CODEX COMMITTEE ON FOOD HYGIENE

(Fifty third Session)
San Diego, United States
29 November – 2 December 2022 and 8 December 2022

European Union Comments on

Agenda item 5:

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 at Step (CX/FH 22/53/5)

(Reply to CL 2022/56/OCS-FH)

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 "Carcase 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 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

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

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.

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

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, <u>may lay down legal requirements and</u> 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 "<u>to a large extent</u>". 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 <u>might be</u> 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.

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, <u>effective</u> control strategies based on preventing STEC infection of cattle or contamination of their environment <u>can</u> would be difficult to implement <u>in a reliable manner."</u> 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 <u>and carcass washing or decontamination is not performed in all countries or slaughterhouses</u>". 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 <u>fit</u> <u>for purpose and</u> of a microbiological quality that minimises animal contamination and, if there is doubt, treat the water <u>ensuring that the water is both chemically and microbiologically safe</u>." 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 <u>reduce the risk of decrease the opportunity for pathogen cross</u> contamination <u>from hides to onto carcasses or hides</u> 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 <u>and supervision</u> (Signorini et al., 2018)." Rationale: need to add supervision in order to make regular adjustments according to the size of the animals.

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 <u>and fecal material should be removed</u> 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, <u>plugs</u>, clips, or bungs to close the weasand hygienically to prevent rumen spillage". Rationale: this is also used.

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**" Rational: 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, <u>by avoiding</u> but the disadvantage of trimming is potential cross-contamination from dirty knives (if not using knife-switching disinfection protocol in-between cuts), <u>and ensuring no contact</u> 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: "<u>The effectiveness of carcase 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." Rational: Need for additional information.</u>

Paragraph 76 last sentence

The EUMS proposes the following change: "Manufacturers should also consider purchase specifications that require that incoming beef to be tenderised <u>has an undetectable level of STEC</u> 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 <u>and</u> <u>validated</u> 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 <u>cold</u> transport" and "<u>cold</u> 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 "<u>Avoid using recycled bags if there is a possibility of prior contamination.</u>" 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 <u>to</u> 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 <u>in potable water</u> to remove hulls and/or to help lower the temperature of the sprouts ant 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.