CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 6c **CX/CAC 15/38/11**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX ALIMENTARIUS COMMISSION

38th Session, CICG

Geneva, Switzerland, 6-11 July 2015

MATTERS REFERRED TO THE COMMISSION BY CODEX COMMITTEES

(OTHER MATTERS)

A. MATTERS FOR INFORMATION

1. The Commission **is invited to note** the following information.

Committee on Food Hygiene (CCFH) / Committee on Contaminants in Foods (CCCF) / Committee on Pesticide Residues (CCPR)

Information documents[1]

2. CCFH46, CCCF9 and CCPR47 agreed to make available the following documents as information documents, in accordance with the "Guidance on information documents":

- Process by which the Codex Committee on Food Hygiene (CCFH) will undertake its work (CCFH);
- Guidance for Risk Management Options in Light of Different Risk Assessment Outcomes (CCCF); and
- Application of the Guidance to Facilitate the Establishment of MRLs for Pesticides for Minor Crops

3. The information documents are available on the Codex website (http://www.codexalimentarius.org/infodoc).

Committee on Fats and Oils (CCFO)

Inclusion of provisions in Tables 3 and 4 into the main body of the *Standard for Named Vegetable Oils* (CODEX STAN 210-1991)[2]

4. CCFO24 agreed to retain the provisions in Tables 3 and 4 in the Appendix of *Standard for Named Vegetable Oils* and that any further proposals for transferring provisions from the Appendix to the main body should be considered only after reviewing the parameters.

Committee on Food Additives (CCFA)

Provision for carrageenan (INS 407) in the in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)[3]

5. CCFA47 recalled that at CCFA39 the provision of carrageenan in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* had not been endorsed pending JECFA evaluation. In view of the outcome of the 79th JECFA evaluation, CCFA47 agreed to endorse the provision for carrageenan (INS 407) in the Standard.

B. MATTERS FOR ACTION

FAO/WHO Coordinating Committee for Europe (CCEURO)

Language regime of CCEURO[4]

6. CCEURO29 had an extensive discussion on the language regime of CCEURO and the posibility to include a fourth official labguage, i.e. Russian.

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[1] REP15/FH para. 10; REP15/CF para. 7; REP15/PR para. 155 and Appendix XI Part B.
[2] REP15/FO para. 69.
[3] REP15/FA para. 28 and Appendix III.
[4] REP15/EURO paras 80-86.

7. It was noted that the Codex Secretariat covered the cost for translation and interpretation services for three official languages of the Commission namely English, French and Spanish for CCEURO. Besides, for this Session, the Netherlands, as Coordinator of CCEURO, had taken responsibility for providing translation and interpretation services of an additional official language of CAC i.e. Russian.

8. With regard to the possibility to include a fourth official language, i.e. Russian, considering that the Codex Secretariat already provided three (i.e. English, French and Spanish) as opposed to the minimum of two languages for the operation of committees e.g. CCEURO, and as demonstrated by the fact that the Host Country was providing extra-funding to make available an additional official language (i.e. Russian), it was noted that the Codex Secretariat was not in a position to commit to provide further resources for translation and/or interpretation services for a fourth official language in CCEURO.

9. The Committee noted that Russian is used as official language in more than 10 countries of the Region. The inclusion of Russian as working language of CCEURO was essential for the smooth preparation and running of sessions of CCEURO. The Coordinator therefore proposed to request the Commission to consider the possibility to finance translation and interpretation services in Russian for the operation of CCEURO.

10. The Committee agreed to request the Commission to consider the possibility to finance translation and interpretation services in Russian in CCEURO.

11. The Commission **is invited to consider** this request.

Committee on Methods of Analysis and Sampling (CCMAS)

Biological and Functional Methods to Determine Paralytic Shellfish Toxicity in the *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008)[5]

12. When considering the adoption of section I-8.6[6] "Determination of Biotoxins" in the *Standard for Live and Raw Bivalve Molluscs*, CAC37 did not adopt section I-8.6.2 "Biological and Functional Methods to Determine Paralytic Shellfish Toxicity". CAC37 returned section I-8.6.2 to CCMAS with a request to review the typing of the methods in this section and encouraged CCMAS to proceed rapidly with its discussion on the way to deal with biological methods from a criteria approach perspective.[7]

13. CCMAS agreed to maintain its endorsement of the methods in section I-8.6.2 Biological and Functional Methods to Determine Paralytic Shellfish Toxicity" in the Standard as Type IV and agreed that the development of criteria for biological methods should be considered as a matter of urgency.

14. The Commission **is invited to adopt** the biological and functional methods to determine paralytic shellfish toxicity as endorsed by CCMAS. The methods are reproduced in Annex I to this document.

Committee on Residues of Veterinary Drugs in Foods (CCRVDF)

Recombinant bovine somatotropins (rbSTs)[8]

15. CCRVDF22 took note of the report from JECFA. The Committee agreed that JECFA had addressed all of the questions posed to it by the Commission, but that there were different opinions regarding the JECFA replies. As no agreement had been reached the above discussion was being forwarded by the Committee for consideration by CAC38.

16. Copy of the discussion is attached in Annex II.

17. The Commission will consider this matter under Agenda Item 5a.

[5] REP15/MAS paras 44 – 59.
[6] Note that this section has been renumberd, I-8.5 in the published *Standard for Live and Raw Bivalve Molluscs* (CODEX STAN 292-2008)
[7] REP14/CAC, paras 53-60
[8] REP15/RVDF paras 33-40.

Annex I

Standard for Live and Raw Bivalve Molluscs **(CODEX STAN 292-2008) - I-8.6.2 Biological and Functional Methods to Determine Paralytic Shellfish Toxicity**

Commodity	Provision	Method	Principle	Type
Live and raw bivalve molluscs	Paralytic Shellfish toxicity	AOAC 959.08	Mouse bioassay	Type IV
Live and raw bivalve molluscs	Paralytic shellfish toxicity	AOAC 2011.27	Receptor binding assay	Type IV

Annex II

CCRVDF22 Discussion on Recombinant bovine somatotropins (rbSTs) (REP15/RVDF paras 34-39)

34. Delegations in support of the outcome of the JECFA evaluation expressed the view that JECFA had clearly and consistently addressed all the questions posed by CAC35 in a robust evaluation assuring the safety of rbSTs for human health. Therefore, these delegations were in favour of the adoption of the proposed MRLs at the Commission. One delegation, referring to CRD11, asked (based on the results of the JECFA evaluation), the Committee to recommend the Commission to stop holding the MRLs for rbSTs at Step 8. It was emphasized that JECFA had evaluated rbSTs three times and with 11 independent experts. Each evaluation had reaffirmed that rbSTs did not represent a risk to human health.

35. These delegations also noted that the concerns about antimicrobial resistance, related to the possible increase of mastitis and of the use of antimicrobials, had been carefully evaluated by JECFA. According to JECFA's report there was no increased incidence of mastitis between rbSTs treated and non-treated cows. It was reiterated that Codex must base its decisions on sound science and for rbSTs all scientific information available had been considered by JECFA. The Delegations in support of the outcome of the JECFA evaluation stated that the draft MRLs for rbSTs had been held at Step 8 since CAC23 (1999). The absence of any opposing scientific data was also noted.

36. Delegations having concerns with respect to the JECFA re-evaluation recognised the efforts of JECFA to consider aspects related to antimicrobial resistance associated with the use of rbSTs through the possible increased use of antibiotics to treat mastitis, in line with the mandate given to JECFA by CAC35. However, they expressed profound concern with respect to the fact that, as JECFA itself had pointed out, there was insufficient evidence (a lack of specific studies) to draw conclusions on the association between the use of rbSTs and the development of antimicrobial resistance. It was the view of these delegations that risks associated with antimicrobial resistance could therefore not be excluded. One delegation raised further concern because they had recent studies indicating that the incidence of mastitis increased due to the higher milk yields brought about through the use of rbSTs. It was further asserted that the direct link between the use of antibiotics in animals and increased levels of antimicrobial resistance in humans had been extensively demonstrated. Delegations highlighted that their concerns were particularly relevant given the global efforts underway to fight the growing threat of antimicrobial resistance which is widely recognised as a serious, global public health threat and which is receiving the fullest attention from Codex's parent organisations: FAO and WHO, amongst others.

37. These delegations highlighted furthermore, that it was expressly due to such concerns that CAC35 had specifically mandated JECFA to consider aspects of antimicrobial resistance (AMR) in its re-evaluation of rbSTs. Given the remaining scientific uncertainty in the JECFA re-evaluation, these delegations could not agree to move forward on this issue.

38. The Observer from NHF supported those delegations not agreeing to move forward on this issue and further noted that the JECFA review of rbSTs was incomplete in that it had failed to consider the industry's own data showing a marked increase in mastitis after rbSTs injection, which in turn led to increased antibiotic use to avoid pus and bacteria in milk.

39. In response to concerns raised regarding antimicrobial resistance, the JECFA Secretariat clarified that the aspects of mastitis and the risk to human health from the use of antimicrobials had been addressed in detail in the JECFA review. While previous publications indicated an increased incidence of mastitis, a systematic review of the literature published since the 50th JECFA did not find any significant difference in the incidence of mastitis between rbST-treated and untreated cows. JECFA had also reviewed data from a post-approval monitoring programme and concluded that the available evidence suggested that the approval of rbSTs did not lead to an increased incidence of non-compliant antimicrobial residues in bulk milk. The systematic search of the literature had not found specific studies correlating the use of rbSTs with the development of antimicrobial resistance in mastitis pathogens. JECFA 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 antimicrobials to treat mastitis or the increased potential for non compliant antimicrobial residues in milk. Based on the extensive review JECFA reaffirmed its previous conclusion that there was no need to establish numerical ADI and MRLs and confirmed the ADI and MRLs 'not specified'.