codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 8 **CX/GP 06/23/8**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON GENERAL PRINCIPLES

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CONSIDERATION OF THE TERM "INTERIM" AS IT RELATES TO THE ADOPTION OF CODEX STANDARDS AND RELATED TEXTS

I. PURPOSE OF DOCUMENT

1. At its 27th Session, held in June-July 2004, the Codex Alimentarius Commission, following a "*proposal by the Delegation of Chile, supported by other delegations agreed to request the Committee on General Principles to clarify the interpretation of the "adoption on an interim basis*"[1]. At its 28th Session, in July 2005, the Commission noted again that the matter would be referred to the Codex Committee on General Principles (CCGP). This document, prepared in response to this request, consists of two parts. The first part gives a detailed overview of the background to the request made by the Commission to the CCGP, with particular reference to the process that has been under way within the Committee on Pesticide Residues (CCPR) since 1999 when the matter formally appeared for the first time while proposing to adopt some temporary Maximum Residue Limits (MRLs). Some pertinent extracts of reports of documents are attached to this document. The second part of the document puts forward a range of considerations, primarily of a legal nature, that the Committee on General Principles may wish to keep in mind when considering the term "*interim*" as it relates to the adoption of Codex standards and related texts.

2. At its 37th Session in April 2005, the CCPR requested the Commission to approve new work on a revision of the Maximum Residue Limits Elaboration Procedure. The 28th Session of the Commission approved such new work. A proposal concerning a revised procedure is, therefore, being referred to the CCPR, at its 38th Session, being held one week prior to the session of the CCGP. While dealing with a number of issues related to the interim nature of the proposed standards and the procedure followed to that effect, the purpose of the document is not to review such procedure as such, which is before the CCPR. Nor has the present document been discussed by the CCPR.

[1] ALINORM 04/21/41, paragraph 5.

II. GENERAL BACKGROUND

3. It is important to provide background on the manner in which the question has been raised, both within the Codex Commission, the CCPR as well as the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF). It is, in particular, to be noted that the matter was the subject of very extensive and rich debates within the CCPR. A clear understanding of the context in which the matter has been raised, including the range of opinions that have been put forward so far, is essential in order for the Codex Committee on General Principles to be able to provide guidance on the matter.

A. Discussions and decisions of the Codex Alimentarius Commission

4. The context in which the above question was raised at the 27th Session of the Commission in 2004 is reflected in the report of the session as follows:

> *"The Commission adopted the Draft and Proposed Draft Revision to Table 1 of the General Standard on Food Additives at Step 8 and Step5/8 as proposed. With regard to benzoates in food category 14.1.4, the Commission adopted the maximum level on an interim basis with the understanding that a review be conducted by CCFAC within 3 years and that comprehensive information on the level of use of benzoates in different types of foods and in different parts of the world and the results of intake studies, particularly in children, and other relevant data should be provided to JECFA to facilitate its further assessment (...)*
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> *The Commission noted the concern of the Delegation of the European Community about the proposed level of 600 mg/kg for benzoates in water-based flavoured drinks (food category 14.1.4) given the potential to exceed the ADI[2], particularly for children and that due regard be given to the technological need. The Delegation of Mexico expressed its reservation on the above level for benzoates in food category 14.1.4 as the level applied in its national legislation was 1000 mg/kg".*[3]

5. At the 28th Session of the Commission, in July 2005, the matter was again much debated. On that occasion, the Commission adopted, on the basis of a recommendation of the Codex Committee on Pesticide Residues, various interim Maximum Residue Limits (MRLs) for Bifenazate, Fludioxonil (211) and Trifloxystrobin (213)[4]. The relevant passage of the report reads as follows:

> *"To the question raised by one delegation regarding the status of the Interim Codex MRLs under WTO, the Representative of WTO stated that Interim MRLs elaborated by Codex could assist Members when provisionally taking measures in accordance with Article 5.7 of the SPS Agreement[5]. This matter however was subject to interpretation by WTO Committees and the dispute settlement body.*

[2] Acceptable Daily Intake
[3] ALINORM 04/27/41 paragraphs 27-29
[4] ALINORM 05/28/24, Appendix V.
[5] Article 5, paragraph 7 of the SPS Agreement reads as follows: "*In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or*

The Commission adopted the proposed draft Interim MRLs as proposed by the Committee, with understanding that these MRLs would be valid for the period of four years. The Delegation of the European Community reserved its position".[6]

B. Discussions within the Codex Committee on Pesticide Residues

6. Within the Codex Committee on Pesticide Residues (CCPR) that whole issue has been much discussed. It should be noted that the matter described under section (a) below is, strictly speaking, separate from the ensuing discussions covered by sections (b) – (f).

(a) 31st Session of the Committee on Pesticide Residues, April 1999

7. The 31st Session of the CCPR (12-17 April 1999) considered the MRLs for carbaryl and decided to recommend to the Commission to replace all existing Codex MRLs with temporary MRLs at the same levels as respective Codex MRLs, as the TMDI[7] significantly exceeds the ADI which had been reduced following a recommendation of the Joint Meeting on Pesticide Residues in 1996. The Committee agreed on a timeframe of 4 years for these temporary MRLs. New studies would be available for toxicological evaluation by the 2000 JMPR and periodic review of residue data in 2001 (ALINORM 99/24A, para. 41).[8]

(b) 33rd Session of the Committee on Pesticide Residues, April 2001

8. At its 33rd Session, in 2001, the CCPR considered an item entitled "*trade vulnerabilities resulting from the lengthy Codex MRL process*", which had already been discussed within the Codex Coordinating Committee for North America and the South West Pacific (CCNASWP). The delegation of the United States, while introducing the issue, indicated that according to normal practice the time between the nomination of a pesticide for consideration and the actual establishment of MRLs resulted in a "*window of trade vulnerability of agricultural commodities*". This delegation pointed out that a number of new pesticides were registered at the national level, as there was a need for safer and more efficient pesticides to address new challenges such as resistance and the introduction of exotic pests. However, under the current system, it would take several years before these pesticides could be evaluated by Joint Meeting on Pesticide Residues (JMPR) and before Codex MRLs were adopted. As a result, growers were faced with serious difficulties to export their products, and the absence of Codex MRLs at the international level for new compounds was likely to create significant barriers to trade. The delegation proposed a number of options to address these difficulties, including a reorientation of the priorities for the Joint Meeting on Pesticide Residues and "*the establishment of 'interim' MRLs that could be used as a reference with the understanding that they would be revised within a limited timeframe*"[9].

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phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time".

[6] ALINORM 05/28//41 paragraphs 57-58

[7] Theoretical Maximum Daily Intake

[8] The 23rd Session of the Commission adopted the proposed MRLs at Step 8 without questioning their "temporary" nature (ALINORM 99/37, paras 141-150). These temporary MRLs "expired" four years later, i.e. in 2003; the Committee on Pesticide Residues is currently working on new proposals for these MRLs.

[9] ALINORM 01/24A, paragraphs 6- 12

9. Some other delegations expressed concern at this proposal. One of these delegations expressed concern with some recommendations in the paper, as they were not consistent with Codex procedures and the status of Codex standards under WTO, and pointed out that the document considered trade aspects and that there should be a balanced consideration of health protection and trade aspects in elaborating MRLs. The Secretariat recalled that according to the *Statement of Principles Relating to the role of Food Safety Risk Assessment*, health and safety aspects of Codex decisions and recommendations should be based on risk assessment, as appropriate to the circumstances. "*The Committee agreed to acknowledge the existence of the problem and requested the delegation of the USA*" with the assistance of other countries to prepare a paper for consideration at its next session[10].

(c) 34th Session of the Committee on Pesticide Residues, May 2002

10. An extensive debate took place within the Committee at its 34th Session in 2002, which is not easy to summarize[11]. The CCPR decided to consider two items together, i.e. a "*discussion paper on trade vulnerabilities arising from the Codex MRL establishment process*" (on the basis of a paper prepared by the group) and a "*review of the working procedures of the joint FAO/WHO meeting on pesticide residues*" (on the basis of a paper prepared by the United States with the assistance of a few other Members). It was recalled that the underlying problem was the lengthy process, ranging from 4 to 8 years, that was required for the elaboration of Codex Maximum Residue Limits for newly introduced, often safer, pesticides. During this period, in those countries where such pesticides had been registered for use, farmers and exporters were reluctant to use them because importing countries that applied Codex MRLs as the basis for their national regulation would reject commodities containing residues of the new pesticides. The paper identified several options broadly categorized into options that were less resource intensive and options that were highly resources intensive. Less resource intensive option 1 (National Government MRLs Become Interim Time-Limited MRLs Pending JMPR Review) and option 2 (Recommendations of the JMPR Become Interim MRLs Pending CCPR Review).

11. There was general consensus that steps needed to be taken to reduce the timeframe for the consideration and adoption of MRLs for new compounds in order to reduce such trade vulnerabilities. It was noted, however, that the Statutes of the Commission (Article 1 (a)) stated that the Commission's mandate referred to "*protecting the health of consumers and ensuring fair practices in the food trade*", rather than trade facilitation *per se*. Several delegations expressed an interest in option 1, i.e. the use of National Government MRLs as Interim Codex MRLs, while other delegations expressed opposition or reservations. There was less support for option 2, whereby JMPR MRLs would be used as Interim Codex MRLs Pending CCPR Review. Several delegations drew attention to a significant problem in accepting the recommendations of JMPR without intergovernmental review as this might raise questions concerning the status of the interim MRLs within the framework of the WTO Agreements.

12. The conclusions of the debate are summarized as follows in the report. The Chairperson noted the divergent views regarding options 1 and 2. He noted that option 1 would provide an additional source of Codex MRLs, whereas option 2 would not, although the process would be accelerated. He also proposed that the Committee should return to its

[10] ALINORM 01/24A, paragraph 12.

[11] In all cases, for a complete review of the very rich debates that took place within the CCPR the reader is invited to refer to the reports of the CCPR.

former practice of considering the proposed draft MRLs at Step 3 on the basis of the Reports of JMPR from the previous year, without prejudice to the possibility of more detailed consideration at a later stage on the basis of the published evaluation. This, in his opinion, would go some small way towards speeding up the process. The Committee agreed to this proposal[12].

13. The Committee also agreed that feasibility and the procedures for the establishment of Codex Interim MRLs on the basis of Option 1 should be explored further on the basis of intergovernmental review by the CCPR and the Commission. In this regard, the CCPR welcomed the suggestion of the United States to develop a working paper on a pilot project for the examination of national MRLs as interim Codex MRLs for safer replacement pesticides. It agreed to establish a Working Group for this purpose led by the United States and composed of Argentina, Australia, Canada, Chile, Egypt, New Zealand, Senegal, South Africa, Sudan, European Community, Consumers International and Crop Life International.

(d) 35th Session of the Committee on Pesticide Residues, April 2003

14. At its 35th Session, an extensive debate took place again on the discussion paper on the pilot project for the examination of national MRLs as interim Codex MRLs to address trade vulnerability. The Committee examined various criteria and procedures proposed in the document. Some delegations supported the proposal while others expressed different views and concerns. Alternatively it was suggested that the same purpose could be achieved through the mutual acceptance of national MRLs on an bilateral basis.

15. The Codex Secretariat indicated that Interim MRLs were not defined in the Codex Elaboration Procedure and therefore had no status in Codex. The establishment of Interim MRLs would require an amendment to the current procedure, for consideration by the Committee on General Principles and adoption by the Codex Alimentarius Commission. The Committee was also informed that paragraph 3(a) of Annexe A – Definitions of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) refers to "*the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drugs and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice*". The Codex Secretariat was asked to seek and provide legal advice on the legal status of such interim MRLs should the intended pilot scheme be progressed and for that advice to be provided to member countries before the next session of the CCGP. Advice on this matter was seen as an essential prerequisite for commencement of a pilot project. The Secretariat indicated that such advice could be provided only by the Codex Alimentarius Commission.

16. Eventually, the Committee agreed in principle to initiate the project at the next session but to request preparatory work for that session. The Committee requested the Drafting Group which had been set up at its earlier session, expanded to include a few other members, to revise the paper so that it could be possible to initiate the project at the next session of the CCPR. The Committee also agreed that advice, by the Commission, should be sought on the initiative[13].

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[12] ALINORM 03/24, paragraph 194.

[13] The Commission at its 26th Session discussed the proposal of the Committee to test a pilot project to use national MRLs as Interim (Step 8) Codex MRLs for limited period of time until the JMPR review became available. The proposed procedure required the Committee to notify the Commission about the proposed Interim MRLs, however, it did not require the adoption of these MRLs itself; however the Commission could reject such

(e) 36th Session of the Committee on Pesticide Residues, April 2004

17. The Committee noted that, at its previous session, it had agreed to initiate the Pilot Project and that the 26th Session of the Commission had approved work on the project with the understanding that the proposed Interim MRLs would be submitted for adoption by the Commission at step 8. The Delegation of the United States introduced the document and indicated that issues and concerns expressed at the last session of the Committee had been addressed during the revision of the document. It clarified that chemicals proposed and accepted for the Pilot Project must meet the criteria of being new, safer and replacement chemicals and that the current document included indicators on how success of the pilot project would be measured. The paper also outlined the procedure that would allow member countries to assess the nominations and conduct a scientific review that should lead to consensus-based MRL recommendations. It was indicated that there was consistency with the normal Codex MRL setting process and that the interim MRL procedure would allow for a faster establishment of MRLs for compounds in Codex which would facilitate use of safe pesticides. After a debate, the Committee concluded that some uncertainties still existed with some of the procedures involved in the Pilot Project but recognized that these uncertainties should be resolved during the pilot phase of the project itself. The Committee agreed to use the procedure for the establishment of interim MRLs as described in CRD 21 and that Interim MRLs established under the scheme should be maintained for not more than four years[14].

(f) 37th Session of the Committee on Pesticide Residues, April 2005

18. At this session the Committee recalled in general terms that following the proposals made earlier, the Commission at its 26th Session had approved work on the Pilot Project for the examination of national MRLs as Interim Codex MRLs, and that the 36th Session of the Committee had agreed that the Pilot Project Working Group would prepare draft proposals on refinements of the procedure, based on comments received, for consideration by the next session of the Committee. The Committee had a long debate on the matter, with particular reference to the procedure for the establishment of Interim MRLs. While some delegations supported the process of elaboration of Interim MRLs, some other delegations questioned the necessity for interim MRLs, the meaning of "*safer*" and "*reduced risk chemicals*" and the status of interim MRLs in Codex.

19. The Secretariat clarified that the CCGP would consider a proposal to clarify the term "*interim*" and that, while the Commission had approved new work on a pilot project for the development of interim MRLs, no proposal had been made to elaborate the Procedure for the Elaboration of Codex Standards. For its part, the FAO joint secretariat to the JMPR drew the

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Interim MRLs if required. The Commission noted the views of the Secretariat that the SPS Agreement referred to the "standards, guidelines and recommendations established by the Codex Alimentarius Commission" but not to texts established by the Commission's subsidiary bodies. Moreover, the Commission noted that under the Rules of Procedure, subsidiary bodies prepared draft standards for submission to the Commission, but could not establish standards, interim or otherwise, themselves. The Commission approved work on the pilot project with the understanding that the Proposed Interim (Step 8) MRLs would be submitted to for adoption by the Commission. The Commission drew the attention of the Committee to the need for scientific integrity and consistency with Principles for Risk Analysis applied in the framework of the Codex Alimentarius. It also noted that national data requirements for the proposed for the proposed Interim MRLs should meet criteria for the submission of data for JMPR and that procedural questions that might arise from the process should be considered carefully. Cf. ALINORM, 03/41, paragraphs 199-201.

[14] ALINORM 04/27/24, paragraph 231.

attention of the Committee to the fact that extensive use of interim MRLs might severely curtail the JMPR, as Interim MRLs should be reviewed within 4 years and that the interim process would introduce inconsistencies in the process currently used by Codex especially as regards independent review of compounds.

20. The Committee decided that the Pilot Project Working Group would prepare a paper containing an evaluation of the Project for its next session. The Committee agreed not to propose new compounds for the Pilot Project. The Committee agreed to ask the Commission to approve new work on the amendment of the MRL elaboration procedure and that the JMRP and the Codex Secretariat with the assistance of the Chairperson would prepare a document for consideration at its next session with the understanding that the proposed draft MRLs would also follow the currently established procedure for the adoption of standards[15].

21. The Commission, at its 28th Session in 2005, approved the initiation of work on the revision of Maximum Residue Limits Elaboration Procedure [16]. Accordingly, a document is being prepared for the 38th Session of the CCPR which is due to be held one week before the CCGP session. There is, thus, a parallel two track process in the course of which each of the Committees will be reviewing the matter under its respective mandate.

C. Discussions within the Codex Committee on Residues of Veterinary Drugs in Food

22. The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) have, in several instances, designated certain draft MRLs under elaboration as "Temporary MRLs" according to the recommendation of JECFA[17]. In some cases all MRLs for a compound were temporary because the ADI set by JECFA was temporary[18]; in other cases the MRLs were temporary because of insufficient data or due to other reasons (e.g. lack of validated analytical methods). The CCRVDF recommended the Commission to adopt Temporary MRLs as such at Step 8 in the following cases.

(a) Moxidection in Deer Tissues

23. The 10th Session of the CCRVDF advanced the proposed draft temporary MRLs for moxidectin in deer tissues (muscle, liver, kidney, fat) to Step 5/8, omitting Steps 6 and 7, for adoption as Temporary MRLs for the period 1997-1999. It was noted that these uses were scheduled for JECFA review in 1998, after which the status of the Temporary MRL would be reviewed by the Committee and the Commission (ALINORM 97/31A, paragraph 47 and Appendix IV). [19]

24. The 11th Session of the CCRVDF in September 1998, while revising the MRLs, noted that the 50th JECFA converted the temporary MRLs for deer tissues to full MRLs maintaining the same levels. As these temporary MRLs had been adopted by the

[15] ALINORM 05/28/24, paragraph 200.
[16] ALINORM 05/28/41, Appendix VIII, page 122.
[17] "Temporary MRL" is used by JECFA when a temporary ADI has been established and/or when it has been found necessary to provide time to generate and evaluate further data on the nature and quantitation of residues.
[18] "Temporary ADI" is used by JECFA when data are sufficient to conclude that use of the substance is safe over the relatively short period of time required to generate and evaluate further safety data, but are insufficient to conclude that use of the substance is safe over a lifetime; a higher-than-normal safety factor is used when establishing a temporary ADI and an expiration date is established by which time appropriate data to resolve the safety issue should be submitted to JECFA.
[19] These temporary MRLs were adopted by the Commission in 1997 (ALINORM 97/37 paragraph 71)

Commission in 1997, the Committee agreed to advance the full MRLs for deer tissues to Step 5/8, with a recommendation to omit Steps 6 and 7 (ALINORM 99/31 paragraph 96).[20]

(b) Dihydrostreptomycin/Streptomycin in Cow's Milk

25. The 12th Session of the CCRVDF in March 2000 advanced the proposed draft Temporary Maximum Residue Limits for Dihydrostreptomycin/Streptomycin in cow's milk to Step 5/8 of the Procedure, with a recommendation to omit Steps 6 and 7 for adoption at Step 8 (ALINORM 01/31 paragraph 80 and Appendix III).[21]

26. The 12th Session of the CCRVDF in March 2003 noted that the 58th JECFA considered new information on the analytical method for the determination of residues in cow's milk and reviewed new data for the establishment of an MRL for milk from sheep. The JECFA recommended adopting the previous temporary MRL for cow's milk from the 52nd meeting as full MRL. The Committee, noting that the temporary MRL for dihydrostreptomycin/ streptomycin in cow's milk was adopted by the 24th Session of the Codex Alimentarius Commission, recommended that the 26th Session of the Commission revise the previously adopted MRL for dihydrostreptomycin/streptomycin in cow's milk as a full MRL (ALINORM 03/31A paragraphs 23-25).[22]

(c) Tilmicosin in Sheep's Milk

27. Tilmicosin was evaluated by the 47th JECFA (1996) that recommended a temporary MRL for sheep's milk, pending the receipt of the results of a study using a radiolabelled tilmicosin in lactating sheep aimed at determining the relationship between total residues and the parent drugs in milk. The 11th Session of the CCRVDF in September 1998 advanced the draft Temporary Maximum Residue Limits for tilmicosin in sheep's milk to Step 8 of the Procedure (ALINORM 99/31 paragraph 82 and Appendix II).[23]

28. The 54th JECFA (2000) did not extend the temporary MRL for sheep milk as results of a study with radiolabelled drug in lactating sheep to determine the relationship between total residues and parent drug in milk were not available. The results of the 54th JECFA were presented at the 12th CCRVDF in 2000, but the CCRVDF has not taken any action to follow up on the recommendation from JECFA.

29. In summary it should be noted that in the case of the CCRVDF, the use of temporary MRLs was connected to the JECFA assessment and that no timeframe for expiration or replacement of Temporary MRLs was tied to their adoption by the Commission.

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[20] The 23rd Session of the Commission adopted the full MRLs for moxidectin in deer tissues whereby replacing their respective temporary MRLs adopted at its 22nd Session (ALINORM 99/37 paragraph 156).
[21] These MRLs were adopted as Temporary MRLs by the 24th Session of the Commission (ALINORM 01/41 paragraph 142).
[22] The 26th Session of the Commission revised the Codex Maximum Residues Limit of Dihydrostreptomycin/ Streptomycin in cow's milk as a full MRL as recommended by the 14th Session of the Committee on Residues of Veterinary Drugs in Foods (ALINORM 03/41 paragraph 203).
[23] These MRLs were adopted as Temporary MRLs by the 23rd Session of the Commission (ALINORM 99/37 paragraph 156).

III. PERTINENT CONSIDERATIONS OF A LEGAL NATURE

30. In reviewing the issue, the Committee on General Principles may wish to keep in mind a series of considerations of a legal nature which should allow it to have an opinion on the matter. The observations presented below are to be seen as broad legal parameters under which the matter could be approached and under which the Committee may review the matter and provide further guidance, as requested by the Commission.

31. **First**, it may be useful to recall that it is not infrequent that in the areas of economic related matters, legal measures are frequently adopted on an interim basis, for a given period of time. It also happens that such measures may contain clauses providing for their own revision. The measures in question are, thus, adopted for specific periods of time and may have to be revised from time to time. In the same vein, provisions calling for the interim application of particular measures are found both in principal and subsidiary legislation. However, it is important to mention that the interim measures that have been under consideration within the Committee on Pesticide Residues and, to a lesser extent, in the Committee on Food Additives and Contaminants are not contemplated in the Procedures for the Elaboration of Codex Standards and Related Texts which form part of the Procedural Manual. A range of views seem to have been expressed in respect of this specific issue from 2001 to 2005. Thus, some Members observed in both reiterated and emphatic terms that the Procedures for the Elaboration of Codex Standards do not foresee the possibility for interim standards to be adopted and this would seem to preclude the adoption of such standards. This has also been the position developed by the Secretariat on a number of occasions. Other Members seemed to favour an *ad hoc* procedure for the adoption of interim standards, in the context of a pilot project. This was essentially the position of the proponents of interim standards. Still other Members expressed the view that if any procedure for the adoption of interim standards were to be followed it should be reflected in the Procedures for the Elaboration of Codex Standards and Related Texts.

32. The 38th Session of the CCPR is considering a document[24] prepared by the JMPR and Codex Secretariat which contains a proposed procedure for improving the Codex process for establishing pesticide MRLs, which would not require deviation from the Elaboration Procedure. If accepted, the adoption of Interim MRLs or establishment of a particular mechanism for their elaboration may become unnecessary. If, on the contrary, the CCPR decides to pursue a process which implies deviation from the Elaboration Procedure and/or the principles whereby Codex standards should be based on scientific risk assessment, there would obviously be a need for such a process to be explicitly defined in the Procedures for the Elaboration of Codex Standards in conformity with accepted principles governing the adoption of such standards. This would presumably involve a review by the Committee on General Principles of the procedure that was followed and, as appropriate and without prejudice to any substantive changes that might be proposed, their adoption by the Commission and insertion in the Procedural Manual.

33. **Second**, the underlying reasons for which a pilot project and subsequently a procedure for the adoption of interim standards have been proposed were described in detail by its proponents. Thus, according to the practice which has been followed for the definition of MRLs, the time between nomination of a pesticide for consideration and the actual

[24] CX/PR 06/38/12

establishment of MRLs has resulted in a "*window of trade vulnerability of agricultural commodities*". In fact, a number of new pesticides were registered at the national level, as there is a need for safer and more efficient pesticides to address new challenges such as resistance and the introduction of exotic pests. However, in the current system, it takes several years before these pesticides could be evaluated by JMPR and before Codex MRLs were adopted. As a result, growers have been faced with serious difficulties to export their products, and the absence of Codex MRLs at the international level for new compounds was considered likely to create significant barriers to trade. The idea was, therefore, that a compound nominated for testing and subsequent review by the JMPR could be covered by interim MRLs pending the completion of the work by the JMPR and the adoption of the relevant standard. Two shortcomings of a legal and practical nature have been put forward, although they may not always have been articulated in a clear manner.

34. From a legal point of view, it is noted that the interim standards would be used for a new pesticide that is a safer replacement for an existing compound. The compound in question must be nominated through a national government and the assessments to that effect must have been made at national level. While, in many cases there could be no reason to doubt the quality of the national assessments, the fact remains that such assessments of the safety aspects related to the pesticide in question have not been sanctioned by the JMPR. Although there might be no grounds to call into question the quality of national testing and the completeness of national data, the scientific authority – notably from a health perspective – of the compound may be open to debate or at least perceived as reflecting national testing procedures, however reliable and efficient they might be. This could be seen as an inappropriate procedure for the adoption of pesticides in the context of an intergovernmental body which could, in extreme situations, have a negative impact upon the credibility of the Codex Commission and its standards. More specifically, it could be argued that the risk assessment component of the process for the adoption of standards, which is supposed to be science-based, was not carried out in a complete manner in the context of the Codex Alimentarius Commission.

35. From a practical point of view, the compounds proposed for an interim standard are compounds designated for testing and subsequent review by the JMPR. The interim standard is intended to allow for trade on products that have been treated by a particular compound, pending the adoption of the full standard. In the course of the discussions regarding the Pilot Project, it was felt that the assessment of the compounds by the JMPR and the adoption of the standard would take some four years and, for this reason, it has been proposed that the interim standard should be in force for a period of 4 years. However, there is a definite possibility that the JMPR may not be able to complete its work and, thus the Commission would not be able to adopt the relevant standard within that time frame. This document does not deal with the options open to the Commission to deal with the situation at that time. However, there is reason to believe that the solution of the interim standards might simply be an expedient allowing for some time to be gained. If the JMPR and the Codex Committee on Pesticide Residues and the Commission, as a whole, are not in a position to expedite the pace at which standards are adopted, then there might be an accumulation of interim standards, either in force, or lapsed ones. It might be useful to seek to assess the situation that is likely to arise in that case. There might be situations where interim standards may expire before the adoption of full standards and such situations could create lack of legal stability at the international level. Consideration should therefore be given to options where the validity of interim standards, if they were adopted, is not tied to a specific number of years.

36. **Third**, it is clear from the above considerations regarding the reasons for which interim MRLs were proposed, that the adoption of a standard on an interim basis involves an admission that, for a reason or another, a particular measure is adopted provisionally pending the formulation and adoption of another measure, deemed to be a more adequate one. As noted above, the Codex Procedural Manual does not contain any provisions allowing for the adoption of Interim MRLs. However, in connection with the revision of standards, the Manual does reflect criteria and considerations bearing some resemblance, at least in their essence, to those which have led the Committee on Pesticide Residues to propose that interim standards be developed. Thus, the "*General Principles of the Codex Alimentarius*" contain a paragraph entitled:

> *"The Codex Alimentarius Commission and its subsidiary bodies are committed to the revision as necessary of Codex standards and related texts to ensure that they are consistent with and reflect current scientific knowledge and other relevant information. When required, a standard or related text shall be revised or removed using the same procedures as followed for the elaboration of a new standard. Each member of the Codex Alimentarius Commission is responsible for identifying, and presenting to the appropriate committee, any new scientific and other relevant information which may warrant revision of any existing Codex standards or related texts".*

37. In addition, the Procedures for the Elaboration of Codex Standards and Related Texts contain many references to the possibility of amending standards. Such procedures include "*a guide to the procedure for the revision and amendment of Codex standards*" and "*arrangements for the amendment of Codex standards elaborated by Codex Committees which have adjourned sine die*". Therefore, there are a number of institutional mechanisms and tools designed to allow the Commission to take into account considerations of the nature of those which led the Commission to adopt interim standards. However, as recalled above, the Procedural Manual does not make provision for the "direct" adoption of interim standards.

38. **Fourth**, should the Committee on General Principles be of the view that there may be situations which make the adoption of interim standards inevitable, then it would be necessary to prescribe that any such standards should be clearly time-bound and this should be done in a precise manner. In this respect, the proposed Interim MRLs were adopted by the Commission at its 28th Session on the understanding that it "*would be valid for the period of four years*". From a legal point of view, at the end of this period, the standard ceases to produce any effect. Admittedly, consistent with the above observations regarding *inter alia* the process followed for the adoption of "*interim standards*" on MRLs there are implications in respect of the authority of standard that is, from the beginning, adopted with the qualification that it will be in force only for a limited period of time. It would seem desirable to avoid the situation highlighted by the interim standard on food additives adopted in 2003, where "*the Commission adopted the maximum level on an interim basis with the understanding that a review be conducted by CCFAC within 3 years and that comprehensive information on the level of use of benzoates in different types of foods and in different parts of the world and the results of intake studies, particularly in children, and other relevant data should be provided to JECFA to facilitate its further assessment"*. In this case, the decision of the Commission could be interpreted to the effect that the maximum level for benzoates will remain in place until it is replaced by a new maximum level, given that the timeframe described only refers to the conduct of a review by CCFAC without specific condition being attached to the outcome of such review. Under this interpretation, the decision is considered as reflecting the commitment

of the Commission to shortly initiate the review of the maximum level and to revise it as and when such need arises. However, in the absence of clarification on the part of the Commission as to the period of validity of the standard, there remains an element of ambiguity. If the Commission is free to express its readiness to review any adopted standards within a specific timeframe and to instruct its subsidiary bodies to that effect, the use of the term "interim", which is open to different interpretations, should be discouraged in the future. In any case there may be instances where the Commission may wish to adopt an interim standard that will expire after a given period of time. In such cases, the actual period of time during which the standard will be in force should be clearly pre-determined. Otherwise, the standard would be considered to remain effective until it is actively withdrawn by the Commission.

39. **Fifth,** the Committee on General Principles may wish to consider whether in the procedure for the elaboration of MRLs standards, insofar as interim MRLs are concerned, there might be a need to insert any provisions to the effect that such procedure should involve an element related to the exceptional nature of the procedure. Indeed, it might be desirable that any such procedure should involve an exceptional dimension in order for it to be restricted to exceptional cases, as there is a risk that the procedure might be extended to other areas and, consequently, that the adoption of interim standards might become an established feature of the working procedures of the Codex Commission.

40. **Finally**, when examining this matter, the Committee on General Principles may wish to note that various specific queries have been raised as to the authority of the interim standards under the WTO Agreements, with particular reference to the Agreement on the Application of Sanitary and Phytosanitary Measures. The determination of the legal value of such interim standards within the ambit of the WTO agreements is primarily, if not exclusively, a matter for WTO Contracting Parties in accordance with the pertinent procedures. The only answer that was obtained so far corresponds is a very limited and prudent one, and does not allow for any conclusive views on the matter. It may however be of some importance to mention that when asked to offer his views on the status of interim MRLs elaborated by Codex, the representative of WTO said that they *" could assist Members when provisionally taking measures in accordance with Article 5.7 of the SPS Agreement*[25]*",* but this would be subject to the views of the WTO Committees and dispute settlement bodies.

IV. SUGGESTED ACTION BY THE COMMITTEE

41. The Committee is invited to review the document and to offer such views thereon as appropriate.

42. In particular, the following recommendations to the Commission could be considered by the Committee:

- The Commission should not adopt any food safety standards at Step 8, whether they are called temporary or interim, that are not substantiated by the scientific advice of

[25] Article 5, paragraph 7 of the SPS Agreement reads as follows: "*In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time*".

expert bodies and consultations recognised by the Commission, in accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius;

- Where draft standards are based on international risk assessments as mentioned above, the Commission may still wish to adopt them and at the same time commit itself to revisiting the matter in the near future; in this case, the Commission should generally refrain from using the term "*interim*" or "*temporary*", which could introduce ambiguity as to their status, including from a legal standpoint;
- The Commission should be very cautious in adopting standards having a limited lifetime; should the Commission choose to do so, then the time period for "automatic" expiration must be clearly defined; otherwise, all standards adopted by the Commission would be considered to remain in force until they are revoked or replaced by new or revised standards adopted by the Commission.