JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

40th Session
CICG, Geneva, Switzerland
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COMMENTS ON AMENDMENT TO THE PROCEDURAL MANUAL

Comments of Ghana

AGENDA ITEM 4 (CX/CAC 17/40/2): AMENDMENTS TO THE PROCEDURAL MANUAL

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING (CCMAS)

Principles for the Establishment of Codex Methods of Analysis

BACKGROUND: CCMAS is proposing to amend Note 2 in the Principles for the Establishment of Codex Methods of Analysis (Codex Procedural Manual, Section II, p. 80 in the 25th Ed.) by adding the statement:

*There are numerous ways in which methods and limits that involve a sum of components can be converted into methods performance criteria, but this should be undertaken with care on a case-by-case basis.*

CCMAS reviewed an information document that provides an overview of the issues and examples of approaches that can be used to develop performance criteria for methods that use the “sum of components” approach. CCMAS concluded that, it was necessary for the *Procedural Manual* to acknowledge that performance criteria could be developed for methods using sum of components even though the approach should be used on case-by-case basis.

POSITION: We support the amendment to Note 2 in the Principles for the Establishment of Codex Methods of Analysis (Codex Procedural Manual, Section II, p. 80 in the 25th Ed.) to include provision on how “sum of components” could be converted to performance criteria.

RATIONALE: This will provide uniform guidance on how performance criteria for the sum of components can be derived.

CODEX COMMITTEE ON NUTRITION AND FOOD FOR SPECIAL DIETARY USES (CCNFSDU)

Nutritional Risk Analysis Principles and Guidelines for the Application to the Work of the Committee on Nutrition and Foods for Special Dietary Uses

POSITION: We support the approval of the amendment

AGENDA ITEM 5 (CX/CAC17/40/3 CX/CAC17/40/4) Final adoption of Codex texts

Comments

CODEX COMMITTEE ON FOOD HYGIENE (CCFH)


POSITION: We support the adoption of the Code of Practice at Step 5/8

RATIONALE: The Code addresses Good Agricultural Practices (GAPs) and Good Hygienic Practices (GHPs) for controlling microbial, chemical and physical hazards associated with all stages of the production of fresh fruits and vegetables, from primary production to consumption.
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES (CCNFSDU)

EDITORIAL AMENDMENTS TO THE GUIDELINES ON NUTRITION LABELLING (CAC/GL 2-1985)
REP17/NFSDU Para. 12 (ii)

BACKGROUND:
CCNFSDU38 noted the existing inconsistencies in sections 3.1 and 3.2 in the Guidelines on Nutrition Labelling (CAC/GL 2-1985) arising out of further amendments to the definition of Recognized Authoritative Scientific Bodies (RASB) in section 2.5 of the guidelines and proceeded with a consequential amendment.

POSITION: We support the adoption of the amendment.


CCNFSDU38 (2016) agreed to the proposals from CCFA on the editorial amendments related to the appropriate use of the term flavourings in the following standards:

- Standard for “baby foods” (CODEX STAN 73-1981)
- Standard for processed cereal-based foods for infants and young children (CODEX STAN 74-1981),
- Standard for follow-on formulas (CODEX STAN 156-1987),

POSITION AND RATIONALE: We support the proposed editorial modifications to ensure coherence and alignment between the different texts of the Codex standards.

NRV-R FOR VITAMINS D AND E AND CONVERSION FACTORS FOR VITAMIN E EQUIVALENTS FOR LABELLING PURPOSES IN THE GUIDELINES ON NUTRITION LABELLING (CAC / GL 2-1985 (REV 1-1993) REP17/NFSDU PARAS. 26 and 28, 36, Appendix II at Step 5/8 and 8

CAC39 adopted the NRV for vitamin E at step 5 noting the need to agree on conversion factors before finalization of NRVs. CCNFSDU30 adopted NRV for vitamin E of 9 mg per day and proposed a conversion factor of 1mg of α-tocopherol as a vitamin-equivalent (vitamin) for vitamin E.

CCNFSDU38 adopted NRV-R for Vitamin D of 5-15 μg/day with a footnote (‘based on minimal sunlight exposure throughout the year”) that leaves it to the competent national authorities to determine the appropriate NRV-R based on exposure to the sun.

POSITION AND RATIONALE: We support the adoption of NRV-R for Vitamin D and E as these values reflect current state of the knowledge.

FAO/WHO COORDINATING COMMITTEE FOR AFRICA (CCAFRICA)

Regional Standard for Unrefined Shea Butter (Proposed Draft) (REP17/AFRICA, Para. 78, Appendix III) at Step 5/8

POSITION: We support the adoption at Step 5/8 of the standard.

RATIONALE: The product is widely traded in Africa. Regional standard for this commodity will therefore facilitate and boost intra-regional trade.

CODEX COMMITTEE ON SPICES AND CULINARY HERBS (CCSCH)

STANDARD FOR CUMIN (DRAFT) (REP17/SCH PARA. 38, APPENDIX II) STEP 8

BACKGROUND: This Standard applies to cumin offered for direct consumption, as an ingredient in food processing, or for repackaging if required. It excludes cumin intended for industrial processing.

POSITION: We support the adoption of the standard for cumin at Step 8.

STANDARD FOR THYME (DRAFT) (REP 17/SCH PARA. 38, APPENDIX III) STEP 8

BACKGROUND: This Standard applies to dried thyme offered for direct consumption, as an ingredient in food processing or for repackaging if required. It excludes dried thyme intended for industrial processing. It excludes cumin intended for industrial processing.

POSITION: We support the adoption of the standard for thyme at Step 8.
STANDARD FOR BLACK, WHITE AND GREEN (BWG) PEPPER (PROPOSED DRAFT) (REP 17/SCH PARA. 42, APPENDIX IV) STEP 5/8

BACKGROUND: This standard applies to Black, White and Green peppers (abbreviated as BWG) offered for direct consumption, as an ingredient in food processing or for repackaging if required. It excludes BWG peppers intended for industrial processing.

POSITION: We support the adoption of the standard for black, white and green pepper at Step 5/8.

CODEX COMMITTEE ON FATS AND OILS (CCFO)

STANDARD FOR FISH OILS (DRAFT) (REP17/FO PARA.28, APPENDIX III) STEP 8

POSITION: We support the adoption of the standard for fish oil at step 8.


POSITION: We support the adoption of the revision to the standard for named vegetable oils (Codex Stan 210-1999).

CODEX COMMITTEE ON FOOD ADDITIVES (CCFA)

SPECIFICATIONS FOR THE IDENTITY AND PURITY OF FOOD ADDITIVES (PROPOSED DRAFT): AMENDMENTS TO THE LIST OF CODEX SPECIFICATIONS FOR FOOD ADDITIVES (CAC/MISC 6) (REP17/FA PARA. 41, APPENDIX III, PART A) STEP 5/8

BACKGROUND: The CCFA is submitting proposed draft specifications for identity and purity of food additives arising from the 82nd JECFA meeting to CAC40 for adoption at Step 5/8.

POSITION: We support the adoption of the specification at step 5/8.

RATIONALE: JECFA as the risk assessment body for the CAC on food additives, contaminants and residues of veterinary drugs in food conducted evaluations on the additives and advised that they were of adequate food grade quality.

DRAFT AND PROPOSED DRAFT FOOD ADDITIVE PROVISIONS OF THE GENERAL STANDARD FOR FOOD ADDITIVES (GSFA) AT STEPS 8 AND 5/8 (REP 17/FA PARAS. 72, 108(I) AND APPENDIX VI PART A) STEPS 8 AND 5/8

BACKGROUND: JECFA assigned acceptable daily intake and international numbering systems to various food additives for inclusion in the General Standard for Food Additives (GSFA). The additive provisions are being proposed for adoption at Step 8 and Step 5/8 by CAC40 for their subsequent inclusion in the GSFA. The GSFA is recognized as the single most authoritative reference for all food additives.

POSITION: We support the adoption of the draft and proposed draft food additives provisions

RATIONALE: JECFA as the risk assessment body for the CAC on food additives, contaminants and residues of veterinary drugs in food conducted an assessment and advised that the food additives did not present dietary intake concerns.

PROPOSED DRAFT REVISION OF THE CLASS NAMES AND THE INTERNATIONAL NUMBERING SYSTEM FOR FOOD ADDITIVES (CAC/GL 36-1989) (REP17/FA PARA. 117(I), APPENDIX X) STEP 5/8

BACKGROUND: The CCFA agreed to forward the proposed draft amendments to the INS to CAC40 for adoption at Step 5/8 (Appendix X). The INS provides a unified and simple coding system for identifying food additives that may be food in the list of ingredients.

POSITION: We support the adoption at step 5/8 of amendments to INS by CAC 40.

RATIONALE: To ensure harmonization of class names and INS for food additives.


BACKGROUND: The CCAF revised the food additives provisions in food category 9.2.1 and 9.2.1. to align the
additives provisions in these commodity standards with the GSFA.

POSITION: We support the adoption of the revisions by CAC 40.

RATIONALE: Alignment is necessary for making GSFA the single reference point for all food additives

DRAFT MRLS FOR BOVINE SOMATOTROPIN (ALINORM 95/3, APPENDIX II), HELD AT STEP 8 BY 23RD
CAC, (ALINORM 03/41, PARA. 34)

BACKGROUND: The Codex Secretariat and the chair reminded the Committee that MRLs established for
rbSTs were held at Step 8 at the Commission and the Committee was asked to examine the JECFA report
and make recommendations on the results of the JECFA evaluation at the thirty eighth session of the CAC
(REP13 / CAC para. 84). The JECFA Secretariat reminded the Committee of the detailed terms of reference
provided by the thirty fifth session of the CAC regarding the re-assessment of rbSTs. JECFA conducted an extensive literature review. The details of this complex literature are available on the JECFA website. JECFA also reviewed the information submitted by a promoter and two members, in response to a public call for data. Detailed answers were given to each question in the report and monographs of JECFA. In light of the lessons learned from this study covering all information material available at its seventy eighth meeting, JECFA reaffirmed its previous decision and decided to retain the ADI and MRLs as "not specified" for somagrebove, somatribove, somavubove and somidobove.

Delegates supporting the results of the evaluation by JECFA mentioned that JECFA has responded with clarity and coherence to all the questions asked during the thirty fifth session of the CAC, through a rigorous evaluation to guarantee the safety of rbSTs to the human body. Also, these delegates spoke in favor of the adoption of the Commission of proposed MRLs. One delegate, referring to CRD11 asked (based on the results of the JECFA evaluation) to the Committee to recommend to the Commission not to maintain the MRLs for rbSTs at Step 8. It was emphasized that JECFA had evaluated rbSTs three times and with the assistance of eleven independent experts. It emerged from each of the assessments that rbSTs does not represent a risk to human health. These delegations also noted that concerns about antimicrobial resistance due to a possible increase in cases of mastitis and the use of antimicrobial agents have been evaluated more stringently by the JECFA.

According to the JECFA report, there would be no more cases of mastitis in cows treated with rbSTs than those untreated. It was recalled that Codex should base its decisions on sound science and that, in the case of rbSTs, all available scientific information had been properly considered by JECFA. The delegations supporting the results of the evaluation by JECFA added that the draft MRLs for rbSTs had been held at Step 8 since the twenty-third session of the CAC (1999). The lack of scientific data that refuted these findings was also highlighted.

Delegations having reservations about the re-evaluation conducted by JECFA recognized the efforts made by the latter to examine issues related to antimicrobial resistance associated with the use of rbSTs through a possible increase in the use of antibiotics to treat mastitis, as mandated by JECFA at the thirty-fifth session of the CAC. Nevertheless, they expressed extremely concerned by the fact that, as JECFA pointed out, there was not enough evidence (lack of specialized studies) to draw firm conclusions about the association between use of rbSTs and the development of antimicrobial resistance. These delegations stated that the risks associated with antimicrobial resistance could therefore not be excluded.

One delegation also expressed concern about the results of recent studies indicating an increase in cases of mastitis due to increased milk yields as a result of the use of rbSTs. In addition, it was stated that the direct correlation between antibiotic use in animals and high prevalence of antimicrobial resistance in humans had been demonstrated repeatedly. Some delegations mentioned that their concerns are particularly found to be true given the current efforts worldwide to fight against the growing threat of antimicrobial resistance, which is recognized by as many as a major risk to public health World.

The Committee took note of the JECFA report. The Committee agreed that JECFA had addressed all the questions, but opinions differed on JECFA answers. Since no agreement was reached, the discussion above was submitted by the Committee for consideration by the 38th Session of the CAC.

At the 38th Session of the CAC in Geneva, Switzerland, from 6th to 11th July 2015, the consensus was not reached. The debate was postponed and the commission decided to continue discussions.
It was noted that further clarification was requested from experts, discussions about risks and the interests of the use of rbSTs in Africa took place and some delegates reported that no new information since the last session of the CAC was available. African Experts have notified the delegates on the scientific opinion issued by JECFA on a possible assessment of rbSTs. African delegations decided to keep their position based on the scientific work of JECFA, and requested the delegates that had reservations not to block the adoption of the standard to the extent that they could legitimately express their reservations.

POSITION: Having reviewed the report based on the questions forwarded to JECFA 78 by CAC35, we support adoption of rbSTs at step 8.

RATIONALE: Based on a systematic review of the literature published since the last evaluation, JECFA reaffirmed its previous decision on the ADI “not specified” for somagrebove, sometribove, somavubove and somidobove. Following are questions forwarded by the 35th CAC to JECFA on rbSTs Matters which in our opinion have been adequately addressed:

- Update the toxicological evaluation: No new toxicological studies were available. Owing to structural differences between bovine and human somatotrophins, species-specific receptor binding of somatotrophins and lack of bio-activity of rbSTs following oral intake, the Committee concluded that if any rbST residues are present in milk or tissues, they would pose a negligible risk to human health.
- Update the exposure assessment based on any new occurrence data in food: The Committee concluded that similar concentrations of total bST were present in milk and tissues of rbST-treated and untreated cows.
- Consider new data and information related to the possibility of increased levels of IGF-I in the milk of cows treated with rbSTs: There is a transient increase in IGF-I concentrations in milk of rbST-treated cows, which fall within the normal physiological range. IGF-I is substantially, if not completely, degraded in the gut and is unlikely to be absorbed from the gut and be bio-available at biologically relevant exposures. Therefore, the contribution of exogenous IGF-I resulting from the ingestion of milk from rbST-treated cows is extremely low in comparison with endogenous production.
- Evaluate potential adverse health effects, including the possibility that exposure of human neonates and young children to milk from rbST-treated cows increases health risks (e.g. the development of insulin-dependent diabetes mellitus): Exogenous IGF-I from milk makes no significant contribution to circulating levels of IGF-I in humans, and there are no significant differences in the composition of milk from rbST-treated cows when compared with the milk from untreated cows. The Committee concluded that there was no additional risk for the development of type 1 diabetes due to the consumption of milk from rbST-treated cows. The Committee also concluded that the literature did not support a link between exposure to IGF-I in milk from rbST-treated cows and an increased risk of cancer.
- Consider new data and information related to the potential effects of rbSTs on the expression of certain viruses in cattle: There was no new information on the link between rbSTs use and either potential stimulation of retrovirus expression or prion protein expression in cattle. The Committee considers that the position expressed by the previous Committee remains valid.

Consider new data and information related to the possible increased use of antimicrobials to treat mastitis in cows and aspects of antimicrobial resistance associated with the use of rbSTs in relation to human health: The Committee concluded that there was no evidence to suggest that the use of rbSTs would result in a higher risk to human health due to the possible increased use of antimicrobial agents to treat mastitis or the increased potential for non-compliant antimicrobial residues in milk. The Committee found no specific studies linking the use of rbSTs with the development of antimicrobial resistance. The Committee considers that the previous position remains valid.

AGENDA ITEM 6 (CX/CAC17/40/5): ADOPTION OF CODEX TEXTS AT STEP 5

COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOOD (CCRVDF)

PROPOSED RMR FOR GENTIAN VIOLET (PROPOSED DRAFT) REP17/RVDF PARA. 50, APPENDIX II) STEP 5

BACKGROUND: CCRVDF22 recommended the establishment of a Risk Management Recommendations (RMR) for gentian violet following risk assessment by the 78th JECFA (2013). However, there were divergent views as to whether the inclusion of the last sentence of the RMR on the example of a risk mitigation measure
to prevent residues of gentian violet in food (e.g. the non-use of this compound in food producing animals) should be part of the RMR. In view of this, the Committee circulated both options (i.e. with and without the example) at Step 3 for further consideration at CCRVDF23 (2016).

POSITION: We support the proposed risk management recommendation presented as Option 1 in Codex document REP15/RVDF (Appendix III) as follows:

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of gentian violet or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of gentian violet in food. This can be accomplished by not using gentian violet in food producing animals.

RATIONALE: JECFA 78th concluded that it was inappropriate to set an ADI for Gentian Violet because it is genotoxic and carcinogenic. Gentian Violet is structurally related to malachite green. Consequently, the Committee could not recommend MRLs, as it was not considered appropriate to establish an ADI. JECFA 78th also noted that there was limited information on residues. AU concurs with JECFA 78th recommendations of no ADI and MRLs for Gentian Violet and should be treated the same way as Malachite Green.

FAO/WHO COORDINATING COMMITTEE FOR AFRICA (CCAFRICA)

Regional Standard for Fermented Cooked Cassava Based Products (Proposed Draft) (REP 17/AFRICA, Para. 74, Appendix II) at Step 5

POSITION: We support the adoption at Step 5 of the regional standard for fermented cooked cassava based products.

RATIONALE: The product is widely traded in Africa. Regional standard for this commodity will therefore facilitate and boost intra-regional trade.

CODEX COMMITTEE ON FATS AND OILS (CCFO)

Revision To The Standard For Named Vegetable Oils (CODEX STAN 210-1999): Addition Of Palm Oil With High Oleic Acid (OOG) (Proposed Draft)(REP17/FO, Para. 43, Appendix V) Step 5

POSITION: We support the adoption of the revised standard.

AGENDA ITEM 7(CX/CAC17/40/7): REVOCATION OF CODEX TEXTS

CODEX COMMITTEE ON PROCESSED FRUITS AND VEGETABLES (CCPFV)


POSITION AND RATIONALE: We support the revocation of the listed standards due to their replacement with new standards.

CODEX COMMITTEE ON FOOD ADDITIVES (CCFA)


POSITION AND RATIONAL: We support the revocation of this standard due to its replacement with new standard

CODEX COMMITTEE ON CONTAMINANTS IN FOOD (CCCF).

CODEX RECOMMENDED METHODS IN CODEX STANDARDS REP17/MAS, PARA 28, APPENDIX II (PART 2) REVOCATION OF CODEX TEXT (AGENDA ITEM 7, CX/CAC 17/40/7 ADD1)

BACKGROUND

The recommended methods for quick frozen vegetables CAC/RM34, 43, and 54 were revoked as a result of their replacement with new methods.

POSITION: We support the revocation of the methods.
CODEX COMMITTEE ON PESTICIDE RESIDUES (CCPR)

CODEX MRLS (CXLS) FOR DIFFERENT COMBINATIONS OF PESTICIDE/COMMODITY (IES) PROPOSED FOR REVOCATION BY CCPR49

BACKGROUND: CCPR49 recommended the revocation of 103 MRLs for 9 pesticides in different crop and animal commodities. The pesticides include Methidathion, Chlorpyrifos-Methyl, Penconazole, Teflubenzuron, Chlorantraniliprole, Sulfentrazone, Benzoquinone, Fluensulfone, and Metrafenone.

POSITION AND RATIONALE: We support the revocation of the MRLs proposed for revocation since the applicable pesticides are either deemed by JMPR to have potential dietary exposure concerns, or their use is no longer supported.

CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING (CCMAS)

Codex Recommended Methods in Codex Standards Rep17/Mas, Para 28, Appendix II (Part 2) Revocation of Codex Text (Agenda Item 7, CX/CAC 17/40/7 Add1)

BACKGROUND

The recommended methods for quick frozen vegetables CAC/RM34, 43, and 54 were revoked as a result of their replacement with new methods.

POSITION: We support the revocation of the methods.

AGENDA ITEM 8 (CX/CAC17/40/8) PROPOSALS FOR NEW WORK

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS (CCRVDF)

Priority List of Veterinary Drugs Requiring Evaluation or Re-Evaluation by JECFA (REP17/RVDF Para 113 and 138, Appendix VI Part A

POSITION: We support the proposal for new work in the provision of priority list of veterinary drugs requiring evaluation of re-evaluation by JECFA.

CODEX COMMITTEE ON SPICES AND CULINARY HERBS (CCSCH)

PROJECT PROPOSALS FOR NEW WORK - PROPOSAL FOR NEW WORK ON STANDARDS FOR SPICES AND CULINARY HERBS SUBMITTED TO CAC40 FOR APPROVAL (REP 17/SCH APPENDIX V-XI):

BACKGROUND: The Codex Committee on Spices and Culinary Herbs (CCSCH) is proposing the development of Codex Standard for dried or dehydrated ginger (Chaired by Nigeria, co-chaired by India & Mali); Codex Standard for dried garlic (Chaired by Nigeria, co-chaired by India & Mali); and the Codex Standard for dried chili peppers and paprika; (Chaired by India, co-chaired by Argentina). The respective project documents were accepted by delegations present at the 3rd Session of CCSCH.

POSITION AND RATIONALE: We support approval for new work on Codex standards for dried or dehydrated ginger, dried garlic, chili peppers and paprika. These spices are internationally traded hence there is need to establish an internationally harmonized commodity standards covering the safety, quality, hygiene and labeling in order to facilitate trade.

CODEX COMMITTEE ON FATS AND OILS (CCFO)


POSITION AND RATIONALE: We support the approval for new work in the revision of the Standard for Named Vegetable Oils (CODEX STAN210-1999)

Revision of the Standard for Named Vegetable Oils (CODEX STAN 210-1999): Replacement of acid value with free fatty acid for virgin palm oil and inclusion of free fatty acids for crude palm oil (REP17/FO Para 77, Appendix VIII)

POSITION AND RATIONALE: We support the approval for new work in the revision of the Standard for Named Vegetable Oils (CODEX STAN210-1999) since this commodity is internationally traded.


POSITION AND RATIONALE: We support the approval for new work in the revision of the Standard for Named Vegetable Oils (CODEX STAN33-1981) since this commodity is internationally traded.