CODEX ALIMENTARIUS COMMISSION







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Agenda Item 5.2

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION

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FOLLOW-UP TO REGULAR REVIEW OF CODEX WORK MANAGEMENT 2017-2018: PERIODIC REVIEW OF CODEX STANDARDS

(Prepared by the Codex Secretariat)

1. INTRODUCTION

- 1.1 The Regular Review of Codex Work Management Report 2017-2018 focused on collaboration between the Codex Alimentarius Commission (CAC) and other international standard-setting organizations¹. The review made four recommendations for consideration by the Executive Committee (CCEXEC), the second of which focused on the need to discuss the merit in setting up a more systematic approach to review of Codex standards.
- 1.2 While the Chairperson of CAC41 noted that "mechanisms for systematic review existed in some Codex committees", the Codex Secretariat stated that many Codex standards² could benefit from review. CAC41³ noted that a more systematic but not necessarily periodic review of Codex standards could increase their relevance and recognized the variation in current practices related to standards review between Codex committees. Therefore, CAC41 requested that CCEXEC advise the Commission further on this matter. CCEXEC76 thus requested the Secretariat to prepare a paper to support further discussion on this recommendation at CCEXEC774.
- 1.3 This paper reviews the current situation regarding the review of existing Codex standards and identifies some options for consideration in terms of building upon and improving current processes.

2. CURRENT SITUATION

2.1 Procedural aspects

2.1.1 Currently it is the responsibility of CAC to "keep under review the revision of "Codex Standards""⁵. While there is no specific guidance regarding the stimulus for or periodicity of the review process, the Procedural Manual (PM) provides guidance on the procedure for the amendment and revision of Codex standards and related texts. The responsibility for identifying and proposing amendments and revisions of Codex standards to the Commission lies with "the subsidiary body concerned, the Secretariat or a member of the Commission where the subsidiary body concerned is not in existence or has been adjourned *sine die*". With regard to the latter the PM goes on to indicate that:

where Codex subsidiary bodies have been abolished or dissolved, or Codex committees have been adjourned *sine die*, the Secretariat keeps under review all Codex standards and related texts elaborated by these bodies and determines the need for any amendments, in particular those arising from decisions by the Commission⁶.

2.1.2 The Guide to the Procedure for the Amendment and Revision of Codex Standards and Related Texts from which the previous paragraph is quoted, is extensive, containing the distinction between amendments and revisions to standards as well as comprehensive guidance on how to decide on substantive

¹ CX/CAC 18/41/13

² Throughout this document Codex standards refers to all Codex texts including standards, guidlelines and codes of practice.

³ REP18/CAC, paras 114-116

⁴ REP19/EXEC1, para. 9

⁵ Procedural Manual, Section II - Procedures for the elaboration of Codex Standards and Related Texts (para 8)

⁶ Procedural Manual, Section II – Guide to the Procedure for the Amendment and Revision of Codex Standards and Related Texts

amendments/revisions when the relevant subsidiary body is not in existence. Only part of this procedure has ever been used and related questions were raised by the Secretariat at CCGP31⁷ and will be further discussed at CCGP32.

2.1.3 Different mechanisms for the review of Codex standards are used within the various subsidiary bodies, tailored to their needs and in line with their working procedures and often linked with procedures for prioritization of their work, (which may include an assessment of the need for development of new standards or revision of existing ones as part of, for example, a forward work plan) which CCEXEC⁸ has recommended all committees should have. One example of such a process is that of the Codex Committee on Food Hygiene (CCFH)⁹.

2.2 Available tools to support review of Codex standards

2.2.1 Circular Letters (CL)

- 2.2.1.1 Most committees (e.g. CCCF, CCFA, CCFH, CCFL, CCPR, CCRVDF, CCSCH and CCFFV) issue a CL between sessions seeking input on new work proposals including the need to revise existing standards. While replies tend to focus on the need for new work or evaluations, some requests are related to the review of existing standards. In the case of CCPR, part of the CL is specifically dedicated to the periodic review of existing standards in line with the Risk Analysis principles agreed and applied by that Committee 10.
- 2.2.1.2 For some committees the CLs (e.g. CCPR, CCFA) also play an important role in sychronizing the risk management work of the committee with the risk assessment work of the FAO/WHO scientific advise bodies (e.g. the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR)), by facilitating the process of establishment of priority lists of compounds for evaluation.

2.2.2 Matters referred from other Codex committees

- 2.2.2.1 The need for revision of existing standards may also arise as a result of discussions in a committee, other than the one responsible for the initial development of the standard. These could be consequential changes to a standard due to the interrelationship between a new or a revised standard and an existing standard.
- 2.2.2.2 In these cases, the information/request is communicated through the agenda item on *Matters referred* by the Codex Alimentarius Commission and/or other Codex subsidiary bodies and it is the responsibility of the receiving committee to take the appropriate follow-up action in line with the procedures.
- 2.2.2.3 This is a particularly important and well-used mechanism by committees such as CCFA, which is working on the alignment of commodity standards with the General Standard of Food Additives (GSFA). Changes in the GFSA need to be reflected in the relevant Commodity standards and the *Matters Referred* document becomes an important means of dialogue between relevant Committees. Recently, CCFA published the information document *Detailed Guidance and Principles to Align Food Additive Provisions in Codex Commodity Standards with the General Standard for Food Additives,* to assist Commodity committees in the revision of their standards.
- 2.2.2.4 This mechanism is also used with other horizontal committees such as CCMAS, whereby decisions of that Committee can have implications which require the revision of standards developed by other Codex committees.
- 2.2.2.5 Another example was the need for CCFH to revise the Recommended International Code of Hygienic Practice for Foods for Infants and Children (1979)¹¹ to address concerns regarding particular pathogens in infant formula, which was first highlighted in CCNFSDU24¹².

2.2.3 Discussion papers

- 2.2.3.1 Discussion papers can explore the need and feasibliity of work in a particular area and lead to the identification of the necessity for a new Codex standard or the revision of an existing one.
- 2.2.3.2 CCCF regularly has on its agenda discussion papers on issues to be addressed through the revision of an existing standard, guideline or code of practice (COP). For example CCCF13 considered a discussion

8 CX/EXEC 15/70/3 para 8 - 9

⁷ CCGP31/ CRD/10

⁹ Process by which the Codex Committee on Food Hygiene will undertake its work. Available at : http://www.fao.org/fileadmin/user_upload/codexalimentarius/committee/docs/INF_CCFH_e.pdf

¹⁰ Procedural Manual; SectionV-Risk analysis. Risk analysis Principels applied by the Codex committee on Pesticide Residues section 5.3.5 Periodic Review

¹¹ The COP was revised by the CCFH and a new COP (CXC 66-2008) adopted in 2008

¹² Alinorm 03/26A

paper on the revision of the COP for the prevention and reduction of lead contamination in foods, and agreed to submit a project document to CAC42 for approval as new work.

2.2.4 Conference Room Documents (CRD)

- 2.2.4.1 In all cases and particularly when a Committee does not issue a specific CL, Members and Observers have the opportunity to submit a request for review of an existing Codex standard through a CRD (highlighting the need and the proposed revision and when relevant accompanied by a project document).
- 2.2.4.2 The issue would then be discussed under the agenda item *Other business*, according to time availability. If the relevant committee is not active (e.g. ajourned *sine die*), Members or Observers can raise their request directly in the Commission with a discussion paper, CRD or verbally.

2.3 Examples from Codex committees

2.3.1 Codex Committee on Pesticide Residues (CCPR)

2.3.1.1 CCPR has a Periodic Review process in place as part of the risk analysis principles underpinning its work. Its purpose is to fully re-evaluate compounds based on specific health concerns identified by Codex Members and confirmed by JMPR, or where a toxicological review may be warranted considering time passed since the compounds were last evaluated from a toxicologically perspective e.g. 15 years or more. This is a standing agenda item for the Committee.

2.3.2 Codex Committee on Food Additives (CCFA)

- 2.3.2.1 The JECFA Secretariat drew the attention of CCFA41 (2009) to the importance of a systematic approach to the review of previously evaluated compounds and proposed discussion on a mechanism that would allow the re-evaluation of substances based on new knowledge and scientific advancements. Mechanisms for a prioritization/re-evaluation process were discussed during 2009 2014 and CCFA considered whether a systematic re-evaluation process for all additives in the Codex system was necessary.
- 2.3.2.2 CCFA was of the view that there are conditions under which re-evaluation of food additives is warranted, but opinions were divided about whether a process should be in place to re-evaluate all eligible food additives or whether additives should only be re-evaluated on a case-by-case basis when, for example, new safety data about the additive become available. CCFA noted the constraints of such an approach including the capacity of JECFA to conduct re-evaluations in addition to its existing workload and data availability for re-evaluation of compounds. CCFA46 (2014) decided to initiate a trial on food colors and allocated a limited proportion of JECFA meetings for re-evaluation of food colors.
- 2.3.2.3 CCFA50 (2018) considered the process for management of its work, and among other things, agreed on a ranking system (from highest to lowest priority) for placement on the Priority List of requests for those additives intended for inclusion in the GSFA. Re-evaluation of an additive, based on an identified safety concern is listed as the highest priority.

2.3.3 Codex Committee on Food Hygiene (CCFH)

- 2.3.3.1 In developing the process by which CCFH would undertake its work, CCFH included a forward workplan and criteria for evaluating and prioritizing new work. Within that workplan CCFH not only lists proposals for new work but maintains an inventory of older standards that have been developed by the Committee and which could benefit from review but have yet to be prioritized.
- 2.3.3.2 The full list is considered by an *ad hoc* Working Group for the Establishment of CCFH Work Priorities that meets in conjunction with each session of the Committee. Evaluation of older standards for revision against the criteria for evaluating and prioritizing new work requires the presentation of a discussion paper outlining the basis for revision, as well as a project document as requested by the PM, and hence the process requires a Member to be proactive if revision is to be considered.

2.3.4 Codex Committee on Methods of Analysis and Sampling (CCMAS)

2.3.4.1 The review and update of the Recommended Methods of Analysis and Sampling (CXS 234-1999) is a regular agenda item of the CCMAS. In order to facilitate this work, CCMAS has agreed an approach whereby a series of workable packages of methods for review and update are identified. The workable packages are prepared by lead Member countries or Observers (standards development organizations) and then considered by the physical working group for endorsement and finally CCMAS.

2.3.5 Codex commodity committees and task forces

2.3.5.1 Specific initiatives have also taken place in commodity committees to review Codex stadards. When CCPFV was re-established in 1998, the Committee was tasked by the Commission to review all existing individual standards for processed fruits and vegetables and has had a specific agenda item to support

management of this work. Also one of the key tasks of the ad hoc Intergovernmental Task Forces on Fruit and Vegetable Juices was to "revise and consolidate existing Codex standards in this area" ¹³

2.4 External factors contributing the the review of Codex standards

- 2.4.1 FAO and WHO can initiate new risk assessments or a review of an existing one independently of Codex if, for example, there is an urgent public health need or food trade issue to be addressed, or when new information becomes available or there is a development in a specific area that was not considered in the risk assessment work to date. JEMRA is also currently initiating a pilot to review its older risk assessments, the outcome of which may inform the need for revision of standards developed by CCFH.
- 2.4.2 FAO/WHO led events may also drive the review process. Probably the strongest recommendation in this regard came from the 1991 FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade, indicating that "the Commission establish an early review programme for previously developed standards to assure their current relevance with a view to facilitating international trade by being suitable as reference standards in GATT (now WTO) related disputes¹⁴". Following this conference CAC19 (1991) noted that the Secretariat had already taken action to determine which standards should be subject to priority review and agreed that "host" countries could be asked for support in this effort. It also agreed that efforts to involve developing countries in the process should be undertaken."
- 2.4.3 The adoption of the WHO Global Strategy on Diet, Physical Activity and Health led to extensive review and development of new work in CCFL and CCNFSDU.
- 2.4.4 The Global Action Plan on Antimicrobial Resistance (AMR)¹⁵ was adopted by the World Health Assembly in 2015. This highlighted the need for regular review and update of the Codex standards on AMR and triggered a review by the Codex secretariat which led to the establishment of a new *ad hoc* Task force to review existing and develop new Codex standards on AMR.
- 2.4.5 Developments in other United Nations organizations or international fora may also highlight a new or (re)emerging issue for which a Codex standard exists and needs further attention.

2.5 Update status of Codex standards

- 2.5.1 A preliminary review on the revision/amendment of certain existing qualitative standards (e.g. commodity standards, guidelines, codes of practice) was undertaken to gain some additional insights into the current approach to standards revision. Reviewing the standards simply based on time elapsed since the most recent modification (as indicated in the standard itself) presented a relatively positive picture for Codex standards (Table 1) suggesting that 60-70% of these standards had been revised (revision or amendment) within the last decade. While limited in nature these data highlight that:
 - Codex standards are regularly reviewed;
 - in many cases this is for the purposes of alignment with more horizontal Codex standards, but nevertheless ensures that key aspects of the Standards (often safety related provisions, such as alignment with the GSFA) remain up to date;
 - the nature of the text can influence the frequency of revision, e.g. COPs, which highlight general
 good practice that tends not to change significantly over time, being reviewed less frequently;
 and,
 - there is a small number of Codex standards and COPs which have not been revisited since the year they were adopted.

<u>Table 1. Overview of Codex Standards, Guidelines and Codes of Practice based on year of most recent modification (amendment or revision)</u>

	>30 years	20-29 years	10-19 years	5-9 years	< 5years	Total
Standards	23 (10%)	21 (9%)	26 (12%)	39 (17%)	114 (51%)	223
Guidelines	-	9 (11.5%)	23 (9%)	29 (37.5%)	19 (24%)	78
Codes of Practice	4 (7.5%)	4 (7.5%)	20 (38%)	15 (28%)	10 (19%)	53

¹³ Terms of Reference available at http://www.fao.org/fao-who-codexalimentarius/committees/committee/en/?committee=TFFJ

¹⁴ Recommendations of the FAO/WHO Conference on Food standards, chemicals in food and food trade are available at http://www.fao.org/3/X2664E/X2664E.htm (Annex 1)

¹⁵ Available at https://www.who.int/antimicrobial-resistance/global-action-plan/en/

2.5.2 One of the issues identified in reviewing the data was that while the dates of revisions and amendments were clearly identified, details on the extent of changes could only be obtained by reviewing the various meeting reports and documents. Also, if the standard was reviewed and a decision taken not to revise it, this information is not readily available. Thus, there is currently limited visibility on the extent of the current efforts to review Codex standards. The previously mentioned discussion paper of the Secretariat to be submitted to CCGP32, will also address this issue (a preliminary version of this paper was submitted at CCGP31 as CRD5.

3. CONCLUSIONS

3.1 Processes for review are in place and applied

- 3.1.1 The PM foresees the need to keep under review the revision of Codex standards permitting the regular review of Codex standards on a needs basis. There is no reference in the PM to the periodicity of such a review. The review of Codex standards can be triggered by the identification of public health concerns, trade related issues or the availability or new data or developments in the area of food science and technology.
- 3.1.2 Many committees have mechanisms by which the need for revision of a Codex standard can be identified. These mechanisms are often integrated into the procedures in place to identify new areas of work. Some committees have further identified a mechanism by which to prioritize revision of Codex standards e.g. CCPR. In other cases the Commission has mandated a committee or task force to review existing standards.
- 3.1.3 The FAO/WHO scientific advice programme has also highlighted the issue of revising standards in line with new scientific data. JMPR works closely with CCPR in their periodic review process and JECFA has also had extensive discussions with CCFA, CCCF and CCRVDF in this regard. However, while recognized as very important for consumer protection, these discussions also highlighted the resources required to undertake additional reviews of new data to underpin any revision of standards. The need to review Codex standards has also been identified and recommended as a result of other initiatives undertaken by FAO and or WHO and the Commission has demonstrated its responsiveness to such recommendations.
- 3.1.4 The preliminary review under 2.5 has shown that the mechanisms in place are used and have led to an acceptable update status of Codex standards.
- 3.1.5 The current review processes have several advantages. They are:
 - Member-driven;
 - primarily guided by the relevant subsidiary bodies which has the greatest expertise in the area;
 - continually improving as more committees implement work management processes;
 - embedded in the current work flow of the committees; and
 - the Secretariat ensures that changes in any standard leads to alignment across all relevant standards.
- 3.1.6 Overall there are extensive ongoing efforts to review existing Codex standards. In the absence of explicit guidance in the PM on the basis for initiating a review, Codex Committees have over the years developed multiple approaches to try and ensure their standards remain up-to date. These processes primarily rely on Members identifying and proposing standards requiring revision, but revisions are also driven by other factors, in particular recommendations from FAO and WHO. The approach means that any revisions are directly related to Members and global priorities, and is therefore in line with the first goal of the Codex Strategic Plan. In this context the current review process can be considered adequate, although committees can be encouraged to continue to improve and implement their existing processes.

3.2 Are there needs for a more structured approach to review of Codex standards?

3.2.1 A number of the other standard setting organizations included in the review identified that they had a periodic review based on time elapsed (every 2-3 years, 5 or 10 years). Discussions at CAC41 already suggest Codex Members did not see the need for a periodic review process for all standards. There have also been concerns raised regarding the periodic review process implemented by CCPR ¹⁶ and the subsequent withdrawal of CXLs and its impact on international trade. These concerns highlighted the need to focus any further discussion on a structured review process rather than one that is simply triggered by the passing of time. Several of the reviewed standard-setting organizations also indicated the use of surveys in their review mechanisms. Codex already extensively uses surveys in different aspects of its work with varying degrees of success and their further use needs to be carefully considered if they are to elicit a useful response from Members.

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¹⁶ REP16/CAC, paras 170-178

3.2.2 Implementation of any new approach would require additional time and resources and this needs to be balanced against the added value it brings to Codex standards. The development and implementation of new work management processes has taken time and is still ongoing, and illustrates the short to medium-term burden of a new process on a committee even though the long-term outcome is beneficial.

3.2.3 In this context, there seems to be little value in developing a new more structured approach for review of Codex standards.

3.3 Challenges and room for improvement of the current approach

- 3.3.1 The current reviews are not centrally documented and can be difficult to follow; much of the information is embedded in the vast archives of Codex meetings documents and reports and therefore the extent of the current review activities are not easily visible; and it is heavily reliant on Members having the capacity to prepare a proposal (discussion paper and/or project document) for further consideration by the subsidiary body and/or Commission, which may disadvantage the needs of Members with limited resources¹⁷.
- 3.3.2 Due to its Member driven nature it does raise the question of whether certain standards that have never been revised are still relevant or no longer needed and if so how could this be determined? The only group of standards which may lack a clear mechanism for review are those developed by a subsidiary body that is adjourned *sine die* or a task force, but even in the case of the latter it has been demonstrated that global priorities can drive the review process (e.g. TFAMR).

4. RECOMMENDATIONS

CCEXEC77 is invited to discuss the information presented above and consider:

- encouraging subsidiary bodies to continue to develop and implement enhanced work management processes which also take into consideration the need to review existing Codex standards;
- ii. encouraging/requesting the Secretariat to develop a means to track and enhance the visibility of the work undertaken on review of Codex standards;
- iii. whether any additional processes are needed to ensure review of standards of Committees adjourned *sine die* are needed or if existing opportunities for a Member to raise the need for a revision are sufficient; and
- iv. encouraging FAO and WHO to continue to raise any issues/proposals related to the review of Codex standards as a result of its risk assessment, foresight and other food safety activities for consideration by the Commission or relevant subsidiary body.

¹⁷ Some of these issues will be addressed in a Secretariat discussion paper for CCGP32 (previously distributed as CCGP31 CRD5)

Appendix I: Overview of current practices across active subsidiary bodies that contribute to the identification of Codex standards for review.

Committee	Mechanisms by which input is sought from Members and Observers	Frequency	Examples of other processes influencing standard review	Other relevant information
General Sul	bject Committees			
CCCF	CL(Request for comments in the priority list of Contaminants and naturally occurring toxicants for evaluation by JECFA)	After every meeting (every year)	Discussion papers FAO/WHO scientific advice	EWG established by CCCF13 to identify the need for review of existing CCCF standards Forward plan for the CCCF(under discussion)
CCFA	CL(Request for proposals for new and/or revision of food additives provision of the GSFA) CL(Request for information and comments in the priority list of substances proposed for evaluation by JECFA) CL (Requests for revision of INS numbers)	After every meeting (every year)	New work management process since CCFA50 FAO/WHO scientific advice	Extensive discussions on approach for standards review Trial approach for the re-evaluation by JECFA of selected food colours
CCFH	CL(New work/forward workplan) Forward workplan	After every meeting (every year)	Discussion papers Matters Referred (e.g CAC, CCNFSDU)	
CCFICS			Discussion paper on consideration of emerging issues and future directions for the work of the CCFICS	
CCFL	CL(Request for information in emerging issues/future work)	After every meeting (every 1 and half year)	WHO Global Strategy	
CCGP			Not setting standards but work on revision of procedures mandated by CAC. Proposals may also be submitted from Members (eg via CRDs)	
CCMAS	Process for the review of methods of analysis and sampling		Matters Referred	
CCNFSDU			Discussion papers/CRDs WHO Global Strategy	
CCPR	CL(Request for comment on the establishment of the Codex schedules and priority lists of pesticides for evaluation by JMPR)	After every meeting(every year)		Contributes to the CCPR periodic review process
CCRVDF	CL(Request for information and comments in the priority lists of substances for evaluation by JECFA)	After every meeting (every 1 and half year)	Discussion papers	
Commodity	Committees			
CCSCH	CL(Proposals for new work)			
CCFFV	CL(Proposals for new work)	Irregular, depending on the work load		
CCFO	CL in line with new work management procedures agreed by CCFO26		Discussion papers	CRD
CCPFV	-		Mandate from CAC	CRD
CCCPL	-		Mandate from CAC	Working by Correspondence
CCS	-		Mandate from CAC	Working by Correspondence