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CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.net

Agenda Item 3 **CX/GP 12/27/3**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON GENERAL PRINCIPLES

Twenty-seventh Session

Paris, France, 2 – 6 April 2012

Report and discussion paper of the Electronic Working Group (eWG) on issues related to Standards Held at Step 8

1. The 26th Session of the Codex Committee on General Principles (CCGP) agreed to establish an eWG co-chaired by Canada and the Netherlands with the following terms of reference:

    1) To prepare a discussion paper examining the issues surrounding paragraph 5 of the Procedures for the elaboration of Codex Standards and Related Texts and, in particular, the second sentence of this paragraph.
    2) The discussion paper will describe the issues that result in draft standards being held by the commission at Step 8, even though the subsidiary body responsible for drafting the standard had concluded its work taking into account the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.
    3) It should be noted that the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are taken into Account are not subject to discussion and are not to be reopened.
    4) The discussion paper will suggest what recommendations CCGP may wish to consider at its 27th Session.

2. On June 14th, 2010 the co-chairs circulated an invitation via the Codex secretariat requesting member governments and observers to submit contact particulars if they were interested in participating in the electronic working group (eWG). The deadline for submission of participants' names was June 30th, 2010. The eWG participants list is attached as Annex "A"

3. During the 33rd Session (July 2010) of the Codex Alimentarius Commission, a brief informal information session was sponsored by the Netherlands to initiate the work of the eWG and provide those delegations present at the CAC who had expressed interest in participating in the eWG with information on the next steps.

4. On July 30th, a request for initial comments was circulated to all participants. In particular, participants were requested to include in their comments their views on:

    Identification of the standard(s) held or being held at Step 8
    1) Background information on the elaboration of that standard(s) through the step process with particular emphasis on decisions taken at the Committee level
    2) Where relevant, the scientific advice provided by the relevant expert body
    3) Identification of issues around which there was a lack of consensus
    4) An analysis as to why those issues could not be resolved.

5. Deadline for submission of the initial input was October 15th, 2010. Comments were subsequently received from nine member governments and two observer organizations.[1] The initial input identified a number of points which are found in the Discussion Paper in paragraphs 8 – 15.

6. A first draft of the discussion paper was prepared taking into account this initial input. This draft was circulated to eWG participants with a deadline for comments on March 31 2011. Comments on this draft were received from several members. Based on comments received a second draft of the paper was prepared and circulated with a deadline for comments on August19 2011 which was extended until September 30th 2011.

7. During the 34th Session (July 2011) of the CAC, another informal information session hosted by Canada in order to provide participants with information on the progress of the development of the discussion paper and to provide the opportunity for participants to seek clarification of comments from other participants.

8. A third draft was subsequently developed for forwarding to Rome for circulation to all Codex members and observers which contained a number of recommendations raised by eWG participants. As the eWG are not to take decisions on the part of the Committee, all recommendations that were identified are contained in paragraph 59 of the discussion paper. It is left to the CCGP to decide which of the recommendations, if any, it will accept and implement.

9. It should be noted that only written comments submitted were taken into account in preparation of the discussion paper in recognition of the fact that not all eWG participants were able to attend the CAC sessions. A compilation of all written comments is being circulated as a separate document.

10. There was almost unanimous agreement that there was no need to develop additional guidance for chairpersons to be incorporated into the Procedural Manual. In fact it was noted by several participants that aside from two "noteworthy" standards, the Codex standard setting process works very well.

11. Several members commented on the need to revisit the issue of "other legitimate factors", citing the need for a clearer framework for risk management decisions and for clearer guidance around the application of the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle. Other members did not agree to revisit the other factors, because it was their view that the role of these factors in Codex decision-making have been thoroughly discussed and documented by Codex members. They did not support re-opening the Criteria stating that the relevant Committee and Commission reports indicate they are intended as a clarification of and an annex to the Statements of Principle, which, under the eWG's Terms of Reference cannot be re-opened as part of this work. The Criteria are intended to assist in interpreting and applying the Statements of Principle and are integral to the Statements.

12. The co-chairs of the eWG noted that the Terms of Reference for the eWG clearly indicated that the Statements of Principle were not subject to discussion and are not to be reopened. With regards to the "criteria", which were developed after the Principles were adopted, it was unclear if the same restriction was intended to be applied. The eWG co-chairs concluded not to include comments provided by eWG participants related to the application or interpretation of the criteria in the discussion paper. However, it is noted that members are free to raise these issues at CCGP.

13. One working group participant expressed concern that the discussion paper dedicates one whole section to discuss factors outside Codex mandate and noted that many reasons may lead to a lack of consensus at the Commission. The participant expressed the view that elements outside the Codex scope can be discussed in many other fora and must not impede the development of Codex work. It was, however, the view of many other participants that these factors were in fact influencing the Codex process and therefore needed to be discussed in the paper.

14. Attached as Annex "B" is the Discussion Paper on Issues Surrounding Standards Held at Step 8 for consideration by the 27th Session of the CCGP.

[1] Comments were received from Australia, Brazil, the European Union, India, Japan, New Zealand, Norway, the Philippines, the United States, ICGMA and IFAH.

ANNEX A

Participants in the electronic Working Group on Issues Related to Standards Held at Step 8

Argentina
codex@minagri.gob.ar

Australia
Ann Backhouse
Manager Codex Australia
Department of Agriculture, Fisheries and Forestry
+61 2 62725692
ann.backhouse@daff.gov.au
codex.contact@daff.gov.au

Brazil
Claudio Melluzi
Codex Contact Point
Ministry of External Relations
55 61 34116369
claudio.melluzi@itamaraty.gov.br

Maria Aparecida Martinelli
Coordinator of the Brazilian Codex Committee
National Institute of Metrology, Standardization and Industrial Quality
55 61 33402211
codexbrasil@inmetro.gov.br

Canada
Bertrand Gagnon
Codex and Food Safety Coordinator C
Canadian Food Inspection Agency
+613 773 6092
bertrand.gagnon@inspection.gc.ca

Colombia
Javier Muñoz Ibarra
Advisor/Colombian Codex Comimmittee
Ministerio de Comercio, Industria y Turismo
57 (1) 6067676 Ext. 1205
jmunoz@mincomercio.gov.co

Elvin Rincón Cárdenas
Professional/Colombian Codex Commitee
Ministerio de Comercio, Industria y Turismo
57 (1) 6067676 Ext. 2133
erincon@mincomercio.gov.co

Denmark
Jytte Kjærgaard
Danish Veterinary and Food Administration
+45 33 95 62 33
jk@fvst.dk

European Union
Jérôme Lepeintre
European Commission
Health and Consumers Directorate-General
+32 22 99 37 01
jerome.lepeintre@ec.europa.eu

Risto Holma
European Commission
Health and Consumers Directorate-General
+32 22 99 86 83
risto.holma@ec.europa.eu

Germany
Niklas Schulze Icking
Codex Contact Point
Federal Ministry of Food, Agriculture and Consumer Protection
+ 49 (0) 30 18 529 3515
314@bmelv.bund.de

Claudia Gehrmann
Codex Coordinator and Contact Point
Federal Ministry of Food, Agriculture and Consumer Protection
+ 49 (0) 30 18 529 3263
Codex.germany@bmelv.bund.de

Honduras
Juan Ramon Velasquez
hondurascodex@yahoo.com

Hungary
Ágnes Szegedyné Fritz
Ministry of Rural Development
Agnes.Fricz@fvm.gov.hu

India
Sumita Mukherjee
National Codex Contact Point
Food Safety and Standards Authority of India
+91 11 23237442
sumita_mukherjee@hotmail.com

Japan
Yoshikiyo Kondo
Associate Director, International Affairs
Food Safety and Consumer Policy Division
Ministry of Agriculture, Forestry and Fisheries
+81 3 3502 8732
yoshikiyo_kondo@nm.maff.go.jp

Noriko Iseki
Senior Technical Officer
Division of Policy Planning and Communication
Ministry of Health, Labour and Welfare
+81 3 3595 2326
codexj@mhlw.go.jp

Mexico
Andrea Barrios Villarreal
International Affairs
Director General Bureau Standards (DGN)
52 55 57299480
andrea.barrios@economia.gob.mx
codexmex@economia.gob.mx

New Zealand
S. Rajasekar
Senior Programme Manager (Codex)
Ministry of Agriculture and Forestry
+64 48942576

raj.rajasekar@maf.govt.nz

Netherlands
Wim van Eck
Nieuwe Voedsel en Warenautoriteit
+ 31 (0) 70 448 4814
wim.van.eck@vwa.nl

Norway
Vigdis Veum Moellersen
Senior Advisor/Codex Contact Point
Norwegian Food Safety Authority
Head Office
visvm@mattilsynet.no

Philippines
Gilberto F. Layese
Director IV and Codex Contact Point
+632 455 2858
bafpsda@yahoo.com.ph

South Africa
Malose Daniel Matlala
National Codex Contact Point
Department of Health, Directorate: Food Control
+27 12 312 0158
CACPSA@health.gov.za

Sweden
Carmina Ionescu
Codex Coordinator
National Food Administration
+46 (0)18 17 56 01 / +46 (0) 709 24 56 01
carmina.ionescu@slv.se

Switzerland
Awilo Ochieng
Federal Department of Home Affairs
+41 31 32 20041 / +41 31 32 21131
awilo.ochieng@bag.admin.ch

Thailand
Pongsapitch Pisan
Senior Expert in Agricultural Commodity and Food Standards
Ministry of Agriculture and Cooperatives
+66 2 5612277 ext 1421
pisan@acfs.go.th codex@acfs.go.th

United States
Karen Stuck
Codex Manager
United States Department of Agriculture
202-720-2057
karen.stuck@osec.usda.gov
USCodex@fsis.usda.gov

Consumers International
Michael Hansen
Senior Scientist
Consumers Union
+1 914-378-2452 or 2455
hansmi@consumer.org

ICGMA
Peggy Rochette
Sr. Director of International Affairs
Grocery Manufacturers Association
(202) 639-5921 / (202) 639-5991
prochette@gmaonline.org

IFAH
Robert Livingston
rlivingston@ahi.org

Olivier Espeisse
Directeur Général – Vétérinaire Responsable
+ 33 (0) 1 55 49 35 35
espeisse_olivier@lilly.com

Barbara Freischem
Executvce Director
bfreischem@ifahsec.org

Chair (Canada)
Allan McCarville
Codex Contact Point for Canada
Health Canada
+613 957 0189
codex_canada@hc-sc.gc.ca

Chair (Netherlands)
Jeroen Friedericy
Codex Coordinator
Ministry of Economic Affairs, Agriculture and Innovation
+31 (0) 70 378 4924
codex.ewg.step8@minlnv.nl

Scientific Advisor to the Chair (Netherlands)
Rob Theelen
Nieuwe Voedsel en Warenautoriteit
+ 31 (0) 70 448 4084
r.m.c.theelen@vwa.nl

ANNEX 2

Discussion Paper on Issues Related to Standards Held at Step 8

Introduction

1. The Codex Alimentarius Commission (Codex), which was established to elaborate international food standards under the Joint FAO/WHO Food Standards Program, held its first session 25th June – 3rd July 1963. While the mandate of Codex has not changed since that first session, the environment in which Codex functions has changed dramatically. More countries, particularly developing countries, have become actively engaged in the international standard-setting process and the advent of the World Trade Organization (WTO), with the subsequent increased importance afforded Codex standards, has altered the dynamics of the Codex process.

2. The subsidiary bodies of Codex develop standards through consensus and it is recognized that without consensus standards will not advance. In order to reach consensus, delegations must be willing to negotiate and compromise. There are instances, however, when members are unwilling or unable to negotiate with the result that standards will not advance through the Codex Step process, or will be forwarded to the Commission where that same lack of consensus results in the standard being held at Step 8.

Mandate from the 26th Session of the CCGP

3. The 26th Session (April 2010) of the Codex Committee on General Principles (CCGP) noted that the Commission had the possibility to hold texts at step 8 as specified in the Codex Procedural Manual[2] but no further guidance on this matter was contained in the Procedural Manual.

4. A number of delegations were of the opinion that it was important to have guidance on the conditions when a text could be held at step 8 and what should be done if a text had been held at step 8 for some time and no new scientific information had become available. Other delegations were of the opinion that the Procedural Manual, and specifically the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are taken into Account,* contained sufficient guidance to deal with the issue on a case-by-case basis and that no new work was needed. It was also mentioned that the number of standards held at Step 8 was small so that it was not clear if new procedures would add much benefit.

5. After an extensive debate on whether there was a need to pursue this issue any further, the delegation of the Netherlands proposed two possibilities: (1) the Committee asks volunteers to prepare a discussion paper analyzing the issues surrounding holding standards at Step 8 for the next session or (2) the Committee creates an electronic working group with the task of preparing such a discussion paper.

6. After some discussion, the CCGP agreed to establish an electronic working group, co-chaired by Canada and the Netherlands, working in English only, with the following Terms of Reference:

    1) To prepare a discussion paper examining the issues surrounding paragraph 5 of the Procedures for the elaboration of Codex Standards and Related Texts and, in particular, the second sentence of this paragraph.
    2) The discussion paper will describe the issues that result in draft standards being held by the commission at Step 8, even though the subsidiary body responsible for drafting the standard had concluded its work taking into account the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

[2] Codex Procedural Manual, 19th Edition (English), Page 22, para. 5. (Note: This is found on page 28 in the 20th Edition (English)).

3) It should be noted that the Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are taken into Account are not subject to discussion and are not to be reopened.
4) The discussion paper will suggest what recommendations CCGP may wish to consider at its 27th Session.

Process

7. The eWG was established as mandated by the 26th Session of the Codex Committee on General Principles (CCGP). After the eWG was established, an informal information session was held during the 33rd Session (July 2010) of the CAC for those participants who were present at the Commission session. The informal session was intended to provide practical information on the conduct of the eWG and to afford participants an opportunity to introduce themselves and to create a first possibility to identify and raise issues that the discussion paper should address. Subsequently participants were requested to submit initial input including their replies to a series of questions formulated by the co-chairs intended to provide some focus for the input. These comments were used to develop a first draft of the paper which was circulated to the eWG participants for comment. A second draft of the discussion paper was prepared taking into consideration comments made on the first draft. A second informal information session was held during the 34th Session (July 2011) of the CAC in order to provide participants with information on the progress of the development of the discussion paper and to provide the opportunity for participants to seek clarification of comments from other participants. A third and final draft was prepared and circulated to eWG participants for an editorial review. It should be noted that only written comments submitted were taken into account in preparation of the discussion paper in recognition of the fact that not all eWG participants were able to attend the CAC sessions.

Considerations/Discussion of Initial Input from eWG Participants

8. Initial comments identified a number of examples of standards that were held at Step 8 including:

7 Pesticide MRLs held at Step 8 in 1985 - ultimately adopted 1987
rBST – held at Step 8 in 1999; still being held.
Draft Code of Practice on Good Animal Feeding; held at Step 8 in 2003, ultimately adopted in 2004.
Proposed Draft Revised Standard for Edam (C-4), Gouda (C-5), Havarti (C-6), Samso (C-7), Emmental (C-9),Tilsiter (C-11), Saint-Paulin (C-13), Provolone (C-15), Cottage Cheese (C-16), Coulommiers (C-18), Cream Cheese (C-31), Camembert (C-33), Brie (C-34) and proposed Draft Standard for Mozzarella; held at Step 8 in 2006; ultimately adopted in 2007.
Cassava, held at Step 8 in 2008, ultimately adopted in 2010.
Ractopamine- held at Step 8 in 2008; still being held.

9. A review of the examples provided by eWG participants revealed that the reasons for the Commission to hold standards at Step 8 were due to one of the following:

To allow for the provision of additional scientific advice or additional guidance from another Committee for the Commission's consideration;
To allow the opportunity to finalize provisions without having to return the entire document to the subsidiary body, and
Inability to reach consensus on how to move forward.

PROVISION OF ADDITIONAL SCIENTIFIC ADVICE

10. Several examples were provided by eWG participants where a standard was held at Step 8 by the Commission to allow additional scientific advice to be developed for consideration.

11. For example, in 1985, residue limits for several pesticides were "adopted as temporary MRLs but not included in the *Codex Alimentarius*" (which at that time would be the equivalent of holding the MRL at

Step 8) as JMPR had only given these substances temporary ADIs. The Codex Committee on Pesticide Residues subsequently converted the temporary MRLs into MRLs based on the advice of JMPR and they were ultimately adopted by the Commission and incorporated into the *Codex Alimentarius* in 1987.

FINALIZATION OF PROVISIONS

12. EWG participants also provided examples where the Commission held a standard at Step 8 to enable specific provisions to be revisited by the relevant subsidiary body and finalized. This avoided returning the entire standard to the Committee.

13. For example, in 2003 the 26th Session of the Codex Alimentarius Commission held the *Draft Code of Practice on Good Animal Feeding* at Step 8 while the Task Force responsible for developing the standard considered several paragraphs on which consensus had not really been reached as well as the definition for "feed additive". An additional session of the Task Force resolved the outstanding issues and the Commission ultimately adopted the Code at its 27th Session (July 2004).

14. Another example of where the Commission has "parked" a standard at Step 8 to allow the opportunity to finalize provisions is the Standard for Cassava which the Commission held in 2008. This allowed the CCFFV and CCFL to address issues around the labelling provisions which were subsequently resolved. The standard was ultimately adopted by the Commission in 2010.

INABILITY TO REACH CONSENSUS

15. A review of the examples provided by participants indicate that there are instances where standards held at Step 8 are the result of a lack of consensus with members being unwilling or unable to make the necessary compromises to reach consensus.

Summary of initial input from electronic working group participants

16. It would appear that there are instances where holding a standard at Step 8 is a useful tool that can be employed by the Commission to take additional steps to achieve consensus, as outlined in (1) and (2) above.

17. However, there are also instances where a standard is advanced to the Commission although the issues hindering consensus were not resolved at the level of the subsidiary body. It has been suggested by some members of the eWG that the factors preventing consensus at Step 8 are also impeding progress of standards at earlier steps of the elaboration procedure but the focus of this document will remain on those Standards held at Step 8 consistent with the Terms of Reference.

18. In examining the examples presented by the members of the eWG, it should be noted that, of all the standards held at Step 8, all have been addressed by the Commission except for the standards pertaining to recombinant bovine somatotropin (rBST)and Ractopamine. Focussing on those two standards should, therefore, provide some insight as to what are the factors that are preventing consensus to be reached on them. A review of the various Commission and Committee reports relevant to these two standards would suggest that the main impediments to consensus were non-science factors (e.g. consumer opinions and preferences) and concerns related to WTO implications.

rBST

19. The 3rd Session (November 1988) of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) considered a proposal from the United States to place both bovine and porcine somatotropins on the priority list for JECFA evaluation as it was their view that an early scientific evaluation could prevent misunderstandings as to the safety of foods containing residues of these substances. This approach was supported by Poland. However, a number of other delegations, particularly from Europe noted that studies on this substance were still at a very early experimental stage and the Committee decided to defer the evaluation to a later JECFA meeting.

20. At the 4th Session (October 1989) of the CCRVDF, the EC advised the Committee that there was a proposal to the European Council that there should be an evaluation period until the end of 1990 regarding bovine somatotropins during which time no Economic European Community (EEC) Member State could unilaterally authorize use of this product. The Committee agreed to place BST on the priority list for evaluation by JECFA in 1992.

21. At its 6th Session (October 1991), the CCRVDF was informed of the results of an evaluation of rBST by the EEC's Committee on Veterinary Medicinal Products (CVMP). The CVMP expressed the opinion that residues of this product did not represent a risk to health of consumers of meat or milk from treated animals. The CVMP did note that some members of the EEC did raise concerns with them regarding the safety of the product for the target animal, in particular regarding the incidence of mastitis and the possibility of injection site reactions.

22. The 7th Session (October 1992) of CCRVDF was informed of the results of the JECFA evaluation. JECFA established an ADI and MRL "not specified". It was clarified that this meant that the margin of safety was so large taking into account proposed use, potential intake of residues and availability of toxicity data that they represented no hazard to human health and therefore did not require a numerical ADI or MRL. The CCRVDF therefore agreed to advance the MRL for bovine somatotropin to Step 5. No reservations were recorded with respect to this decision.

23. The 20th Session (July 1993) of the Codex Alimentarius Commission adopted the proposed draft MRL for bovine somatotropin at Step 5.

24. The 8th Session (June 1994) of the CCRVDF subsequently agreed to advance the MRL to Step 8 for adoption by the 21st Session (July 1995) Codex Alimentarius Commission. While no reservations were recorded, the European Community (EC), noted that there was a moratorium in place within the members of the EEC on the use of BST until the end of 1994; therefore the EC could not take a position on the matter. The EC did not object to the decision to advance the standard to Step 8.

25. However, consensus could not be reached at the 21st Session (July 1995) of the Commission, and it decided, by means of a vote, to hold the MRL at Step 8. (33 in favour of holding, 31 opposed 6 abstentions).

26. The adoption of the MRL for BST was further considered by the 22nd Session (June 1997) of the Codex Alimentarius Commission but again no consensus was reached. A number of countries and observers favoured adoption of the MRL because:

    - JECFA evaluation indicated there was no adverse human health effect and there was no new evidence presented to the contrary

    - Product was already in use in several countries and there was a concern that the lack of an adopted MRL could be used as a non-tariff trade barrier.

Other countries and observers were opposed to the adoption of the MRL expressing concerns of an ethical nature, safety concerns or because information indicated that use of BST:

    Could reduce livestock immune system which could lead to more viral and bacteria infections which could result in an increased use of antibiotics

    Could increase the incidence of mastitis

    - Was of no value to consumers and would not improve the quality or safety of the milk.

27. The Commission decided, again on the basis of a vote, to suspend further consideration of this issue until its next Session. (38 in favour, 21 against, and 13 abstentions).

28. The 50th Session of JECFA (February 1998) re-evaluated rBST and reached the same conclusion, i.e. it established an ADI and MRL "not specified".

29. At the 23rd Session (July 1999) of the CAC consensus still could not be reached so the Commission decided to hold the MRL at Step 8. The MRL is still being held at Step 8.

30. The 34th session (July 2011) of the Commission agreed to consider the draft MRLs for rBST at its next session. In order to facilitate its discussion, the Commission requested the Codex Secretariat to prepare a paper, which would describe the history of the development and discussion of the MRLs in Codex, including a summary of the JECFA evaluation.

Ractopamine

31. The 14th Session (March 2003) of the CCRVDF added Ractopamine to the priority list of substances to be evaluated by JECFA. The 15th Session (October 2004) of the CCRVDF considered the establishment of MRLs based on the JECFA evaluation. However, the EU stated that they could not support the advancement of the MRLs for Ractopamine as they had not had sufficient time to consider in detail the report of the 62nd JECFA due its late distribution. They also noted that Ractopamine had not been evaluated within the European Community and that a number of questions had been raised on the safety of the substance at the previous JECFA evaluation. In view of the lack of consensus, the CCRVDF retained the MRLs for Ractopamine at Step 4.

32. The 16th Session (May 2006) of the CCRVDF agreed to advance the MRLs proposed by the 62nd JECFA meeting for Ractopamine in cattle and pig's tissues to Step 5, as there was no consensus to advance them to Step 5/8. These MRLs were adopted at Step 5 by the 29th Session of the Commission and no reservations were recorded.

33. There was an extensive discussion on the issue at the 17th (September 2007) Session of the CCRVDF. Several delegations supported the advancement of the MRLs for Ractopamine to Step 8 in view of the positive outcome of the completed JECFA evaluation. In this regard, the importance of the JECFA evaluation for those countries that do not have adequate resources to conduct their own safety evaluation was noted. The EU, however, opposed the advancement of the MRLs to Step 8 in view of the fact that their legislation did not allow for the use of beta-agonists for growth promotion. While there was no consensus, the Committee, noting that the justification for not supporting the advancement of the MRLs to Step 8 was not based on scientific arguments, agreed to advance the draft MRLs for Ractopamine in cattle and pig tissues to Step 8, while noting the strong reservation of the Delegations of the European Community, Norway and Switzerland to this decision.

34. The adoption of the MRLs for Ractopamine was considered by the 31st Session (July 2008) of the Commission but a consensus could not be reached. The Commission agreed to hold the MRLs at Step 8 for further consideration at its next session. It further requested Members to submit relevant information on the availability of scientific data to the 18th Session of the Committee on Residues of Veterinary Drugs in Foods (May 2009) thus allowing for a decision by the Committee regarding the inclusion of Ractopamine in the priority list of substances for evaluation/re-evaluation by JECFA. The Commission further agreed that at its 32nd Session, it would decide on the adoption of the MRLs for Ractopamine based on the report of the 18th Session of the Committee on Residues of Veterinary Drugs in Foods.

35. At the 18th Session (May 2009) the CCRVDF again discussed the MRLs for Ractopamine. The EU indicated that the European Food Safety Authority (EFSA) had conducted a review of the JECFA evaluation regarding the safety of Ractopamine. EFSA's review pointed out a number of uncertainties and weaknesses in the data underlying the JECFA assessment. The EU therefore was of the view that Ractopamine should be placed on the priority list for re-evaluation by JECFA. The WHO JECFA Secretariat noted that no new data were reviewed by EFSA. China briefly described the results of residue studies carried out in pigs in China and pointed to high residue levels at early time points after cessation of treatment and that significant levels of residues were also found in other tissues such as lung and intestine. The delegation expressed the view that the current MRLs for Ractopamine would not be compatible with a zero withdrawal period, and that in China tissues other than those included in the established food basket were regularly consumed. The delegation of China also stated that they could not support the draft MRLs and requested JECFA to conduct a comprehensive re-evaluation of the

substance. The Committee concluded that there was no significant new data available that would justify inclusion of Ractopamine in the Priority List for complete re-evaluation by JECFA. However, the Committee did place Ractopamine on the priority list for re-evaluation of residue depletion in pork tissue, based on the data to be provided by China. The JECFA Secretariat expressed the view that the data to be presented by China on residue depletion in pork tissue would not constitute significant new data requiring a re-evaluation of the recommended MRLs currently at Step 8.

36. At the 32nd Session (July 2009) of the Commission, no consensus was reached on adoption of the MRLs. The Commission decided to hold the draft MRLs for Ractopamine at Step 8 and also agreed to request JECFA, as a matter of priority, undertake a review of new data submitted to the 18th Session of the Committee on Residues of Veterinary Drugs in Foods by China (data that had not been formally reviewed by JECFA), focusing on the implications of these data for the MRLs for Ractopamine currently held at Step 8.

37. JECFA subsequently reviewed the data provided, including those from the three breeds of pigs in the studies undertaken by the People's Republic of China, and corresponding dietary information. The review concluded that the MRLs provide the level of protection needed considering the consumption of pig tissues of muscle, liver, kidney and fat and the established ADI.

38. The 33rd Session (July 2010) of the Commission considered the matter once again including the most recent evaluation from JECFA. However, consensus could still not be reached and the Commission agreed to hold the MRLs at Step 8 for consideration at its 34th Session (July 2011). In an effort to find a way forward, a "Friends of the Chair" group was formed under the direction of the Chairperson of the Codex Alimentarius Commission, to attempt to shape a consensus for this issue.

39. The Friends of the Chair group presented two options to the 34th Session (July 2011) of the Commission, one supporting adoption and the other supporting discontinuation of work or holding the standard in abeyance for a period of time. A vote on adoption was requested, and the Commission voted on the question of whether a vote should be held. The Commission voted against conducting a vote on adoption of the MRLs, and they remain at Step 8.

Analysis

40. In reviewing the reports of the various meetings as well as submitted comments, it is noted that opponents to the adoption of these MRLs cite their opposition based on non-science issues such as consumer preferences, impact on consumer confidence, prohibition in national legislation, etc.

41. In both the case of rBST and Ractopamine, opponents to the adoption of the relevant MRLs also cited concerns over human health effects as a basis of their opposition. However, it must be observed that in both of these cases, JECFA, which, for Codex, is the authoritative risk assessment body providing advice to the Commission concluded that there were no adverse human health affects with either substance when used in accordance with good agricultural/animal husbandry practices.

42. Supporters of the adoption of the MRLs have argued that the science demonstrates that the substances are safe when used in accordance with good agricultural/animal husbandry practices and that the lack of adopted MRLs could impede trade.

43. It would seem, therefore, that the root causes for the Commission's inability to reach consensus in these instances are due to "other factors" and concerns with respect to WTO implications regarding trade (either permitting trade or conversely, ability to reject product that does not meet national requirements). The question, therefore, is what guidance is offered to the Commission on how to address issues related to "other factors" and "WTO implications"?

44. In the Codex Step process, there is explicit reference to the need to consider comments which Members may have concerning implications for their economic interests[3]. Therefore, national economic implications related to the impact of an international standard on trade might, in certain instances, be a valid consideration. However, factors related to economic interests should be based on objective data and the onus of providing that detail resides with the member or members making the statement.

Factors outside of the Codex mandate

45. It is recognized that the Commission can hold a draft proposal at step 8 as this option is clearly specified in paragraph 5*, Introduction, Procedures for the Elaboration of Codex Standards and Related Texts*, Codex Procedural Manual.

46. According to Codex procedures, standards are set on a scientific basis. The scientific process in Codex is independently conducted by scientific organisations such as JECFA and JMPR. The Procedural Manual describes the risk assessment policies and risk analysis principles and guidelines for a number of Codex Committees and how they interact with various risk assessment bodies. Each country, however, has the right to apply its own risk assessment and its own level of public health protection. Such evaluations should be consistent with the *Working Principles for Risk Analysis for Application by Governments* which would include consideration of the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are taken in Account.*

47. The *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are taken in Account* were adopted by the 21st Session (1995) of the Codex Alimentarius Commission and were developed to provide some guidance as to how "other factors" should be incorporated into the decision-making process. When deciding upon food standards, risk managers can identify other factors relevant for health protection of consumers and promotion of fair trade practices. The *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* allow for the consideration of other legitimate factors (Article 28) but also state that measures developed should be "no more trade-restrictive than necessary" (Article 34). Therefore, in the application of risk analysis in the development of international standards, the only other factors besides science which should be considered are those relevant to protecting the health of the consumer and to ensuring fair practices in the food. This recognition of course, begs the question, "How does the Commission determine if a factor or factors are indeed "legitimate" and should be taken into account?"

48. In this regard, the Procedural Manual specifies criteria that can be used to determine if a particular factor is "legitimate" in the context of the *Statements of Principle* and therefore should be taken into account. The onus for demonstrating that a factor satisfies the criteria and is hence "legitimate" should reside with the member or members who wish that factor to be taken into account in establishing the international standard. The issue that arises is that the current Codex mechanism does not provide a procedure as to how the Commission should proceed when consensus is not reached based on a factor or factors that are not, in fact, legitimate in the context of the international standard-setting process. Clear guidance on the role of the Chairperson in such circumstances and how the Commission should deal with issues that are outside of its mandate but are nonetheless affecting the decision-making process appear to be lacking.

49. Elaboration of Codex standards appears to have become more contentious since the referencing of Codex texts by the WTO in the SPS Agreement and, thus, Codex standards carry weight in trade disputes at the WTO. While not explicitly expressed during Codex sessions, it appears that the lack of consensus may be resulting from concern over the status of national regulatory requirements which may differ from the international standard being developed, and hence the potential for a WTO challenge, that subsequently results in a lack of consensus.

[3] Uniform Procedure for the Elaboration of Codex Standards and Related Texts, Steps 3, 5, 6 and 8 and Uniform Accelerated Procedure for the Elaboration of Codex Standards and Related Texts, Steps 3and 5.

50. However, objective data is not often provided given that some members do not always communicate concerns regarding the possible WTO implications of a standard as the basis for their position. This usually results in the noted lack of consensus. Instead, countries tend to try to influence the standard during its development with the objective of attaining a favourable trade outcome by striving to have the international standard incorporate or exclude requirements even if those requirements are not globally applicable.

51. The question for consideration is therefore related to how the Commission deals with situations where objections to the adoption of a standard are not based either on sound science or on other factors that are globally applicable. There are also questions as to how should the Commission address trade issues which, while not specifically raised by members, are nevertheless impeding progress. While the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which Other Factors are taken into Account* are clear as to what the Commission should base its' decisions on, there is no clear guidance on how Chairpersons should apply those principles where consensus is lacking due to factors outside of the mandate of Codex.

Recommendations/Considerations for the 27th Session of the CCGP

52. The view was expressed that the issue is not holding a standard at Step 8 for reasons related to science but rather holding standards for reasons other than science. It was noted that the Codex risk analysis framework endeavours to address the need for risk management to take other factors into account but should other factors" be the basis of a decision to adopt or not to adopt a standard? The view was expressed that there is a need for Codex members to have a free and open discussion around current standards setting procedures and the perceived failures and challenges. It was further suggested that this discussion could be best achieved through a facilitated discussion or workshop either in conjunction with CCGP or as a separate workshop or forum.

53. Most working group participants indicated that in their view there was no need for additional guidance for chairpersons to be developed. They expressed the view that Committee Chairs and the Chair of the Commission currently have the tools needed to address the types of blockages demonstrated in the eWG draft discussion paper, for example the *Guidelines to Chairpersons of Codex Committees and Ad Hoc Inter-governmental Task Forces* and *Measures to Facilitate Consensus* in the Appendix of the Codex Procedural Manual. Nevertheless, it was generally recognized that there is a need to provide training and support to chairpersons to enable them to apply the available guidance in a consistent manner in all Committees. It was further noted by some participants that a thorough discussion at the Committee level was essential before advancing a draft text to the Commission.

54. It was noted by several participants that it was important that members be transparent in terms of their concerns in respect of a standard so that these may be assessed against the Commission's decision making principles and criteria. In this regard many participants noted the need to identify potential challenges to the elaboration of a standard very early in the decision making process. It has been suggested this can be accomplished by either modifying the content of the Project Document as found in *Part 2: Critical Review; Proposals to Undertake New Work or to Revise a Standard* or alternatively to revise the *Criteria for the Establishment of Work Priorities*, both of which are contained in the Codex Procedural Manual.

55. It was also suggested that consideration could be given to the use of "concern forms" where Members would be requested to objectively list and justify the reasons why a standard should be held at Step 8 and what are the suggested procedures to be taken while the standard is being held at this stage. However, other participants did not support the use of these forms as they were of the view they would not be applicable outside of the CCPR context. The co-chairs noted that the intent of the suggestion to use "concern forms" was to enable the timely identification of issues that needed resolution. It is the view of the co-chairs that initiating revisions to either the project document or to the Criteria as indicated in paragraph 54 above would accomplish the same effect. The co-chairs further stress that regardless of any procedural changes made in an attempt to identify issues early in the process, transparency on the part of members is essential to ensure such efforts are effective.

56. Some working group participants suggested that paragraph 5 of the Procedures for the Elaboration of Codex Standards and Related Texts be amended by deleting the final sentence, i.e. delete “The Commission may also decide that the standard be held at Step 8”. However this was not supported by other participants. It was noted that the possibility is sometimes needed to allow the opportunity to resolve outstanding issues without having to send the entire standard back to the subsidiary body.

57. A suggestion was made by a couple of participants that where there is a lack of consensus, consideration could be given to the adoption of the standard as a regional standard with the possibility to convert it to a global standard in the future should consensus eventually emerge. Respecting this suggestion it should be noted that in the Codex Procedural Manual, regional standards are intended to be established for “food products moving exclusively or almost exclusively in intra regional trade”. Hence, in view of the current definition for regional standard, it may not be appropriate to establish regional standards for products traded globally.

58. It was also suggested that a mechanism whereby if a standard has been held at Step 8 for a specified number of years (e.g. 5 years) then a vote will be taken. It was further suggested that such a vote would require a two-thirds majority rather than an simple majority and should the vote for adoption fail, then work on the standard would be discontinued. Other comments noted that after all avenue to reach consensus had been explored, a vote would be likely. In this regard it was suggested that Rule XII, Paragraph 2 should be reviewed and consideration given to clarifying when voting may be appropriate and the procedures to do so. In order to implement either of these suggestions, amendments to the Rules of Procedure will be required.

59. The terms of reference for the eWG indicate that it should suggest what recommendations the CCGP may wish to consider at its 27th Session. It is further noted that the Guidelines for Electronic Working Groups explicitly states that “No decision on behalf of the Committtee, nor vote, either on point of substance or procedure shall take place in electronic working groups”. In view of this, the following recommendations have been identified by eWG participants and are being presented to the CCGP for its consideration and decision as to what, if any, actions will be taken:

    1) A facilitated discussion or workshop be held to allow Codex members a free and open discussion around current standards setting procedures, perceived failures and challenges.
    2) No work be undertaken to develop additional guidance for chairpersons in the Codex Procedural Manual. However, there is a need to provide training and support to chairpersons to enable them to apply the available guidance in a consistent manner in all Committees.
    3) New work be undertaken to revise the Codex Procedural Manual to ensure early identification of potential challenges to the elaboration of a standard either by revising the content of the Project Document as found in *Part 2: Critical Review; Proposals to Undertake New Work or to Revise a Standard* or alternatively to revise the *Criteria for the Establishment of Work Priorities.* It should be noted that the principle of transparency needs to be incorporated into these discussions.
    4) Use of “Concern Forms” be implemented, recognizing that this form as used by CCPR may need to be modified to be applicable in other Committees.
    5) Amend the elaboration procedures in the Codex Procedural Manual to amendparagraph 5 of the Procedures for the Elaboration of Codex Standards and Related Texts by deleting the final sentence, i.e. delete “The Commission may also decide that the standard be held at Step 8”.
    6) The Procedural Manual be revised to allow for the adoption of a standard on a regional basis should consensus not be achieved to adopt the standard as a global standard.
    7) The Rules of Procedure with respect to voting be reviewed with a view to providing for a vote if a standard has been held at step 8 for a specified number of years and to provide clarity regarding the second sentence of Rule XII.2.