

IUPAC Representative Report

Codex Committee on Pesticide Residues
32nd Session

May 1-8, 2000

The Hague, Netherlands

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CCPR is the policy group which annually discusses and recommends international guidelines for maximum residue limits (MRLs) of pesticides on food commodities. CCPR receives detailed technical reports and MRL proposals from the WHO/FAO Joint Meeting on Pesticide Residues (JMPR), and CCPR makes final recommendations for MRLs to be officially approved by the Codex Alimentarius Commission (CAC). Also in attendance as part of the IUPAC delegation was Sue-Sun Wong of the Commission on Agrochemicals and the Environment.

General

The meeting included approximately 55 national and 15 observer delegations (including IUPAC). The Codex MRL-setting process is a slow one, and the current meeting provided evidence that this will continue to be the case for the foreseeable future. CCPR is active both in recommending new MRLs and in reviewing existing MRLs via a periodic review program. For a third consecutive year the meeting was attended by a small but quite vocal activist group, Consumers International (CI). This group made many comments related to the sensitivity of children, the need for conservative approaches for dietary risk assessment, and need for cumulative exposure assessment of pesticides with a common mechanism of toxicity. A large observer delegation also attended on behalf of Industry (Global Crop Protection Federation), which distributed a series of position papers on several topics of interest.

Chronic Dietary Assessment and Risk Management Options

CCPR continues to use calculations of the Theoretical Maximum Daily Intake (TMDI: based on MRL intake) and International Estimated Daily Intake (IEDI: based on supervised trial median residues - SMTR) against the ADI to determine the acceptability of newly proposed or reevaluated MRLs. This methodology was refined and supported by the recently concluded IUPAC project "Optimum Use of Available Residue Data in the Estimation of Dietary Intake of Pesticide Residues" (*Pure Appl. Chem.*, 1997, **69**:1373-1410).

Some controversy had arisen at the last CCPR meeting as to what risk management steps are available when the IEDI is exceeded. Australia had prepared a discussion paper titled "Proposed Measures When Dietary Exposure Estimates Exceed the ADI". Current practice is to withhold final approval of MRLs pending production of additional data to allow a more refined assessment and/or withdrawal of one or more uses by the manufacturer. The option of whether to instead proceed with approval of MRLs in such instances but, recognizing the conservative nature of the IEDI calculation, flag such CXLs as candidates for further assessment by national regulatory authorities. After spirited discussion, the Committee agreed to maintain the current practice but by circular letter obtain from national authorities their views of such practices and options CCPR should consider in the future. Some potential options identified in the discussion paper included use of monitoring data for intake assessment refinement, consideration of percent crop treated, and reliance by CCPR on more sophisticated national dietary intake assessments.

Australia agreed to summarize inputs from national authorities and bring these forward at the 2001 CCPR. [CX/PR 00/7]

Acute Dietary Assessment and Risk Management Options

A topic of much interest once again at CCPR was acute dietary risk assessment. Having reached agreement on the basic methodologies for the International Estimate of Short-Term Dietary Intake (IESTI) through a couple of past consultations and an ad hoc expert meeting prior to the 1999 CCPR, JMPR had been directed to begin implementation of such calculations for adults and children for acutely toxic pesticides. Although the JMPR has been setting Acute RfD when it felt necessary during the past several years, the 1999 JMPR was the first to employ and report such IEDI calculations (see 1999 JMPR Report, Appendix IV). For each commodity for which an MRL is proposed or already exists, a single-tier of assessment is available which is based on maximum residues observed in field trials multiplied by an uncertainty factor; there is no level of refinement available short of generating new field residue data. One change suggested by JMPR and endorsed by CCPR was to employ a variability factor of 7 instead of 10 for medium-sized commodities.

The CCPR chair, Wim van Eck, had prepared a discussion paper titled "Acute Dietary Risk Assessment of Pesticide Residues and Risk Management Options" to summarize his proposal for how the IESTI calculations would be used by CCPR in setting and reviewing MRLs. Basically, if the IESTI for a given commodity exceeds the ARfD and further refinement through generation of new data will not result in an acceptable calculation the proposed MRL will not be advanced. It was understood that this same approach would be used also with existing CXLs for acutely toxic pesticides. The CCPR endorsed such

an approach on an interim basis, but also agreed to continue to seek refined approaches to acute dietary intake assessment and also solicit national authority comments on their approaches to acute dietary intake assessment. This refinement should be greatly assisted by the ongoing IUPAC project on "Acute Dietary Intake Assessment."

Several delegations expressed concern over the highly conservative nature of the current approach. For example, the Netherlands indicated that some comparison of probabilistic acute dietary calculations at the 99.99 percentile with the IESTI employed by CCPR revealed the latter of these to be more conservative. It was anticipated that at some point in the future an expert consultation on refined approaches to acute dietary assessment will likely be held, and this was tabled for discussion until the 2001 CCPR.

[CX/PR 00/3]

Development of Databases for Acute Exposure Assessment

Dr. Jerry Moy shared a "Progress Report on the Development of Databases for Acute Exposure Assessment". The CCPR-endorsed methodology for the IESTI calculation employs 97.5 percentile body weights for adults and children and also 97.5 percentile consumption data (eaters only) for each commodity of interest for acute intake assessment. Because consumption data had only been provided by 6 countries (Australia, Japan, U.S., France, Netherlands, UK), it has not been possible to construct regional diets as is the case for chronic dietary assessment. Instead, the highest 97.5 percentile consumption among each of these 6 countries has been chosen so as to create a single database of global "super-eaters". [CX/PR 00/3-Add.1]

Sensitivity of Infants and Children

Significant discussion occurred related to the issue of the potentially greater sensitivity of infants and children than adults to pesticides. Based on a request from last year's CCPR, the 1999 JMPR had reviewed this issue and concluded in its report that "The routine use of safety factors in addition to those currently used is not justified on the basis of current information." JMPR/WHO Joint Secretary John Herrman indicated that JMPR evaluates all the relevant data for each pesticide, including studies on developmental toxicity, and makes a case-by-case determination based on the most sensitive endpoints for establishment of NOELs and ADIs. A room document circulated by Consumers International castigated the JMPR for its inability to reach the same answer as the U.S. National Academy of Sciences had several years ago and pressed for an expert consultation of pediatric specialists to provide guidance on the issue. The delegations of Germany and France made statements regarding their concerns also for proper protection of infants although the former had a more sweeping concern whereas the latter a narrower concern (i.e., perhaps only 10 or so pesticides really are of high concern). After some discussion (see also section below on babyfood MRLs), the CCPR agreed to support the JMPR position, but encouraged the JMPR to consider with each individual chemical review the specific evidence available that would indicate greater sensitivity of the young. In addition, a circular letter from CCPR to national governments will request information on the nature and rationale for their concerns related to infant and child sensitivity to pesticides, including a listing of specific pesticides already identified as of national concern. The 2001 CCPR would then consider further the option of an expert consultation on child sensitivity to pesticides. [CRD 16]

Establishment of Special MRLs for Cereal-Based Baby Food

At the last meeting of CCPR, the German delegation had been asked to prepare a paper dealing with pesticide considerations and baby foods, and a document introduced for review by the 2000 CCPR was titled "Feasibility of Establishing Specific MRLs for Cereal-Based Foods and Infant Formula". The paper was strongly focused on age-related differences in susceptibility to pesticides and contained a set of 10 recommendations which included development of additional data requirements (e.g., developmental neurotoxicity), adoption of a very low common limit for residues of pesticides in processed cereal-based foods for infants and children and infant formula, and consideration of whether to require new residue testing data for processed children's foods or to set separate child-MRLs for the raw agricultural components of these foods. Although the common very low limit proposal was supported by the EC Delegation, several delegations (e.g. Australia, Canada, U.S.) expressed strong reservations about the approaches outlined in the German paper or the real need for any special approach on cereal foods and infant formulae. At the end of the discussion, CCPR concluded that 1) at present CXLs were not being set for composite foods, 2) such an approach would require new methodology so complicated as to be infeasible, 3) some delegations questioned the need for such an approach, 4) consensus could not be reached on setting a low MRL for baby food or child-MRLs for raw commodities, 5) endorsed the ALINORM 99/26 statement that if the presence of pesticide in such baby foods is technically unavoidable, they are to be reduced to the maximum extent possible. [CX/PR 00/9]

FAO Specifications: Future Link with JMPR Reviews

Some discussion occurred related to the proposal of the 1999 JMPR report to schedule only those pesticides for a first or periodic review for which FAO specifications have been established. JMPR recognized that it might take some time before this recommendation is fully implemented. Several concerns related to this proposal were raised, including whether expecting specifications to be set for new pesticides (i.e., still under patent and not subject to generic manufacture) was reasonable to expect prior to Codex MRL establishment. CCPR, however, supported the recommendation of JMPR in linking the Codex MRL and FAO specification processes and directed the informal Working Group on Priorities to explore ways of aligning the JMPR future schedule with that of the FAO specification process.

Establishing MRLs to Accommodate GMO Crops

A short discussion paper on the above subject was advanced by Canada for discussion. The primary focus was on herbicide-tolerance GMO crops, which may have either an altered balance of metabolite vs. parent or new metabolites as compared with non-GMO crops. The paper concluded that an MRL for a given commodity must accommodate both traditional and GMO crops, but that it is not possible to establish separate MRLs for GMO crops due to analytical difficulties. A number of delegates supported this approach, but a few (e.g., Germany) seemed interested in establishing separate residue definitions in some cases where new metabolites occurred in the GMO. Based on discussion, it was agreed to issue a circular letter to national authorities as to how they presently deal with residue definition and enforcement monitoring for GMO

crops. A summary of responses will be collected by Canada and advanced at the 2001 CCPR for further discussion. [CX/PR 00/8]

Proposal for a Baker's Dozen of New Regional Diets

A proposal to replace the 5 existing world diets used for chronic dietary assessment with 13 regional "consumption cluster" diets was again advanced in a report from WHO. A statistical method was employed to group countries into the 13 units. The proposal would require compilation of an extensive dietary survey of a number of the clusters for which inadequate consumption data is currently available. There was general concern from the Committee about the proliferation of regional diets and complication of the dietary assessment process. Questions arose as to whether the 5 existing diets might not already be adequate and whether an increase to 9 regional diets might be more reasonable. In addition, several delegations expressed concern that proliferation of the number of world diets would potentially increase the likelihood that the TMDI or IEDI would exceed the ADI for at least one region thus blocking future progress in advancing MRLs. The present European diet, which most often is the region with a calculated ADI exceedence, was used as an example; it would be split into 5 separate clusters with the new system. Based on these concerns, WHO agreed to prepare a revised proposal for the 2001 CCPR and also bring forward some example chronic intake calculations for the 5 vs. 13 dietary region approaches. [CX/PR/00/4]

Harmonization of MRLs for Crop Pesticides and Animal Drugs

A discussion paper on harmonization of MRL-setting for compounds used both as pesticides and veterinary drugs was advanced by the WHO. At present, CCPR establishes animal product MRLs for plant pesticides and external veterinary products (e.g., sheep dips, cattle sprays), whereas the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) develops MRLs for internal veterinary products. At times different residue definitions and MRLs for the same commodities and pesticides have been established by each Committee. Harmonization of some animal commodity definitions has already occurred, but CCPR refused to rename "meat" per the CCRVDF term "muscle". The Committee agreed to seek fuller cooperation with CCRVDF and also directed JMPR to seek liaison with the CCRVDF-equivalent (JECFA) earlier in the evaluation process for chemicals of joint interest, but clearly harmonization in the Codex world has a long road ahead. [CX/PR 00/6]

Pesticide Residue Problems in Developing Countries

The ad hoc working group on problems related to pesticide residues in food in developing countries considered two papers. South Africa brought forward a discussion document which highlighted issues related to import residue problems of tropical and minor crops, which often lack Codex as well as national MRLs in importing countries. The best option at present appears to be for developing countries as well as bilateral partnerships such as COLEACP (Europe-Africa-Caribbean-Pacific Liaison Committee for the Promotion of Tropical Fruits, Off-Season Vegetables,,...) to generate and submit residue trial data to JMPR and/or national governments to establish MRLs. India brought forward a discussion document which focused on the need for MRLs or EMRLs for spices, which frequently are found to contain violative residues of existing or banned (e.g., DDT)

pesticides presumably due to spray drift or environmental contamination (or unauthorized use?). Although field residue trials data is required to set MRLs for spices, monitoring data are required instead for setting EMRLs for environmental contaminants. India agreed to serve as data collection coordinator for spice residue information to be brought forward to JMPR in the future. [CX/PR 00/14] [CX/PR 00/14-Add.1]

Priority List for Future JMPR Evaluations

The listing of new pesticides and older ones for periodic review was updated during the meeting and presented as a discussion document. [CX/PR 00/13-Add.1]

New chemicals for review during upcoming JMPR sessions are as listed below:

- * 2000 JMPR: chlorpropham, fipronil
- * 2001 JMPR: imidacloprid, spinosad
- * 2002 JMPR: esfenvalerate, flutolanil
- * 2003 JMPR: acibenzolar-S-methyl, quinclorac
- * 2004 JMPR: famoxadone, alpha-cypermethrin, zeta-cypermethrin

Compounds for which manufacturer support for periodic review were withdrawn included chlorfenvinphos, permethrin, flucythrinate, and vamidothion.

The updated listing of tentative JMPR agenda should be available soon at:
<http://www.fao.org/waicent/FaoInfo/Agricult/AGP/AGPP/Pesticid>