Working with the JMPR and CCPR

A Manual for the Agrochemical Industry

Web-based Version

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Introduction

Purpose

This manual serves as a resource for agrochemical companies, providing:

- Basic guidance on how to interact with Codex Alimentarius Commission (‘Codex’) and its subsidiary bodies (like the CCPR, Codex Committee on Pesticide Residues) to get and maintain Codex Maximum Residue Limits (CXLs)
- A comprehensive summary to understand Codex and its processes relevant for CXL-setting
- Reference documents that provide detailed guidance and essential information, for example on data submission requirements

Please regularly visit the websites of the Codex, FAO and WHO for more detailed information on:

- Data requirements
- Recent decisions made
- The status of CXLs
- General policies
- Schedules

Background on Codex and Subsidiary Bodies

Codex – The Codex Alimentarius Commission (CAC) was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme.

The main purposes of this Programme are:

- protecting health of consumers
- ensuring fair trade practices in the food trade
- promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations

For more information on Codex and the CAC, see Appendix 1.

CCPR – The Codex Committee on Pesticide Residues (CCPR) is a subsidiary body to the CAC. 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 decisions to the CAC.

For more information on the CCPR, see Appendix 1.

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

It is important to note that neither JMPR nor CCPR are regulatory authorities, thus they do not regulate or approve pesticides or the use thereof, but provide
recommendations in the area. Unlike for many national review procedures, JMPR and CCPR provide their work and advice free of financial contributions/charges for the interested parties.

For more information on the JMPR, see Appendix 1.

**New Compound Submissions**

**How to get a new compound into the process**

The official nomination for a candidate compound is done by a Codex Member State government. Manufacturers have several options to support this process:

1. If the manufacturer is approached by the government, he can agree to supply data (or not).
2. Manufacturers, when sending a request for evaluation to a nominating country, should copy this request to the Chair of the priorities electronic working group and to the FAO and WHO JMPR Secretariats. The JMPR Secretariat also requested to have an indication on the number of crops for which residue evaluations are requested. The process is described in detail below:
   a) Country-sponsored submissions should be lodged with the Chair of the electronic working group on priorities and the JMPR Secretariat by 30 November.
   b) Submissions should indicate the current status of national registrations for the compound along with a clear indication of availability of data and national evaluations.
   c) The Chair will consult closely with the JMPR Secretariat prior to drafting a revised schedule. Submissions should include a commitment regarding the date that data will be available to JMPR.
   d) The Chair will draft a revised Priority List of Compounds for circulation via the Codex Secretariat through a Circular Letter with a two month comment period. The due date for comments and proposed amendments to the Priority List is 1 March. These comments should be forwarded directly to the Chair of the Electronic Working Group and JMPR Secretariat.
   e) Following consideration of comments and amendments, the final Priority List of Compounds will be prepared for circulation to member countries during March. This will be the agenda paper for discussion in CCPR plenary.
   f) 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.
   g) By the time the Priority List of Compound is considered in plenary, member countries will all have had an opportunity to seek amendment or provide comment, and will still have the CCPR agenda paper well in advance of the meeting.
   h) 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.
i) Discussions and the final Priority List of Compounds will be recorded in the draft CCPR report and adopted by the Committee.

Nomination procedure for new compounds

CCPR Member State governments nominate through their contact points compounds mainly to CCPR’s electronic Working Group on Priorities for an evaluation by the JMPR, if the compound meets the agreed criteria (for details see the CCPR report). In brief, JMPR is concerned with evaluating compounds which have measurable residues in commodities moving in international trade. Such residues should be (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade. And, of course, the compound/product must be registered in a member state and be available for use.

The proposal for a JMPR evaluation is done in a questionnaire, which asks in brief for the:
- identity,
- field of use,
- registration situation, and
- availability of data for the subsequent submission to the JMPR

The latter prerequisite is that a contact to the company/data owner was made before. The required data and criteria for inclusion into the priority list are currently under discussion. The most recent draft is available in APPENDIX XV of the 2005 CCPR report.

The final agenda for the JMPR FAO- and WHO-Panel is made available by WHO in a form of a data-call-in and on the FAO website.

Another international process, which is linked to the JMPR, has been established to develop pesticide product quality criteria for active substances, so-called pesticide specifications, through the Joint FAO/WHO Meeting on Pesticide Specifications (JMPS).

The data on which FAO and WHO specifications are based on are provided by the pesticide industry. To conduct the JMPS and the JMPR evaluation at similar times was suggested because this ensures comparability of data provided and minimises duplication of effort in providing the data. Although the 32nd session of CCPR recommended to develop a specification before a compound is evaluated by JMPR it is often not practical to submit proposals for specifications before entering the JMPR process.. The 34th session of CCPR decided that pesticide specifications were not considered as a prioritization criterion in order to not delay JMPR evaluations.

Preparing a JMPS Dossier

The joint FAO/WHO specification process was introduced in 2001. It is based on a new procedure as FAO/WHO specifications apply only to the products of manufacturers whose technical materials have been evaluated and it therefore
includes provisions for the establishment of equivalence between active ingredients coming from different sources. The process is designed to set criteria for the active ingredient, relevant impurities and some physico-chemical properties of the various formulations. This new specification procedure requires the submission of summary toxicological and eco-toxicological information and confidential information on the manufacturing process and the identification of all impurities present at concentrations greater than 0.1 mg/kg, supported by analytical data for at least five typical manufacturing batches. This information will be kept confidential by FAO and WHO. The manual can be accessed on the FAO website and at the WHO website.

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

Until the late 90’s the WHO panel requested that submissions be prepared on paper and in the format and detail defined in their submission guidelines. This option continues to be the default approach, but it has been complemented by the option to submit an EU dossier (M II document). Either document has to be supplemented with the full set of complete studies.

With the progress made in electronic data handling, the importance of paper documents has decreased and has been increasingly replaced by electronic media. Companies are advised to check with the WHO secretariat and possibly with the reviewer about acceptable/preferred technologies. Preference is given to those not requiring any special software.

For standard submissions, there is a recent guidance document (December 2000) available which provides all details needed to compile an adequate submission for the WHO panel.

The Guidelines for the preparation of toxicological working papers is found under the WHO website.

For better understanding of the process, it is also recommended to be familiar with the WHO procedural guidelines. WHO asks for a submission of data before 20 December of the year before the JMPR.

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.

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

The FAO panel requested as well that submissions be prepared on paper and in the format and detail defined in their submission guidelines. This option continues to be the default approach, but it has been complemented by the option to submit an EU dossier (M II document). The EU dossier has to be amended for those crops, which are not covered in it and the labels of registered products. Labels should be available in English. Either document has to be supplemented with the full set of complete studies.

With the progress made in electronic data handling, the importance of paper documents has decreased and has been increasingly replaced by electronic media. Companies are advised to check with the FAO secretariat and possibly with the reviewer about acceptable/preferred technologies. Preference is given to those not requiring any special software.

For standard submissions, there is a recent guidance document (Rome, 2009) available, which provides all details needed to compile an adequate submission for the FAO panel. This document, "Submission and evaluation of pesticide residue data for the estimation of maximum residue levels in food and feed", (referred to also as “FAO Manual” in our document) can be found on the [FAO website](http://www.fao.org).

By 30 October in the year before the JMPR evaluation, a directory of the planned submission is requested to get an overview of the size of the submission. The whole data submission is to be delivered before 20 December in the same year (in the calendar year prior to the JMPR evaluation).

Right now the FAO is requesting only an electronic copy, but a hard and electronic copy to the FAO Panel member assigned to review the compound. This FAO panel member will be nominated by 30 December in the year before.

**Evaluation process prior to the JMPR**

By looking at schedules for compound reviews and evaluations it becomes obvious that the JMPR capacity for a compound review is very limited. This is related mainly to the limited resources available to the program, but to some extent also to the small number of available internationally recognized experts and the fact that the JMPR Panels meet only once a year. It is important to understand that JMPR experts are not paid for this work and often spend a significant amount of their own spare time to conduct the reviews. The resource issue and possible proposals for solutions have been addressed several times in the past in a report by WHO/FAO in 2002 but have not yet (status 2010) resulted in convincing solutions that can overcome this bottleneck. Therefore
manufacturers are advised to ensure that their submissions are well prepared, to allow for a smooth review by JMPR advisors. 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 ask any question via the joint FAO/WHO secretaries.

**JMPR Meetings**

**JMPR Panel meetings**

The FAO/WHO JMPR Panels hold their non-public meetings in 2 weeks during September/October each year. The meetings alternate between the FAO headquarters in Rome and the WHO headquarters in Geneva. During the meetings, JMPR usually goes out of session at one day to clarify in hearings with industry representatives additional questions that have not been cleared in preparation of the meeting or require additional clarifications from the manufacturers.

These questions are sent to the contact points ideally by the end of the week prior to the JMPR hearings. Sometimes those questions become only available in the week of the hearings, which makes proper planning and preparation very demanding. Therefore it is crucial that the company contact is available. Answers can be provided either in writing or, by (a) representative(s) who will attend the hearing for a specific compound. The name of these experts must be sent in advance to the joint secretaries as the access to the FAO or WHO building is restricted. The expert should be familiar with the submitted data and technically competent to answer the open questions. It is helpful if these experts are either familiar with, or accompanied by company staff that is familiar with the procedures at JMPR.

The hearing will discuss sequentially one substance after another. The order of discussions is sent to manufacturer’s contact person in advance by CropLife, so that the experts get a rough idea of when to attend the hearing. As the options are limited to accommodate specific wishes from manufacturer representatives regarding the timing of their hearing, it is recommended to keep the entire day open for these hearings.

For each compound under discussion, the submitter(s) are invited to send their technical experts in person. So far, phone or teleconferences have not been routinely practiced. It is recommended to primarily answer the questions normally transmitted 2-3 days before to the focal company person and provide additional information. While there is room for short scientific statements in the hearing, timing does not allow for extended presentations unless agreed beforehand via the secretariat. Any need for technical support (overhead projector, beamers etc.) should be announced to the secretariat beforehand. If any additional documentation is requested, it should be submitted within one day, as the panel normally disbands 2-3 days after the meeting and will not reconvene until the next year.
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.

It should be recognized that most of the panel members do their work for JMPR besides their normal job, thus they put in extra effort for usually little recognition. Quite frequently, this can lead to work (appraisals, questions) being finished only just to the deadline or even with some delay. Although unsatisfactory, industry representatives should be as tolerant as possible in these situations.

The panel members are under close observation from critical NGOs and have to do everything to maintain their scientific integrity and independence from industry. Accordingly, it is highly recommended not to try to approach them outside of the official sessions or to try to socialize with them in any form beyond the casual friendly encounter and small talk.

**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. Monographs that have been published are available on [INCHEM](#).

**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 is published in the [FAO Plant Production and Protection Paper series](#) (last edition 2009). Also, a listing of all publications on pesticide residues is available on the [WHO website](#).

In addition, shortly after each meeting an electronic summary report is published on the FAO and WHO JMPR websites, which describes in tabular form all the results.

**CCPR and its Working Groups**

The MRL proposals, which the CCPR discusses, are those which have first been developed by the JMPR. In dealing with these proposals, the CCPR follows a stepwise procedure. Inevitably the procedure is 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 CCPR reports progress in the stepwise procedure, as well as in other matters, to the Codex Alimentarius Commission (CAC) for approval. Thus, countries which could not be represented at the CCPR but which can attend the meeting of the Codex Alimentarius Commission (comprising 171 member countries) have an opportunity to comment as requested in a Circular Letter.

Proposals for maximum residue limits, which have reached the final step in the adoption procedures, are regularly published jointly by FAO and WHO in Codex Alimentarius Vol.2 "Pesticide Residues in Food". This is the stage at which maximum residue limits are formally recommended by the FAO/WHO Food Standards Programme to governments for acceptance, as Codex MRLs (also referred to as CXLs). They can also be found under the FAOSTAT website.

Once a Codex MRL is approved by the CAC it is a global standard and serves as a basis in international trade. Individual countries may disagree with the value and declare "non adherence" based on local conditions.

The CCPR report of each year summarizes the status in the stepwise procedure for the proposed MRLs. The most recent and the previous reports are available from the Codex Alimentarius website.

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.

In addition to the electronic Working Group of Priorities already mentioned before, other Working Groups have been established by the CCPR in order to support its functions. The problems related to sampling procedures as part of the regulatory enforcement of MRLs in food were considered sufficiently important to merit further collaborative effort. This issue and the question of methods of residue analysis, and the problems related to a common approach in recommending analytical methods to be used for regulatory purposes, prompted the establishment of an ad hoc Working Group on Methods of Analysis and Sampling.

Problems which countries have in adopting CXLs led to the formation of an ad hoc Working Group on Regulatory Principles. A fundamental step forward was made when the CCPR, in collaboration with the Codex Committee on General Principles, agreed on a modified acceptance procedure, geared to the specific problems of the CCPR. The present procedure now provides, among other things, for a "limited acceptance". This implies that a country will not hinder the importation of food complying with CXLs. It also implies that it will not impose a CXL which would be more stringent than a limit which it applies domestically. It was hoped that this procedural system of acceptance would enable the CCPR to expedite its work and enable member countries to accept CCPR proposals more readily; this was particularly important since CCPR proposals have to take into account globally varying pest control conditions in different countries.
Although the extent of participation and support is encouraging, the fact that several member countries still have difficulties in accepting a number of proposed CCPR standards should not be ignored (see also next Section). There is every reason to examine these difficulties carefully and, where necessary, to seek ways and means to improve the rationale underlying the proposals, to increase the availability of the CCPR recommendations amongst member countries.

The CCPR has produced a nine-part "Guide to Codex Recommendations Concerning Pesticide Residues". The parts cover the following subjects in the following order:

1. General notes and guidelines, including definitions.
2. Information on the current status of MRLs in the Codex review procedure.
3. Information on guideline levels.
4. Classification of foods and animal feedstuffs.
5. Recommended methods of sampling of commodities moving in trade, for the determination of pesticide residues.
6. Portion of commodities to which MRLs apply.
9. Recommended national regulatory practices to facilitate acceptance and use of CXLs.

Copies are available during sessions of the CCPR. In the period between CCPR meetings, copies are available from the Secretariat of the Joint FAO/WHO Food Standards Programme at FAO in Rome.

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

1. work sharing project, i.e. feasibility to use national/regional evaluations as basis for JMPR evaluations,
2. setting CXLs for spices based on monitoring data,
3. risk analysis policies in establishing MRLs and
4. classification of foods and animal feeds.

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. They are coded as ALINORM, followed by the year and then marked by the end-figures 24.

**International Acceptance of Codex MRLs (CXLs) by Regulatory Authorities**

Under the Sanitary and Phytosanitary (SPS) agreement, the World Trade Organization (WTO) established CXLs as worldwide trading standards.

In line with this agreement the Codex Alimentarius Commission states that:
'A particularly important aspect of the work of Codex Committees results from the agreement that scientific, risk-based standards established by the Codex Alimentarius Commission should be employed under terms of the Sanitary and Phytosanitary (SPS) agreement to address fair trade practices. Governments wishing to argue particular cases at WTO are likely, therefore, to turn increasingly to Codex, and through Codex to JMPR and other scientific bodies, for advice on their own legislation.’

Regrettably only very few countries, e.g. Costa Rica, Indonesia, New Zealand, approve Codex MRLs in lieu or in addition to their own standards or generally rely on CXLs.

In the European Community MRL Regulation 396/2005 it is stated that ‘MRLs set at the international level by the Codex Alimentarius Commission should also be considered when Community MRLs are being set taking into account the corresponding good agricultural practices.’

Nevertheless in absence of European Community MRLs for an active substance/crop combination an existing Codex MRL might help the inspection services to decide whether imported agricultural products containing traces of residues are considered to be safe and can be further traded.

In the USA, the laws state clearly that food is considered adulterated if pesticide residues exceed established US standards. The existence of a different Codex level does not influence this acceptability decision at the time of importation. If a Codex level exists at the time a US tolerance is established, EPA may chose to set the same level where possible.

Although the WTO-SPS agreement came into force already in 1996 it seems that Codex MRLs hardly ever are used to solve trade disputes at the WTO level, probably related to administrative hurdles and costs involved to file a WTO complaint.

Codex MRLs are acknowledged by countries which might not have an own legislation in place or to set MRLs, or they might use them in addition to their own nationally established MRLs, especially as Import Tolerances.

Life Cycle of Evaluated Compounds

New data, additional MRLs etc (evaluations)

After the "first JMPR evaluation" resulting in the establishment of an ADI, an ARFD and proposed MRLs shorter “evaluations” on special issues are possible. There are several reasons for this type of evaluation:

- Sometimes the meeting concludes that further studies would provide information useful for a continued evaluation of the compound. It is made clear by the meeting whether it needs this information before a final conclusion can be made or not. If it is a pre-requisite and the company does not meet this request the whole process might stop.
- A country can submit additional data regarding residues or other properties. The WG on Priorities will place that on the JMPR agenda.
• In case new data become available by the company, which have the potential to change the conclusion of a JMPR evaluation, the company ought to inform the Secretariat of either Panel to enable a further evaluation.
• A country can disagree with the entire conclusion or only with a part of it. In this case the matter will be prioritized again and it is the obligation of the country to bring forward the data supporting its case. It is advisable for the company to cooperate.
• If new crops shall be evaluated either requested by a country or a company, the WG on Priorities will handle this matter in principle in the same way as for a new compound.

Periodic re-evaluations (4 years clause)

As the state of the art of testing and evaluating the properties of a compound is constantly progressing, it is advisable and feasible to repeat evaluations done years before. The CCPR decides to propose to the JMPR a so-called "periodic re-evaluation", for example, if:
• the compound has not been reviewed for more than 15 years
• the intake of the compound and/or the toxicity profile indicates some level of public health concern.

More detail can be found in Alinorm 05/28/24, Appendix XV, page 108 to 110.

The procedure for a periodic re-evaluation is briefly described below:
1. WG on Priorities discusses during the yearly session of the CCPR which compounds meet the criteria.
2. The company gets the information of the candidacy of its compound through its representative at CCPR, the CCPR report or the country Codex contact point. For the latter no time frame is given.
3. A company should respond to the Codex Secretariat and the Chair of the Working Group on Priorities within 6 months.
4. The response should contain a clear statement which of the existing MRLs are further supported and the commitment to submit respective data in time. Alternatively, it is of course feasible for the company simply to state that it is not its policy to submit proprietary data to the JMPR. Such a reply is, however, inadvisable, especially if appropriate data may be available from other sources.
5. The WG on Priorities will provide a report to the next CCPR on the status of commitments received.
6. The CCPR will propose withdrawal of MRLs by the next session of CAC for those crops which are not supported.
7. The WG on Priorities will include those compounds/crops on the tentative JMPR agenda for which commitments were received.
8. If sufficient data are submitted, the MRLs will remain in place.
9. In case of insufficient data, the company has to state further support (or not) by the commitment to elaborate new data within 4 years. This time period may be extended by the CCPR for special reasons.
10. The existing MRLs will remain in place for this period (in case of a commitment).
11. The then submitted data would be evaluated by the JMPR. The result will lead to the same consequences as described above.

More detail on the procedure for periodic re-evaluation can be found on the March 2005 Codex document.

An excellent description of the process for periodic review compounds including the four years’ clause in the case of insufficient information available to JMPR is given in Appendix IV of the FAO Manual.
Appendix I: Background Information

CODEX Alimentarius and the Codex Alimentarius Commission (CAC)

The Codex Alimentarius is a collection of international food standards that have been adopted by the Codex Alimentarius Commission. The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop and publish food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. Hereunder fall the Codex MRLs and the procedures used in their derivation and uses. All decisions including MRLs at step 8 taken by the CCPR have to be endorsed by the CAC.

The pesticide industry has no direct interaction with the CAC, as this Commission is manned with representatives from the member governments. Membership of the Commission is open to all Member Nations and Associate Members of FAO and WHO. In 1998, membership comprised 163 countries, representing 97 percent of the world's population.

The CAC meets annually, alternately at FAO headquarters in Rome and at WHO headquarters in Geneva to discuss proposals from the different Codex Subcommittees: Plenary sessions are attended by as many as 500 people. Representation at sessions is on a country basis. National delegations are led by senior officials appointed by their governments.

To facilitate continuous contact with member countries, the Commission, in collaboration with national governments, has established country Codex Contact Points and many member countries have National Codex Committees to coordinate activities nationally.

Codex standards cover all the main foods, whether processed, semi-processed or raw. Therefore the Codex Alimentarius has relevance to the international food trade. With respect to the ever-increasing global market, in particular, the advantages of having universally uniform food standards for the protection of consumers are self-evident. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on Technical Barriers to Trade (TBT) both encourage the international harmonization of food standards. A product of the Uruguay Round of multinational trade negotiations, the SPS Agreement cites Codex standards, guidelines and recommendations as the preferred international measures for facilitating international trade in food. As such, Codex standards have become the benchmarks against which national food measures and regulations are evaluated within the legal parameters of the Uruguay Round Agreements.

The Codex website offers a comprehensive description of the Codex Alimentarius.

By providing an international focal point and forum for informed dialogue on issues relevant to food, the Codex Alimentarius Commission fulfils a crucial role. In support of its work on food standards and codes of practice, it generates reputable scientific texts, convenes numerous expert committees and consultations as well as international meetings attended by the best-informed
individuals and organizations concerned with food and related fields. For our industry, the primary focus is the establishment of Codex MRLs (CXLs) and their safety assessment. The main body of interest under the Codex Alimentarius Commission (CAC) is the Codex Committee on Pesticide Residues (CCPR). The Joint Meeting of Experts on Pesticide Residues (JMPR), although not under the umbrella of CAC, provides scientific advice. Loosely linked is also the Joint Meeting on Specifications, as specifications should be established before JMPR evaluation.

The Codex Alimentarius has such a well-established reputation as an international reference that it has become a major reference for health authorities, government food control officials, manufacturers, scientists, and consumer advocates.

The Codex Committee on Pesticide Residues (CCPR)

The CCPR is an inter-governmental meeting. 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.

The government of the People’s Republic of China is hosting the CCPR from 2007 on in Beijing. 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 CropLife International (CLI). In total, some 200 people usually attend.

Company representatives wishing to be at the CCPR may attend as members of the CLI Delegation - fuller details are available from the CLI Manager International Regulatory Policy (Agrochemicals) upon request.

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

The JMPR is 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. During the 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 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.

Purpose - JMPR serves as an independent scientific advisory body to FAO, WHO, to FAO and 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, see EHC 70, EHC 104, the JMPR at WHO, and the JMPR at FAO.

The CCPR electronic Working Group on Priorities

The electronic Working Group of Priorities considers proposals that the JMPR should evaluate a compound either for the first time or a special issue for an already evaluated one, or perform a periodic re-evaluation for a compound evaluated years before. It works according to the time schedule outlined on page 3 of this document.

Through the plenary session of the CPPR it recommends to FAO and WHO priority lists of compounds for the agendas of future JMPR meetings considering established prioritization criteria (see below). The priority lists for the next 4-7 years are published within the CCPR report. See for example 2005, Appendix XIV.

Priority lists are also available on the FAO and WHO websites but no remark is given for the last update.

Another term of reference of the electronic WG of Priorities is the drafting of criteria for the prioritization process of compounds for the evaluation by the JMPR. These criteria are as well published in the CCPR report.
The Joint Meeting on Pesticide Specifications (JMPS)

The primary function of the JMPS is to produce recommendations to FAO and/or WHO on the adoption, extension, modification or withdrawal of specifications. Normally, all participants need to fill in confidentiality agreements and declarations of interest, independent of where they come from. The JMPS is composed of scientists collectively possessing expert knowledge of the development of specifications. Their opinions and recommendations to FAO/WHO are provided in their individual expert capacities, not as representatives of their countries or organizations. Experts appointed by FAO are drawn from the FAO Panel on Pesticide Specifications, Registration Requirements, Application Standards and Prior Informed Consent. Experts appointed by WHO are drawn from the WHO Panel of Experts on Vector Biology and Control, together with a representative of the WHO/PCS.

FAO and WHO may also invite academic or government experts (who will be subject to declarations of confidentiality and conflict of interest) with special skills or knowledge to attend the JMPS as special advisors.

In addition, industry experts may be invited for either of two purposes. Firstly, they may be invited to provide explanations or additional information in support of specifications proposed by their own company (there is no access to other companies’ information or proposals).

Secondly, industry scientists with special skills or knowledge of technical issues (not related to a particular company’s proposals or specifications) may be invited. Industry experts do not, and the other additional experts may not, participate in drafting the recommendations of the JMPS.

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

The Codex Alimentarius Commission takes decisions to elaborate Worldwide Codex Standards and assigns committees or other Subsidiary Bodies to the preparatory/operational work. Codex MRLs (CXLs) are one of several standards in Codex Alimentarius. The subsidiary bodies for CXLs are the CCPR, CCFAC and CCRVDF.

**Step 1:** Following it’s notification by a Codex member (governmental body) the CCPR schedules a compound for review.

**Step 2:** The JMPR undertakes the review and passes their report (through the FAO and WHO secretaries) to the Codex Secretariat. Following the review of a data submission by the JMPR several scenarios are possible depending on the outcome of the evaluation: e.g., the JMPR is unable to set an ADI or an ARfD, or available residue data are insufficient to propose Codex MRLs. For new compounds this scenario is seen as a less likely event, than for older compounds where sometimes support is lacking. In a case of a 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 a JMPR review. Additional uses would be scheduled for evaluation.

**Step 3:** The Codex Secretariat sends proposed draft standard to members. Members are returning concerns using a specific form.

**Step 4:** Comments for the proposed or amended standards are sent via the Codex secretariat to the CCPR. The CCPR will either propose advancement to step 5, or if the following conditions are met, use an accelerated procedure to send MRLs via step 5/8 for adoption to the CAC:

1. The JMPR has no intake concerns
2. The JMPR report is available at least 2 months prior to the CCPR to allow Codex members to review JMPR’s position.

In case of concern Codex members are encouraged to submit their concern by using a specific form (‘concern sheet’) to the JMPR Secretariat for evaluation with the understanding that adopted MRLs would be revised if appropriate. In that case Codex members should provide additional data which have not been reviewed by the JMPR before.

**Step 5:** The amended proposed MRL is sent to the CAC/Executive Committee for adoption as draft standard.

**Step 6:** The adopted draft is sent to members by the Codex Secretariat for comments. If an MRL is returned twice to step 6 (e.g. because of to acute intake concerns) then the JMPR will be asked whether a lower MRL/safer GAP can be proposed. (This case would involve actions from the manufacturer to provide 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 sent to the CAC/Executive Committee for adoption as Codex MRL (CXL).
The CCPR ad hoc Working Group of Method of Analysis and Sampling

This working group meets during the session of the CCPR and is open to all participants. The WG updates the list of methods which are used for the compounds being in the Codex system, proposes methods of sampling for residue trials and enforcement activities, analytical methods for fatty items and how to perform collaborative analysis and single laboratory validations, and last but not least describes the GLP for analytical work in general.

The results of the discussions are published in the CCPR report.
Appendix II: CropLife International Resources

For more information, please visit the following CropLife resources:

- [www.croplife.org](http://www.croplife.org)
- International Code of Conduct e-learning tool, with guide available in English, Spanish and French.