CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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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: PROPOSED DRAFT ANNEX IV ON SPROUTS

Comments in reply to CL 2024/22-FH

Comments of Argentina, Australia, Canada, Colombia, Ecuador, Egypt, European Union, Indonesia, Iraq, Japan, Kenya, Malaysia, New Zealand, Peru, Thailand, United Arab Emirates, United Kingdom, Uruguay and USA

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2024/22-FH issued in January 2024. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

Explanatory notes on the appendix

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

Annex I

GENERAL COMMENTS

COMMENT	MEMBER / OBSERVER
Ecuador agradece a la Presidencia del Grupo de Trabajo, la oportunidad de emitir comentarios en la construcción de la referida norma alimentaria; en tal virtud y una vez revisado el proyecto de norma propuesto, nos permitimos señalar que, el documento abarca la mitigación de la probabilidad de contaminación en las fases de producción primaria y cadenas de comercialización, por tanto, los documentos son completos y están apegados a la realidad productiva de la región andina y el Ecuador; sin embargo, nos permitimos sugerir se analice la factibilidad de incorporar las siguientes pruebas de análisis microbiológicos a fin de identificar patógenos y prevenir brotes de enfermedades transmitidas por alimentos: Pruebas fenotípicas y moleculares, como la qPCR (reacción en cadena de la polimerasa en tiempo real), así como la secuenciación genómica, para fortalecer la capacidad de detección y caracterización de microorganismos patógenos. Pruebas fenotípicas: para determinar las características físicas y bioquímicas de los microorganismos, así como también para la identificación de patógenos, sin embargo, a veces no son suficientemente sensibles para identificar a los organismos por lo que se complementan con pruebas moleculares. qPCR: nos ayudaría a detectar y cuantificar la presencia de material genético específico de microorganismos. Esta técnica es altamente sensible y específica, por lo que se utiliza para la detección temprana de patógenos específicos, incluso en concentraciones bajas, lo que facilita la intervención rápida para prevenir brotes. Secuenciación genómica: para identificar la presencia de un patógeno, y caracterizar su genética, incluidas las mutaciones, factores de virulencia asociados a la producción de toxinas, genes de resistencia y seguimiento de brotes. Esto es fundamental para rastrear la fuente o fuentes de contaminación de alimentos, identificar brotes potenciales y determinar estrategias de control.	**Ecuador**
Egypt approves proposed draft annex IV on sprouts	**Egypt**
The EUMS generally support the draft, subject to the considerations of the comments made below and the outcome of the discussions at CCFH54.	**European Union**
Agree with proposal	**Iraq**
Guidelines on control measures should be specific and effective for STEC, while ensuring flexibility in the choice of control measures, taking into account the diversity and feasibility of primary production.	**Japan**
Kenya thanks the EWG Chair and fellow co-chair for this work well done and proposes that the draft Annex 4 on Sprouts be advanced in the Codex Step process with the inclusion of the following comments.	**Kenya**
Malaysia appreciates the work of the Electronic Working Group chaired by Chile and co-chaired by New Zealand, Kenya and the United States of America on the 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 (CXG 99-2023): Proposed Draft Annex IV on Sprouts. Malaysia supports the Proposed Draft Annex IV on Sprouts for adoption at Step 5/8.	**Malaysia**
The United States as a co-Chair of the STEC EWG has had many opportunities to review and propose revisions to Annex IV on Sprouts and is generally satisfied with the resulting text. The United States believes that Annex IV on Sprouts could progress to Step 5/8 for final adoption by CAC47 (2024).	**USA**

SPECIFIC COMMENTS

1. INTRODUCTION	
Paragraph 1	
Sprouts are commonly consumed raw and often without application of a kill step that would eliminate microbial pathogens, prior to consumption. Consequently, it is necessary to ensure safe production of sprouts by preventing or minimizing contamination of incoming seeds, in the production environment and in the finished products. While no single step will reliably eliminate all pathogenic microorganisms that may survive on sprouts, using a series of preventive and risk-reduction steps **(i.e. a multi-hurdle approach)** can greatly reduce the food safety risks that may be associated with sprouts. Japan would like to ask JEMRA whether JEMRA differentiate between “multi-hurdle” and “multi-barrier” approach	**Japan**
Sprouts are commonly consumed raw and **often** without application of a kill step that would eliminate microbial pathogens, prior to consumption. Consequently, it is necessary to ensure safe production of sprouts by preventing or minimizing contamination of incoming seeds, in the production environment and in the finished products. While no single step will reliably eliminate all pathogenic microorganisms that may survive on sprouts, using a series of preventive and risk-reduction steps (i.e. a multi-hurdle approach) can greatly reduce the food safety risks that may be associated with sprouts. Reword: "....consumed raw, sometimes without application of a biocidal step that would eliminate microbial pathogens." Reason: In clauses 74 and 75, there is also mention of cooking, so there is nothing to say that sprouts are more often consumed raw than cooked	**New Zealand**
United Arab Emirates proposes to modify the following statement “Sprouts are commonly consumed raw and often without application of a kill step that would eliminate microbial pathogens, prior to consumption” by the proposed following statement: “Sprouts are commonly consumed raw and often without application of an elimination step that would eliminate microbial pathogens, prior to consumption), Justification: the object is to eliminate microbial pathogens by any available suitable way (removing or inhibitions. Etc., and not just killing).	**United Arab Emirates**
Paragraph 3	
Australia suggests Paragraph 3 could be deleted as not necessary for the text.	**Australia**
Paragraph 5	
During seed production, conditioning, storage, and distribution for sprouting, the application of Good Agricultural Practices (GAPs) and Good Hygienic Practices (GHPs) should aim to prevent the contamination of seeds by microbial pathogens such as STEC. During sprout production, any step for the microbiological decontamination of seeds is ~~aimed at reducing~~ used to reduce potential contaminants, while GHPs are ~~aimed at preventing~~ used to prevent the introduction of microbial pathogens and ~~minimizing~~ minimize their potential growth. The degree of control in these two areas has a significant impact on the safety of sprouts.	**Australia**
2. OBJECTIVE	
Paragraph 6	
The objective of this Annex is to provide guidance to reduce the risk of foodborne illness from STEC associated with sprouts intended for human consumption without cooking, The Annex applies during production, harvesting, packing, processing, storage, distribution, and marketing as well as addressing consumer awareness.	**Australia**
Kenya proposes editorial amendments to this para by replacing ‘addressing’ with ‘for’ to read: The objective of this Annex is to provide guidance to reduce the risk of foodborne illness from STEC associated with sprouts intended for human	**Kenya**

consumption without cooking, during production, harvesting, packing, processing, storage, distribution, and marketing as well as for consumer awareness. Justification: For clarity	
United Arab Emirates proposes to modify the following statement: "The objective of this Annex is to provide guidance to reduce the risk of foodborne illness from STEC associated with sprouts intended for human consumption without cooking, during production, harvesting, packing, processing, storage, distribution, and marketing as well as addressing consumer awareness. By the proposed following statement: The objective of this Annex is to provide guidance to eliminate/reduce to the accepted limits), the risk of foodborne illness from STEC associated with sprouts intended for human consumption without cooking, during production, harvesting, packing, processing, storage, distribution, and marketing as well as addressing consumer awareness".	**United Arab Emirates**
3. SCOPE, USE, AND DEFINITIONS	
Uruguay considera que debería adecuarse los nombres y las numeraciones al documento CXC1-1969-Rev 2022	**Uruguay**
Paragraph 7	
This Annex covers specific guidance for the control of STEC related to sprouts that are intended for human consumption without ~~cooking~~ cooking~~or other microbicidal treatment~~. Rational: The scope should be in line with the Objective and the detail in this Annex does include the use of treatment to reduce the presence of pathogens. Also, the text should be in line with the Scope of Annex 2 Fresh leafy vegetables of this guideline.	**Thailand**
Paragraph 8	
Home-sprouting, ~~and~~ shoots, cress, and microgreens[2] where the seed is not kept in the final product are outside the scope of this document. The comment is for footnote 2. For cress, suggest using wording from MRA 43 as the sentence here is disjointed when referring back to shoots. From MRA 43: Cress – grown in substrate and true leaves are developed. The shoots and the leaves are cut during harvest and the final product does not include the seed and roots.	**Canada**
3.2 Use	
3.2 Utilización Uruguay entiende que debería considerarse el documento de Directrices para el uso y la reutilización inocuos del agua en la producción y la elaboración de alimentos (CXG 100-2023)	**Uruguay**
Paragraph 9	
This Annex is supplementary to and should be used in conjunction with the main document, the *General Principles of Food Hygiene* (CXC 1-1969) and the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003), including Annex II for Sprout Production. To be consistent with the main document, para 13, and to clarify that this annex is under the main document.	**Japan**
3.3 Definitions	

Sprouts - Sprouted seeds or beans harvested when the cotyledons (or seed leaves) are still un- or ~~underdeveloped~~ under-developed 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)[3]	**Canada**
4. PRIMARY PRODUCTION OF SEEDS FOR SPROUT PRODUCTION	
Paragraph 12	
In addition, nearby fields with livestock can increase the likelihood of STEC contamination. Livestock should be located as far as feasibly possible from fields growing seeds for sprout production, because the risk of contamination decreases as the distance to livestock increases (Berry et al., 2015, 2019).	**Australia**
In addition, nearby fields with livestock can increase the likelihood of STEC contamination. Livestock should be located as far as feasibly possible from fields growing seeds for sprout production, because the risk of seed contamination decreases as the distance to livestock increases (Berry et al., 2015, 2019).	**Canada**
In addition, nearby fields with livestock can increase the likelihood of STEC contamination. Livestock should be located as far as feasibly possible from fields growing seeds for sprout production, particularly livestock that are uphill of production sites, due to risks from surface run-off via precipitation, because the risk decreases as the distance to livestock increases (Berry et al., 2015, 2019). The UK suggests the amendment as livestock kept uphill of seeds may also pose contamination risks, due to surface run-off.	**United Kingdom**
Paragraph 14	
When evidence of potential contamination is found (e.g., the plant or seed is visibly contaminated with animal excreta), growers should evaluate whether the seed should ~~not~~ be ~~harvested~~ excluded from harvest due to the potential ~~for~~ contamination with pathogens such as STEC. Growers should then take measures to identify the contaminated ~~seedand/or~~ seeds and/or the contaminated area (e.g., mark the affected area) ~~so~~ in a manner that ~~such seed~~ is clear and that will ~~not subsequently be harvested~~ remain in the event weather conditions, or other ~~occurrences, make~~ events that would obscure or render the evidence of potential contamination no longer visible.	**Canada**
Kenya proposes editorial amendments to para 14 by insertion of a space between 'seed' and 'and' in line 4 to read: 'When evidence of potential contamination is found (e.g., the plant or seed is visibly contaminated with animal excreta), growers should evaluate whether the seed should not be harvested due to the potential for contamination with pathogens such as STEC. Growers should then take measures to identify contaminated seed and/or the contaminated area (e.g., mark the affected area) so that such seed will not subsequently be harvested in the event weather conditions, or other occurrences, make the evidence of potential contamination no longer visible.' Justification: For clarity.	**Kenya**
When evidence of potential contamination is found (e.g., the plant or seed is visibly contaminated with animal excreta), growers should evaluate whether the seed should not be harvested due to the potential for contamination with pathogens such as STEC. Growers should then take measures to ~~identify~~ label (or otherwise indicate) contaminated ~~seedand/or~~ seed and/or the contaminated area (e.g., mark the affected area) so that such seed will not subsequently be harvested in the event weather conditions, or other occurrences, make the evidence of potential contamination no longer visible. The word "identify" in English could be understood as measures to find evidence of potential contamination as opposed to the intended meaning in the statement.	**USA**
Paragraph 16	
The presence of nearby animal production facilities (e.g., animal feed operations, poultry farms, dairy farms) or other related factors such as slope of land, lack of runoff controls, and manure spreading that could lead to contamination of the seed or irrigation water with untreated ~~manure~~ manure, should be assessed and appropriate actions taken to prevent contamination of growing areas and seed with STEC. Added a comma.	**Canada**

Paragraph 18	
filtrar el agua o realizar un tratamiento químico del agua, para reducir cualquier patógeno del agua; Para especificar el objetivo	**Colombia**
filtrar el agua o realizar un tratamiento químico del agua; Uruguay considera que sería más adecuado expresarlo como "Sistema de tratamiento de agua que incluya el filtrado", por ejemplo	**Uruguay**
Paragraph 19	
Debería verificarse la efectividad de estas medidas mediante análisis periódicos del agua basados en el riesgo. Cuando sea necesario, los productores deberían analizar el agua que utilizan, para detectar la presencia de microorganismos indicadores adecuados y, cuando se determine que es necesario, de ECTS, de acuerdo con el riesgo asociado a la producción. La frecuencia de los análisis dependerá de la fuente de la que proceda el agua (por ejemplo, menor para pozos profundos debidamente mantenidos y más elevada para las aguas superficiales), los riesgos de contaminación ambiental, incluida la contaminación temporal o intermitente (por ejemplo, lluvias torrenciales, inundaciones) o de la aplicación de un nuevo proceso de tratamiento de aguas por parte de los productores. Si hay alguna regulación de inocuidad por alguna autoridad para indicadores de microbiología, estos se deben analizar. Considerar la reglamentación sobre indicadores microbiológicos de inocuidad.	**Colombia**
El CCFH Perú sugiere se deba ejemplificar cuales serían los microorganismos indicadores adecuados para el análisis periódico del agua, señalados en el numeral 19 del Apéndice 1 del CX/FH 24/54/6	**Peru**
The effectiveness of these actions should be verified by periodic risk-based water testing. Where necessary, growers should test the water they use for appropriate indicator microorganisms and, where identified as necessary, STEC, according to the risk associated with the production. The frequency of testing will depend on the water source (e.g., lower for adequately maintained deep wells, higher for surface waters), the risks of environmental contamination, including intermittent or temporary contamination (e.g., heavy rain, flooding), or the implementation of a new water treatment process by growers. Trending of current indicator test results alongside historical indicator test results may help growers notice emerging issues. The UK notes that trending is mentioned below, however finds that there might be utility to include a reference to trending here.	**United Kingdom**
Paragraph 20	
Where possible, growers should be able to identify or have a contingency plan in place that identifies an alternative source of fit-for-purpose water if the primary water source is found to have unacceptable levels of indicator microorganisms or is contaminated with STEC. **Refer to the Guidelines for the Safe Use and Reuse of Water in Food Production and Processing (CXG 100-2023), including Annex 1 "Fresh Produce".** At this point it is necessary to refer to the Guidelines for the Safe Use and Reuse of Water in Food Production and Processing	**Argentina**
United Arab Emirates proposes to modify the following statement: Where possible, growers should be able to identify or have a contingency plan in place that identifies an alternative source of fit-for-purpose water if the primary water source is found to have unacceptable levels of indicator microorganisms or is contaminated with STE, by the proposed following statement: Where possible, growers should be able to identify or have a contingency plan in place that identifies an alternative source of fit-for-purpose water if the primary water source is found to have unacceptable levels of indicator microorganisms or is contaminated with STEC, in parallel with review the preventive and corrective actions (mentioned in point no 18) in order to prevent that the contamination of water supplies with STEC will not occur again.	**United Arab Emirates**
Paragraph 21	

Growers who use biological soil amendments of animal origin (e.g., manure) on fields producing seeds for sprouting should only use them in such a way that they do not contaminate the seeds for sprouting. Manure, biosolids, and other natural fertilizers are potential sources of bacterial pathogens. Only properly composted manure/biosolids treated to reduce or eliminate STEC should be used during seed production to reduce the risk of seed contamination. The word "properly" is added for clarity given the discussion of improperly composted manure/biosolids in paragraph 28.	**USA**
Paragraph 22	
Refer to ~~section 3.2.1.2 of~~ the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003) for practices to minimize microbial pathogens such as STEC in manure, biosolids and other natural fertilizers. We suggest considering whether it would be best to refer to the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003) in general instead of specific sections. The reason for this suggestion is that all specific mentions to sections will need to be updated again when the alignment of the Code of Practice for Fresh Fruits and Vegetables with the General Principles of Food Hygiene is done.	**Canada**
If untreated or partially-treated natural fertilizers are used, the time period between the application and the planting and harvesting of seed should be maximized, as bacterial pathogens die off over time.**4.1.4 Personnel health, hygiene, and sanitary facilities** Should begin on a new line.	**Japan**
If untreated or partially-treated natural fertilizers are used, the time period between the application and the planting and harvesting of seed should be maximized, as bacterial pathogens die off over time.**4.1.4 Personnel health, hygiene, and sanitary facilities** Kenya proposes an editorial amendment to the subtitle by starting 4.1.4 in its own line after para 22 to read. 4.1.4 Personnel health, hygiene, and sanitary facilities Justification: Editorial	**Kenya**
If untreated or partially-treated natural fertilizers are used, the time period between the application and ~~the planting and~~ the harvesting of seed should be maximized, as bacterial pathogens die off over time. Rationale: We are of the opinion that time period should be maximized between the application and harvesting as the seed is collected for further sprouting process. The time period between application and planting might not be relevant in this case.	**Thailand**
Paragraph 23	
Worker hygiene and health requirements **detailed in section 12 of General principles of food hygiene (CXC 1-1969),** should be followed to ensure that personnel who have direct contact with seeds for sprouting prior to, during or after harvesting will not contaminate them with STEC. Refer to the specific point of CXC 1-1969	**Argentina**
Paragraph 24	
Adequate access to, and use of, hygienic and sanitary facilities, including adequate means for **hygienically washing and drying hands**, are critical to minimize the potential for workers to contaminate seeds for sprouting. For consideration, in Canadian regulations (SFCR 67 (2)) it refers to facilities that permit the effective cleaning of hands. It is worded this way to allow other hand cleaning options (e.g. hand sanitizers) supported by evidence that they are effective.	**Canada**
Paragraph 25	

People known or suspected to be suffering from diarrheal illness should not be allowed to enter any area where handling seeds destined for ~~sprouting~~sprouting occurs, including the growing and harvest area.	**Canada**
Paragraph 26	
Refer to the section 3.2.3 of the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003) and section 6 of the General Principles of Food Hygiene CXC 1-1969 for more recommendations that may apply.~~Refer to the General Principles of Food Hygiene CXC 1-1969 section 3.2.3 and section 6 for more recommendations that may apply.~~ Section 3.2.3 corresponds to Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003)	**Argentina**
Refer to the ~~General Principles of Food Hygiene~~ *General Principles of Food Hygiene* CXC 1-1969 section 3.2.3 and section 6 for more recommendations that may apply. Title to be in Italics.	**Canada**
Refer to the General Principles of Food Hygiene CXC 1-1969 **section 3.2.3 and section 6** for more recommendations that may apply. The section numbers should be updated to the revised General Principles of Food Hygiene.	**Canada**
Refer to the General Principles of Food Hygiene ~~CXC 1-1969~~ (CXC 1-1969) section ~~3~~9.2.3 and section ~~6~~ 12 and the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003) section 3.2.3 for more recommendations that may apply. The UK suggests the amendments to the sections referenced in the General Principles and has added reference to the Code of Hygienic Practice for Fresh Fruits and Vegetables	**United Kingdom**
4.1.5 Equipment associated with growing and harvesting of seeds for sprouting	
United Arab Emirates proposes to delete the below section (27) and (29) because it is an additional requirement, and the subsequent points are enough to achieve the goal that is to prevent introduction of pathogens such as STEC onto seeds for sprouting.	**United Arab Emirates**
Paragraph 28	
Growers should avoid moving harvesting equipment across fields where manure or ~~compost non – properly composted~~compost, has been applied. Australia suggest the following deletion to align with similar text in the leafy vegetable Annex.	**Australia**
Growers should avoid moving harvesting equipment across fields where ~~manure or compost non – properly composted, has~~ improperly composted manure/biosolids have been applied. The edited text in the comment above is for readability and clarity, and to be consistent with terminology in paragraph 21.	**USA**
Paragraph 31	
Equipment used to transport the seeds should be clean and, where necessary, disinfected prior to use.	**Canada**
Paragraph 33	

Seeds for sprouting should be held and stored in ~~closed~~ solid bags (e.g. new or ~~covered~~ recycled bags) or completely closed/covered containers, in a clean, dry area dedicated only to seed storage. Open weave bags or containers with holes or uncovered openings should not be used to store seeds. Paragraphs 33, 35, and 36 are all related to storage containers for seeds and are duplicative. The United States proposes deletion of paragraphs 35 and 36. It is unclear why the statement in paragraph 36 is written only for recycled bags and it is unclear when there would not be a "possibility of prior contamination," therefore this language was not retained in the proposed edits to paragraph 33.	**USA**
Paragraph 35	
Use solid bags or other containers to hold or storage seeds for sprouting., ~~open~~ Open weave bags or ~~other~~ containers ~~which includes~~ with holes ~~on it,~~ should not be used to protect the seeds from contamination.	**Australia**
Solid bags or other containers should be used to hold or store seeds for sprouting.~~Use solid bags or other containers to hold or storage seeds for sprouting, open~~ Open weave bags or other containers ~~which includes~~ with holes ~~on it,~~ should not be used to protect the seeds from contamination. Suggest a modification in the sentence to align with the structure of the second sentence in paragraph 35 and other sentences in this Annex i.e., the use of "should" in the recommendations. Also Suggest breaking into two sentences to improve the readability.	**Canada**
~~Use solid bags or other containers to hold or storage seeds for sprouting, open weave bags or other containers which includes holes on it, should not be used to protect the seeds from contamination.~~ See comments for Paragraph 33.	**USA**
Paragraph 36	
~~The use of recycled bags should be avoided if there is a possibility of prior contamination.~~ See comments for Paragraph 33.	**USA**
Paragraph 37	
Each container should be marked to identify the source and lot and if the seed has been **treated**. This should be clearly indicated on the label. It is not clear what "treated" is referring to here. It seems to imply treatment by the seed grower. Treatments done by the sprout growers is mention below, but not the seed grower.	**Canada**
5. SPROUT PRODUCTION	
Paragraph 39	
HACCP principles should be applied to sprout production, with all ~~the~~ steps well documented and potential critical control points (e.g., decontamination of the seeds) identified and controlled. If a problem is identified (e.g., STEC contamination of sprouts), corrective actions should be taken and a critical review of all the steps should be performed to determine whether changes are needed.	**Canada**
5.1 Sourcing and Receiving t seeds for sprouting	
5.1 Sourcing and Receiving ~~t~~ of seeds for sprouting	**Canada**
5.1 Sourcing and Receiving t seeds for sprouting Kenya proposes an editorial amendment to the subtitle by replacing 't' with of 5.1 Sourcing and Receiving of seeds for sprouting Justification: For clarity	**Kenya**

Paragraph 40	
Seeds should be obtained from suppliers, (producers or distributors) that follow GAPs and GHPs during production, storage, ~~distribution,~~ and ~~commercialization~~ distribution of ~~the seeds~~seeds for sprouting. When possible, microbiological testing/certificates of analysis or a letter of guarantee should be obtained from the supplier. It is unclear what is meant by "commercialization". This term is not used elsewhere in the annex and is not needed in the statement. The edits provided are consistent with the statement in current paragraph 76.	**USA**
Paragraph 42	
Keeping seeds and sprouts from different batches separated can facilitate the identification of contaminated batches and help trace seeds back to the supplier**. Water used throughout sprouts production should be fit for purpose.** Suggest moving this sentence (possibly after paragraph 39) as this section is about sourcing and receiving seeds.	**Canada**
Keeping seeds and sprouts from different batches separated can facilitate the identification of contaminated batches and help trace seeds back to the supplier~~.~~ .43. Water used throughout sprouts production should be fit for purpose. The last sentence "Water used throughout sprouts production should be fit for purpose." should become a new paragraph 43 since it is completely different subject from the first line of this paragraph 42.	**Indonesia**
Keeping seeds and sprouts from different batches separated can facilitate the identification of contaminated batches and help trace seeds back to the supplier**.** ~~Water used throughout sprouts production should be fit for purpose.~~ The proposed deleted statement is not positioned correctly in the annex. This statement applies to all water used in the production of sprouts, and therefore should be added below the current paragraph 39 to make a new paragraph 40 under the main section 5 heading and before section 5.1.	**USA**
Paragraph 42	
Seeds should be stored and handled in conditions (e.g., temperature and relative humidity) that will prevent growth of microorganisms, such as STEC. Seeds should also be stored and handled in a manner that will avoid damage and keep them protected from pests and other sources of STEC contamination. Australia suggest the second sentence should be a separate paragraph given it's importance. Keeping seeds and sprouts from different batches separated can facilitate the identification of contaminated batches and help trace seeds back to the supplier. Water used throughout sprouts production should be fit for purpose.	**Australia**
Seeds should be stored and handled in conditions (e.g., temperature and relative humidity) that will prevent growth of microorganisms, such as STEC. Seeds should also be stored and handled in a manner that will avoid damage and keep them protected from pests and other sources of STEC contamination. Kenya proposes a proper numbering of para 43 since it is repeated as para 42	**Kenya**
Paragraph 43	
Seeds should be rinsed thoroughly to remove dirt or debris before any ~~antimicrobial~~ treatment is applied. The word "antimicrobial" may be understood as using antimicrobials which is not correct. The possible treatments are extensively explained in paragraphs 46 to 48, so no details are needed here.	**European Union**

Paragraph 44	
Kenya proposes editorial amendments to para by deleting 'with fit for purpose water' in para44 to read: Seeds should be rinsed and agitated in large volumes of fir for purpose water. Repeat the process until the dirt or debris are removed and rinse water remains clear. Justification: the process of repeating is already captured in the first sentence. Comment: Kenya takes note of the application of the scope where microbicidal treatment is not allowed yet at section 5.4 Treatment and pre-germination soak of seeds for sprouting, allows the use of chemical methods in para 47 and other Physical treatments in para 48 which are microbiocidal. Kenya, therefore seeks clarification on the same.	**Kenya**
Paragraph 47	
Los siguientes productos químicos, si se utilizan en concentraciones adecuadas, pueden lograr al menos una reducción de 3 log de patógenos: hidróxido de calcio (Holliday *et al*., 2001), hipoclorito de calcio (Ding *et al*., 2013), hipoclorito de sodio, (Ding *et al.*, 2013) ácido caprílico (Chang *et al.,* 2010), ácido acético gaseoso (Nei *et al.*, 2011; Nei *et al.*, 2014), peróxido de hidrógeno (Holliday *et al.*, 2001), ácido láctico (Sikin *et al*., 2013), monocaprilina (Chang *et al.*, 2010), ácido oxálico (Sikin *et al.*, 2013) y ácido fítico (Sikin *et al.*, 2013). Cuando se utilice un tratamiento químico, se deberían medir y registrar con precisión la duración del tratamiento y la concentración del producto químico **utilizado.** Uruguay sugiere que se incluya que estos productos deben estar autorizados por las Autoridades competentes	**Uruguay**
Paragraph 48	
Physical treatments have been reported to achieve a 5-log or greater reduction in pathogens, including *E. coli* serotype O157:H7, on seeds (Bari et al, 2010, Ding et al., 2013, Neetoo et al., 2013). Physical treatments, such as heat (dry heat or hot water), high pressure, and irradiation are reported to have better penetration characteristics for reaching bacteria on microscopically rough surfaces as well as the interior of the seed as compared to chemical treatments (Ding et al., 2013). ~~Physical and~~ Combinations of several physical and/or chemical ~~combination~~ treatments have been reported to be the most effective for removing pathogens from seeds for sprouting. Combination ~~methods~~ treatments applied sequentially or simultaneously may be more effective than using a single treatment alone. The edits clarify the sentence to mean that a combination treatment can consist of 2 or more physical treatments, 2 or more chemical treatments, or a combination of both physical and chemical treatments.	**USA**
Paragraph 51	
DEBE DE DECIR: 5.5. Enjuague después del tratamiento de las semillas 51. Puede ser necesario enjuagar las semillas después de someterlas a tratamiento (por ejemplo, semillas tratadas con productos químicos). La duración de la fase de enjuague debería ser la adecuada para limitar la posible proliferación microbiana y reducir el residual de los productos químicos En razón que también la finalidad del enjuague después de un tratamiento químico de las semillas sería la reducción del residual de productos químicos en las semillas.	**Peru**
Paragraph 53	
Seeds for soil-grown sprouts are generally rinsed and soaked to allow for initial germination before sowing in soil in plastic trays. Water is sprayed over the trays daily. **Sprouts such as alfalfa, broccoli, clover, and radish are grown hydroponically in rotating drums with frequent water sprays. If present at the growing stage, microbial pathogens such as STEC can multiply, significantly increasing the risk for illness.**	**New Zealand**

Reword - Sprouts such as alfalfa, broccoli, clover, and radish are grown hydroponically at ambient or higher temperature, in rotating drums with frequent water sprays. Because of the relative high temperature, if present at the growing stage, microbial pathogens such as STEC can multiply rapidly, significantly increasing the risk for the consumer. Reason: It is necessary to explain that the temperature used to grow sprouts (RT or higher) is favourable to pathogen growth too, which makes sprouts more dangerous compared to other vegetables	
5.7 Harvesting	
5.7 Harvesting, Final Rinsing and Cooling To be in line with the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003), the title of the section 5.7 may be revised to "Harvesting, Final Rinsing and Cooling". This also to facilitate the addition of a new paragraph discussing about cooling, as this cooling term is mentioned in paragraph 55, but is not discussed anywhere in the current document.	**Indonesia**
Paragraph 54	
Sprouts are harvested manually by removing them from growing units.55. Sprouts may be washed to remove hulls and/or to help lower the temperature of the sprouts and then spin-dried. Soil-grown sprouts are harvested by cutting them from the trays, prior to washing and packaging, or the sprout trays are sent to retailers and cut at the point of sale. GHPs should be applied to prevent these operations from being a source of contamination (e.g., if some of the sprouts are contaminated with STEC from the environment or from handlers). Remove the second line "Sprouts may be washed to remove hulls and/or to help lower the temperature of the sprouts and then spin-dried." from the para 54 to a new para 55.	**Indonesia**
United Arab Emirates proposes to elaborate the specifications of water using for washing, and if it may contain disinfectants, to avoid Sprouts contamination during washing	**United Arab Emirates**
Paragraph 55	
Sprouts should be maintained at appropriate refrigerated temperatures after cooling to minimize growth of any STEC that may be present. The temperature of cold storage should be controlled, monitored, and recorded. 56. If additional cooling time is necessary, steps should be taken to facilitate rapid cooling (e.g. product placed in smaller containers with adequate air flow between containers). The suggested new paragraph is copied from the Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003).	**Indonesia**
Paragraph 58	
Documentation of key information for incoming seeds (e.g., supplier details, date of receipt, ~~quantity~~ quantity, production batch/lot code, etc.) should be maintained. Of all the information that would be key in maintaining, the production batch/lot code would be very important for traceability and should be included in this paragraph.	**USA**
6. MICROBIOLOGICAL CRITERIA AND OTHER SPECIFICATIONS FOR LABORATORY TESTING	
Australia supports advancing Annex 4 in the Codex Step process with the following comment. Section 6 Microbiological criteria and other specifications for laboratory testing The purpose for this testing is to verify process control. Current drafting of paragraph 65 could be interpreted as suggesting indicator organism testing is	**Australia**

required for lot clearance – which is not the intent. Australia suggests some minor redrafting is necessary to focus the messaging that the purpose of indicator testing of lots is to evaluate and verify the effectiveness of control measures and processes. Testing is not used primarily for the purposes of lot clearance as food safety is ensured through a system of control measures applied at appropriate points along the sprout production flow.	
Paragraph 62	
Where appropriate and when possible, ~~sprouts or~~ spent sprout irrigation water ~~(SSIW)~~(SSIW) (or in-process sprouts), and possibly seeds, should be tested for the presence of pathogens such as STEC; in particular, strains demonstrated to be a country's highest priority due to their public health burden (e.g., those strains with virulence factors capable of causing severe illness or considered to cause significant illness in that country)~~.~~. The samples collected for testing should be representative of the production batch. As explained in paragraph 70 further down, testing SSIW is the preferred approach, but when SSIW is not available (e.g. due to the growing method), collecting in-process sprouts is generally the next best option. Making this change here clarifies that we are not requesting operations test their finished product and sets up the discussion in paragraph 70. The statements on the advantages of testing SSIW or in-process sprouts in paragraph 63 is duplicative with those in paragraph 68. The statements on representative sampling in paragraphs 63 and p64 have been moved to paragraph 62.	**USA**
Paragraph 63	
Testing ~~spent sprout irrigation water~~ SSIW or in-process sprouts collected during sprouting increases the likelihood of detecting the pathogens that may be present in seed. It also enables early detection of contamination in the production batch before products enter the marketplace. Testing ~~spent sprout irrigation water~~ SSIW is preferred over testing sprouts because water may pick up bacteria as it passes through the production batch, making it easier to collect a representative sample. To make consistent with other paragraphs	**Japan**
~~Testing spent sprout irrigation water or in-process sprouts collected during sprouting increases the likelihood of detecting the pathogens that may be present in seed. It also enables early detection of contamination in the production batch before products enter the marketplace. Testing spent sprout irrigation water is preferred over testing sprouts because water may pick up bacteria as it passes through the production batch, making it easier to collect a representative sample.~~ See comments on paragraph 62.	**USA**
Paragraph 64	
~~The volume of sample collected should be sufficient to be representative of the production batch and for testing target pathogens.~~ See comments on paragraph 62.	**USA**
Paragragh 65	
Testing for indicator microorganisms, can be a useful tool to evaluate and verify the ~~safety of the product, the~~ effectiveness of the control measures, and to provide information about an environment, ~~a process~~ or ~~even~~ a ~~specific product lot~~ process 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) and *Principles and Guidelines for the conduct of microbiological risk management (MRM)* (CAC/GL 63-2007).	**Australia**
Testing for indicator ~~microorganisms~~microorganisms (e.g., generic E. coli), can be a useful tool to evaluate and verify the safety of the product, 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	**USA**

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) and *Principles and Guidelines for the conduct of microbiological risk management (MRM)* (CAC/GL 63-2007). The insertion retains the example of an indicator microorganism from paragraph 71, which the United States proposes deleting since it is duplicative in concept with paragraph 68.	
Paragragh 66	
~~Testing lots of sprout seeds for pathogens such as STEC can help identify contaminated lots. Thus, some~~ Some seed producers or seed suppliers may opt to test their seed for pathogens to help identify contaminated lots before distribution. However, the likelihood of detecting the presence of pathogens such as STEC in seeds is low, due to the heterogeneous distribution and low numbers of STEC contaminating the seeds. A negative test does not assure the absence of STEC on the seeds. The first sentence is repetitive to paragraph 62. The United States also moved the language on identifying a contaminated lot to the second sentence since that does not appear in the line in paragraph 62.	**USA**
Paragragh 67	
~~Testing of seed lots for indicator microorganisms may be used as an indicator of potential STEC contamination. If initial testing indicates the possible presence of STEC, additional testing for STEC is recommended.~~ This paragraph is repetitive and not as clear as paragraph 65.	**USA**
Paragragh 68	
Microbial testing of SSIW (or in-process sprouts) is an important part of a multi-hurdle approach to ensure contaminated sprouts do not enter the marketplace. Testing SSIW (or in-process sprouts) for STEC from each production batch of sprouts may be a much more reliable indicator than testing seed to determine whether the sprouts and potentially the seeds used to produce the batch, are contaminated with STEC. The highly perishable nature of sprouted seeds generally makes routine microbiological testing of finished sprouts impractical. The insertion retains the concept from paragraph 71, which the United States proposes deleting since it is duplicative in concept to paragraph 68.	**USA**
Microbial testing of SSIW (or in-process sprouts) is an important part of a multi-hurdle approach to ensure contaminated sprouts do not enter the marketplace. Testing SSIW (or in-process sprouts) for STEC from each production batch of sprouts **may be** a much more reliable indicator than testing seed to determine whether the sprouts and potentially the seeds used to produce the batch, are contaminated with STEC. Reword - ..."sprouts is a much more reliable indicator than testing seeds..." Reason: It is certain and proven that testing SSIW is better than testing seeds	**New Zealand**
Paragragh 70	
If testing SSIW is not practicable (for example, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water), ~~each production batch of~~ sprouts could be tested at the in-process stage (i.e., while sprouts are still growing).	**Australia**
Paragragh 71	

The highly perishable nature of sprouted seeds generally makes routine microbiological testing of finished sprouts impractical. Testing ~~spent sprout irrigation water of seed lots~~SSIW , or in-process sprouts is more practical. However, periodic testing of the finished sprouts for generic *E. coli* may be beneficial for evaluating the overall effectiveness of hygiene practices and post sprouting treatments (e.g., final rinse). Japan propose to delete "of seed lots" as it does not appear elsewhere in this document where SSIW is mentioned.	**Japan**
The highly perishable nature of ~~sprouted seeds~~ sprouts generally makes routine microbiological testing of finished sprouts impractical. Testing spent sprout irrigation water of seed lots, or in-process sprouts is more practical. However, periodic testing of the finished sprouts for generic *E. coli* may be beneficial for evaluating the overall effectiveness of hygiene practices and post sprouting treatments (e.g., final rinse). Rationale: We would like to suggest using the term 'sprouts' as defined in the Section 3.3 Definitions for consistency.	**Thailand**
~~The highly perishable nature of sprouted seeds generally makes routine microbiological testing of finished sprouts impractical. Testing spent sprout irrigation water of seed lots, or in-process sprouts is more practical. However, periodic testing of the finished sprouts for generic *E. coli* may be beneficial for evaluating the overall effectiveness of hygiene practices and post sprouting treatments (e.g., final rinse).~~ The United States proposes deletion of the paragraph as it is duplicative with paragraph 68.	**USA**
7. DISTRIBUTION AND POINT-OF-SALE	
Paragragh 72	
STEC growth and contamination can occur during transport, distribution and at point-of-sale due to improper handling and poor personal hygiene, and contamination through comingling with other raw food commodities and animals/animal products, and exposure to ~~unsanitary~~ insanitary surfaces and/or water**.** Control measures should be applied during distribution and at point of sale to prevent contamination with STEC. The term “unsanitary” is not typically used in this context. If the term “insanitary” does not translate to other languages with an appropriate meaning, then the United States suggests a term such as “unclean”.	**USA**
7.1 Transportation	
7.1. Transporte El CCFH Perú sugiere que en el numeral 73 del subtítulo 7.1 Transporte, se precise rangos de temperatura y humedad de transporte o los límites máximos de temperaturas de refrigeración en transporte a fin de minimizar o controlar el crecimiento de microorganismos. 7.1. Transporte El transporte debería realizarse en vehículos limpios, cerrados y refrigerados, y se debería controlar la temperatura del compartimento refrigerado de dichos vehículos.	**Peru**
Paragragh 73	
Sprouts should be transported ~~Transportation should be done~~ in clean, enclosed, and refrigerated transport vehicles and the temperature in the refrigerated compartment of such transport vehicles, should be monitored. Edits provided above for clarity and readability.	**USA**
8. PRODUCT INFORMATION AND CONSUMER AWARENESS	
Paragragh 74	

Producers should provide relevant information to the consumer to assure the safety of ~~sprouted seeds~~ sprouts during storage, handling, and preparation of the product. This information may include, but is not limited to: (1) recommended temperature of storage; (2) the date by which the sprouts should be consumed or discarded (e.g. use-by date); (3) cooking or washing instructions, which should be included on the label if the product is intended to be consumed as non-RTE or cooked before consumption. Rationale: To utilize the term already defined in Section 3.3 Definitions for consistency throughout the text.	**Thailand**
Producers should provide relevant information to the consumer to assure the safety of sprouted seeds during storage, handling, and preparation of the product. This information may include, but is not limited to: (1) recommended temperature of storage; (2) the date by which the sprouts should be consumed or discarded (e.g. use-by date); (3) ~~cooking or~~ washing instructions, which should be included on the label if the product is intended to be ~~consumed as non-RTE or cooked~~ washed before consumption. Given the scope of the document, the United States agrees with other comments that the statement in (3) could be deleted in whole. Although not a practice in the United States if sprouts are labeled elsewhere with the intent to wash before consumption, then the United States offers the suggested edits to paragraph 74.	**USA**
9. TRAINING	
All personnel involved in the production and handling of seeds for sprouting or sprouts across the supply chain should receive training on the principles of food hygiene and food safety, in particular the high risk of sprouts and the illness associated with them, as well as personal health and hygiene requirements. This should be para 76.	**Japan**
Kenya proposes that the bullet under Training in section 9 should be given an independent number and the word ‘nature’ added to read: All personnel involved in the production and handling of seeds for sprouting or sprouts across the supply chain should receive training on the principles of food hygiene and food safety, in particular the high-risk nature of sprouts and the illness associated with them, as well as personal health and hygiene requirements. Justification: For the flow of the sentence.	**Kenya**
Paragragh 77	
Control measures~~Interventions~~ designed to reduce microbiological hazards in sprouts can be highly technical and difficult to implement. Specific training related to seed sourcing and storage, seed treatment, cleaning and disinfecting, sampling and microbiological testing, and record keeping should be done to ensure successful implementation. The meaning of the word ‘interventions” is not clear in this context.	**USA**
10. RETAIL AND FOODSERVICE	
Paragragh 78	
Kenya proposes that ‘and recorded’ be added to para 78 to read: Sprouts for retail sale should be held at an appropriate refrigeration temperature to minimize growth of STEC. Temperatures should be monitored and recorded. Justification: Indicates the evidence of monitoring.	**Kenya**
Paragragh 80	

For in-restaurant sprouting~~, interventions~~ , control measures recommended for sprout operations to minimize the potential for STEC should be considered, including seed sourcing programs, seed treatment (if appropriate), prevention of cross-contamination, sampling, and testing of spent sprout irrigation water (samples to be tested by contract laboratories), as well as cleaning and disinfecting food contact surfaces. The meaning of the word 'interventions" is not clear in this context.	**USA**
Figure 1 Sprouts Flow Diagram	
Kenya seeks clarification on the meaning of deposit in the flow diagram	**Kenya**