IUPAC Representative Report
Codex Committee on Pesticide Residues
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This report provides a brief summary and major highlights of the 34th Meeting of the Codex Committee on Pesticide Residues (CCPR), held in Den Haag, Netherlands, 13-18 May 2002. I attended the meeting as head of the IUPAC observer delegation, which also included Dr. Sue-Sun Wong of Taiwan. IUPAC has had an observer delegation at CCPR for the past 5 years or more, and several past and ongoing projects sponsored by the Division of Chemistry and the Environment (VI) have directly addressed vexing technical issues faced by the Committee.

Background

The mission of CCPR is to promulgate recommendations concerning international standards for maximum residue levels (MRLs) of pesticides on agricultural commodities moving in international trade. In this capacity CCPR serves as a forum for discussion and decisions regarding risk management aspects of the MRL process, since dietary intake assessment and protection of consumer safety and confidence are nearly as important as ensuring the reduction of potential barriers to international trade. Technical recommendations regarding proposed toxicological endpoints (ADIs, ARfDs) and MRLs arise from annual meetings of the FAO/WHO Joint Meeting on Pesticide Residues (JMPR), and MRLs recommended by CCPR are subject to formal approval by the biennial Codex Alimentarius Commission (CAC) as Codex MRLs (also referred to as CXLs).

General Considerations

The 34th CCPR meeting was attended by more than 250 delegates who represented 51 countries and 15 international organizations. There were a number of interesting and important items of discussion which occurred during the 6 days of meetings, but as is rather typical for CCPR there

were few definitive outcomes or concrete decisions reached. The *modus operandi* of CCPR is to enthusiastically debate particular topics and position papers at the annual meeting, appoint working groups to prepare new or revised position papers for future discussion, refer technical matters for learned consideration to the JMPR, and eventually recommend finalized policies and MRLs which have proceeded through an 8-step process to the CAC for formal adoption. Critical topics discussed at CCPR included dietary intake assessment methodology, trade vulnerabilities posed by the lengthy period for Codex MRL establishment, and prioritization criteria for future evaluations. In addition, MRL recommendations from the 2000 JMPR meeting were discussed as were MRLs from previous CCPR meetings held at intermediate steps in the MRL finalization process.

The current chairman of CCPR, Wim van Eck of the Netherlands Ministry of Health, Welfare, and Sport, announced his departure from this post in conjunction with a transfer to WHO. Dr. van Eck has piloted CCPR since 1991 with unusual aplomb, a wry sense of humor, incredible patience, and an uncanny skill to guide the ungainly committee of 250+ forward in the midst of a variety of technical and policy matters which range from the highly technical to the highly contentious to the highly mundane (read: dry as dust!). Other long-time committee members and experts who bid adieu to CCPR this year included the indomitable Dr. Renate Hans of Germany, the irrepressible Mr. Alan Hill of the UK, and wise old owl Dr. John Herrman of the JMPR/WHO Joint Secretariat. In addition to the frequent interventions of delegations from the EC, Australia, USA, France, Germany, Japan, and Morocco, opinions aplenty were also forthcoming from the representative of the manufacturers (CropLife International) and the self-appointed committee conscience, Consumers International. As might be anticipated, these latter two delegations found little common ground with CropLife International anxious to see reasonable and pragmatic progress in promulgation of MRLs and Consumers International most concerned that the precautionary principle be observed with every action.

Final Report and Committee Working Documents

The meeting agenda and working documents are available at the CCPR web site link below, and the final report should also be released in upcoming weeks.

http://www.codexalimentarius.net/ccpr34/pr02_01e.htm

Referrals from Codex and JMPR

One of the first agenda items concerned matters referred to CCPR by either the CAC or the JMPR. It was noted that a comprehensive review of the standard setting and technical evaluation processes employed by all Codex-sponsored bodies, including that of CCPR and JMPR, was being initiated. It has been recognized that the entire Codex system is at the breaking point of

sustainability based on the ability and willingness of Codex member countries to continue to participate and direct resources to the many policy-making committees and technical evaluation groups. The report of an independent panel of experts will be available for discussion at the Jul-2003 meeting of CAC, which could yield recommendations for changes (or further study!) that might affect also the pesticide MRL establishment process. Included in the ongoing review will be an overall consideration of harmonized approaches toward food standards establishment and the associated risk analysis and management aspect across all Codex bodies.

Several general considerations from the 2001 JMPR were briefly discussed. WHO will be developing a guidance document on acute reference dose (ARfD) establishment. A pilot program for sharing of chemical reviews from national regulatory authorities with the JMPR will be advanced in the future. The JMPR also noted impending availability of a new guidance document (FAO Plant Production and Protection Paper 170) on the submission and evaluation of pesticide residues data for the estimation of MRLs in food and feed. The Consumers International delegation objected to the continued use of human volunteer data by JMPR in estimation of toxicological endpoints (ADI, ARfD) since no benefit is gained by volunteers in these studies and the only purpose they serve is to allow more refined (i.e., lower) estimates of dietary intake to benefit chemical company sales. Dr. John Herrman, JMPR/WHO Joint Secretary, indicated that detailed discussion regarding use of human studies had already occurred at the 1999 JMPR and, although the issue would continue to be discussed periodically, there was no need for further action at this time.

Protection of Infants and Children

The 2000 CCPR had debated the need for default MRLs for processed commodities (e.g., infant formula and cereals) and concluded that no such initiative was warranted since children were already well-protected by the current MRL-setting process. Instead, the CCPR had recommended that food preparation methods be generally practiced for such dietary items which would best serve to minimize pesticide residue carryover. The CCPR recommendation to the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) for adoption of such language had been debated and supported with one additional amendment. The Consumers International delegation again requested that CCPR give further consideration of special MRLs for such commodities, but the Committee decided that such fruitless reconsideration was inimical to progress in the work of MRL setting. The Committee made special note of the continued position of CCPR that existing MRLs for agricultural commodities are already protective of consumption of processed products by infants and children. The Committee also recommended acceptance of a slightly modified version of the food preparation amendment recommended by CCNFSDU.

Acute Dietary Intake Assessment

For the past couple of years, JMPR has undertaken to establish ARfDs and conduct acute dietary intake assessments on a commodity-by-commodity basis using a simple, deterministic calculation (i.e., assumes intake of one "hot" commodity at the highest observed field residue value multiplied by an uncertainty factor of 7-10, plus additional intake of that commodity at the maximum or average field residue value). As opposed to the long-term dietary intake assessment, which infrequently is observed to exceed the ADI, the short-term intake calculations are resulting in a significant number of cautions to be raised which are blocking advancements of MRLs for approximately one-half of the pesticides examined. Dr. Jerry Moy of WHO shared example calculations for the OP insecticide disulfoton, and also highlighted his reliance for large portion size estimates on the data matrix he has constructed to reflect the highest intake for each commodity at the 97.5 percentile reported from any single country. He reported that the delegation of South Africa had just supplied data which would increase the highest maize grain intake by some 25-fold. The delegation from India also indicated that 97.5 percentile consumption data would be forthcoming for the Indian diet. Based on the new data from South Africa, the Committee agreed with the suggestion of Dr. Moy that all past short-term intake assessments for maize be recalculated.

The topic of probabilistic acute dietary intake assessment was then discussed based on the paper prepared by the USA in cooperation with Netherlands, Australia, CropLife International, and Consumer's International. The paper presented by the USA highlighted the probabilistic assessment methodology employed by the U.S. EPA and, while emphasizing the refined nature of such an approach in providing the most accurate reflection of the likelihood of any particular exposure across all crop commodities, also reflected its data-intensive nature. Although a few delegations (e.g., Canada, Netherlands, UK) were enthusiastic about the investigation of such methodology at the international level, the majority of delegations (e.g., France, Germany, Japan, Consumers International) were much more pessimistic about the utility of such an approach in light of the scarcity of data distributions at the international level on large-portion size consumption and limited JMPR technical resources. Germany also indicated that significant policy decisions would also be required in addition to the technical advances, and cited the selection of reference level (e.g., 99.9% or 99.99% intake) as a particularly thorny issue. Based on the interest but lack of firm support, the Committee decided to refer the matter to JMPR for a technical opinion and also to await the outcome of the general evaluation of risk assessment approaches planned as part of the ongoing CAC review process.

Regarding refinement of the currently employed methodology for acute dietary intake assessment, an IUPAC project on acute dietary intake assessment was also noted as nearing completion http://www.iupac.org/projects/1999/1999-009-1-600.html. The Committee agreed to consider advancements in acute dietary assessment calculations, and appointed the Netherlands to work with IUPAC and several other delegations to bring specific discussions forward for the 2003 CCPR meeting.

Cumulative Dietary Intake Assessment

At earlier meetings of CCPR the Committee had expressed an intention in the future to take into consideration the cumulative dietary intake for pesticides which share a common mechanism of toxicity. The USA delegation presented a paper which outlined the current approach being pioneered by the U.S. EPA with the OP class of insecticides. The USA delegation noted the very preliminary nature of methods for such an assessment, but projected finalization of a first example by mid-2002. A few delegations (e.g., Germany, Netherlands, Consumers International) noted the importance and desirability of including such considerations at the international level, but there were considerable reservations expressed for such an approach based on the complexity and data-rich nature of such methodology. Several delegations (Netherlands, USA, IUPAC) also noted the prerequisite of development of a probabilistic methodology before such cumulative intake assessments could be considered. The Committee agreed that, given the immature nature of cumulative assessment approaches at even the national level, it was too early for CCPR to undertake any actions related to cumulative dietary intake assessment.

Criteria for Prioritization and Tentative JMPR Schedule

The criteria employed by CCPR in prioritizing new chemical evaluations and periodic reevaluations of existing chemicals were debated based on presentation of a paper by the Australian delegation. The need for prioritization is driven by overcapacity of the JMPR in handling a significant backlog of technical evaluation requests. As a general principle, the Committee agreed to maintain an approximate 50:50 ratio of new vs. existing chemical evaluations. With the assumption that candidate products must give rise to residues in food commodities moving in international trade and which may give rise to public health concerns and/or impediments to trade, CCPR agreed once again that when establishing priorities, preference be given to those chemicals:

- the intake and/or toxicity profile of which indicate a high level of public concern
- that are new and safer with a potential to replace existing chemicals that present a public health concern (e.g., “safer” or “reduced risk” pesticide)
- on which national reviews are available
- that may be responsible for actual or potential losses owing to trade disruption

A few delegations (e.g., USA, Consumer's International) were supportive of making the "safer" or "reduced risk" pesticide prioritization criterion broader in scope than just public health (e.g., reduced environmental impacts, safer for applicators, replacement of ozone depleters such as MeBr). The Committee agreed that such factors could be taken into account in prioritization, but that they were secondary to public health considerations and likely already being taken into account by national delegations nominating "reduced risk" pesticides for CCPR prioritization.

The Australian delegation also presented the report of the Ad Hoc Working Group on the Establishment of Codex Priority Lists of Pesticides, which had met just prior to the CCPR. The report was accepted with several modifications related to agenda items which had arisen during the week-long CCPR meeting. Of particular interest are the new chemical evaluations scheduled for future JMPR meetings, and these are summarized below with respect to toxicological (T) and residue chemistry (R) evaluations:

- 2002 JMPR: esfenvalerate (T,R), flutolanil (T,R), imidacloprid (R)
- 2003 JMPR: cyprodinil (T,R), famoxadone (T,R), methoxyfenozide (T,R), pyraclostrobin (T,R)
- 2004 JMPR: fludioxinil (T,R), zeta-/alpha-cypermethrin (T,R), trifloxystrobin (T,R)
- 2005 JMPR: dimethenamid-P (T,R), fenhexamid (T,R), indoxacarb (T,R), novaluron (T,R)

Accelerating the Codex MRL Process

The meeting enjoyed considerable discussion regarding a reports focused on ideas for refinement and acceleration of the Codex MRL process. Unfortunately, few practical steps were agreed upon by the Committee, and a move toward acceleration appears likely to proceed at an agonizingly slow pace. The bulk of discussion centered around a paper introduced by the USA delegation (and co-authored by 8 other delegations) which focused on options to solve the "window of vulnerability" in trade resulting from the extensive time required to establish Codex MRLs. The process from nomination of a new compound for MRLs and promulgation of those MRLs may take from 4 to 8 or more years, and many farmers are experiencing difficulties for use of such new compounds related to the potential trade barriers resulting from the lengthy delay between receipt of national approvals and Codex MRLs. The discussion paper highlighted 8 practical suggestions for solving the problem which ranged from simple, no-cost administrative changes (e.g., hold JMPR meeting 3 months earlier so that first CCPR discussion can occur the next year) to extensive and costly overhauls of the program (e.g., replace the volunteer JMPR with a full-time staff of technical evaluators). Savings of from 1-6 years in the process were projected. An idea that attracted much discussion was the establishment of "interim Codex MRLs" based on early adoption of the JMPR evaluations or reference to national evaluations and MRLs. Although a number of delegations (e.g., Australia, Canada, Israel, Netherlands, USA, CropLife International, IUPAC) supported serious consideration of such options, other delegations

(e.g., Belgium, EC, Japan, Consumers International) were concerned about the need for caution and additional procedural safeguards. The only points of consensus which emerged included 1) the preparation of yet another paper by the USA (with other delegations assisting) for further discussion at the 2003 CCPR meeting about interim MRLs, procedures, and safeguards, and 2) CCPR to review MRL proposals at Step 3 the year following the JMPR meeting (instead of automatically postponing by another year).

MRLs for Minor Crops

A paper prepared by the Spice Trade Association (and introduced by South Africa) which highlighted the problem of MRLs for dried spices was also the basis of discussion. Many of the products in question come from small farms in developing countries where adequate description of GAP and supervised field residue trials are lacking. Given the generally limited dietary intake of such commodities, it was proposed to base Codex MRLs and EMRLs on available monitoring data as long as several criteria were met (e.g., per capita consumption <0.5% of regional diets, spice involved in substantial trade, ongoing residue monitoring data is available from the producing country). With the support of most delegations (EC generally having the most caveats), the Committee agreed to ask JMPR to establish guidance on submission of monitoring data and also to have South Africa prepare a paper for discussion at the 2003 CCPR providing a definition and listing of candidate spices. The Committee noted that current considerations be restricted to spices and not include tea, fresh herbs, or tropical fruits (minor crops with similar MRL problems as spices). Future discussion on these leftover points is anticipated in the future, and a recently initiated IUPAC project dealing with international chemistry and regulatory aspects for minor crops should also provide additional guidance http://www.iupac.org/projects/2001/2001-039-1-600.html.

OPs and Carbamates

Some of the more acutely toxic organophosphorus (OP) and carbamate insecticides were the subject of CCPR discussions and actions. Due to implementation of the periodic reevaluation process and acute dietary intake assessment, a number of Codex MRLs for these insecticides are being put on hold or being revoked based on inadequate numbers of residue trials at GAP (especially for minor crops) as well as short-term intake concerns. Compounds for which most or all MRLs are being revoked included bendiocarb, fenitrothion, fenthion, mebarbam, mevinphos, monocrotophos, parathion, and phosphamidon. Compounds for which a significant number of MRLs are being stalled or revoked included aldicarb, carbofuran, diazinon, dimethoate, methamidaphos, methomyl, parathion-methyl, phosalone, and phosmet.

Extraneous MRLs

In addition to MRLs based on approved uses, CCPR has also established EMRLs for compounds no longer used but for which inadvertent contamination of food commodities may occur. There are a number of EMRLs for DDT (21) which exist, and the 1996 JMPR had recommended revised values for mammal meat and poultry products based on available monitoring data and projected frequency of non-compliance rates for commodity shipments. The CAC had considered revised (decreased!) EMRLs for meat during 2001 based on a CCPR proposal, but could not reach consensus on a decision. The Committee agreed to indefinitely shelve the revised meat MRL proposal for DDT, but would in the future determine availability of new monitoring data to support future discussions. A proposed poultry meat MRL was advanced to Step 5, however, for future consideration. The 1996 JMPR had concluded no dietary intake concerns would result from the existing or revised EMRLs. Although the Canada delegation indicated that a national intake assessment had flagged short-term intake concerns for children, the Netherlands delegation reported that short-term dietary intake was estimated at 14% of the ARfD for children based on a recent assessment (note: Canada tends to adopt additional uncertainty factors based on endocrine-disruption concerns).

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