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European Union comments

CODEX COMMITTEE ON FOOD HYGIENE

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Agenda Item 8: Proposed Draft Guidelines for the Control of Shiga Toxin-producing *Escherichia coli* (STEC) in beef, leafy greens, raw milk and cheese produced from raw milk, and sprouts (CX/FH 19/51/8

Mixed Competence
European Union Vote

The European Union and its MS (EUMS) would like to thank and congratulate Chile and the United States of America for the development of these draft guidelines.

General comment:

There should be a References part, detailing the literature cited in the text. The references should be organized in such a way, that it readily becomes clear what statements made in the text are covered by them. All important statements should be backed by an appropriate reference. Throughout the paper there is an unbalanced reference to the literature.

Specific comments with regard to the draft main guidelines (Appendix I), the EUMS would like to make the following comments:

- Title: The following amendment is proposed: "Guidelines for The Control of Shiga Toxin-Producing *E. coli* (STEC) in Beef Meat, Leafy Greens, Raw Milk**,** ~~and~~ Cheese Produced From Raw Milk, and Sprouts"

  Rationale: Language edit. Raw milk does not need to be qualified as being produced from raw milk which the inclusion of the word 'and' does. We would suggest concomitant changes in this wording throughout the document as it is used in several places.

- Paragraph 2: The following amendments are proposed: "~~Most c~~**C**linical symptoms of ~~the~~ disease in humans arise as a consequence of **consuming food contaminated with *E. coli* that produces** ~~the production of~~ Shiga-toxin type 1 (*stx1*) **and/or** type 2 (*stx2*) ~~or a combination of these genes~~. **Serotype data of STEC strains is not reliable for predicting risk and the potential of the STEC to cause severe diseases. Risk and the severity of STEC infections are best predicted** ~~using~~ **by Shiga toxin encoding**

stx genes (stx 1, stx 2 or a combination of these genes). Other genes including an adherence gene, Intimin, encoded by *eae* ~~and a plasmid-encoded enterohemolysin (ehxA) has been used as a possible epidemiological marker for pathogenic STEC. These virulence genes and the O157:H7 specific single-nucleotide polymorphism (SNP) at position +93 of the uidA housekeeping gene (+93 uidA) have been related to assess the potential pathogenicity of STEC isolates. It must be pointed out that additional~~ **and** adherence genes such as aggR have been identified **in addition to genes encoding stx as predictors of the pathogenicity of strains.** ~~associated with causing illness~~. These genes are mobile and can be transmitted to related organisms or be lost. Symptoms and their severity are determined by the variability in these genes. Because STEC are primarily a genotype-based hazard, this has implications for hazard identification and characterization, which will be discussed in this Guidance document. The utility of genotyping, serotyping and culture-based detection in hazard identification and characterization will also be discussed in this document.'

Rationale: It is important that the Introduction is general and consistent with advice from JEMRA. The current wording does not specifically address the recommendation from JEMRA on serotyping of STEC and it does not address gene combinations associated with less severe presentations of disease. The ability of STEC to cause illness should not be solely focussed on gene combinations associated with severe illness. Also, some of the genes mentioned and SNP advice regarding the decisions on pathogenicity, reflects some country specific practice and is not sufficiently general for an international guideline. The proposed changes provide a more general overview suitable for an introduction, it includes wording taken from the JEMRA report on serotyping and is consistent with Table 5 of the WHO/FAO JEMRA report: *Shiga toxin-producing Escherichia coli (STEC) and food: attribution, characterization, and monitoring.*

- Paragraph 4: The following changes are proposed: 'It is generally accepted that animals, in particular ruminants **are one** of the primary source of STEC. STEC-positive ruminants are typically asymptomatic. Contamination with intestinal content or feces is the likeliest ultimate source of STEC in most foods. **For example,** STEC outbreaks associated with field-grown leafy greens have been linked to contaminated irrigation water **while** raw milk is most commonly contaminated as a result of soiled udders and teats as well as poor hygiene at processing. ~~[Note to EWG – this paragraph needs to be expanded on sources and to include the other commodities.]~~'

  Rationale: "one of the sources" might be more convenient since all the contamination sources are not identified in every case of contamination; for example, the primary source of the contamination of recycled irrigation water might be difficult to identify precisely. By citing leafy greens and raw milk as examples of foods contaminated with feces, it is not necessary to further expand on the paragraph to cover other commodities.

- Paragraph 11, first sentence: The following change is proposed: 'These Guidelines provide information to governments and industry on the control of STEC in raw beef meat, leafy greens, raw milk**,** ~~and~~ cheese produced from raw milk, and sprouts that aim to reduce foodborne disease whilst ensuring fair practices in the international food trade.'

  Rationale: Language edit. Raw milk does not need to be qualified as being produced from raw milk which the inclusion of the word 'and' does.

- Paragraph 13: The following change is proposed: 'These Guidelines are applicable to public health **relevant~~e~~** STEC that may contaminate raw beef meat, leafy greens, raw milk**,** ~~and~~ cheese produced from raw milk, and sprouts and cause foodborne disease.'

  Rationale: editorial.

- Paragraph 17: The following amendment is proposed: "The primary production section**s** **related to animal production,** of these guidelines…."

  Rationale: there are several sections in these guidelines and their Annexes that deal with primary production and OIE only deals with primary production as regards animals (not for leafy greens, sprouts, …, also covered by these Codex guidelines)

- 4. DEFINITION:

  - Paragraphs not numbered

  - Leafy greens: It should be clarified if leafy greens, not intended for direct consumption e.g. spinach, are covered by the guidelines (Annex 2). If so, it should be indicated (in Annex 2), if control measures are different for such leafy greens. In addition, in the document vegetables are defined as "leafy greens" in the body text, and as newly proposed in the document, "fresh leafy green vegetables" in Annex 2-. Now however, there are two terms in use for the same products which may cause confusion. Thus the term "fresh leafy green vegetables" should be uniformly used and incorporated in the definition section

  - Raw milk: The following amendment is proposed: 'Milk which has not been pasteurized by heating ~~beyond 40°C~~ or undergone any other treatment that has an equivalent effect to reduce pathogens to an acceptable level.'

    Rationale: This may be a definition used elsewhere but it is a misleading and potentially dangerous definition which we should take the opportunity to modify. By inclusion of a temperature of 40°C it suggests that a process of heating milk to 41°C for example, is enough to reduce pathogens to an acceptable level. This isn't the case.

  - *Shiga Toxin-Producing E. Coli* (STEC): the following amendments are proposed: 'A large, highly diverse group of ~~bacterial strains~~ **E coli** that are

demonstrated to carry stx **toxin gene** produc**ing** Shiga toxin (Stx), **pathogenic** to humans by entry into the human gut, attachment to the intestinal epithelial cells and production of Stx.'

Rationale: Language edit. More consistent with JEMRA terminology and the definition needs to be clear what is meant by "stx".

- Paragraph 22, point b): It is proposed to add the following sentence at the end: "**These risk management metrics might be adapted to the serotypes or strains of greatest local concern."**

  Rationale: all stereotypes of STEC have not the same pathogenicity level. The distribution of pathogenic strains differs from one region to another, which explains an adapted management of the risk.

- Paragraph 23: The following additional wording is proposed at the end: "…that are appropriate to their national context, **including to adapt the options according to the most locally worrying serotypes or strains."**

  Rationale: See above: The distribution of pathogenic strains differs from one region to another, which explains an adapted management of the risk.

- Paragraph 24: Here it could be included that humans working in primary production could also be source of STEC strains.

- Paragraph 25: Propose to replace by: **"Appropriate controls to prevent the contamination and cross contamination of commodities during processing by STEC are important."**

  Rationale: The current expression may be misleading, although later in 10. CONTROL MEASURES (28-33) these measures are explained. The current wording could be misinterpreted in such a way that during processing there should be performed microbiological tests for STEC.

  An analogous change should be made in 9. DISTRIBUTION CHANNEL CONTROL MEASURES (26-27), although later in the text it becomes clear that „STEC controls" or „STEC control measures" are any measures appropriate for controlling STEC, e.g. proper refrigeration, etc.

- Paragraph 26: Propose to delete.

  Rationale: This is generic guidance for control measures that may be applied to product in distribution. The para is superfluous and should be deleted.

- Paragraph 28 till 33: it might be considered to put these paragraphs before paragraph 24.

Rationale: these paragraphs are on control measures in general, while paragraph 24 to 27 are control measures at specific steps of production.

- Paragraph 28, first sentence: The following change is proposed: 'GHPs provide the foundation for most food safety control systems. Where possible and practicable, food safety control measures for STEC should incorporate hazard based control measures ~~and risk assessment~~….'

  Rationale: Risk assessment is addressed in the next sentence.

- Paragraph 29: propose to delete or merge with paragraph 18.

  Rationale: repetition + very confusing: are GHP-based and hazard- based control measures not risk-based control measures? Although this was copied from previous Codex guidelines, it should be clarified why "risk-based control measures" need to be developed by the competent authorities at the national level and can they not be included (examples) in these guidelines?

- Section 10.1: to reconsider based on the outcome of a discussion on paragraph 29 (see previous comment)

- Paragraph 51: The following change is proposed: 'For instance, the monitoring systems for STEC and/or indicator organisms, where appropriate, in raw beef meat, leafy greens, raw milk**,** ~~and~~ cheese produced from raw milk, and sprouts may include testing at the farm **(including animals as appropriate)**~~, animal level~~, in the slaughter and processing establishments, and the retail distribution chains where appropriate.'

  Rationale: Editorial

- Heading of Section 12.2 /Paragraph 58-61: The following change is proposed: "Laboratory analysis criteria for detection **and management** of STEC"

  Rationale: The EUMS very much support these paragraphs and in particular the reference and insertion of the recommendation FAO/WHO STEC Expert Report 2018, which provides the scientific input for these guidelines. The Section/paragraphs should however try to better reflect the purpose of the recommendations which is not only on criteria for the detection of STEC but also on the management of food commodities contaminated with STEC showing certain virulence factors. This should be at least be reflected in the heading of 12.2.

- Paragraph 59, first sentence: The following change is proposed: 'The risk of severe illness from STEC infections is best predicted ~~based on~~ **by** virulence factors (encoded by genes) identified for an STEC strain and should be used as an analysis criterion for detection of STEC in food samples
  Rationale: editorial.

- Paragraph 59, third sentence: The following change is proposed: ‘Strains of STEC with other *stx* subtypes may cause diarrhoea **or bloody diarrhoea** but their association with HUS is less certain and can be highly variable.’
  Rationale: This wording more accurately reflects the information in table 5 of the WHO/FAO JEMRA report: Shiga toxin-producing Escherichia coli (STEC) and food: attribution, characterization, and monitoring. We should differentiate between normal diarrhoea and bloody diarrhoea which is a more severe illness

Draft specific control measures for raw beef meat (Annex 1), the EUMS would like to make the following comments:

General comments

As a general comment, referring to (the last part of) paragraph 3 of this Annex and Section 12.2 of the draft main document, the EUMS did not find how the FAO/WHO recommendation with regard to criteria that include risk levels and "guidance on when beef meat contaminated with STEC should be fit for human consumption in order to minimize the potential for disputes and facilitate global trade" (quoted from Paragraph 3) has been taken into account. The EUMS consider that the Annex could substantially benefit from such guidance. At least an attempt should be made to provide such guidelines (e.g. by a decision tree taking into account further processing and eating habits), although the EUMS recognised that it might not be easy to reach consensus on this aspect at global level. Without such addition, this Annex contains no STEC specific controls, except for the use of bacteriophages and vaccination. The rest of the text concerns mainly general information about the control of fecal contamination. The latter is already covered in an existing Codex text[1].

Secondly, the draft lays down guidelines for control measures but does not indicate if procedures based on the HACCP principles are relevant for the control of STEC in raw beef meat. It seems appropriate that these guidelines provide external, generic guidance whether Good Hygiene Practices are sufficient at specific steps of raw beef production to control STEC and, if not the case, provide examples on CCPs that could be considered (e.g. visual inspection of faecal contamination of carcases in slaughterhouses, sampling of carcases for indicators of faecal contamination, …).

Specific comments:

- Paragraph 1, line 4: The statement „…and 3.6% to 19.4% of animals for all **non-O157** STEC…“ cannot be verified from the reference.
  Rationale: correction of wrong statement.
- Paragraph 2, third sentence (DE): the relevance of „potential STEC contamination during further processing“ due to contaminated surfaces is not sufficiently detailed and backed by reference(s).
- Paragraph 3, first sentence (DE): The first sentence is not really helpful (references?), since the draft guidelines do not identify acceptable strains of STEC.

[1] CXG 87-2016 Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork Meat

- Section 5: Primary production. The EUMS are surprised by the Section which is largely considered as the competence of OIE. The EUMS would like to know if the chairs consulted the OIE if it intends to work on this, and, if not, if OIE agrees that this is no longer within its remit.
- Paragraphs 11, 12 and 13 (DE): references for these statements should be added.
- Paragraphs 16-21: Propose to replace all these paragraphs by: **"There have been scientific studies about the effectiveness of feed additives, such as probiotics, in the reduction of STEC prevalence. However, up to now results of these studies have been inconclusive or have not provided sufficient scientific evidence on the effect of STEC reduction. Either way, the use of these substances needs to be put in perspective with the initiatives taken to fight against the emergence of antimicrobial resistance and be approved by competent authorities"**

  Rationale: There is no conclusive scientific evidence about the effectiveness of feed additives in the reduction of STEC prevalence. Therefore, it is not appropriate and justified to indicate feed additives amongst the specific control measures at farm level It would also be good to stress the concerns as regards antimicrobial resistance and should in any case remain the competence of competent authorities to authorise them or not.

- Paragraph 24, second bullet point: EHEC is mentioned for the first time in this paragraph. We suggest to provide additional explanation on EHEC.
- Paragraph 24, third bullet point: The sentence is not clear. Should one avoid sharing water troughs between animals (each animal has its own water trough) of should one avoid sharing water troughs between pathogen shedding animals and non-shedding animals?
- Paragraph 25, first sentence : Is this a subtitle? If not, it should be a complete sentence
- Paragraph 26: it should be clarified what kind of controls would be useful.
- Paragraph 28: Proposed to replace "must" by "should".

  Rationale: consistency/appropriateness of wording.

- Paragraph 29: is spraying of chlorinated water useful (reference)?
- Paragraph 31: „as much as possible" is very flexible, what about aerosols? and allowing to dry?
- Paragraph 32: Cows with wet hides after washing might be difficult to handle during subsequent slaughter. Shouldn't they be allowed to dry before? The feasibility and efficiency of washing during a commercial slaughtering process is questionable anyway.
- Paragraph 35
  - Cross-contamination from „waste"?? „visible soiling": there is some contradiction with washing the life animal in paragraph 32.

- This paragraph sounds disproportionately negative as regards certain measures, being rather discouraged instead of recommended. This contradicts the recommendations in Paragraph 38. In the views of the EUMS, removal of visible soiling needs to be pushed and carcase trimming is one of the best ways to remove visible soiling, reducing the bacterial risk. The paragraph should be revised and trimmings added as a control measure in paragraph 38.

- Paragraph 38: inconsistent citation of journal (Meat Science).
- Paragraph 39: inconsistent citation of journal (Meat+Poultry), is any of these methods useful?
- Paragraph 40 and preceding heading: The following changes are proposed: "Specific control measures at Mechanical Tenderization **and Meat Mincing**
  Processes such as marinating, brine injection, ~~and~~ mechanical tenderisation **or meat mincing** in which blades or …"

  Rationale: the paragraph and its recommendation seem also relevant for minced meat.

- Paragraph 43: this is vague; in the context of this draft guidelines it should read „monitoring programme for STEC".
- Paragraph 45: It is unclear why minced products are excluded. Also in minced meat, the distribution of the pathogen can be heterogeneous.
- Paragraph 47: The first two sentences are trivial and may not be removed. The third one sounds incomplete.

Draft specific control measures for fresh leafy green vegetables (Annex 2), the EUMS would like to make the following comments:

General comments

As a general comment, referring to Section 12.2 of the draft main document, the EUMS did not find how the FAO/WHO recommendations with regard to criteria that include risk levels have been taken into account. The EUMS considers that the Annex 2 could substantially benefit from such guidance. While such insertion might be challenging for raw beef meat (Annex 1), leafy greens are mostly directly consumed without any treatment that may reduce pathogens (e.g. cooking) and therefore their consumption results in the direct exposure of people to the STEC virulence factors found. Guidance on when leafy greens contaminated with STEC containing certain virulence factors, are still fit for consumption, should therefore be included. Without such addition, this Annex contains no STEC specific controls. The rest of the text concerns mainly general information about the control of fecal contamination. The latter is already covered in an existing Codex text[2].

Secondly, the draft lays down guidelines for control measures but does not indicate if procedures based on the HACCP principles are relevant for the control of STEC in leafy greens. It seems appropriate that these guidelines provide external, generic guidance whether Good Hygiene Practices are sufficient at specific steps of leafy greens production to control STEC and if, if not the case, provide examples on CCPs that could be considered (for example analysis of water for faecal contamination at final washing steps).

[2] CXC 53-2003 Code of Hygienic Practice for Fresh Fruits and Vegetables