

Working with the JMPR and CCPR

A Manual for the Agrochemical Industry

Version 2016

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Disclaimer

The intention of this document is to provide basic guidance to the Reader on how to interact with Codex Alimentarius Commission and its subsidiary bodies in order to establish and maintain Codex Maximum Residue Limits.

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1. About this document

The intention of this document is to provide basic guidance to agrochemical companies on how to interact with [Codex Alimentarius Commission](#) ('Codex') and its subsidiary bodies (such as the [CCPR, Codex Committee on Pesticide Residues](#)) in order to establish and maintain Codex Maximum Residue Limits (CXLs).

This document also provides a summary to understand Codex and its processes relevant for CXL setting and to reference documents that provide detailed guidance and essential information e.g. on data submission requirements.

This version evolved from earlier, much more comprehensive versions. Today we assume that most readers will consult the internet and therefore we believe that an overview is more suitable. Substantial information is available on the websites of the Codex, the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) and the reader is encouraged to refer to these websites on a regular basis. These websites provide essential information on data requirements, recent decisions made, the current status of CXLs, general policies and review schedules.

In the document we follow a certain order which we believe is most relevant for CropLife International members who wish to support their compounds.

- general information on Codex, committees and meetings.
- Step 1 of the Codex stepwise procedure (see Appendix B for details) explaining how compounds are nominated and scheduled.
- procedures for the scientific review by the JMPR, discussion and recommendations made by the CCPR (Step 3 to 8) and adoption of Codex limits by the Codex Alimentarius Commission (CAC).
- the lifecycle of compounds in Codex, once the first standards have been established and we finish with additional matters other than MRL setting which are of interest to CropLife International members.

2. About Codex Alimentarius, the CCPR and the JMPR

Codex Alimentarius is in the strict sense a catalogue of food standards to protect Consumers health to which their members voluntarily adhere. Under WTO's SPS agreement Codex standards are accepted as standards for international trade of agricultural commodities, food and feedstuff.

The CAC was created in 1963 by the FAO and the WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main goals of this Programme were to protect the health of consumers and to ensure fair trade practices in food commodities. Work was also undertaken to promote coordination of all food standards work carried out by international governmental and non-governmental organizations. The CAC meets annually in July and adopts standards proposed by their committees. Since the meeting is held about 2 months after the CCPR meeting, proposed MRLs can be adopted and notified to the WTO without much delay.

The Codex Committee on Pesticide Residues (CCPR)

The CCPR is subsidiary body to the CAC. The prime objective is to reach agreement between governments on maximum limits for pesticide residues (MRLs) in food and feed commodities moving in international trade. This committee is formed from national delegations and other interested parties such as industry representatives and NGOs. The CCPR discusses all matters of pesticide residues and proposes risk management decisions to the CAC.

In recent years the meetings have taken place in April or May.

Usually about 40 to 60 countries send delegations to the CCPR. FAO and WHO are also represented, as are a range of recognised governmental and non-governmental international organisations. The latter include the industry association, CropLife International. In total, some 200 people usually attend.

Industry representatives wishing to attend the CCPR may participate as members of the CropLife delegation - fuller details are available from CropLife International upon request.

An excellent description of procedures and policies applied by the CCPR are given in the most recent version¹ of CAC's Procedural Manual: see

<http://www.codexalimentarius.org/procedures-strategies/procedural-manual/en/>

In this document we only can provide some key elements of these principles. Readers who are interested in a more thorough understanding of how CAC and CCPR operate are advised to read relevant chapters of the Procedural Manual.

While not officially part of the Codex Alimentarius Commission structure, the [Joint FAO/WHO Meeting on Pesticide Residues \(JMPR\)](#) provides independent scientific expert advice to the Commission and its specialist Committee on Pesticide Residues.

¹ The Risk Analysis Principles applied by the CCPR have been revised in their 46th session in 2014 and are available as Appendix XIII of the CCPR report. These changes are not (status June 2014) yet reflected in the 21th edition of the Procedural manual.

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

The JMPR is a meeting of an international scientific expert group that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). Normally, all participants need to fill in confidentiality agreements and declarations of interest to ensure their independence.

During these meetings, the FAO Panel of Experts is responsible for reviewing residue and analytical aspects of the pesticides under consideration, including data on their metabolism, fate in the environment, and use patterns, and for estimating the maximum residue limits based on the residues that might occur as a result of the use of the pesticides according to good agricultural practices. The WHO Core Assessment Group is responsible for reviewing toxicological and related data and for estimating toxicological guidance values for humans, such as the Acceptable Daily Intake (ADI) and the Acute Reference Dose (ARfD), of the pesticides under consideration.

JMPR serves as the independent scientific advisory body to FAO and WHO as well as to FAO/WHO member governments and to the [Codex Alimentarius Commission](#). Advice to the Codex Alimentarius Commission on pesticides is provided via the Codex Committee on Pesticide Residues (CCPR).

Evaluations

JMPR establishes ADIs and ARfDs on the basis of the toxicological data and related information available on the substances that are being evaluated. In addition, JMPR reviews pesticide use patterns, data on the chemistry and composition of pesticides and methods of analysis of pesticide residues, and recommends maximum residue limits (MRLs) for pesticides that occur in food commodities following their use according to Good Agricultural Practice. The potential intake of pesticide residues is compared with the ADI and the ARfD to estimate the potential dietary risks associated with the adoption of the MRLs.

In addition to reviewing active substances of crop protection products, the JMPR develops general principles for assessing the safety of chemicals in food. The requirement to keep abreast of scientific disciplines requires continuing review and updating of evaluation procedures. JMPR participants are also expected to conduct extensive literature searches on substances they are considering in addition to reviewing the information submitted by sponsors of the chemicals under review. Although the majority of JMPR members work for national authorities/agencies which are involved in the regulation of crop protection products, in their role as JMPR reviewers/advisors they contribute an independent scientific opinion and do not represent any national position.

For further information on the toxicological assessment of pesticide residues, see²:

Principles (EHC 240, 2009), http://www.inchem.org/documents/ehc/ehc/ehc240_index.htm

Guidance for reviewers: <http://www.who.int/foodsafety/publications/JMPR-guidance-document/en/>

Link to JMPR at WHO: http://www.who.int/foodsafety/areas_work/chemical-risks/jmpr/en/

Link to JMPR at FAO: <http://www.fao.org/agriculture/crops/core-themes/theme/pests/jmpr/en/>

It is important to note that neither the JMPR nor the CCPR are regulatory authorities but scientific advisory bodies. Thus they do not regulate or approve pesticides or the use

² A revised version of this document is expected in Q3/2014

thereof, but provide scientific advice and risk management measures as recommendations for the CAC to set international trade standards.

The JMPR activities are exclusively financed out of FAO's and WHO's budget and by donations of Codex members to ensure the independence and integrity of scientific decisions.

3. Processes and Procedures in the CCPR and JMPR

In the following we describe the most relevant processes and procedures for manufacturers to explain how compounds are nominated and uses are added. CXLs for pesticides residues are periodically re-evaluated. The periodic review interval depends on the urgency of any concerns that have been raised, the available capacity and resources available and a number of other criteria. Generally, MRLs will remain in place for between 15 and 25 years, if not more. CXLs once they are established can only be revoked once a compound is scheduled for review.

The CCPR electronic Working Group on Priorities

The electronic Working Group of Priorities maintains the schedule for review of new compounds and additional evaluations for existing molecules, e.g. for new uses and periodic reviews of adopted CXLs. Compounds will be scheduled according to the risk analysis principles of CCPR. The chair of this EWG will (via the Codex secretariat) invite compound nominations in September of each year by Circular letter. Additional nominations can be added on request of Codex members during the CCPR. The updated schedule is discussed and adopted during each CCPR meeting. The priority lists for the next 4-7 years are published within the CCPR report.

Nomination of a New Compound

The official nomination for a candidate compound occurs by a Codex Member governmental delegation, but Manufacturers play a key role in the process.

- 1.) If the Manufacturer is approached by the government, the Manufacturer may agree to supply the relevant data, or it may decide not to support the compound.
- 2.) Manufacturers wishing to have a particular compound evaluated should first contact a potential governmental delegation to seek their agreement and support for making the official nomination. Once agreement has been obtained, the Manufacturer completes the official nomination form (see Appendix A to this Manual) and forwards it to the governmental delegation. Nomination criteria are as follows:
 - There is an intention to register the compound for use in a member country;
 - The commodities proposed for consideration should be traded internationally;
 - There is a commitment by the Manufacturer of the compound to provide supporting data for review in response to the JMPR "data call-in" (see later);
 - The use of the compound is expected to give rise to residues in or on a food or feed commodity moving in international trade;
 - The compound has not been already accepted for consideration;
 - A nomination form has been completed
- 3.) The actual nomination process and timing are described below:
 - a. Country-sponsored nominations should be lodged with the Chair of the Electronic Working Group (eWG) for the CCPR Schedule and Priority Lists

- with a copy to the JMPR Secretariat by 30 November in any given year.
- b. Nominations must indicate the current status of national registrations for the compound along with a clear indication of availability of data and national evaluations.
 - c. Nominations must also indicate the number of crops for which residue evaluations are requested as well as the number of trials that will be submitted to support each crop.
 - d. The Chair will consult closely with the JMPR Secretariat prior to drafting a revised schedule. To allow the scheduling of a compound, submissions must include a commitment regarding the date that data will be available to JMPR.
 - e. Scheduling criteria used by the eWG are as follows:
 - The compound must be registered for use in a member country and approved commercial product labels made available by the time of JMPR “data call-in”;
 - The compound must give rise to residues in or on a food or feed item moving in international trade;
 - If the compound does not give rise to detectable residues in foods and feeds it will be assigned a lower priority compared to compounds that do give rise to measurable residues.
 - f. The Chair will draft a revised Priority List of Compounds for circulation via the Codex Secretariat through a Circular Letter with a two month commenting period. The due date for comments and proposed amendments to the Priority List is 1 March in any given year. These comments should be forwarded directly to the Chair of the Electronic Working Group and the JMPR Secretariat.

Following consideration of comments and amendments, the final Priority List of Compounds will be prepared for circulation to member countries during March. This will become the basis for the agenda paper and discussion in the CCPR plenary meeting.
 - g. Should a late country-sponsored nomination be necessary, it may be considered by the Chair and the JMPR Secretariat. The Chair will provide notice of a late nomination to member countries via email correspondence or by means preferred by Codex Secretariat.
 - h. By the time the Priority List of Compound is considered in CCPR plenary, member countries will all have had an opportunity to seek amendment or provide comment, and will still have received the final CCPR agenda paper well in advance of the meeting.
 - i. Major discussions on the priority list should be handled in plenary of the CCPR. Plenary discussion would cover amendments resulting from considerations of the MRLs and any final changes to the priority list which may be considered necessary.

- j. Discussions and the final Priority List of Compounds will be recorded in the draft CCPR report and adopted by the Committee.

CCPR Members through their contact points, nominate compounds to CCPR's electronic Working Group for an evaluation by the JMPR, providing the compound meets the agreed criteria as above.

The proposal for a JMPR evaluation is made using the official nomination form (see Appendix A to this Manual), which asks, in brief, for the identity, field of use, registration situation, and the availability of data for the subsequent submission to the JMPR.

The final CCPR Schedule and Priority Lists as agreed in plenary of the CCPR meeting are made available each year as an Appendix to the CCPR report. In the 4th Quarter of each year the JMPR Secretariat sends out data-call in notices to Manufacturers' representatives informing them of the dates that dossiers must be submitted by, in order to support the WHO and FAO evaluations scheduled for the following year.

How to prepare a JMPR dossier for "Toxicology" (WHO Panel)

A submission of toxicological data to the WHO panel is required for both new compound evaluations and periodic re-evaluations, but not generally for evaluation of new uses of previously evaluated compounds.

Two forms of guidance are available from the WHO which will be of help to sponsors:

- A WHO technical guideline (2000) which details the technical inputs needed to compile a submission for the WHO panel
- A WHO procedural guideline (2001) which describes the processes and roles/responsibilities during a WHO evaluation

Both of these can be found at the following link:

<http://www.who.int/foodsafety/chem/jmpr/guidelines/en/>

The details described in these guidelines continue to be the default approach, but it can be complemented by the option to submit an EU type dossier or a Global Joint Review (GJR) type dossier. The submission documents need to be supplemented with the full set of studies relevant to the submission. In recent years the importance of paper documents has decreased and has been increasingly replaced by electronic media. Therefore, manufacturers are advised to check with the FAO secretariat and possibly with the assigned reviewer about their preferred method for receiving data. Where electronic submission of data is preferred it is clearly desirable that specialist software is not required.

For all types of evaluation the complete dossier has to be delivered to the WHO secretariat and the assigned WHO reviewer by 1st December. In contrast to the FAO dossier a data directory is not required for the WHO dossier.

Each year confirmation of the exact dates and any technical details are published as a so-called FAO/WHO "Request for Data". This usually occurs in October of the year prior to the evaluation.

<http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/en/>

How to prepare a JMPR dossier for "Residues" (FAO Panel)

There are three main types of evaluation conducted by the FAO panel:

- New compounds
- Periodic re-evaluations of pesticides with existing Codex MRLs
- New uses of pesticides previously reviewed by the JMPR

For the evaluation of new compounds and the periodic re-evaluations the full data set as specified in the "FAO Manual" (see below) has to be submitted. For the evaluation of new uses, only the data relevant to the specific crops in question need to be provided e.g. residue data and approved label.

The FAO panel requests that submissions be prepared in the format and detail defined in their submission guidelines. This document on the "Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed" (2016), also referred to as the "FAO Manual" can be found at the following link:

<http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-docs/en/>

The details described in this document should continue to be the default approach, but it can be complemented by the option to submit an EU type dossier or a Global Joint Review (GJR) type dossier. These alternative dossiers are likely to need amending for those crops which are not included and also to include the labels of registered products; submitted labels must be available in English. The submission documents need to be supplemented with the full set of studies relevant to the submission. In recent years the importance of paper documents has decreased and has been increasingly replaced by electronic media. Therefore, manufacturers are advised to check with the FAO secretariat and possibly with the assigned reviewer about their preferred method of receiving data. Where electronic submission of data is preferred it is clearly desirable that specialist software is not required.

For all types of evaluation a data directory of the planned submission is requested by 1st September in the year before the JMPR evaluation. This enables the FAO to understand the approximate size of each submission and to start to plan FAO resources accordingly. The complete dossier has to be delivered to the FAO secretariat and the assigned FAO reviewer by November 30 in the year before the JMPR evaluation.

Each year confirmation of the exact dates and any technical details are published as a so-called FAO/WHO "Call for Data". This usually occurs in October of the year prior to the evaluation.

<http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/en/>

After data submission: Evaluation process prior to the Joint Meeting

By looking at schedules for compound reviews and evaluations, it becomes obvious, that the JMPR capacity for compound evaluations is limited. This is related mainly to the resources available to the programme. Only a relatively small number of internationally recognized experts are available to conduct the reviews required under the JMPR and the fact that the JMPR Panels meet only once a year puts additional restrictions on the programme. The resource issue and proposals for possible solutions have been put forward several times in the past and are documented in a report by WHO/FAO in 2002, but so far none of these efforts (status 2014) have resulted in sustainable solutions that can overcome this bottleneck. Therefore, manufacturers are advised to ensure that their submissions are well prepared, in order to allow for a smooth review by JMPR evaluators. The joint FAO/WHO Secretaries encourage experts to contact manufactures during the preparation of the draft to clarify open questions and issues and manufacturers have to be prepared to reply on short

notice. However, manufacturers should not approach reviewing experts pro-actively. Instead they should direct any questions they may have via the joint FAO/WHO secretaries.

JMPR Panel meetings

The FAO/WHO JMPR Panels hold their non-public meetings in two weeks during September/October each year. The meetings alternate between the FAO headquarters in Rome and the WHO headquarters in Geneva.

Questions for manufacturers which arise during the JMPR are sent by the FAO and WHO Joint secretaries at the latest, at the end of the 2nd JMPR week and need to be addressed without delay and during the meeting if possible. When relevant information cannot be made available at the meeting, the JMPR Secretariat can consider re-scheduling the review (to another year). There is no possibility to submit additional information other than that requested for consideration by the JMPR in the same year. Final decisions on each compound are reached before closure of the meeting, i.e. the final report is adopted at the meeting and undergoes only further technical editing.

In previous meetings, JMPR scheduled one day to address with manufacturer representatives additional questions that have not been cleared in preparation of the meeting or points raised in the meetings that may have required additional clarification. These questions are sent to the contact points ideally by the end of the week before the final joint meetings of the WHO and FAO panel. Hearings with manufacturers to clarify open questions are no longer standard practice and are only used in exceptional cases. Manufacturers are advised to consult with the Joint secretaries in FAO and/or WHO on how best to discuss the item of concern. This can be done either in a teleconference or in a physical meeting with JMPR.

It should be recognized that most of the panel members provide their expertise to the JMPR process as an addition to their daily professional work, e.g. as experts in governmental organizations, thus they put in extra effort for little recognition. Quite frequently, this can lead to work being finished only just before the deadline or even with some delay. Although unsatisfactory, industry representatives should be sensitive to this situation.

The panel members are under close observation from critical NGOs. It is in the primary interest of CropLife International Members to contribute in an appropriate manner both in correspondence and in direct contact with the panel members in order that their scientific integrity and independence are not compromised.

Reports and publications on JMPR meetings

The conclusions of Joint Meetings are summarized in reports published in the FAO Plant Production and Protection Paper series. Reports reflect the agreed view of the JMPR as a whole and describe the basis for the conclusions. Final reports are adopted before closure of the meeting.

Toxicological monographs are published after the meetings by WHO. These describe in detail the data used in the Meeting's evaluations and provide full references to the relevant literature. See.

<http://www.who.int/foodsafety/publications/jmpr-monographs/en/>

Residues monographs, which contain information on pesticide use patterns, data on the chemistry and composition of pesticides, methods of analysis for pesticide residues, and information on MRLs are published in the FAO Plant Production and Protection Paper series

<http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmpr/jmpr-rep/en/>

In addition, shortly after each meeting an electronic summary report is published on the FAO and WHO JMPR websites, which describes in tabular form the key results, i.e. ADI, ARfD and the proposed MRLs.

In view of the publications of the “Evaluations” which contain summaries of the reports, the question on the protection of **intellectual property** may be of concern. The matter has been discussed thoroughly and has resulted in the following statement in each document:

Use of JMPR reports and evaluations by registration authorities:

Most of the summaries and evaluations contained in this report are based on unpublished proprietary data submitted for use by JMPR in making its assessments. A registration authority should not grant a registration on the basis of an evaluation unless it has first received authorization for such use from the owner of the data submitted for the JMPR review or has received the data on which the summaries are based, either from the owner of the data or from a second party that has obtained permission from the owner of the data for this purpose.

To further ascertain confidentiality once the review is done, submitters are asked by WHO whether they want the documents returned or destroyed in a safe way.³

³ At the time this version was written WHO was revising their policy how to interact with the private sector. One of these policy elements foresees a higher degree of transparency, e.g. the publication of all information received on WHO's website. CropLife is following up on that matter and will provide advice to their members on future interactions with WHO.

4. CCPR MRL decisions

CCPR follows a stepwise procedure to advance the MRL recommendations made by the JMPR. Inevitably the procedure can be rather long. However, its advantage is that member countries and other interested parties have ample opportunity to comment on the proposals during and between the CCPR sessions. This opportunity is given at several stages of the stepwise procedure.

The collaboration between the JMPR and CCPR follows a two-way traffic pattern. Not only does the CCPR formally make use of the proposals emanating from the JMPR, but in case the CCPR has additional questions or does not feel satisfied with the data underlying the JMPR proposals, the matter may be referred back to the JMPR for further consideration. These so-called "Codex referrals" are a regular item on the agenda of the JMPR meetings.

The CCPR reports progress in the stepwise procedure, as well as in other matters, to the Codex Alimentarius Commission (CAC) for approval and adoption of MRLs as Codex limits. Thus, countries which could not be represented at the CCPR but which can attend the meeting of the Codex Alimentarius Commission (comprising 185 member countries) have an opportunity to comment as requested in a Circular Letter.

Maximum residue limits, which have reached the final step in the adoption procedure are regularly published jointly by FAO and WHO

<http://www.codexalimentarius.net/pestres/data/index.html>

Unfortunately the database might be updated with some delay. Therefore it is recommended to check the Codex Alimentarius Commissions report, which usually available within 2 months after the CAC meeting.

Once a Codex MRL is approved by the CAC it is a global standard and serves as a basis in international trade. As some countries might have sent reservations to the CAC they might be not accepting these Codex MRLs.

Each year, the CCPR report summarizes the status of the proposed MRLs in the stepwise procedure. The most recent and the historical reports are available from the Codex Alimentarius web page:

<http://www.codexalimentarius.net>

The life-cycle of evaluated compounds

Pesticides previously evaluated by JMPR may be listed for further toxicological and/or residue evaluations by the JMPR as a result of requests from CCPR or members when:

- A member seeks to obtain a revised MRL for one or more foods or feeds; for example, on the basis of an alternative GAP;
- The CCPR requests a clarification or reconsideration of a recommendation from the JMPR;

- New toxicological data becomes available to indicate a significant change in the ADI or ARfD;
- A data deficiency is noted by JMPR during a new pesticide evaluation or periodic review and members/observers will supply the required information;
- The CCPR elects to schedule the pesticide under the four-year rule.

In this latter case, the four-year-rule is applied when insufficient data have been submitted to confirm or amend an existing CXL. The CXL is therefore recommended for withdrawal. However, members/observers may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years. The existing CXL 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.

Periodic Review procedure

Pesticides are listed for periodic review according to the process and procedures described in section "Selection of pesticides for JMPR evaluation". The process provides members/observers a notice of a periodic review.

When a pesticide is listed for periodic review, members/observers are able to support it, regarding the two following possibilities:

- Case A: The pesticide is supported by the original sponsor, who is committed to submit a complete data package to meet JMPR's data requirements. If the original sponsor does not support some uses, members/observers may support them.
- Case B: The pesticide is not supported by the original sponsor; in this case, interested members / observers may support the review of the pesticide.

Commitment to support pesticides or existing CXLs or new proposed MRLs

The commitment of members/observers to provide data for the periodic review should be addressed to the Chair of the EWG on Priorities and the JMPR Joint Secretariat according to the FAO Manual and the considerations of the JMPR on pesticides no longer supported by the original sponsor.

For Case A and Case B, data should be submitted in accordance with the guidance of the JMPR for the respective cases.

- In cases where some uses are not supported by the manufacturer, but are supported by members/observers:
- If the current GAP supports the current CXL, justification for it, as well as relevant labels are required;
- If the GAP were modified, supervised residue trial studies conducted according to current GAP, and relevant studies to support new MRL in animal and processed foods are required.

CCPR matters other than MRL establishment for target crops (examples)

Beside this principle work CCPR is dealing on mid-term scale with special issues such as the:

- Setting of CXLs for spices: The CCPR decided on request of developing countries that MRLs for spices can be set based on monitoring data and not based on a critical GAP. The justification given, was that often spices are grown as secondary crops together with primary crops and that they receive the same pesticide application as contamination because the treatment of primary crops is unavoidable,
- Extraneous MRLs for persistent pesticides which are no longer approved for agricultural use,
- Classification of foods and animal feeds,
- Methods of Analysis (mainly used for enforcement purposes)

5. CCPR Meeting reports

The reports of the CCPR meetings are available through the Codex Secretariat, the country Codex contact points or participants. They also can be found on the Codex Alimentarius website:

http://www.codexalimentarius.net/web/index_en.jsp

And the FAO Codex website:

<ftp://ftp.fao.org/codex/Reports/>

APPENDIX A

CCPR Nomination Form



Nomination Form for
2014 CCPR- Attachm

See Appendix VIII: FAO Manual on the Submission and Evaluation of Pesticide Residues
Data 2009

APPENDIX B

The Step procedure in Codex Alimentarius:

The Eight Step Procedure in Codex Alimentarius for Adoption of Codex Standards:

The Codex Alimentarius Commission takes decisions to elaborate Codex Standards worldwide and assigns committees for the preparatory/operational work. Pesticide Codex MRLs (CXLs) are among several standards promulgated by Codex Alimentarius and the committee that manages the work is the Codex Committee on Pesticide Residues (CCPR). The CCPR relies upon scientific evaluations and input from WHO and FAO experts who meet annually in September as the Joint Meeting on Pesticide Residues (JMPR) in order to propose the Codex MRLs for discussion at the next annual CCPR meeting. Elaborating a CXL is an eight step process:

Step 1: Following notification by a Codex member (governmental body) the CCPR schedules a compound for review. The electronic Working Group for the CCPR Schedule and Priority Lists coordinates the work

Step 2: The JMPR undertakes a compound's review and passes its report containing the proposed Codex MRLs (through the FAO and WHO secretaries) to the Codex Secretariat for discussion at the next CCPR meeting. However, different outcomes are possible which may result in no Codex MRLs being proposed: e.g., the JMPR is unable to set an ADI and/or ARfD, or available residue data are insufficient to propose Codex MRLs. Insufficient data is generally not a problem for new compounds but it can be an issue for older compounds where support is sometimes lacking. In a case of data deficiency the Manufacturer is informed on concerns or data gaps and is asked for a commitment to provide additional information. Following that commitment the new substance would then be re-scheduled for continued JMPR review. Additional uses may also be scheduled for evaluation.

Step 3: The Codex Secretariat sends the proposed draft MRLs to members for a first round of comments. This commenting period occurs in advance of the CCPR meeting.

Step 4: Comments for the newly proposed or amended MRLs are sent via the Codex secretariat to the CCPR. The CCPR will either propose advancement to Step 5, or if no concerns are raised in plenary, use an accelerated procedure to forward the MRLs, via Step 5/8, for adoption by the CAC (see note below).

In case of a concern, the proposed MRLs advance only to Step 5, and the Codex member raising the concern is required to submit a concern to the JMPR Secretariat using a specific form ('concern sheet'). Manufacturers and/or other Codex members may have to provide additional data for further consideration by JMPR in order to address the concern(s).

Step 5: The proposed MRL is sent to the CAC/Executive Committee for adoption as a draft standard (CXL).

Step 6: The adopted draft MRL is sent to Codex members by the Codex Secretariat for a second round of comments. If a draft MRL is returned twice to Step 6 (e.g. because of acute intake concerns) then the JMPR will be asked whether a lower MRL/safer GAP can be proposed. (This example would involve the Manufacturer providing additional information). The amended MRL would be then returned once to Step 6.

Step 7: The comments are sent via the Codex Secretariat as draft/or amended draft to the CCPR.

Case 7A: The draft MRL is held at Step 7 because the ADI is temporary. As soon as the final ADI has been evaluated it will be submitted to the CAC at step 8

Case 7B: The draft MRL is held at Step 7 pending further consideration by the JMPR. After such consideration it will be returned to Step 6 for comments by Codex members.

Case 7C: The draft MRL is held at Step 7 to await information (other than review by the JMPR) which is essential for the CCPR to take decisions to proceed. Once this information has been made available the draft MRL will be returned to Step 6.

Step 8: The proposed MRL is advanced to the CAC/Executive Committee for adoption as Codex Limit (CXL).

Note: CCPR Step 5/8 accelerated procedure

At the CCPR38 session it was agreed that if the JMPR Report becomes available by early February in the year following the JMPR meeting, CCPR would consider the advancement of all newly proposed or amended MRLs circulated at Step 3 to Step 5/8 for adoption as Codex CXLs. This would eliminate Steps 6 and 7, under the condition that no concerns are raised in plenary. Therefore in an ideal case CXLs can become available 18 months after FAO/WHO's call for data.

MRLs will not be advanced to Step 5/8 if the JMPR identifies intake concerns or if a Codex Member expresses a science-based concern and has committed to submit information/data in support of its concern within one month of the CCPR meeting.