CHAPTER 2

SELECTION OF COMPOUNDS FOR EVALUATION

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2.1 SELECTION OF NEW COMPOUNDS

The Secretariat of the Joint FAO/WHO Food Standard Programme regularly invites member countries of CAC to propose pesticides to be added to the Codex Priority List of Pesticides for subsequent recommendation to the JMPR for evaluation. The proposals are considered by CCPR at the successive meeting. Based on the information received, CCPR prepares the priority list of pesticides and the tentative lists of compounds to be considered by the JMPR at its subsequent meetings.

When prioritizing new chemicals for evaluation by the JMPR, the Committee follows the criteria described in the Codex Alimentarius Procedural Manual¹.

2.1.1 Procedure for proposing pesticides for Codex Priority List

The procedure is described in the Circular of Codex Secretariat, CL 1996/35-PR. The procedure to be followed when proposing pesticides for inclusion in the Codex Priority List is given below. The form in which information is to be provided is given in Appendix VIII.

Criteria for inclusion of compounds in the Priority List

Before a pesticide can be considered for the Priority List it:

- a. must be registered for use in a member country
- b. must be available for use as a commercial product
- c. must not have been already accepted for consideration
- d. must give rise to residues in or on a food or feed commodity 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.

Criteria for selecting food commodities for which codex MRLs or EMRLs should be established

The commodity for which the establishment of a Codex MRL or EMRL is sought should:

- a. form a component of international trade
- b. represent a significant proportion of the diet

¹ Codex Alimentarius Commission Procedural Manual –Eighteenth edition, 2008, www.codexalimentarius.net

c. contain pesticide residues as evidenced in monitoring programmes (for EMRL).

Procedures to be followed for commodity-pesticide combinations which meet the selection criteria

Governments are recommended to check if the pesticide is already in the Codex system.

NOTE: Pesticide-commodity combinations which are already included in the Codex system or under consideration are found in a working document prepared for and used as a basis of discussion by each Session of the Codex Committee on Pesticide Residues. Consult the most current revision of the document to see whether or not a given pesticide has already been considered.

If "YES",-proceed to section (b) below,

If "NO ",-proceed as follows in (a):

a.

- (i) Consult the manufacturer(s) regarding the existence of sufficient toxicological, residue and critical supporting data and confirm that the manufacturer(s) would be willing to submit data to the JMPR, and in which year, and
- (ii) Submit the information to the person designated by the CCPR using the form given in Appendix VIII.
- b. Where the pesticide has already been evaluated by the JMPR and MRLs, EMRLs or GLs have been established, two situations may arise:
 - (i) Interest exists in proposing MRLs for a new commodity. Consult the most recent working document containing all MRLs to ensure that MRLs have not already been established or considered for the commodity-pesticide combination. Where interest exists in developing data for a new commodity, governments are urged to discuss with industry the possibility of collaborative programmes, e.g., manufacturers may be willing to analyse samples from supervised residue trials conducted in accordance with the basic requirements described in Chapter 3. Proposals for new commodity-pesticide combinations and new residue data may be submitted directly to the FAO Joint Secretary of the JMPR, who may decided on scheduling the new proposal for evaluation, without the need for submissions according to Appendix VIII, as described in (a) above.
 - (ii) In those cases where additional toxicological data have become available, governments may wish to propose a pesticide for re-evaluation. The form given in Appendix VIII should be used for this purpose. Where a serious public health concern exists in relation to a particular pesticide, governments should notify the WHO Joint Secretary of the JMPR promptly and provide appropriate data.

Copies of correspondence

All communications to the various persons mentioned above should be copied to the Chairperson of the CCPR and the designated person without enclosing the detailed toxicological or residue data.

Data deadline

The above procedures relate mainly to the establishment of Codex Priority Lists. The 2009 Session of CCPR confirmed² that proposals for evaluation by the JMPR would be finalized by the Committee for adoption by the CAC in the same year and no further changes to the current year's schedule would be possible. Once the agenda of the JMPR has been agreed, the Secretariat of the JMPR requests that detailed residue and toxicological data be submitted by a stated deadline.

Starting in 2010, the data directory should be submitted to the joint FAO Secretary by 1 September and the full residue data submissions are required by 30 November of the year before the scheduled review. Less substantial submissions to support FAO Panel consideration of questions from a CCPR meeting, (usually raised by way of a 'CCPR Concerns Form') may normally be accepted by 31 May of the year in which the issue will be considered. The agreed Priority Lists indicating the pesticides scheduled to be evaluated by the JMPR are attached to the Reports of the Sessions of the CCPR and distributed to Member Countries.

Industry contact points

Further information about industry contact points on specific chemicals is available from the Technical Director of CropLife International, Avenue Louise 143 B-1050 Brussels, Belgium, info@croplife.org, www.croplife.org.

2.2 PERIODIC REVIEW OF OLD COMPOUNDS

Since the use conditions of the compounds may change with time, older existing Codex MRLs may not reflect current use patterns. Furthermore, some of the old toxicological studies and residue trials may not meet the contemporary standards. Within the CCPR, and also within the JMPR, there has been concern with respect to maintaining official Codex MRLs (CXLs) that may no longer reflect the current information. Consequently, old compounds are re-evaluated under the CCPR Periodic Review Programme (Appendix IV).

When prioritizing chemicals for periodic re-evaluation by the JMPR, the CCPR will consider the following criteria:

- a. if the intake and/or toxicity profile indicate some level of public health concern
- b. 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
- c. the year the chemical is listed in the list for Candidate Chemicals for Periodic Reevaluation Not Yet Scheduled

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² Report of the forty-first session of the codex committee on pesticide residues, para 187, Beijing, China, 20 – 25 April 2009

- d. the date that data will be submitted
- e. whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption
- f. if there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently
- g. the availability of current labels arising from recent national re-evaluations.

2.2.1 Periodic review of compounds currently being re-registered nationally

The following information should be provided to the FAO Joint Secretary for compounds notified for periodic review while undergoing re-registration by national authorities.

- current registered uses
- current registered uses that will be supported
- envisaged new or amended uses
- the status of the registration and an estimate of the date on which new or amended uses will become GAP
- an estimate of the date on which old registered uses will be revoked
- a clear description of the uses (new, amended or current but not to be supported) to which the data from supervised trials of residues relate.

See also section 3.4.1 "Periodic review of compounds undergoing re-registration by national authorities".

2.3 RE-EVALUATION OF COMPOUNDS

After a compound has been evaluated by the JMPR, changes in the authorized uses may occur or new information on the properties of the pesticide may become available which may affect the recommended MRLs or require the estimation of new maximum residue levels for the additional commodities.

Where a pesticide has already been evaluated by the JMPR, new evaluations may be initiated if one or more of the following situations arise:

- a. New toxicological data becomes available to indicate a significant change in the ADI or ARfD.
- b. The JMPR may note a data deficiency in a Periodic Re-evaluation or New Chemical evaluation. In response, national governments or other interested parties may pledge to supply the information to the appropriate Joint Secretary of the JMPR with a copy for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data should be submitted subsequently to the appropriate Joint Secretary of the JMPR.
- c. The CCPR may place a chemical under the four-year rule, in which case the government or industry should indicate support for the specific MRLs to the FAO Joint Secretary of the JMPR. Following scheduling in the JMPR tentative schedule,

- any data in support of maintenance of the MRL(s) would be submitted to the FAO Joint Secretary of the JMPR.
- d. A government member may seek to expand the use of an existing Codex chemical: that is, obtain MRLs for one or more new commodities where some MRLs already exist for other commodities. Such requests should be directed to the FAO Joint Secretary of the JMPR and submitted for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.
- e. A government member may seek to review a MRL due to a change in GAP. For example a new GAP may necessitate a larger MRL. In this case the request should be made to the FAO Joint Secretary and submitted for consideration by the CCPR. Following scheduling in the JMPR tentative schedule, the data would be submitted to the FAO Joint Secretary of the JMPR.
- f. The CCPR may request a clarification or reconsideration of a recommendation from the JMPR. In such cases the relevant Joint Secretary will schedule the request for the next JMPR.

In the above cases the compound is re-evaluated by the JMPR at subsequent meetings.