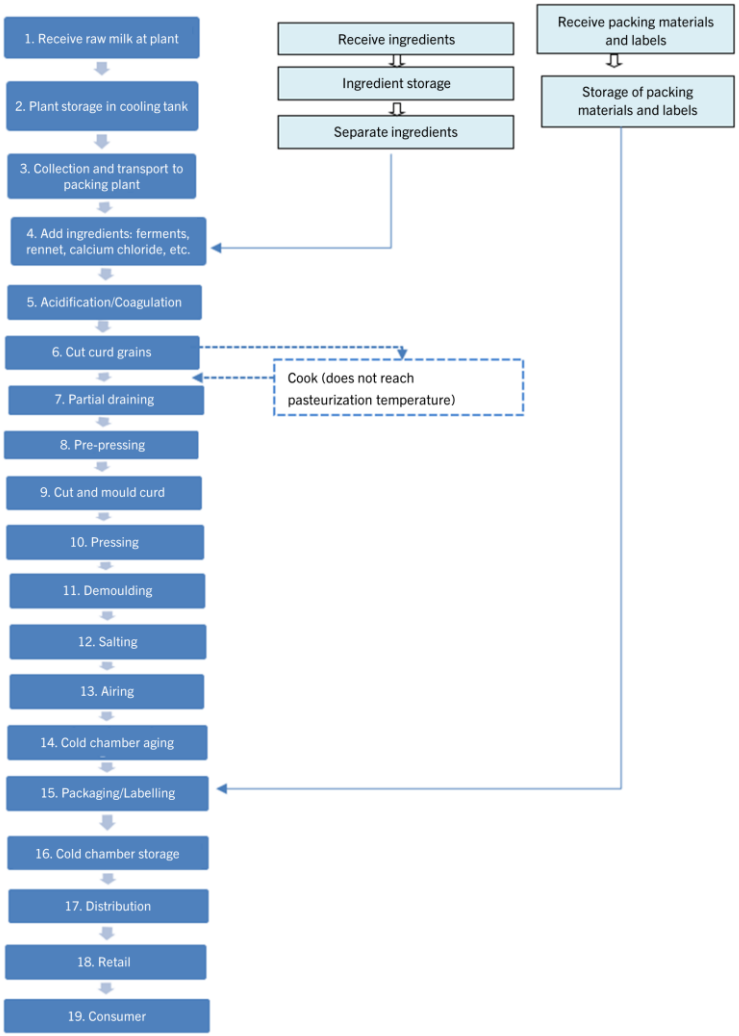


Figure 2. Making Cheese from Raw Milk



Par. 45. Sampling and testing of raw milk cheeses are an important part of verification plans, to confirm that practices and procedures described in the food safety program are successful. Accurate ~~quality~~ safety and ~~compositional~~ quality test results are crucial and depend on appropriate sampling and sample handling, the type of representative samples and proper methods…. Rationale: The relevance of compositional tests with STEC control is unclear; we have retained “quality” and included safety testing.	**USA**