CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 3

CX/PR 11/43/2
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

43rd Session
Beijing, P.R. China, 4 - 9 April 2011

MATTERS REFERRED TO THE COMMITTEE BY THE CODEX ALIMENTARIUS COMMISSION AND CODEX COMMITTEES

A. MATTERS ARISING FROM THE 33RD SESSION OF THE CODEX ALIMENTARIUS COMMISSION

Matters for Information

1. The 33rd Session of the Commission (July 2010) adopted proposed draft and draft maximum residue limits for pesticides at Steps 8 and 5/8 as proposed by the 42nd Session of the Committee (April 2010). The Commission noted the reservations of the European Union and Norway on the MRL for methomyl (094) in apples due to acute intake concerns and the reservation of Egypt on the MRLs for chlorphyrifos-methyl (090) in potato and cypermethrin (118) in wheat.[1]

2. The Commission adopted proposed draft MRLs for pesticides at Step 5 as proposed by the 42nd Session of the Committee and advanced them to Step 6 for additional comments and further consideration by the next session of the Committee. The Commission noted the reservations expressed by the European Union and Norway on the MRLs for fluopicolide (235) for celery, head cabbage and leafy vegetables due to intake concerns and haloxyfop (194) for all the commodities due to the EU chronic intake concerns.[2]

3. The Commission revoked a number of Codex MRLs for pesticide/commodity combinations as proposed by the 42nd Session of the Committee.[3]

4. The Commission approved the Priority List of Chemicals Scheduled for Evaluation and Re-evaluation by JMPR as proposed by the 42nd Session of the Committee.[4]

Matters for Action

5. The 32nd Session of the Commission (July 2009) agreed to establish an electronic working group on future work on animal feeding to, amongst others, review existing Codex risk analysis principles as to their applicability to animal feed.[5] The 33rd Session of the Commission noted the report of the electronic working group which identified some gaps in the applicability of the risk analysis texts in relation to animal feed including the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues and made a number of proposals for their revision.

6. The Commission agreed to refer the proposals for revision to the relevant committees for review i.e. Committee on General Principles, Committee on Food Additives, Committee on Contaminants in Foods, Committee on Pesticide Residues, Committee on Residues of Veterinary Drugs in Foods and Committee on Food Import and Export Inspection and Certification Systems. The Commission further agreed to request the CCGP to ensure consistency of the risk analysis texts after they have been reviewed by the relevant committees.[6]

7. The Committee is invited to consider the review of the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues (relevant excerpt of CL 2010/8-CAC is attached as Annex II) and to report back on its findings and decisions to the Committee on General Principles. This request should be considered in the framework of the ongoing revision of the Risk Analysis Principles applied by the CCPR (see Agenda Item 11).

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1 ALINORM 10/33/REP, para. 43 and Appendix III.
2 ALINORM 10/33/REP, para. 69 and Appendix IV.
3 ALINORM 10/33/REP, para. 74 and Appendix V.
4 ALINORM 10/33/REP, para. 79 and Appendix VI.
5 ALINORM 09/32/REP, paras. 170-176.
6 ALINORM 10/33/REP, paras. 95-97 and paras. 100-101.

B. MATTERS ARISING FROM OTHER CODEX COMMITTEES

Committee on General Principles

Matters for Action

Review of the Risk Analysis Policies of Codex Committees

8. The 26th Session of the Committee (April 2010) agreed that risk analysis policies developed by Codex committees were generally consistent with the Working Principles for Risk Analysis, which complied with the mandate given to the Committee under Activity 2.1 - Review the consistency of risk analysis principles elaborated by the relevant Codex Committees, of the Strategic Plan 2008-2013. The Committee also agreed to forward the review presented in CL 2010/1-GP to the committees concerned for their consideration and review of their risk analysis policies, which would initiate Activity 2.2 - Review risk analysis principles developed by relevant Codex Committees of the Strategic Plan.[7]

9. The Committee is invited to consider the review of the Risk Analysis Principles applied by the Codex Committee on Pesticide Residues (relevant excerpt of CL 2010/1-GP is attached as Annex I) and to report back on its findings and decisions to the Committee on General Principles. This request should be considered in the framework of the ongoing revision of the Risk Analysis Principles applied by the CCPR (see Agenda Item 11).

Proposal for revision of the definition of "hazard" in the Procedural Manual

10. The 26th Session of the Committee could not reach a conclusion on a proposal to revise the definition of "hazard" in the Procedural Manual by adding the following footnote: "*This definition of hazard as an agent differs from the definition as an effect in many of the authoritative scientific references cited by several Codex committees in their documents on risk analysis. This difference should not be interpreted as producing any conflict in the interpretation or application of the Working Principles of Risk Analysis."*

11. In view of the general relevance of the "hazard" definition, the CCGP agreed to forward the above proposal to the committees concerned (Committee on Food Additives, Committee on Contaminants in Foods, Committee on Residues of Veterinary Drugs in Foods, Committee on Pesticide Residues, Committee on Nutrition and Foods for Special Dietary Uses and Committee on Food Hygiene) for advice and to consider this question further at its next session, taking into account the views of these Committees.[8]

12. The Committee is invited to consider the above proposal and provide its advice to the Committee on General Principles.

7 ALINORM 10/33/33, para. 55.
8 ALINORM 10/33/33, paras. 56-58.

ANNEX I

PESTICIDE RESIDUES

(Excerpt of CL 2010/1-GP)

Pesticide Residues

1. The 24th Session of the Committee on General Principles (2007) considered the *Draft Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues*, and several comments were made in the discussion, especially as regards the need to ensure consistency between the documents describing risk analysis policies throughout Codex, and the discrepancies between the documents under consideration for pesticide residues, veterinary drugs, additives and contaminants.

2. The Committee did not consider substantial changes and agreed that, following the adoption of the text, all adopted risk analysis policies should be reviewed by the Committee, especially as regards their consistency with the general *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.* The Committee endorsed the above document and also recommended that the Committee on Pesticide Residues review the *MRL Periodic Review Procedure* in the light of more recent documents related to the MRL setting process and consider the publication of this procedure in the Procedural Manual (ALINORM 07/30/33, para. 27-34 and 159). The 31st Session of the Commission subsequently adopted the document (ALINORM 07/30/REP para. 30-34).

3. The proposal for new work from the 40th Session of the Committee on Pesticide Residues on the revision of the *Risk Analysis Principles applied by the Codex Committee on Pesticide Residues*, which would incorporate the *Criteria for the Prioritization Process of Compounds for Evaluation by JMPR* and the *MRL Periodic Review Procedure* was approved by the Commission in 2008.

4. The 41st Session of the CCPR (2009) considered a first version of the document and agreed that it would be revised for consideration at its next session. The Committee acknowledged that the revision should be finalized by 2010 as the Committee on General Principles would review the consistency of risk analysis principles elaborated by relevant subsidiary bodies of the Commission in 2011 (ALINORM 09/31/24, paras 184-185). The 42nd Session of the CCPR (2010) will consider the revised version presented in CX/PR 10/42/12.

5. As indicated above, several issues were raised in the Committee on Pesticide Residues, the Committee on General Principles and the Commission on these risk analysis principles. They are currently under revision and will be considered further by that Committee. The present review will not consider the new draft under discussion as this is the responsibility of the CCPR, but concentrates on the issue of consistency with the general Working Principles as specified the Strategic Plan. The recommendations that the Committee may wish to make in this regard could also be considered by the CCPR to provide further orientation in the revision of the current *Risk Analysis Principles*.

6. As regards the general issue of consistency, the structure of the principles applied to pesticide residues does not follow the general *Working Principles* and as mentioned in the general considerations, the Committee may consider a general recommendation to reorder the document according to the three components of risk analysis. However, this may not be sufficient as the provisions for inclusion in each section need further consideration, especially to take into account the recommendations that appear in the Annex or in other documents addressing the process of MRL setting.

7. A general section on risk analysis for pesticides could be added to address the specificities of MRL setting for pesticides, such as the application of paragraph 9 of the *Working Principles* referring to the separation between risk assessment and risk management, as in the case of pesticide residues, MRLs are initially proposed by JMPR.

8. While discussing the general approach at the last session of the Committee on General Principles, it was pointed out that different approaches existed to MRL setting (based on GAPs or on ADIs). A general description of the approach taken for pesticides (based on GAPs) could be included in a general section on risk analysis.

9. In the first section of the Principles, *Interaction between CCPR and JMPR*, paragraph 2 could be included in the scope while some other paragraphs (3 and 4) could be placed under a new “risk communication” section, or possibly in a general section on risk analysis (paragraph 5).

10. The sections on risk assessment and risk management could incorporate most of the provisions currently presented under the “Role of JMPR” and “Role of CCPR” respectively.

11. As in the case of other risk analysis principles, there is no section on risk assessment policy and its inclusion would also be useful to describe the specificities of MRL setting. For example, paragraph 17 of the CCPR Risk Analysis Principles is related to paragraph 16 of the *Working Principles* on the possibility of asking risk assessors to evaluate the potential changes in risk resulting from different risk management options. This section could also incorporate paragraphs 15 and 16 which address the selection of substances for evaluation by JMPR.

12. The Committee, when endorsing the Risk Analysis Principles, recommended that the Committee on Pesticide Residues review the MRL *Periodic Review Procedure* in the light of more recent documents related to the MRL setting process. The use of this procedure is currently under discussion in the CCPR and how it will be revised or further used is not for discussion in the present review. However, the CCGP may recommend that whatever the future content and form of the section, it should be integrated into the risk analysis principles and included in the Procedural Manual.

Annex and Criteria

13. Several recommendations presented in the sub-sections of the *Annex : List of Risk Management Policies Used by CCPR* may be relevant for inclusion under “risk assessment policy” or “risk management”: Procedure for Proposing Pesticides for Codex Priority List, MRLs for Commodities of Animal Origin, MRLs for ready-to-eat foods or feeds, MRLs for spices and MRLs for fat-soluble pesticides, and could be reintegrated into the main text of the Risk Analysis Principles.

14. As the *Procedure for Proposing Pesticides for Codex Priority List* and the *Criteria for the Prioritization Process of Compounds for Evaluation by JMPR* both address prioritisation, consideration could be given to grouping all the provisions on prioritisation in a single section in the Risk Analysis Principles, or in an annex, as may be the case.

15. The four sections on the establishment of specific types of MRLs could be considered for integration into the “risk assessment policy”, while some provisions related to the studies considered by JMPR could be part of risk assessment.

16. The *Establishment of MRL* section could be integrated into the main text according to the relevance of each paragraph to risk management or risk assessment, in view of its importance to describe the process. Paragraph 17 refers to the establishment of the ARfD and approach followed by JMPR and could be included under Risk Assessment.

17. Under *Utilization of Steps 5/8 for elaboration of MRLs*, the process described is not related to risk analysis as such but to the procedure for decision in the Committee and consideration might be given to deleting it from the Risk Analysis Principles and including it in another section of the Manual.

18. The section on the Establishment of EMRLs includes both elements of risk assessment and risk management. It could be deleted as a separate section and EMRL setting would be addressed according to the risk assessment and risk management components of the process, to be included in the relevant sections. Paragraph 29 is a record of a discussion held in the Committee, not an element of risk analysis and therefore could be deleted in its present form, or rewritten as a statement concerning the criteria for EMRLs.

19. As the section on *Deleting Codex MRLs* is related to the provisions described in the *Procedure for Proposing Pesticides for Codex Priority Lists*, especially paragraph 7 (third indent) and the risk management decisions of the Committee, these provisions could also be integrated into the Risk Analysis Principles.

20. As regards *MRLs and Methods of Analysis*, paragraph 34, which refers to JMPR, might be considered under “risk assessment”. Paragraph 35 might be transferred to the risk management section or alternatively the Committee might review the need for its inclusion, as it is not systematically applied.

21. The *Criteria for the Prioritization Process of Compounds for Evaluation by JMPR* also include section 2.2 *Periodic Re-Evaluation* and it might be useful to group all provisions on the periodic review in a single section instead of retaining the separate document on the *MRL Periodic Review Procedure*, the review of which was earlier recommended.

22. In section 2.3 *Evaluations* of the *Criteria*, some recommendations relate to the interaction between risk assessors and risk managers, not only to the criteria for prioritisation in the Committee, and may be considered for inclusion in the main text of the document.

23. As a result of the above, the main points proposed for consideration are the reordering of the current sections according to the three components of risk analysis; the reconsideration of current provisions as to their relevance for each section; the inclusion of a general section on risk analysis and a section on risk assessment policy; and the integration of the relevant recommendations provisions from the Annex and the Criteria into the main text of the *Risk Analysis Principles*.

ANNEX II

PESTICIDE RESIDUES

(Excerpt of CL 2010/8-CAC)

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES

Proposed changes in ***italics and bold***

Scope

1. This document addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) as the risk management body and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) as the risk assessment body and facilitates the uniform application of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. This document should be read in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius. ***This document also applies to pesticides in food originating from residues of pesticides in feed[1] for food producing animals where it can impact food safety.***

Roles CCPR and JMPR in Risk Analysis

Interaction between CCPR and JMPR

2. In addressing pesticide residue issues in Codex, providing advice on risk management is the responsibility of the Codex Alimentarius Commission (CAC) and CCPR while conducting risk assessment is the responsibility of JMPR.

3. CCPR and JMPR recognize that an adequate communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.

4. CCPR and JMPR should continue to develop procedures to enhance communication between the two bodies.

5. CCPR and JMPR should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to members[2].

6. JMPR, in consultation with CCPR, should continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments.

7. These requirements should be used by CCPR as a fundamental criterion as described in the Annex in preparing its Priority List for JMPR. The JMPR Secretariat should consider whether these minimum data requirements have been met when preparing the provisional agenda for meetings of JMPR

Role of CCPR

8. CCPR is primarily responsible for recommending risk management proposals for adoption by the CAC.

9. CCPR shall base its risk management recommendations, such as MRLs, to the CAC following JMPR's risk assessments of the respective pesticides, and considering, where appropriate, other legitimate factors such as relevant to the health protection of consumers and for the promotion of fair practices in food trade.

10. In cases where JMPR has performed a risk assessment and CCPR or the CAC determines that additional scientific guidance is necessary, CCPR or CAC may make a specific request to JMPR to provide further scientific guidance necessary for a risk management decision.

11. CCPR's risk management recommendations to the CAC shall take into account the relevant uncertainties as described by JMPR.

12. CCPR shall consider maximum residue limits (MRLs) only for those pesticides for which JMPR has completed a full safety evaluation.

13. CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns on a global scale when recommending MRLs in food ***or feed***. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members.

14. When establishing its standards, CCPR shall clearly state when it applies any considerations based on other legitimate factors in addition to JMPR's risk assessment and recommended maximum residue levels and specify its reasons for doing so.

15. CCPR shall consider the following when preparing its priority list of compounds for JMPR evaluation:

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[1] The term "feed" refers to both "feed (feedingstuffs)" and "feed ingredients" as defined in the *Code of Practice on Good Animal Feeding* (CAC/RCP 054/2004).

[2] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6.

- CCPR's Terms of Reference;
- JMPR's Terms of Reference;
- The Codex Alimentarius Commission's Strategic Plan;
- The Criteria for the Establishment of Work Priorities;
- The Criteria for Inclusion of Compounds on the Priority List;
- The Criteria for Selecting Food *or Feed* Commodities for which Codex MRLs or Extraneous Maximum Residue Limits (EMRLs) should be Established;
- The Criteria for Evaluation of New Chemicals;
- The Criteria for Prioritization Process of Compounds for Evaluation by JMPR;
- A commitment to provide the necessary data for the evaluation in time.

16. When referring substances to JMPR, the CCPR shall provide background information and clearly specify the reasons for the request when chemicals are nominated for evaluation.

17. When referring substances to JMPR, the CCPR may also refer a range of risk management options, with a view toward obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option.

18. CCPR shall request JMPR to review any methods and guidelines being considered by CCPR for assessing maximum limits for pesticides.

Role of JMPR

19. The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. It is an independent scientific expert body convened by both Directors General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on pesticide residues.

20. This guidance document applies to the work of JMPR in the context of Codex and in particular as it relates to advice requests from CCPR.

21. JMPR is primarily responsible for performing the risk assessments upon which CCPR and ultimately the CAC base their risk management decisions. JMPR also proposes MRLs based on Good Agricultural Practices (GAPs)/registered uses or in specific cases, such as EMRLs, based on monitoring data.

22. JMPR provides CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCPR's risk-management discussions. JMPR should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and Acute Reference Doses (ARfDs) where appropriate.

23. JMPR should identify and communicate to CCPR in its assessments any information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children).

24. JMPR is responsible for evaluating exposure to pesticides. JMPR should strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to GEMS/Food data, monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the available high percentile consumption data as provided by members.

25. JMPR should communicate to CCPR the magnitude and source of uncertainties in its risk assessments. When communicating this information, JMPR should provide CCPR a description of the methodology and procedures by which JMPR estimated any uncertainty in its risk assessment.

26. JMPR should communicate to CCPR the basis for all assumptions used in its risk assessments.

ANNEX: LIST OF RISK MANAGEMENT POLICIES USED BY CCPR

1. This part of the document addresses the risk management policy that is used by the Codex Committee on Pesticides Residues (CCPR) when discussing the risk assessments, the exposure to pesticides and the proposals for MRLs which are the outcomes of the Joint FAO/WHO Meeting on Pesticides Residues (JMPR).

ESTABLISHMENT OF MRLs/EMRLs

Procedure for Proposing Pesticides for Codex Priority Lists

2. CCPR has developed a policy document in relation to establishing a priority list of pesticides for evaluation or re-evaluation by JMPR[3].

3. Before a pesticide can be considered for the Priority List, it must:

- be available for use as a commercial product; and
- not have been already accepted for consideration.

4. To meet the criteria for inclusion in the priority list, the use of the pesticide must: give rise to residues in or on a food or feed commodity*, including also byproducts or coproducts of industrial productions e.g. biofuels entering into the food chain through feed* moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.

5. When prioritising new chemicals for evaluation by the JMPR, the Committee will consider the following criteria:

1. If the chemical has a reduced acute and/or chronic toxicity risk to humans compared with other chemicals in its classification (insecticide, fungicide, herbicide);
2. The date when the chemical was nominated for evaluation;
3. Commitment by the sponsor of the compound to provide supporting data for review with a firm date for data submission;
4. The availability of regional/national reviews and risk assessments, and coordination with other regional/national lists; and
5. Allocating priorities to new chemicals, so that at least 50% of evaluations are for new chemicals, if possible.

6. When prioritising chemicals for periodic re-evaluation by the JMPR, the Committee will consider the following criteria:

1. If the intake and/or toxicity profile indicate some level of public health concern;
2. Chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits for 15 years;
3. The year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation –Not Yet Scheduled;
4. The date that data will be submitted;
5. Whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
6. If there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and
7. The availability of current labels arising from recent national re-evaluations.

7. Once the JMPR has reviewed a chemical, three scenarios may occur:

- the data confirm the existing Codex MRL, it remains in place; or
- a new MRL is recommended or an amendment of an existing MRL. The new or amended proposal enters at Step 3 of the Codex procedure. The existing MRL remains in place for no more than four years; or
- insufficient data have been submitted to confirm or amend an existing Codex MRL. The Codex MRL is recommended for withdrawal. However, the manufacturer or countries may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years. The existing Codex MRL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

MRLs for Commodities of Animal Origin

8. Farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed*, **in*** forage crops, ~~*or in*~~ plant parts that could be used in animal feeds, *including also byproducts or coproducts of industrial productions e.g. biofuels entering into the food chain through feed*. The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in animal products.

[3] Criteria for Prioritization Process of Compounds for Evaluation by JMPR, Procedural Manual.

9. If no adequate studies are available, no MRLs will be established for commodities of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation, MRLs at the LOQ must be established for animal commodities. MRLs should be established for all mammalian species where pesticides on feeds are concerned and for specific species (e.g cattle, sheep) where direct treatments of pesticides are concerned.

10. Where the recommended maximum residue limits for animal commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or JECFA, and from residues in animal feed do not agree, the higher recommendation will prevail.

MRLs for Processed or Ready-to-eat Foods or Feeds

11. CCPR agreed not to establish MRLs for processed foods and feeds unless separate higher MRLs are necessary for specific processed commodities.

MRLs for spices

12. CCPR agreed that MRLs for spices can be established on the basis of monitoring data in accordance with the guidelines established by JMPR.

MRLs for fat-soluble pesticides

13 If a pesticide is determined as "fat soluble" after consideration of the following factors, it is indicated with the text "The residues are fat soluble" in the residue definition:

- When available, it is the partitioning of the residue (as defined) in muscle versus fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being "fat soluble".
- In the absence of useful information on the distribution of residues in muscle and fat, residues with logPow>3 are likely to be "fat soluble".

14. For fat soluble pesticides, two MRLs are recommended if data permit: one for whole milk and one for milk fat. For enforcement purposes, a comparison can be made either of the residue in milk fat with the MRL for milk fat or of the residue in whole milk with the MRL for milk.

Establishment of MRLs

15. The CCPR is entrusted with the elaboration of Maximum Residue Limits (MRLs) of pesticide residues in food and feed. The JMPR is using the WHO Guidelines for predicting dietary intake of pesticides residues (revised)(1997)[4]. The JMPR is recommending MRLs establishing Supervised Trial Median Residues (STMRs) for new and periodic review compounds for dietary intake purposes. In cases the intake exceeds the Acceptable Daily Intake (ADI) in one or more of the regional diets, the JMPR, when recommending MRLs, flags this situation indicating the type of data which may be useful to further refine the dietary intake estimate.

16. When the ADI is exceeded in one or more regional diets, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level. If further refinement is not possible then MRLs are withdrawn until the remaining MRLs give no longer rise to intake concerns. This procedure should be reviewed at regular interval.

17. The JMPR is currently routinely establishing acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. The 1999 JMPR for the first time calculated the short-term dietary intake estimates following an approach using the International and National Estimates of Short-term Intake (IESTI, NESTI). The procedure allows for estimating the short-term risk for relevant subgroups of the population, like children. The JMPR flags cases when the IESTI for a given commodity exceeds the acute RfD.

18. When the ARfD is exceeded for a given commodity, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level.

19. When a Draft MRL has been returned to Step 6 three times, the CCPR should ask JMPR to examine residue data from other appropriate GAPs and to recommend MRLs which cause no dietary intake concerns if possible.

20. If further refinement is not possible then MRLs are withdrawn. More sophisticated methodologies such as probabilistic approaches are under investigation at the moment.

21. The estimate of the short-term dietary intake requires substantial food consumption data that currently are only sparsely available. Governments are urged to generate relevant consumption data and to submit these data to the WHO.

Utilization of Steps 5/8 for elaboration of MRLs

22. Preconditions for utilization of Step 5/8 Procedure:

[4] Programme of Food Safety and Food Aid; WHO/FSF/FOS/97.7.

- New MRL circulated at Step 3;
- JMPR report available electronically by early February;
- No intake concerns identified by JMPR;

23. Steps 5/8 Procedure (Recommendation to omit Steps 6 and 7 and adopt the MRL at Step 8):

- If the preconditions listed above are met;
- If a delegation has a concern with advancing a given MRL, a concern form should be completed detailing the concern along with a description of the data that will be submitted to substantiate the concern preferably as comments at Step 3, or at the latest, one month after the CCPR session;
- If the JMPR Secretariat or the CCPR can address that concern at the upcoming CCPR session, and the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 5/8;
- If the concern cannot be addressed at the meeting, the MRL will be advanced to Step 5 at the CCPR session and the concern will be addressed by the JMPR as soon as possible but the rest of the MRLs should be advanced to Step 5/8;
- The result of the consideration of the concern by the JMPR will be considered at the next CCPR session. If the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 8;

Establishment of EMRLs

24. The Extraneous Maximum Residue Limit (EMRL) refers to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of the pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity or animal feed.

25. Chemicals for which EMRLs are most likely to be needed are persistent in the environment for a relatively long period after uses haven been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.

26. All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade. JMPR has developed a standard format for reporting pesticide residues monitoring data[5].

27. The JMPR compares data distribution in terms of the likely percentages of violations that might occur if a given EMRL is proposed to the CCPR.

28. Because residues gradually decrease, CCPR evaluates every 5 years, if possible, the existing EMRLs, based on the reassessments of the JMPR.

29. The CCPR generally agreed at the 30th Session on the potential elements for inclusion in a set of criteria for estimation of EMRLs while it also agreed not to initiate a full exercise of criteria elaboration.

Periodic Review Procedure

30. The Committee agreed on the Periodic Review Procedure, which was endorsed by the CAC and attached to the list of MRLs prepared for each session of the CCPR. Those Codex MRLs confirmed by JMPR under the Periodic Review shall be distributed to members and interested organizations for comments.

Deleting Codex MRLs

31. Every year new compounds are introduced. These compounds are often new pesticides which are safer than existing ones. Old compounds are then no longer supported/produced by industry and existing Codex MRLs can be deleted.

32. If information is delivered between two sessions of CCPR, that a certain compound is no longer supported, this information will be shared during the first coming session (t=0). The proposal will be to delete the existing MRLs at the following session (t=0+1 year).

33. It may happen that compounds are no longer supported in Codex, but are supported in some selected countries. If there is no international trade in commodities where the active compounds may have been used, CCPR will not establish MRLs.

MRLs AND METHODS OF ANALYSIS

34. JMPR needs data and information for their evaluations. Among these are methods of analysis. Methods should include specialized methods used in supervised trials and enforcement methods.

35. If no methods of analysis are available for enforcing MRLs for a specific compound, no MRLs will be established by CCPR.

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[5] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6.