

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 7

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

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PROPOSALS FOR NEW WORK¹

A list of proposals to elaborate new standards and related texts is presented below, including the reference of the project document in the relevant report. The Commission is invited to decide whether or not to undertake new work in each case, taking into account the critical review conducted by the Executive Committee, and to decide which subsidiary body or other body should undertake the work. The Commission is invited to consider these proposals in the light of its *Strategic Plan 2014-2019* and the *Criteria for the Establishment of Work Priorities* and *Criteria for the Establishment of Subsidiary Bodies of the Codex Alimentarius Commission*.

Codex Body	Text	Reference and project document
CCFICS	Project document for new work on the consolidation of Codex Guidelines related to equivalence	REP19/FICS Para 32 (ii) and (iii) (b), Appendix II
CCFH	Project document for new work on development of guidelines for the control of Shiga toxin-producing <i>Escherichia coli</i> (STEC) in beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts	REP19/FH Para 76

¹ For Codex meetings held in April and May 2019, proposals for new work will be issued as Add. 1 to this document.

PROJECT DOCUMENT FOR NEW WORK ON THE CONSOLIDATION OF CODEX GUIDELINES RELATED TO EQUIVALENCE

1. Purpose and scope of the proposed new work

The purpose of the work is to consolidate all equivalence guidelines to provide clear, consistent and useful guidance to countries considering the use of any form of equivalence. The scope of the consolidated guidelines will cover equivalence with respect to the protection of the health of consumers and ensuring fair practices in the food trade. They will include the process to be followed for considerations of equivalence for a specifically identified measure or set of measures as well as the National Food Control Systems (NFCS) in whole or the relevant part. It would also include guidance on how any such recognition of equivalence may be formalized in an agreement or arrangement. This work builds upon the Committee's ongoing work developing guidelines on the use of system equivalence, which will continue through to adoption, noting the Committee was also tasked to consider consequential modifications of existing work that may be necessary.

2. Relevance and timeliness

Consolidation of all guidelines related to equivalence (Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CXG 34-1999), Guidelines on the Judgment of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CXG 53-2003) and the results of the ongoing (job number N25-2017) work on guidance on the use of system equivalence) will improve the clarity of the guidance for countries considering the use of any or all forms of equivalence and ensure there is appropriate consistency as to which process to follow in different situations. This will be a more productive use of the time of the Committee than just considering minor consequential amendments to the existing guidance as previously proposed.

3. The main aspects to be covered

The proposed new work will consolidate all guidelines related to equivalence (CXG 34-1999, CXG 53-2003 and the results of the ongoing work on the guideline on the use of systems equivalence) into a single cohesive guide that provides clear guidance as to which process may be appropriate in different situations. Minor amendments to other Codex guidance documents that mention equivalence may also be considered if appropriate.

4. An assessment against the Criteria for the Establishment of Work Priorities

The proposal is consistent with the criteria as follows:

General Criterion: Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries. The proposed new work will further facilitate the trade of safe food while freeing up resources to allow better targeting of greater risk scenarios, thus meeting the general criterion of consumer protection.

Criteria Applicable to General Subjects:

a) Diversification of national legislations and apparent resultant or potential impediments to international trade: Countries are increasingly prescribing not only standards for end products but also detailed production and processing requirements, resulting in increased requests for information, audit visits and product inspections. Recognition of equivalence, where competent regulatory systems are already in place, could reduce the burden on resources and unnecessary restrictions on trade caused by such processes.

b) Scope of work and establishment of priorities between the various sections of work:

Refer to Scope above.

c) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies):

The WTO/SPS Committee's decision (G/SPS/19) provides for some further clarification on how WTO members should make use of the "equivalence" provisions of the SPS Agreement i.e. Article 4. This decision, published in 2001 encouraged CODEX to complete its work developing guidelines on equivalence as expeditiously as possible. To that end, CCFICS has developed a number of standards that provide for the use of equivalence including the work currently progressing to develop specific guidance on a process for the potential recognition of the equivalence of whole or parts of NFCSs Consolidating all of the guidance on equivalence would further facilitate and enable better use of existing Codex guidelines and the results of the Committee's ongoing work on the use of system equivalence. The Committee will take into account any relevant international work in this area that is identified during the course of the work.

d) Amenability of the subject of the proposal to standardisation:

The Committee believes that consolidation of all three guidelines will further assist standardisation and improve clarity.

e) Consideration of the global magnitude of the problem or issue:

The Committee has assessed that there is currently a significant burden imposed on importing and exporting countries due to the lack of recognition of the equivalence of existing food control measures or the whole or parts of NFCSs and that further practical international guidance in a consolidated form in this area will help reduce that burden. The scarcity of notified equivalence agreements to the WTO/SPS Committee in accordance with G/SPS/7/Rev.2/Add.1 is further evidence that greater clarity of guidelines in this area is both timely and relevant.

5. Relevance to Codex strategic objectives

The proposed work is directly related to the purpose of the Codex Alimentarius Commission, according to its statutes, to protect the health of the consumers and ensure fair practices in the food trade, as well as to the first Strategic Goal of the Codex Alimentarius Commission's Strategic Plan 2014-2019 "establish international food standards that address current and emerging food issues", and is consistent with Objective 1.2 "proactively identify emerging issues and member country needs and, where appropriate, develop relevant food standards". Further, it contributes to Activity 1.2.2 "develop and revise international and regional standards as needed, in response to needs identified by Members and in response to factors that affect food safety, nutrition and fair practices in the food trade". It is also consistent with Objective 1.3 "strengthen coordination and cooperation with other international standards-setting organizations seeking to avoid duplication of efforts and optimize opportunities".

6. Information on the relation between the proposal and other existing Codex documents

The proposed work will take into consideration the results of the ongoing work being progressed by the Committee on the use of system equivalence; the Guidelines for the Development of Equivalence Agreements Regarding Food Import and Export Inspection and Certification Systems (CXG 34-1999); the Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems (CXG 53-2003); and the relevant parts of Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems (CXG 26-1997). The proposed work will also take into account aspects of the recently promulgated Guidelines for National Food Control Systems (CXG 82-2013); the Guidelines for Food Import Control Systems (CXG 47-2003); and the Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food (CXG 89-2016). Minor amendments to other Codex guidelines that mention equivalence may also be considered, if appropriate.

7. Identification of any requirement for and availability of expert scientific advice

Not required.

8. Identification of any need for technical input to the standard from external bodies so that this can

be planned for: Not required at this time.

9. Proposed timeline for completion of the new work and other conditions

Subject to the approval of the Codex Alimentarius Commission at its 42nd session in 2019, it is expected that the new work can be completed within three or four sessions of CCFICS, should it continue to meet as currently scheduled i.e. every 18 months.

PROJECT DOCUMENT FOR NEW WORK ON DEVELOPMENT OF GUIDELINES FOR THE CONTROL OF SHIGA TOXIN-PRODUCING ESCHERICHIA COLI (STEC) IN BEEF MEAT, LEAFY GREENS, RAW MILK AND CHEESE PRODUCED FROM RAW MILK, AND SPROUTS

1. The purposes and scope of the Standard

The purpose and scope of the work is to draft guidelines for the control of STEC in beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts.

2. Its relevance and timeliness

Strains of pathogenic *Escherichia coli* that are characterized by their ability to produce Shiga toxins are referred to as Shiga toxin-producing *E. coli* (STEC). STEC are an important cause of foodborne disease, and infections have been associated with a wide range of human clinical illnesses ranging from mild non-bloody diarrhoea to bloody diarrhoea (BD) and haemolytic uremic syndrome (HUS), which often includes kidney failure. A high proportion of patients are hospitalized, some develop end-stage renal disease (ESRD) and some die.

This pathogenic group of *E. coli* has been referred to using multiple terms and acronyms. Some of these, e.g. verotoxin-producing *E. coli* (VTEC) and Shiga toxin-producing *E. coli* (STEC), are synonymous and refer to toxin producing capability of the organism. Another, non-O157 STEC, refers to the STEC group aside from serotype O157:H7. STEC is becoming the most common term to apply broadly to all strains that produce Shiga toxin; however, not all strains of STEC are pathogenic.

The Codex Committee on Food Hygiene (CCFH) has discussed the issue of STEC in foods since its 45th Session (November 2013) and at the 47th Session (November 2015), it was agreed that it was an important issue to be addressed². To commence this work, the CCFH requested the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) to develop a report compiling and synthesizing available relevant information, using existing reviews where possible, on STEC. A Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) panel of experts was created and a report entitled *Shiga Toxin-Producing Escherichia coli (STEC) and Food: Attribution, Characterization, and Monitoring*³, was published in June 2018.

In 2015, WHO published the first estimates of the global burden of foodborne disease, which estimated that in 2010 more than 600 million people fell ill from foodborne disease caused by 31 microbiological and chemical agents (including STEC), resulting in 420,000 deaths and 33 million Disability Adjusted Life Years (DALYs). The Foodborne Disease Burden Epidemiology Reference Group (FERG), which conducted the work for WHO, estimated that foodborne STEC caused more than 1 million illnesses, resulting in more than 100 deaths and nearly 13,000 DALYs.

Of the microbiological hazards considered by FERG, STEC ranked towards the lower end in terms of burden; however, the expert group concluded that STEC is indeed a global problem. After considering additional data on human STEC illness from both FAO and WHO member countries and the peer reviewed and grey literature, it was noted that human STEC illnesses have been found in most countries. In addition, STEC poses an economic impact in terms of disease prevention and treatment and has implications for domestic and international trade. Because of international trade, STEC has the potential to become a risk management priority in countries in which it is not currently a public health priority.

Rapidly evolving international trade demands associated with the need to mitigate the risk of international outbreaks and the severe human consequences and potential trade embargoes that could result from emergence of STEC in less developed areas suggest that all countries should have the ability to detect and monitor STEC in foods destined for domestic or international consumption. In terms of international food standards developed by the Codex Alimentarius, which serve as the benchmark for the safety and quality of foods traded internationally, it was also noted that STEC is one of the few foodborne pathogens that was considered in FERG's global burden on foodborne disease work for which Codex has not as yet developed explicit risk management guidance.

According to the data compiled by the JEMRA expert panel, the most important sources of STEC estimated globally are produce (attribution proportion of 13%), beef (11%), and dairy products (7%). More than half of the outbreaks globally could not be attributed to any source (60%). The dairy products proportion is largely attributed to the consumption of raw milk and cheese produced from raw milk. While beef was identified as the

²REP16/FH, para. 48

³ FAO/WHO Shiga toxin-producing *Escherichia coli* (STEC) and food: attribution, characterization, and monitoring. <http://www.fao.org/3/ca0032en/CA0032EN.pdf>

most important food category in the African, European and Eastern Mediterranean regions and the Americas, analysis of the outbreak data indicated that fresh produce (i.e., fruits/vegetables) was almost as important as a source of outbreaks in North America and Europe. In the Southeast Asian region where beef makes up less of the overall meat consumed, meat from small ruminants was significant. Outbreak data in North America and Europe indicate that leafy greens (e.g. lettuce, spring mix, spinach) and sprouts caused the majority of outbreaks. Sprouts represent a special food safety concern because the conditions under which sprouts are produced (time, temperature, water activity, pH and available nutrients) are also ideal for the growth of pathogens if they are present. Since leafy greens and sprouts are produced using distinctive practices and conditions, they will be discussed in separate sections even though both are produce. Based on these data, it is proposed that the guidelines focus on controlling STEC in beef meat (indicating those practices that would also have benefits for controlling STEC in small ruminants such as sheep and goats), raw milk and cheese made from raw milk, leafy greens, and sprouts.

3. The main aspects to be covered

The Guidelines will follow the examples of the overarching *Code of Hygienic Practice for Meat* (CXC 58-2005), *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003), and *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004), to provide an “enabling” framework that countries can use to establish control measures appropriate to their national situation for the most globally important food sources estimated by the JEMRA expert panel. It is not the intention of the Guidelines to set quantitative limits for STEC in meat, raw milk and cheese produced from raw milk, leafy greens, and sprouts in international trade.

The projected format will follow the *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011) and *Guidelines for the Control of Nontyphoidal Salmonella spp. in Beef and Pork Meat* (CXG 87-2016). The proposed structure is as follows;

General guidelines for the control of STEC in beef meat (with consideration for meat from small ruminants), leafy greens, raw milk and cheese produced from raw milk and sprouts, taking into account the characteristics of Shiga toxin-producing *Escherichia coli* (STEC) and their virulence factors.

Annex 1: Specific control measures for beef meat

Annex 2: Specific control measures for leafy greens

Annex 3: Specific control measures for raw milk and cheese produced from raw milk

Annex 4: Specific control measures for sprouts

Annexes 1-4 would include (similar to the previously mentioned guidelines) for each food type, as applicable:

- Control measures for primary production (CCFH will work with OIE for beef)
- Control measures for processing
- Control measures for distribution channels
- Validation of control measures
- Verification of control measures
- Laboratory analysis detection criteria for control of STEC in food utilizing virulence factors (based on the recommendations made in the JEMRA review “Shiga toxin-producing *Escherichia coli* (STEC) and food: attribution, characterization, and monitoring”)
- Monitoring and review of control measures

4. An assessment against the *Criteria for establishment of work priorities*

The guidelines need to be developed in order to meet the General criterion: Consumer protection from the point of view of health, food safety, ensuring fair practices in the food trade and taking into account the identified needs of developing countries.

The proposed work is directed primarily at the control of STEC, a microbial hazard that is a public health problem world-wide. This document will provide guidance to all countries on the control of STEC in the production of beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts.

Also, under the Criteria applicable to general subjects, the guidelines are needed in consideration of the global magnitude of the problem or issue.

STEC-related illnesses have been reported in most parts of the world, thus making this a global concern. In addition, to the burden of disease, STEC also poses an economic impact in terms of disease prevention and

treatment, and has implications for domestic and international trade. STEC is the sole remaining foodborne hazard considered by FERG for which risk management guidance has not been developed by Codex.

5. Relevance to the Codex strategic objectives

The proposed work directly relates to several Codex strategic goals from the Codex Strategic Plan: 2014-2019.

- Strategic Goal 1: Establish international food standards that address current and emerging food issues:

These Guidelines would establish a new Codex standard in response to needs identified by Members and in response to factors that affect food safety and fair practices in the foods trade. As noted previously, control of STEC is currently an issue world-wide.

- Strategic Goal 2: Ensure the application of risk analysis principles in the development of Codex standards

The development of the Guidelines will be consistent with the use of scientific advice and risk analysis principles in the articulation of the control measures. Scientific advice from the FAO/WHO expert bodies, particularly JEMRA, and scientific input from all countries will be solicited.

- Strategic Goal 3: Facilitate the effective participation of all Codex Members

The development of these Guidelines will be open to all Codex Members to participate and provide useful and meaningful contributions.

- Strategic Goal 4: Implement effective and efficient work management systems and practices

It is expected that the working group efforts will be effective, efficient, transparent, and consensus-based for a timely adoption of these Guidelines. The process has begun with initial discussions at the ad hoc working group on new work at CCFH50 and in plenary, and will be followed by an electronic working group (EWG) to establish the initial framework..

6. Information on the relation between the proposal and other existing Codex documents

The proposed Guidelines will follow the example of the overarching *Code of Hygienic Practice for Meat* (CXC 58-2005), the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CXC 53-2003) and *Code of Hygienic Practice for Milk and Milk Products* (CXC 57-2004) to provide an “enabling” framework which countries can utilize to establish control measures appropriate to their national situation.

The projected format will follow the *Guidelines for the Control of Campylobacter and Salmonella in Chicken Meat* (CXG 78-2011) and *Guidelines for the Control of Nontyphoidal Salmonella spp. In Beef and Pork Meat* (CXG 87-2016) and include only provisions of particular importance for the safety of beef meat, leafy greens, raw milk and cheese produced from raw milk, and sprouts.

7. Identification of any requirement for and availability of expert scientific advice

To commence this work, CCFH requested FAO and WHO to develop a report compiling and synthesizing available relevant information, using existing reviews where possible, on STEC that would be the basis for the guidelines development.⁴ We anticipate that there may be a need for additional scientific advice from FAO and WHO on the scientific and practical soundness of the proposed control measures and their validation, verification, and review activities. This activity would likely be reaching out to the JEMRA expert panel that developed the report entitled *Shiga Toxin-Producing Escherichia coli (STEC) and Food: Attribution, Characterization, and Monitoring the Risk* published in June 2018.

8. Identification of any need for technical input to the standard from external bodies so that this can be planned for

Since the OIE’s Working Group on Animal Production Food Safety has been discussing the issue of STEC in food-producing animals, particularly for pre-harvest (production level, farm level) controls, OIE should be notified and cooperation encouraged. At CCFH49, OIE indicated it would consider new work on STEC if CCFH also initiated work on STEC. This was reiterated in the Information from the World Organisation for Animal Health (OIE) at CCFH50.

9. The proposed time-line for completion of the new work

A five-year timeline is proposed for the completion of the guideline and annexes by moving in a stepwise fashion, first working on the guideline and annexes 1 and 2, followed by working on Annexes 3 and 4. Assuming approval of this new work by the Codex Alimentarius Commission (CAC) in 2019 at CAC42, a proposed draft

⁴REP16/FH, para. 49

guideline document including Annexes 1 and 2 would be projected for initial discussion by CCFH51 in 2019 with a projected date for a recommendation for adoption at Step 5 in 2020 at CCFH52 and subsequent adoption at Step 5 by CAC44 in 2021. Recommendation for adoption of the guideline and Annexes 1 and 2 at Step 8 is proposed to take place at CCFH53 in 2021, followed by adoption by CAC45 in 2022. Annexes 3 and 4 would be projected for initial discussion by CCFH53 in 2021, with a projected date for a recommendation for adoption at Step 5 in 2022 at CCFH54 and subsequent adoption at Step 5 by CAC46 in 2023. Recommendation for adoption of Annexes 3 and 4 at Step 8 is proposed to take place at CCFH55 in 2023, followed by adoption by CAC47 in 2024.