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Proposed Draft Guidelines for the Control of Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef, Fresh Leafy Vegetables, Raw Milk and Raw Milk Cheeses, and Sprouts

(Comments of Brazil, European Union, India, Indonesia, Morocco, Philippines and Uruguay)

Brazil

General Section

Paragraph 2. Clinical symptoms of the disease in humans arise as a consequence of consuming food contaminated with *E. coli* that produces Shiga toxin type 1 (Stx1) (encoded by the gene *stx1*) and/or Shiga toxin type 2 (Stx2, encoded by the gene *stx2*). Historically, the term verotoxin has also been used for the Shiga toxins of *E. coli* and the term verotoxigenic *E. coli* (VTEC) used synonymously 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* and produce Stx. STEC are pathogenic to humans after ingestion and attachment to the intestinal epithelial cells where production of Stx occurs. Attachment to intestinal epithelial cells is the result of other proteins, including the principal adherence protein intimin, encoded by *eae*. The aggregative adherence fimbrial adhesins commonly associated with enteroaggregative *E. coli*, regulated by the *aggR* gene, when found in isolated strains with *stx*, have also been linked to severe illness and have been used as predictors of pathogenicity. (Table 1 shows combinations of virulence genes and their association with disease severity that can be used for risk management purposes.) There may be additional genes involved in pathogenicity that have not been identified yet. Some of these virulence genes are located on mobile genetic elements (e.g., plasmids, bacteriophages, pathogenicity islands) and can be horizontally transmitted to related microorganisms or be lost. Symptoms and their severity of the disease are determined by the variability in the virulence genes, among other factors such as gene expression, dose, host susceptibility, and age. Because STEC are primarily a genotype-based hazard, this has implications for hazard identification and characterization, which will be discussed in these Guidelines.

Rationale: Editorial

Raw beef Annex

Questions for CCFH53:

Do you think it relevant for the purpose of this document to add a “Post-Mortem inspection step” to this flow diagram between Splitting and Carcass Washing? Yes

Rationale: Since this step is subject to introduce hazards, then control measures may be necessary.

Paragraph 2. Grinding/mincing and mechanical tenderisation processes such as marinating, in combination with knife scoring, proteolytic enzymes, or vacuum brine injection, and mechanical tenderisation in which blades or needles penetrate the muscle surface, create a potential for increased food safety risks due to the transfer of pathogens from the surface to the interior, resulting in internalization of STEC into previously intact raw beef.

Rationale: We believe that the wording should be revised to emphasize that the greater risk is mechanical action through knives or needles, since it causes the penetration of STEC from the surface of the meat to its interior. It is important to harmonize with the scope of the document, as products marinated, subjected to proteolytic enzymes and vacuum brine injection are not included in the scope.

Paragraph 30. Good hygiene practices (GHP) and emphasis on good manufacturing practices (GMP) at

slaughter are necessary to prevent transfer of STEC from the hide and digestive tract to the carcass. Particular focus should be given to ensuring best practice in the operations of dehiding, head removal, clipping the weasand, bunging and evisceration, as these operations are the initial sources of microbiota that contaminate meat surfaces (Gill and Gill, 2010). Interventions during primary processing (slaughter and dressing) at the slaughterhouse include physical, chemical, or biological interventions that can be applied alone or in combination; these are likely to reduce the number of STEC microorganisms but should not be considered to eliminate STEC on every carcass.

Rationale: Brazil suggests changing the order of sentences. It is better to reverse the wording of the paragraph, starting with the emphasis given to good hygienic practices (GHP) instead of using of physical, chemical, or biological interventions. GHPs alone may be sufficient to manage the hazards.

Paragraph 32. Determining the effectiveness of interventions to reduce microbial pathogens is complex, particularly as multiple interventions may be applied simultaneously or in sequence. Interventions aimed at removing STEC from the surface of beef carcasses should consider that tolerance to salt and acid has been observed in some STEC strains. The impact of interventions should be quantified by conducting experimental trials with surrogate microorganisms that have similar or greater resistance to individual treatments than STEC. Careful consideration is needed when determining suitable strains for validation of interventions, since surrogates may not necessarily be equivalent to wild-type strains isolated from raw beef.

Rationale: It would be better to reverse the order and place the first sentence after the general mention of the need to determine the effectiveness of interventions.

Paragraph 43. In slaughter, special attention should be paid to avoid a delay in tying the weasand to minimize contamination of neck meat with STEC.

Rationale: Move this paragraph to section 4.4.4. Specific control measures at rodding.

Paragraph 65. To prevent contamination of the carcass by employees during evisceration, techniques can include:

- The appropriate use of knives and equipment to prevent damage (i.e., puncturing) to the rumen and intestines.
- Using footbaths or separate footwear by employees on moving from evisceration lines to prevent contaminating other parts of the operation.
- Using trained and experienced individuals to perform the evisceration; this is particularly important at higher line speeds.

Rationale: Brazil requests clarification about the second bullet. Brazil thinks that it is very specific to the processing in which the employee walks on the platform where the viscera will be deposited, it does not occur in many countries. About the third bullet, Brazil thinks that adequate training is of fundamental importance in the production of meat. It is important recommendation for any stage of slaughter. Therefore, as “training” is included in the “Code of Hygienic Practice for meat”, it is not necessary to include it here.

4.5.3 Specific Control Measures at Carcass Washing/Treatment

Rationale: In general, Brazil thinks that it is not necessary to inform the logarithmic reductions of microorganisms obtained in each stage of treatment. With the logarithmic reduction expressed in the text, FBOs can be less careful about GHPs and prioritize the use of treatments to achieve a significant reduction in STEC counts.

Paragraph 72. Carcass washing with antimicrobial agents, such as organic acids (e.g., citric acid, lactic acid, acetic acid), oxidising agents (e.g., chlorine, peroxides, ozone) or other antimicrobial agents, in accordance with label directions, may be effective in reducing STEC. Such Some antimicrobial treatments may be applied with hot water to have a combined thermal impact. Factors determining the effectiveness of such treatments include the concentration of the agent, uniformity of surface coverage, the temperature of the solution, and the contact period. Individual STEC strains may vary in their sensitivity to such treatments. Organic acids alone can reduce but not completely eliminate STEC serotype O157:H7.

Rationale: Not all antimicrobials can be heated.

Paragraph 75. Rapid chilling minimizes the potential for bacterial growth; STEC can only replicate at temperatures of 7 °C and above. The potential for bacterial growth is also dependent upon the water activity at the carcass surface, and if water activity is low enough (less than a_w 0.95), a decline in bacterial numbers will occur. Thus, controlling the humidity of the chilling process can impact STEC levels on the carcass. Alternatively, spray chilling with antimicrobial agents may reduce STEC survival.

Rationale: Is the second sentence relevant? The decrease in water activity leads to a decrease in microbial growth. Is there evidence that this practice (rapid chilling) slows down the growth of STEC?

Paragraph 76. Manufacturers should also consider purchase specifications that require that incoming beef to be tenderised has been treated to eliminate or reduce STEC to an undetectable level or should apply such treatments prior to mechanical tenderization.

Paragraph 76 bis. Manufacturers should ensure that mechanical tenderizers and associated processing equipment are cleaned and disinfected on a regular basis to minimize the potential for translocating STEC from the exterior surface of the product to the interior and to minimize the potential for cross-contamination among lots of production.

Rationale: At first, Brazil suggests splitting it into two paragraphs. Leave the sentence about reception and quality control of incoming beef in the biggining. We think that this sentence must be changed, since treatment to reduce or eliminate STEC appears to be mandatory, before performing mechanical tenderization, either by the supplier or the manufacturer.

Paragraph 77. Antimicrobial washes, such as lactic acid, peroxyacetic acid and acidified sodium chlorite have been shown to reduce the concentration of *E. coli* serotype O157:H7 and other STEC on beef (i.e., carcasses, primal cuts, or other cuts) and could be used, when authorized by competent authorities, to minimize contamination of materials used to manufacture ground/minced beef.

Rationale: It is important since in many countries there is no authorization for antimicrobial washes.

Paragraph 78. To minimize STEC contamination and/or the spread contamination of ground/minced beef with STEC, measures may include, where appropriate:

- Storing products to prevent the growth of STEC. Multiplication of STEC is inhibited below 7°C, but low temperatures do not significantly reduce STEC. Establishments need to control STEC, using adequate time/temperature combinations.
- Cleaning equipment and the environment on a regular basis and ensuring employees follow good hygiene practices to avoid contamination.
- Specifying that all beef which will be used for grinding or already minced beef be ~~pretested and found negative~~ included in a monitoring program for specific strains of STEC, e.g., *E. coli* serotype O157:H7.
- Treating the outer surfaces of the meat with ~~organic acid sprays or other~~ approved treatments before grinding/mincing.
- Appropriately chilling raw meat during production to reduce possible multiplication of STEC if they are present.

Rationale: It is more feasible that all beef will be used for grinding/minced be included in a monitoring program prior its use. About fourth bullet, it is not necessary specify which chemicals treatments will be used.

Fresh Leafy Vegetables Annex

Questions for CCFH53:

In paragraph 2, we say that “There is no processing treatment applied that would eliminate or inactivate STEC, although contamination can be reduced by washing in water containing antimicrobials.” One comment asked about ozone treatments. Should we say that “...contamination can be reduced by treatments such as washing in water containing antimicrobials?” Yes

Is there something we should add about ozone based on information from JEMRA? No

The definition of Fresh Leafy Vegetables refers to those intended for consumption without cooking. However, there are processes other than cooking that can adequately reduce microbial pathogens. JEMRA has defined “fresh fruits and vegetables” as “Fruits and vegetables that are not processed in a manner that changes their physical properties. Cooked, canned, juiced, frozen, candied, dried, pickled, fermented, or otherwise preserved foods derived from fruits and vegetables were excluded from this definition and this report.” In this annex we only refer to “cooking,” but in the Code of Hygienic Practice for Fresh Fruits and Vegetables, Annex III “fresh leafy vegetables,” the scope refers to those “intended to be consumed without further microbiocidal steps” (terminology also used in the definition of ready-to-eat fresh fruits and vegetables). Do we need to consider other processes and say, “for consumption without any further microbiocidal steps” instead of “for consumption without cooking”?

Brazil suggests “for consumption raw” instead of “for consumption without cooking”.

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

Paragraph 33. Microbiological testing of fresh leafy vegetables and of water for primary production for

STEC is currently of limited use due to difficulty in detecting STEC because of low prevalence and low numbers of the organism in fresh leafy vegetables and in water. Testing of fresh leafy vegetables for indicator microorganisms, supplemented, where appropriate, by periodic testing for STEC strains considered to be a country's highest priority (e.g., those strains with virulence factors capable of causing severe illness or considered to cause significant illness in that country ~~country~~), can be a useful tool to evaluate and verify the safety of the product and the effectiveness of the control measures and to provide information about an environment, a process or even a specific product lot when sampling plans and testing methodology are properly designed and performed. Measures to be undertaken in case of positive results for STEC (or when indicator microorganisms reach a pre-defined threshold) need to be established and defined. Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997).

Rationale: Editorial

Raw milk and Raw milk cheeses Annex

Paragraph 1. Although most milk for drinking is either pasteurized or sterilized by ultra-high temperature (UHT) processing, raw drinking milk is consumed in many countries. [Consuming raw drinking milk without any control measures is associated with a higher risk of illness]. Raw milk cheeses are fermented products made from raw milk that are consumed in a variety of countries around the world. [Without any control measures, they are associated with a higher risk of foodborne illness than those cheeses made from milk subject to heating such as thermization²⁴ or pasteurization to reduce the risk from foodborne pathogens]. Cheeses are produced by both large manufacturers and small factories such as farm cheese producers, artisanal cheese producers or large-scale industry and cheese makers. Specific combinations of ingredients and cheese-making processes are used by manufacturers to obtain a wide variety of cheeses with desired characteristics that meet consumer expectations.

Rationale: Thermization and pasteurization are considered treatments with the same effectiveness. Is it true? Could CCFH provide reference that thermization reduce foodborne pathogens? Was thermization included in "Processing and post-processing control strategies for STEC in raw milk and raw milk cheese, at JEMRA document (MRA39)?"

Paragraph 35. Enhanced monitoring should be implemented when STEC strains have been detected in milk ~~or in cheeses~~ and production and sale of the products that have not undergone effective treatment should be ceased until the contamination issue has been resolved. In such situations input from technical experts or professional association guidance, as well as guidance from competent authorities, can help to identify the risk factors for milk contamination. Finally, a criterion should be defined for when to return to routine monitoring. This criterion should be based on experience and statistical evaluation of the history of microbiological analyses results.

Rationale: Delete the term "or in cheeses", as this step refers to the primary production of milk, on the farm. Brazil suggests that only the sale of products that have not undergone effective (heat) treatment to control microorganisms be ceased.

Sprouts Annex

Questions for CCFH 53:

- In paragraph 48 there are several chemical treatments mentioned. Since scientific references will be deleted in a later step of the document, should we include the concentrations that were shown in the referenced studies to achieve the log reduction (after JEMRA validation)?

No, some countries do not authorize chemical treatments. In addition, conditions of use, including concentration and application time, depend on the manufacturer's instructions.

- In paragraph 49 there are several physical treatments mentioned. Do you think it would be useful include examples (e.g., time and temperature) for each one of the treatments recommended (after JEMRA validation)?

No, time and temperature conditions depend on product and initial microbial load.

- Microgreens share characteristics with sprouts. They have the same initial process and steps, originate from similar seeds, and seed contamination will spread similarly. However, STEC outbreaks have not been associated with them to date. Should we include microgreens under the scope of this annex?

No, for microgreens should apply the annex of fresh leafy vegetables. The definition of sprouts proposed in this document does not include microgreens. Although the seed process is similar, this part of food is not eaten.

European Union

Mixed Competence

European Union Vote

In response to the request for comments, the European Union and its Member States (EUMS) would like to make the following comments.

I. General Comment

The EUMS would like to thank and congratulate Chili and the United States with the drafting of these guidelines.

As a general comment, the EUMS do not agree with the change from “high risk STEC” to “STEC considered to be a country’s highest priority” throughout the guidelines. Rationale: nowhere in scientific evidence, nor in the JEMRA report there is any evidence of a different geographic distribution of virulent factors. In addition, these guidelines are used in a global trade context and therefore national priorities are less relevant. The EUMS do recognise that the management measures may vary between different countries.

Also, the EUMS would prefer to use the word “microbiocide” instead of “antimicrobial”. Rationale: a more general term is more appropriate. In addition, ‘antimicrobials’ could be confused with ‘antibiotics’.

II. Reply to the questions/recommendations in the report

In respect to the raw beef Annex (Annex 1):

- The EUMS consider it relevant to add a “Post-mortem inspection step” (PMI). Rationale: appropriate to have a complete flow diagram and to be consistent with the inclusion of antemortem inspection. PMI may play a role in STEC control as illustrated in the EFSA opinion on meat inspection in cattle¹. Therefore additional guidelines should be added e.g. “Manual handling of meat, including use of palpation/incision techniques, during post mortem inspection does not contribute to the detection of the identified high-priority bovine meat-borne hazards; in fact, it may increase and spread these hazards by cross contamination. In addition, PMI is important to detect visual faecal contamination.”. Rationale: Cross-contamination should be avoided. Touching the carcasses with hands, tools or garments may cause cross-contamination. The need for routine palpations and incisions during post-mortem inspection should be weighed against the potential impact on cross-contamination with STEC through the application of these techniques. Another rationale is consistency with CXG 87-2016.
- The EUMS consider that an additional step should be included in the flow diagram, being “Carcass trimming” before or after splitting. Rationale: this is a step, very relevant for the control of STEC.

In respect to the fresh leafy vegetables Annex (Annex 2):

- The EUMS would like to make the following suggestion on the proposed sentence in paragraph 2: “... contamination can be reduced by treatments such as washing in water containing, **when considered appropriate, antimicrobials microbiocides.**” Rationale: washing may already reduce contamination. The addition of microbiocides is not always needed/appropriate and can furthermore generate antimicrobial resistance.
- As regards the definition of “fresh leafy greens”, the EUMS prefer the wording “intended to be consumed without further microbiocidal steps”. Rationale: consistency with the definition in the *Code of hygiene Practice for Fresh Fruits and Vegetables* and the JEMRA report, clearly indicating that cooking is not the only possibility to reduce the load of microbial pathogens.

In respect to the sprouts Annex (Annex 4):

- As regards paragraph 48, the EUMS prefer not to mention the concentrations. Rationale: information on effective concentrations and products may evolve over time. The information may therefore become misleading.
- As regards paragraph 49, the EUMS consider it useful to include a number of validated examples. Alternatively, a similar wording as in paragraph 48 could be used: “at combinations of time and

1 oul <https://www.efsa.europa.eu/en/efsajournal/pub/3266>

temperature that have been validated to reduce STEC in sprouts to an acceptable level.” Rationale: validated examples are useful information.

- As regards microgreens, the EUMS consider that they are covered by Annex II on fresh leafy vegetables

In respect to the recommendations: Pending on the discussion in the physical working group and at CCFH53, the EUMS will decide on a possible advancing in the Codex Step process. It should be noted that the comments of the EUMS are still substantial.

III. Specific comments

General part

Paragraph 1 last sentence

The EUMS propose the following change: “The burden of the disease ~~and the cost of control measures~~ are significant; STEC outbreaks...” Alternatively, the deleted wording can be moved to another paragraph. Rationale: This sentence describes the cost of illnesses and the impact on public health.

Paragraph 2 last sentence

The EUMS propose to delete the following (or the whole sentence): “... this has implications for hazard identification and characterisation, which will be discussed in these guidelines”. Rationale: it is unclear to which part of the guidelines the last part of the sentence refers to.

Paragraph 2-3

The EUMS propose that one of these paragraphs mentions that a substantial proportion of human STEC cases are derived from person to person infections or direct contact with animals (goats, calves etc.) although a minor contamination route. Rationale: additional relevant (background) information.

Paragraph 5 second sentence

The EUMS propose the following change: “...different approaches to control the various ~~serotypes~~ STEC ...” Rationale: pathogenicity and ability to cause severe illness is related to the genotypes and not so much the serotype, as also stated in several other paragraphs throughout the document.

Paragraph 13

“CXG 1-1969” must be replaced by “CXC 1-1969”. Rationale: editorial.

Paragraph 16 last wording (+ paragraphs 31, 55, 56 and paragraph 13 of the raw beef annex)

The EUMS propose to replace “food safety (control) systems” by “food hygiene systems”. Rationale: consistency with the wording in the *General Principles of Food Hygiene*.

Paragraph 18-28

The EUMS suggest adding a definition of “control measure”, being the same as in CXC 1-1969.

Paragraph 37

The paragraph seems to refer only to the incidence, number of animals, ... contaminated with STEC. Controls in the primary production phase should also aim at contributing to the reduction of the quantity of STEC, if contaminated. The paragraph should be revised to address this.

Paragraph 39

The EUMS propose the following change: “Control measures during distribution to ensure product is stored at an appropriate temperature to prevent growth of STEC ~~beyond a detectable level~~ and to minimize cross contamination by STEC are important.” Rationale: it is unclear what is meant by “beyond a detectable level”.

Paragraph 42

The EUMS propose to remove the sentence between bracket. Rationale: competent authorities sometimes specify targets for validation and the issue is better described in the following paragraph 43.

Paragraph 47

The EUMS propose the following change: “The competent authorities, working with the relevant food sector, **may lay down legal requirements and** may provide guidelines...”. Rationale: regulatory systems may include legal requirements.

Paragraph 50

The EUMS propose to refer to CXC 1-1969 at the end of this paragraph. Rational: refers to verification which is extensively explained in CXC 1-1969.

Paragraph 51 last but one sentence

The EUMS propose the following change: “Monitoring of hygiene indicator microorganisms can be supplemented by periodic testing for STEC ~~where appropriate~~, **in particular for those processes for with the correlation may be less evident (e.g. water, milk and dairy)** and as needed to make risk-based decisions.”. Rational: “where appropriate” is very vague and can in this case be replaced by more specific guidance and examples.

Paragraph 55 last sentence

The EUMS propose the following change: “Effective monitoring ~~includes verifying~~ **is essential to verify** the effectiveness of STEC control processes throughout the food chain”. Rationale: the rewording better reflect the purpose of the recommendation.

Paragraph 64 and 70

Duplication of the word “country” to be removed. Rationale: editorial.

Paragraph 65

See general comment on high risk STEC.

Paragraph 65 first sentence

The EUMS consider that, no matter how this is formulated (see general comment), it would be good to add **to a large extent**. Rationale: Table 1 contains several footnotes that indicate exceptions from the general association between virulence genes and seriousness of illness. This should be reflected in the text.

Paragraph 66 first sentence

The EUMS propose the following change: “The severity of STEC illness and the potential to cause diarrhoea, bloody diarrhoea and haemolytic uremic syndrome, hence the degree of public health relevance, can be defined **to a large extent** by the combination of virulence genes within an isolated strain of STEC”. Rationale: see remark on paragraph 65 first sentence.

Paragraph 67

The EUMS propose the following sentence at the end of this paragraph: **“Knowledge on virulence factors and their correlations is evolving and may result in an improved knowledge of their public health importance. New scientific evidence should therefore be monitored carefully.”** Rationale: research is ongoing and may result in further finetuning of the ranking as proposed by JEMRA.

Paragraph 69 last sentence

The EUMS propose the following change: “The isolation of STEC by immunomagnetic separation (IMS) or by traditional culture-based methods ~~is~~ **might be** essential to confirm presumptive PCR positive samples. Rationale: IMS is effective only for a few serotypes. The original sentence therefore is too sharp.

Paragraph 70

It might be useful to include examples of “factors other than the virulence genes” (second sentence) e.g. ready to eat food or not, cooking habits, susceptibility of the population.

In addition, the EUMS would like to replace the last two sentences (starting: “The priority of STEC strains ...”) by the following: **“Priority given to corrective actions should take into account the ranking of the risk level based on the STEC virulence genes. It is up to national authorities to decide for which level corrective actions are needed, starting at the highest level, and which ones.”** Rationale: the EUMS believe that the priority of STEC strains carrying specific virulence genes does not vary from country to country but should be in line with the JEMRA ranking in Table 1. The JEMRA report (MRA31) does not provide evidence of differences in STEC strains per country or regions and the testing strategy in that report (p32) results in the detection of the most relevant virulence genes in any case. The flexibility or variation for national authorities is on the decision for which level corrective actions are needed, starting at the highest levels.

Annex 1 Raw Beef

The EUMS insist on a clear differentiation when reference is made to washing with water only or to decontamination (washing with microbiocides). If both are possible recommendations it should read “washing

or decontamination”. Rational: clarity of the guidance.

In general, the EUMS do not agree with the change from “high risk STEC” to “STEC considered to be a country’s highest priority” throughout this Annex. Rational: nowhere in scientific evidence, nor in the JEMRA report there is any evidence of a geographic distribution of virulent factors.

Paragraph 4 first sentence

The EUMS propose the following change: “...allows STEC to spread between animals **and herds.**” Rational: live trade may be an important risk factor for STEC in cattle herds.

Paragraph 6

The EUMS propose to delete the first sentence. Rational: repetition of paragraph one. The footnote (18) on “non-intact raw beef products” should be moved to the Section on definitions as a new definition.

Paragraph 12

The EUMS propose the following change: “...therefore, **effective** control strategies based on preventing STEC infection of cattle or contamination of their environment ~~can would be difficult to implement in a reliable manner.~~” Rational: clarity and because the EUMS believe that implementation can be carried out in a reliable manner but without the wanted effect.

Paragraph 15

The EUMS propose the following change to the second sentence: “Grinding/mincing, for example, can be done at sites other than the slaughter or fabrication site **and carcass washing or decontamination is not performed in all countries or slaughterhouses**”. Rationale: The current wording implies that all the mentioned steps should be carried out, but maybe in another order. Carcass washing is not a necessary step nor is it considered to be an effective control measure in all countries. It may even facilitate a humid environment and an increased risk for the spread of STEC and other pathogens.

In addition, the EUMS propose to switch in the flow diagram “head removal/head washing” and “rodding/tying the weasand”. Rational: Rodding happens first in several countries, to prevent spillage from the weasand. This is reinforced in paragraphs 43 and 54.

Paragraph 18 first sentence

The EUMS propose the following change: “Many of these proposed pre-slaughter control methods have not been demonstrated to ~~reliably~~ **effectively** reduce the prevalence or the level of STEC shedding from cattle in a commercial setting.”. Rationale: improved wording.

Paragraph 22

On the use of seaweed *Ascophyllum nodosum* as a supplement for cattle feed: other control measures have been considered not to be reliable/effective. The EUMS therefore wonder if it is appropriate to recommend such a supplement in the control of STEC.

Paragraph 23

The EUMS consider that the paragraph on vaccination should include a conclusion: Is vaccination recommended or not? Are vaccines an effective control measure?

Paragraph 24

The EUMS propose the following change to the second dot of the 5th bullet: “Ensure water is **fit for purpose and** of a microbiological quality that minimises animal contamination and, if there is doubt, treat the water **ensuring that the water is both chemically and microbiologically safe.**” Rationale: treated water should be safe.

The EUMS also propose an additional bullet point: “**Hides may become heavily contaminated when animals are kept in slatted houses. Mitigation measures can include appropriate stocking density; with overcrowding animals may defaecate on each other, with understocking there may not be enough animals to keep the dung pushed through the slats. Other measures include clipping the tails and backs to prevent sweating and the avoidance of sudden changes of diet during the housing period.**” Rationale: additional relevant recommendation.

Paragraph 26

The EUMS propose the following change to first sentence of the 4th bullet: “Ensure animals are as clean as possible to **reduce the risk of** ~~decrease the opportunity for~~ pathogen **cross** contamination **from hides to** ~~onto~~ carcasses ~~or hides~~ during the slaughter and dressing processes.” Rationale: improved wording.

Paragraph 27, fourth bullet

The EUMS propose to further elaborate the bullet and clarify when visual inspection and controls need to be implemented. Rationale: improved guidance “when needed” by further clarification.

Paragraph 30

The EUMS propose the following changes: **“Good hygiene practices (GHP) and emphasis on good manufacturing practices (GMP) at slaughter are necessary to prevent transfer of STEC from the hide and digestive tract to the carcass. Particular focus should be given to ensuring best practice in the operations of dehiding, head removal, clipping the weasand, bunging and evisceration, as these operations are the initial sources of microbiota that contaminate meat surfaces (Gill and Gill, 2010). Other interventions during primary processing (slaughter and dressing) at the slaughterhouse may include physical, or chemical, or biological interventions that can be applied alone or in combination; these are likely to reduce the number of STEC microorganisms but should not be considered to eliminate STEC on every carcass. Good hygiene practices (GHP) and emphasis on good manufacturing practices (GMP) at slaughter are necessary to prevent transfer of STEC from the hide and digestive tract to the carcass. Particular focus should be given to ensuring best practice in the operations of dehiding, head removal, clipping the weasand, bunging and evisceration, as these operations are the initial sources of microbiota that contaminate meat surfaces (Gill and Gill, 2010).”** Rationale: important to mention strict hygienic measures in the first sentence, because GHP is fundamental. The choice of additional interventions should be based on the efficiency of GHP to reduce pathogens on the surface. Also, not all countries use chemical interventions. Additionally, what is meant by biological interventions? Finally, “Primary processing” might be confused with “primary production”, the sentence is clearer without these wordings.

Paragraph 32, second part

The EUMS wonder if it is realistic to include recommendations on experimental trials with surrogate microorganisms in these guidelines addressed to food business and competent authorities. Rationale: it seems to belong rather to research activities and difficult to implement in businesses as a kind of validation method.

Paragraph 34

The EUMS proposes to add the following at the end: “... but needs proper adjustment **and supervision** (Signorini et al., 2018).” Rationale: need to add supervision in order to make regular adjustments according to the size of the animals.

Paragraph 36

The EUMS proposes the following change to the first sentence: “In this stage the condition of the animals should be evaluated; animals should be as **dry as possible and as** clean as possible to minimize the initial load ~~count~~ of microorganisms, which potentially includes STEC, on their hide.” Rationale: word not needed.

Paragraph 37

The EUMS proposes to add the following at the end: **“A dry bedding area is preferable where possible. The use of straw-bedded pens may be considered. Waiting time at the lairage should be limited.”** Rationale: additional relevant recommendations.

Paragraph 38

The EUMS consider it unclear what is exactly recommended in this paragraph.

Paragraph 40

The EUMS suggest reconsidering the usefulness this paragraph. Rationale: effective measure? In paragraph 38 washing is not considered as very effective.

Paragraph 41

The EUMS propose the following change: “The stunning box and sticking table should be kept as clean as possible **and fecal material should be removed** to avoid contamination of the animal's hide in the fall after the stunning process.” Rationale: additional relevant recommendation.

Paragraph 44

The EUMS propose the following change: “Sticking and bleeding should be done in a manner to reduce transfer of hide contamination to the carcass. **This includes cleaning and disinfection of knives.** Preparing the penetration or cut sites (e.g., with steam/vacuum treatment **or a mechanical process like scraping the hide surface**) can reduce the likelihood of contamination.” Rationale: the importance of clean and disinfected knives should be added and not all slaughterhouses have a steam/vacuum equipment, so an alternative method should be mentioned.

Paragraph 47

The EUMS propose to delete this paragraph. Rationale: If the evidence in reducing the transfer of STEC from hide to carcass is low, this measure should not be recommended, in particular since it may even add to the spread and growth of pathogens. Removal of excess liquid is not easy.

Paragraph 48

The EUMS propose to delete the last sentence. Rationale: It is not a recommendation and the fact that they are frequently used does not mean that hide-on carcass washes are effective.

Paragraph 50

The EUMS propose to delete this paragraph or further elaborate into more clear recommendations. Rationale: this recommendation is very vague and does not indicate how the number of workers and rotation needs to be considered or which procedures to use to prevent cross-contamination.

Paragraph 54, second bullet

The EUMS proposes the following change: "Using ties, **plugs**, clips, or bungs to close the weasand hygienically to prevent rumen spillage". Rationale: this is also used.

Paragraph 56

The EUMS agree with the paragraph, but the last sentence seems to be a general statement and not only for "specific control measures at dehiding". It could be moved to introduction.

Paragraph 64 last bullet

The EUMS proposes to add at the end: "if still present". Alternatively, the recommendation should be inserted elsewhere. Rationale: This paragraph is on evisceration and according to the flow diagram the head may already have been removed at this stage.

Paragraph 64

The EUMS proposes to add another bullet reading: "using belly spreaders". Rationale: Additional relevant and useful recommendation.

Section 4.5.2 Title

The EUMS propose to amend the title as follows: "Specific Control Measures at Carcass Splitting **and Trimming**" Rationale: The section is more on trimming (being most relevant for STEC control) than on splitting.

Paragraph 69

The EUMS proposes the following change: "Targeted removal of visible contamination on carcasses by trimming may be applied to carcasses, **by avoiding** ~~but the disadvantage of trimming is potential cross-contamination from dirty knives (if not using knife-switching disinfection protocol in-between cuts),~~ **and ensuring no contact** with aprons mesh gloves, and waste ..." Rationale: improved wording.

Paragraph 71

It is unclear if this paragraph refers to washing with potable water only, or with microbiocides. This should be clarified. In addition, the EUMS propose to add the following sentence at the end: "**However, abusive washing of carcasses can lead to splashing and spread of contamination.**" Rationale: Important to highlight this risk.

Section 4.5.3

The EUMS propose the following additional paragraph relevant for the whole section: "**The effectiveness of carcass washing with microbiocides depends on concentration, temperature, application and the end result also depends on the initial load of STEC on the carcass. For carcass washing, pasteurization and steam vacuuming a validation should be carried out to ensure the efficiency (and cost effectiveness) at the specific slaughterhouse. Steam vacuum is hand held (at least some places) and the training of the operator is crucial.**" Rationale: Need for additional information.

Paragraph 76 last sentence

The EUMS proposes the following change: "Manufacturers should also consider purchase specifications that require that incoming beef to be tenderised **has an undetectable level of STEC** ~~has been treated to eliminate or reduce STEC to an undetectable level or should apply such treatments prior to mechanical tenderization.~~" Rationale: How to achieve a low/undetectable level of STEC is up to the FBO and should be carried out according to legal provisions which is up the CA.

Paragraph 78 second and fourth bullet

The EUMS proposes the following change: “

- Cleaning **and disinfection of** equipment and the environment on a regular basis and ensuring employees follow good hygiene practices to avoid contamination.
- treating the outer surfaces of the meat with organic acid sprays or other approved **and validated** treatments before grinding/mincing.”

Rationale: important to add disinfection and validation.

Paragraph 80

It is not very clear what is recommended. Is it to be aware of the dependency of the effect and final outcome on various factors?

Paragraph 82-83

The EUMS proposes to add another recommendation/paragraph: “**Raw beef should be stored and prepared separately from cooked or ready to eat food to prevent cross-contamination.**” Rationale: Additional relevant recommendation at retail.

Title 6

The EUMS propose the following change: “Monitoring of Control measures **by FBOs**”. Rationale: paragraphs under this title are exclusively addressed to FBOs. That should be made clear.

Paragraph 91

The EUMS proposes to delete this paragraph. Rationale: This is a verification operation and already said in the following paragraph.

Annex 2 Fresh Leafy Greens

Paragraph 2, last but one sentence

The EUMS propose the following change “... although contamination can be reduced by washing in water, **when considered appropriate** containing antimicrobials ~~microbiocides~~.” Rationale: washing may already reduce contamination. The addition of microbiocides may is not always needed/appropriate and can furthermore generate antimicrobial resistance.

Sections 3.1.1 and 3.1.2

These sections seem to be on the same issue: presence of animals near or on the production side. There is therefore probably no need to split into two separate sections.

Paragraph 17bis

The EUMS propose an addition paragraph: “**The timing of the application of manure, biosolids and other natural fertilisers is important to reduce the risk of STEC contamination of fresh leafy vegetables. These organic materials should only be applied to fallow land followed by a suitable interval before planting and not during the growing period for fresh leafy vegetables.**” Rationale: The EUMS are of the opinion that an important safety consideration is missing in section 3.2.2. The timing of use of organic fertilisers can be important in protecting leafy vegetables from STEC contamination.

Annex 3 Raw Milk and Raw Milk Cheeses

Paragraph 1

The EUMS propose maintaining the two sentences between square brackets. Rationale: Both statements are epidemiologically valid and serve to highlight the risks putting the best practice guidelines into context.

Paragraph 6, first sentence

The EUMS propose the following change: “This guidance describes ~~the surveillance and~~ the good hygiene practices **and the monitoring** that can contribute....” Rationale: it is unclear what it meant by “surveillance”, a wording not further used in the text. It is assumed to refer to monitoring, included in Section 9.

Paragraphs 26

The wording “cooking” needs further clarification or needs to be defined. Rationale: very confusing wording

since the Annex is on raw milk cheese production, raw milk being defined as not heated beyond 40°C. In our understanding, “cooking of cheese curd” uses higher temperatures e.g. 46°C.

Paragraph 29-30

The EUMS in principle agree with the content. However, the paragraphs are quite contradictory, telling that STEC testing is uncommon (29) but stressing the lack of correlation and need for STEC testing (30). The paragraphs should be reworded. A solution could be to start by indicating the lack of a strong correlation between STEC and indicators, therefore underlining to monitor milk for STEC and indicators, until such monitoring has demonstrated the correlation and further monitoring can largely be on indicators.

Paragraph 46

It would be good to include examples of the application of HACCP principles in this specific production chain. Rationale: the paragraph refers to the need for a combination of control measures, including GHPs and HACCP. While numerous examples of GHPs are included in the guidelines, it seems that not a single recommendation is made as regards HACCP.

Figure 1

The EUMS propose the following changes in the flow diagram: “raw milk collection and **cold** transport” and “**cold** storage”. Rationale: to highlight that transport and storage should be cold + consistency with cheese flow diagram

Annex 4 Sprouts

Paragraph 19 second sentence

The EUMS propose the following change: “Where necessary, growers should test the water they use for appropriate indicator microorganisms ~~and, where necessary, STEC~~, according to the risk associated with the production.”

Section 4.1

The EUMS wonder if this section, perhaps except 4.1.6 could not be replaced by a simple reference to Section 3 of the Annex on fresh leafy green. Rationale: all control measures are similar.

Paragraph 37

The EUMS propose to replace “Avoid using contaminated or recycled bags” by “**Avoid using recycled bags if there is a possibility of prior contamination.**” Rationale: recycling of bags should not be avoided but done without creating a risk of contamination.

Paragraph 38

The EUMS propose to amend as follows “Mark each container to identify source...” Rationale: editorial.

Paragraph 42

The EUMS propose to add some examples: “**keeping the seed bags closed, correct stowage, keeping the bags separated from surfaces, clean and disinfected surfaces, storage place free of humidity. Once the bags have been opened, they should be closed again.**” Rationale: additional practical guidance.

Paragraph 52

The EUMS propose to replace the paragraph by: “**When seeds are soaked for up to 12 h to soften hulls and improve germination, potable water should be used.**” Rationale: the paragraph should be formulated as a recommendation and it is needed to specify that potable water should be used._

Paragraph 53

The EUMS propose to amend as follows: “Seeds may need to be rinsed after a seed treatment (e.g., seeds treated with chemicals). Time of rinse should be adequate to limit potential microbial growth **and the water used should be potable.**” Rationale: important to clarify that it should be potable water.

Paragraph 57

The EUMS propose to amend as follows: “Sprouts may be washed **in potable water** to remove hulls and/or to help lower the temperature of the sprouts and then spin-dried.” Rationale: important to clarify that it should be potable water.

Paragraph 66

The EUMS propose to add the following sentence at the end of the paragraph.

“The sensitivity of testing of a batch of seeds can be increased by carrying out by microbiological testing on a sprouted sample from a batch of seeds or on the first sprouts from a new batch of seeds”

Rationale: this is a scientifically documented more sensitive method for testing batches of seeds. See <https://www.efsa.europa.eu/en/efsajournal/pub/2424> .

India

Appendix-1, Para 12, Line no: 4

Sentence may be modified as:

“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, fresh leafy vegetables, raw milk **for drinking purpose** and raw milk cheeses, and sprouts”

Rationale

To keep the wording focused only on raw milk intended for drinking purpose and keep the processed milk out of the scope of this document.

Annex 2, Para 2, Line no 14 & 15

Sentence may be modified as:

“There is no processing treatment applied that would eliminate or inactivate STEC, although contamination can be reduced by washing in water containing **permitted disinfectants/ sanitizers.**”

Rationale

‘Antimicrobials’ are a broad term which includes pharmacologically active substances which may not be suitable for the said use. Using specific terms will be more appropriate.

Annex-3, Para 3, Line no:3

Sentence may include yak also as:

“STEC have also been isolated from the faeces of other species of animals, including buffaloes, goats, camels, sheep and **yak** that are commonly milked for human consumption.

Rationale

STEC has been isolated from the faeces of Yak as well.

(Bai, X., Zhao, A., Lan, R., Xin, Y., Xie, H., Meng, Q., Jin, D., Yu, B., Sun, H., Lu, S. and Xu, J., 2013. Shiga toxin-producing *Escherichia coli* in yaks (*Bosgrunniens*) from the Qinghai-Tibetan Plateau, China. *PLoS one*, 8(6), p.e65537.)

Annex-3, Para 3, Line no: 5

Sentence may be modified as:

“Detailed investigations have shown that without observance of appropriate cleaning and disinfecting steps and **good udder hygiene practices**, faecal matter can contaminate the cow’s teats and udders, which can increase the risk of microbial contamination of the milk during the milking process”.

Rationale

For better clarity and comprehension.

Annex-3, Para 7, Line no:24

Sentence may include yak also as:

“This guidance focuses on control of STEC during raw milk production (cows, buffaloes, goats, camels, sheep and **yak**), raw milk cheese making, storage, and distribution to consumers.

Rationale

Rahaman, H., Bhattacharya, D., Bera, A.K., Ahmed, F.A., Mahanti, A., Samanta, I., Mondal, D.K., Bandyopadhyay, S., Sarkar, S., Dutta, T.K. and Maiti, S., 2012. Characterization of shiga toxin producing (STEC) and enteropathogenic Escherichia coli (EPEC) in raw yak (*Capra hircus*) milk and milk products.

Annex-3, Para 12, Line no: 5

Sentence may be modified as:

“Excretion also varies among individual ~~cows~~ animals, with some individuals considered to be “high shedders” (a high-level excretion of STEC), and excretion levels may even differ between droppings of the same animal”.

Rationale

The objective of the annex should include other animals.

Annex-3, Para 12, Line no: 14

Sentence may be modified as:

“Keep litter and bedding as dry as possible and remove them when they become soiled with ~~excess~~ manure **to a level that increases the risk of contamination of milk**”

Rationale

For better clarity and comprehension.

Annex-3, Para 14, Line no: 6

Sentence may be modified as:

“keep young ~~cattle~~ animals in the same groups throughout rearing without introducing new animals”

Rationale

The objective of the annex should include other animals as well.

Annex-3, Para 15, Line no: 1

Sentence may be modified as:

“Environmental transmission has also been demonstrated due to poor housing conditions or to the survival ~~period~~ of STEC (potentially more than a year) in effluent and the environment (soil, plants, crops, grain and water).

Rationale

For better readability and comprehension.

Annex-3, Para 22, Line no: 3

Sentence may be modified as:

“ Temperatures $\geq 6^{\circ}\text{C}$, extended storage of raw milk, and high ~~initial~~ bacterial counts in raw milk during collection, storage and transportation have been associated with increased counts of *E. coli* in raw milk”

Rationale

Irrespective of the stages (collection, storage, transportation), high bacterial count will always be associated with increased counts of *E. coli*. Currently, the wording of the sentence may give impression that if the initial bacterial count is high during collection, only then associated with increased counts of *E. coli* in raw milk .

Annex-3, Para 25, Line no: 1

Sentence may be modified as:

“At the initial stages of cheese-making, the temperature (ranging from 27°C – 35°C), a_w value and nutrients of milk provide favorable conditions for the growth of STEC”

Rationale

For inclusion of missing information.

Annex-3, Para 34, Line no: 1

Sentence may be modified as:

“Testing potential contamination sources such as **water, feed, milk, and milking equipment** periodically for microorganisms that are indicators of faecal contamination or hygiene in milk can be implemented”

Rationale

It is not specified what is to be tested. Inclusion of **water, feed, milk, and milking equipment** will assist the FBO.

Annex-3, Para 35, Line no: 2

Sentence may be modified as:

“Enhanced monitoring should be implemented when STEC strains have been detected in **raw** milk or in **raw** milk cheeses and production and sale of **these** products should be ceased until the contamination issue has been resolved”.

Rationale

In case of presence of STEC in raw milk and raw cheese product, the production and sale of **only** these products should be ceased, until the contamination issue is resolved.

Ceasing production and sales of other products not using raw milk and using microbiocidal treatments and meeting regulatory requirements otherwise will result in financial loss to FBO.

Annex-4, Para 8, Scope

Microgreens shall not be included under the scope

Rationale

Sprouts and Microgreens differ as per their definitions given in the document.

Indonesia**General Comment**

In general, Indonesia agrees with the contents of this document and is of the view that the proposed draft guideline is ready to progress at Step 5. However, we provide specific comments on several sections for further consideration by the Committee.

Specific Comments:**2. OBJECTIVES Para 10**

Indonesia proposes to open the square bracket in para 10, so the para becomes:

These Guidelines provide information to governments and food business operators (FBOs) on the control of STEC that aims to reduce foodborne disease from raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts. They provide a {science-based and practical} tool for the effective control of STEC in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts according to national risk management decisions. The control measures that are selected can vary among countries and production systems

Rationale:

Indonesia is of the view that the science-based and practical tools are important things for the effective control of STEC in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts.

4. DEFINITIONS Para 26

Indonesia agrees with the definition of Sprouts in para 26 and proposes to open the square bracket.

26. {Sprouts: Sprouted seeds or beans harvested when the cotyledons (or seed leaves) are still un- or underdeveloped and true leaves have not begun to emerge. They can be grown in water, soil or substrate and can be harvested with or without the root (cut sprouts)⁷}

Rationale:

Indonesia is of the view that definition of sprouts needs to be included in this document, and the proposed definition is already in accordance with its definition in FAO/WHO Microbiological Risk Assessment document.

Morocco

Titre :

Position nationale 2 :

Le Maroc propose d'ajouter le terme « Générales » dans le titre de ces directives pour se lire :

Directives **Générales** pour la maîtrise des Escherichia coli producteurs de shigatoxines (STEC) dans la viande de bœuf crue, les légumes-feuilles frais, le lait cru et les fromages produits à partir de lait cru et les graines germées.

Argumentaire :

Ce document fournit des directives et des orientations **d'ordre général** pouvant être utilisées dans la prévention, la diminution ou l'éradication de la contamination par les STEC.

Section générale :

Position nationale 3 : la définition des graines germées

Le Maroc propose de supprimer les crochets et maintenir cette définition avec la suppression du terme « haricot » de la version française pour se lire comme suit :

« **Graines germées** : Germes récoltés lorsque les cotylédons (ou feuilles de germe) sont encore sous- ou non-développées et avant l'apparition de véritables feuilles. Ils peuvent pousser dans l'eau, la terre ou un substrat et peuvent être récoltés avec ou sans racines (graines germées coupées) »

Position nationale 4 : Paragraphe 32

Le Maroc propose d'ajouter **par l'autorité compétente** vers la fin de cette phrase : Les FBO (Food Business Operators) sont également en mesure de proposer des mesures de maîtrise fondées sur une évaluation des risques. Ces mesures de maîtrise doivent être validées.

Pour ce lire comme suit « Ces mesures de maîtrises mise en œuvre par les FBO doivent être validés **par l'autorité compétente** ».

Position nationale 5 : 10.3.2. Systèmes réglementaires (Paragraphe 48)

Le Maroc propose de **remplacer « peut » par « doit » dans le paragraphe** : « L'autorité compétente ~~peut~~ **doit** évaluer les systèmes de maîtrise des procédés documentés afin de vérifier leur fondement scientifique et établir des fréquences de vérification. Des programmes de tests microbiologiques, ou des programmes de tests moléculaires, doivent être établis en vue d'une vérification des mesures de maîtrise des STEC ».

Argumentaire :

Etant donné que le rôle principal de l'autorité compétente est de contrôler et de vérifier si les opérateurs respectent les exigences fixées.

Annexe sur Bœuf cru :

Position nationale 6 : Diagramme des opérations

Le diagramme des opérations est une représentation systématique de la séquence des étapes utilisées dans la production ou la fabrication d'un aliment.

L'inspection post mortem est une étape essentielle qui doit être intégrée entre la découpe et le lavage des carcasses et aussi c'est une étape réglementée par la plupart des pays.

Position nationale 7 : 4.4.5. Mesures de maîtrise spécifiques pour le bondonnage (Paragraphe 57)

⁷ FAO/WHO. 2022. Microbiological Risk Assessment Series 43: *Prevention and control of microbiological hazards in fresh fruits and vegetables – sprouts*.

Le Maroc propose d'ajouter la définition du terme **bondonnage** comme suit :

Le bondonnage : le fait de boucher et d'occlure le rectum pour éviter la sortie du contenu gastro intestinal et des matières fécales en dehors du rectum.

Annexe sur les légumes feuilles frais :

Position nationale 8 : la définition de « légumes-feuilles frais »

Le Maroc propose de maintenir l'expression « destinés à la consommation **sans cuisson préalable** ».

L'utilisation de l'expression « destinés à la consommation **sans autres étapes microbicides** » peut donner confusion avec l'utilisation des produits chimiques qui est aussi une étape microbicide et qui est autorisé pour être utilisé dans ce cas de produit frais.

Annexe sur les graines germées :

Position nationale 9 : l'inclusion des concentrations des traitements chimiques après validation de JEMRA chimiques (paragraphe 48)

Le Maroc soutient l'ajout des concentrations rapportées dans le document du JEMRA dans ce paragraphe mais juste à titre d'exemple (études scientifiques)

Position nationale 10 : l'inclusion des exemples (ex : durée et température pour chaque traitement recommandé (paragraphe 49)

Le Maroc soutient l'inclusion des exemples pour les traitements rapportées dans le document du JEMRA mais juste à titre d'exemple (études scientifiques).

Position nationale 11 : l'inclusion des jeunes pousses dans le champ d'application de cette annexe

Le Maroc soutient l'inclusion des jeunes pousses dans le champ d'application de l'annexe des graines germées.

Les jeunes pousses partagent les mêmes caractéristiques avec les graines germées. Elles présentent les mêmes processus et étapes initiales, sont issues de graines similaires et la contamination des graines s'y propage de la même manière.

Philippines

General Comments:

Comment Type	Category	Proposed Change	Comment
General	Substantive	N/A	The Philippines supports the progression of the proposed document in the step procedure with some specific comments.

Specific Comments:

Comment Type	Category	Proposed Change	Comment
Appendix 1, Objectives Paragraph 10,	Substantive	They provide a {science-based and practical} tool for the effective control of STEC in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts according to national risk management decisions.	The Philippines agrees to use "science-based and practical tool" as the statement highlights the importance for these guidelines to be based on facts and research and those useful and applicable to the setting in the Philippines as controls can vary among countries.
Appendix 1, Definition, Paragraph 26,	Substantive	{Sprouts: Sprouted seeds or beans harvested when the cotyledons (or seed leaves) are still un- or underdeveloped and true	The Philippines agrees to use the definition of sprouts based from Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (MRA 43) on the Prevention and Control of

Comment Type	Category	Proposed Change	Comment
		leaves have not begun to emerge. They can be grown in water, soil or substrate and can be harvested with or without the root (cut sprouts)7]–	Microbiological Hazards in Fresh Fruits and Vegetables (Part 3 Report: Sprouts) Rationale: The proposed definition in the document agrees with the definition of sprouts based from Department of Agriculture - Bureau of Plant Industry (BPI) who is mandated to promote the development of plant industries through research and development, crop production and protection in the Philippines. This may be adopted to the Code of Hygienic Practice for Fruits and Vegetables (PNS BAFS 233_2018) which mentions sprout production in Annex B of the document.
Appendix 1, Paragraph 50	Editorial	and sampling and testing for indicator microorganisms and STEC, where appropriate.	Add comma before where appropriate
Appendix 1, Paragraph 58	Editorial	For instance, the monitoring programmes for STEC and/or indicator microorganisms, when appropriate, in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts may include testing at the farm (e.g., for fresh leafy vegetables), in the slaughter and processing establishments, and the retail distribution chains, where appropriate, and according to the monitoring objective.	Add comma before where appropriate
Appendix 1, Par 64	Editorial	in that country country	Remove redundant word “country”
Annex 1, Par 21	Substantive	[Use of probiotics or direct-fed microbials, involves feeding animals with viable microorganisms which are antagonistic toward pathogens, either by modifying environmental factors in the gut or producing antimicrobial compounds. There is evidence that specific direct-fed microbial treatments, such as <i>Lactobacillus acidophilus</i>	The Philippines suggests that JEMRA's recommendation should be taken into consideration before inclusion of the use of probiotics or direct-fed microbials in the text. Rationale: The Philippines does not practice the use of probiotics or direct-fed microbials to ruminants as this will disturb the normal microflora of the animal. The Philippines follows Code of Hygienic Practice for

Comment Type	Category	Proposed Change	Comment
		(NP51) and <i>Propionibacterium freudenreichii</i> (NP24), can reduce STEC serotype O157:H7 shedding by cattle (Wisener et al., 2015, Venegas-Vargas et al 2016). The probiotics used should not contain antimicrobial resistance genes.]	Meat (PNS BAFS168-2015) where the use of probiotics or direct-fed microbials was not mentioned. The paragraph states the evidence from the reference Wisener et al., 2015, Venegas-Vargas et al 2016 that specific direct-fed microbial treatments, such as <i>Lactobacillus acidophilus</i> (NP51) and <i>Propionibacterium freudenreichii</i> (NP24), can reduce STEC serotype O157:H7 shedding by cattle. JEMRA's recommendation should be taken into consideration before inclusion in the text.
Annex 2, Par 15	Substantive	{Growers should periodically test the water they use for appropriate indicator microorganisms and, where necessary, STEC,}	The Philippines agrees to retain the statement. Rationale: Throughout the document (General to Annex 1 to 4), the test for indicator microorganisms has been mentioned as a monitoring tool and hygiene indicator which may be supplemented by periodic testing for STEC, where appropriate, and as needed to make risk-based decisions.
Annex 3, Par 1	Substantive	{Consuming raw drinking milk without any control measures is associated with a higher risk of illness}.	The Philippines agrees to retain the statement. Rationale: The statement in square bracket holds true. On a general context, the National Dairy Authority, the Food Safety Regulatory Agency mandated to regulate milk from its primary production to post harvest handling in the Philippines, does not recommend direct consumption of raw milk or any of its derivatives without undergoing processing (i.e. pasteurization). This is due to the prevalence of high microbial counts in raw milk observed in various dairy farms under the Philippine setting.
Annex 3, Par 1	Substantive	{Without any control measures, they are associated with a higher risk of foodborne illness than those cheeses made from milk subject to heating such as thermization or pasteurization to reduce the risk from foodborne pathogens}.	The Philippines agrees to retain the statement. Rationale: The statement holds true in general. Cheeses made from raw milk has a high risk on causing foodborne illnesses than those made from milk that have undergone heating since the likelihood of contamination has been decreased because of the heating step.

SPECIFIC QUESTIONS FOR CCFH53

Question for CCFH53 with respect to the raw beef annex:

Do you think it relevant for the purpose of this document to add a “Post-Mortem inspection step“ to this flow diagram between Splitting and Carcass Washing?

Philippine Position:

Yes, the Philippines agrees that it is relevant for the purpose of this document to add a “Post-Mortem inspection step” to this flow diagram and it should be placed after carcass washing.

Rationale: Post-mortem inspection is one of the processes steps in meat as stated in the Philippine National Standard, Code of Hygienic Practices for Meat (PNS/BAFS 168-2015) and this step is defined in the PNS as any procedure or test conducted by an official inspector on all relevant parts of slaughtered animals for the purpose of judgment of safety and suitability for human consumption to make the appropriate disposition. This definition is also consistent with Code of Hygienic Practice for Meat (CAC/RCP 58-2005).

Postmortem inspection is done after carcass washing and after removal of entrails or offals and it is conducted to make a judgement on the safety and suitability of parts intended for human consumption. The manner in which it is implemented may increase the risk of bacterial cross-contamination of carcasses including STEC

Questions for CCFH53 with respect to the Fresh Leafy Vegetables Annex:

In paragraph 2, we say that “There is no processing treatment applied that would eliminate or inactivate STEC, although contamination can be reduced by washing in water containing antimicrobials.” One comment asked about ozone treatments. Should we say that “...contamination can be reduced by treatments such as washing in water containing antimicrobials?” Is there something we should add about ozone based on information from JEMRA?

Philippine Position:

The Philippines supports that additional information from JEMRA is needed to provide science-based data and information as to whether ozone treatments should be added in the document.

In the Philippines, there are no existing guidelines for ozone treatments for fresh leafy vegetables. If this will be included, it will also provide guidance on the need to revise/amend our existing national standards on code of practice Code of Hygienic Practice for Fruits and Vegetables (PNS BAFS 233_2018) to incorporate guidance on ozone treatments.

The definition of Fresh Leafy Vegetables refers to those intended for consumption without cooking. However, there are processes other than cooking that can adequately reduce microbial pathogens. JEMRA has defined “fresh fruits and vegetables” as “Fruits and vegetables that are not processed in a manner that changes their physical properties. Cooked, canned, juiced, frozen, candied, dried, pickled, fermented, or otherwise preserved foods derived from fruits and vegetables were excluded from this definition and this report.” In this annex we only refer to “cooking,” but in the *Code of Hygienic Practice for Fresh Fruits and Vegetables*, Annex III “fresh leafy vegetables,” the scope refers to those “intended to be consumed without further microbiocidal steps” (terminology also used in the definition of ready-to-eat fresh fruits and vegetables). Do we need to consider other processes and say, “for consumption without any further microbiocidal steps” instead of “for consumption without cooking”?

Philippine Position:

The Philippines agrees to use the definition of Fresh Leafy Vegetables from the *Code of Hygienic Practice for Fresh Fruits and Vegetables* where it is defined as “for consumption without any further microbiocidal steps.”

This is to be in consistent with Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003) and the JEMRA definition that does not limit the process of reducing microbial pathogens to only cooking.

Question for CCFH 53 with respect to the Sprouts Annex:

- In paragraph 48 there are several chemical treatments mentioned. Since scientific references will be deleted in a later step of the document, should we include the concentrations that were shown in the referenced studies to achieve the log reduction (after JEMRA validation)?

Philippine Position:

The Philippines agrees that the concentrations in the chemical treatments mentioned in the document be retained and included if this data is validated by JEMRA.

Philippines does not have data for the chemical treatments mentioned in the document and this information will be beneficial on the development of guidelines that may be used by the competent authorities as its basis for national policies and standards.

Uruguay

Comments on APPENDIX 1

Comments from Uruguay:	
Consider	
<i>Uruguay appreciates the invitation to participate and agrees with the document in general. We provide suggestions and comments in the table below.</i>	
<i>Uruguay considers that the document is ready to advance in the Codex Step process.</i>	
In submitting comments on the proposed draft Members and Observers are invited to reflect of the specific questions posed in the report of the EWG namely those related to the raw beef annex (paragraph 11); the fresh leafy vegetables annex (paragraph 12); the raw milk and raw milk cheeses annex (paragraph 13) and the sprouts annex (paragraph 14) and provide specific input on these questions.	
General Section:	
Paragraph 1 of the introduction that STEC have occasionally been linked with neurological symptoms, including epileptic seizures and cognitive dysfunction.	<i>Uruguay agrees with the proposed additions</i>
Deleted in paragraph 14 a footnote reference to “FAO/WHO 2009. Risk characterization of microbiological hazards in food. Microbiological risk assessment series 17.” This reference was updated by “FAO/WHO 2021. Microbiological risk assessment: guidance for food (MRA 36)”. However, the updated reference is not applicable to the statement about needing to validate under commercial conditions.	<i>Uruguay agrees with the new footnote referring to the latest version FAO/WHO 2021</i>
Revised commodity definitions for consistency with those in the annexes. (The Sprouts definition is in square brackets pending agreement on definition by CCFH.)	<i>Uruguay agrees with the definition</i>
Revised the order of the paragraphs in section 11.2 (Laboratory Analysis Criteria for Detection of STEC) for better understanding.	<i>Uruguay agrees with the new order</i>
Revised paragraph 69 to explain what is meant by a “country’s highest priority” and how this relates to	<i>Uruguay agrees with the proposed change</i>

corrective actions.	
<u>Raw Beef Annex</u>	
A definition for tenderized raw beef was included in the annex. In the case of a definition for raw non-intact beef products, a footnote was inserted in paragraph 6 of the introduction instead of a definition since it is not mentioned in the document more than once.	<i>Uruguay suggests adding "Mechanically tenderized raw beef" in the definition of "Tenderized raw meat", as it appears in the flowchart (this definition does not include all possible forms of mechanical tenderization according to footnote)</i>
The flowchart step of bunging was arranged in a different order and the word "mechanical" was added before tenderization to avoid confusion with other means of tenderization.	<i>Uruguay agrees with the changes proposed</i>
The word serotype was included every time <i>E. coli</i> O157:H7 was mentioned in the text.	<i>Uruguay agrees with the changes proposed</i>
The term "High risk STEC" was changed to "STEC considered to be a country's highest priority." To provide clarity, the following text was inserted in parentheses to indicate which strains should be considered as such after the term is first mention, "e.g., those strains with virulence factors capable of causing severe illness or considered to cause significant illness in that country."	<i>Uruguay agrees with the changes proposed</i>
Do you think it relevant for the purpose of this document to add a "Post-Mortem inspection step" to this flow diagram between Splitting and Carcass Washing?	<i>Uruguay suggests adding a Post Mortem inspection step, in the flow diagram between Splitting and Carcass Washing</i>
<u>Fresh Leafy Vegetables Annex</u>	
In paragraph 10 added square brackets around the following statement pending the JEMRA report: "[Once product is contaminated with STEC it is not possible to eliminate it and there are limited control measures that can be implemented to reduce it.]" (Note that paragraph 9 similarly says "The assessment of environmental conditions is particularly important because subsequent interventions would not be sufficient to fully remove STEC contamination that occurs during primary production...")	<i>Uruguay suggests the next wording: "Once product is contaminated with STEC it is difficult to eliminate it and there are limited control measures that can be implemented to reduce It"</i>
In paragraph 15, revised the first sentence and added square brackets pending the JEMRA report: "[Growers should periodically test the water they use for appropriate indicator microorganisms and, where necessary, STEC,] according to the risk associated with the production."	<i>Uruguay considers it is convenient to wait for the JEMRA report</i>

<p>Revised the flow diagram to use dotted lines instead of color around two boxes and added asterisks with a footnote that “Boxes with broken lines indicate steps that may not be included, depending in part on the commodity.”</p>	<p><i>Uruguay agrees with the clarification</i></p>
<p>In paragraph 2, we say that “There is no processing treatment applied that would eliminate or inactivate STEC, although contamination can be reduced by washing in water containing antimicrobials.” One comment asked about ozone treatments. Should we say that “...contamination can be reduced by treatments such as washing in water containing antimicrobials?” Is there something we should add about ozone based on information from JEMRA?</p>	<p><i>Uruguay considers it is convenient to wait for the JEMRA report</i></p>
<p>The definition of Fresh Leafy Vegetables refers to those intended for consumption without cooking. However, there are processes other than cooking that can adequately reduce microbial pathogens. JEMRA has defined “fresh fruits and vegetables” as “Fruits and vegetables that are not processed in a manner that changes their physical properties. Cooked, canned, juiced, frozen, candied, dried, pickled, fermented, or otherwise preserved foods derived from fruits and vegetables were excluded from this definition and this report.” In this annex we only refer to “cooking,” but in the <i>Code of Hygienic Practice for Fresh Fruits and Vegetables</i>, Annex III “fresh leafy vegetables,” the scope refers to those “intended to be consumed without further microbiocidal steps” (terminology also used in the definition of ready-to-eat fresh fruits and vegetables). Do we need to consider other processes and say, “for consumption without any further microbiocidal steps” instead of “for consumption without cooking”?</p>	<p><i>Uruguay considers that the best option is "Fresh fruits and vegetables ready for consumption"</i></p>
<p>Raw Milk and Raw Milk Cheeses Annex</p>	
<p>Changed in the two diagrams at the end of the document:</p> <ol style="list-style-type: none"> a) For the flow diagram in figure 1 (entitled “Process Flow Diagram for Raw Milk Production, Distribution and Sale”): <ol style="list-style-type: none"> i) Added “Raw” before milk in the box “Milk collection and transport” (3rd box from the top) ii) Added “Raw” before milk in the box “Milk” (box on the left of the figure). b) For the flow diagram in figure 2 (entitled “Making Cheese from Raw Milk”): <ol style="list-style-type: none"> i) Added “Raw” before milk in the box “Milk” (box on the left of the figure and 3rd box from the top). ii) Added a dotted arrow from “receive raw milk” to “addition of ingredients” (Some cheeses are made directly without cold storage) 	<p><i>Uruguay agrees with the two flow diagrams. In flow diagram in figure 2, Uruguay suggests adding “Salting” as a new step, between “Form/Press/Drain” and “Aging”</i></p>
<p>Revised what is meant by a “country’s highest priority”</p>	<p><i>Uruguay agrees with the proposed</i></p>

and how this relates to corrective actions to be consistent with paragraph 69 in the general section.	<i>change</i>
<u>Sprouts</u>	
In paragraph 48 there are several chemical treatments mentioned. Since scientific references will be deleted in a later step of the document, should we include the concentrations that were shown in the referenced studies to achieve the log reduction (after JEMRA validation)?	<i>Uruguay considers it is appropriate to include concentrations</i>
In paragraph 49 there are several physical treatments mentioned. Do you think it would be useful include examples (e.g., time and temperature) for each one of the treatments recommended (after JEMRA validation)?	<i>Uruguay considers useful the incorporation of examples for the treatments recommended</i>
Microgreens share characteristics with sprouts. They have the same initial process and steps, originate from similar seeds, and seed contamination will spread similarly. However, STEC outbreaks have not been associated with them to date. Should we include microgreens under the scope of this annex?	<i>Uruguay agrees with the incorporation of microgreens under the scope of this annex</i>