codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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DISCUSSION PAPER ON THE TRADE VULNERABILITIES ARISING FROM THE CODEX MRLS ESTABLISHMENT PROCESS

OPTIONS TO SOLVE THE WINDOW OF VULNERABILITY IN TRADE RESULTING FROM THE EXTENSIVE TIME REQUIRED TO ESTABLISH A CODEX MRL

Transmitted by the United States of America [1]

Background

The Codex Committee on Pesticide Residues (CCPR) at its 33rd Session (The Hague, The Netherlands, April 2001) deliberated a matter referred from the CCNASWP concerning trade vulnerabilities resulting from the lengthy Codex MRL process (Agenda Item 3, CRD 3). New pesticides, some being safer replacements for old pesticides with potential health risks, are registered on a continuing basis by national authorities. After a national registration is obtained, the pesticide sponsor, typically the manufacturer, may petition CCPR through a national Delegation to consider the establishment of MRLs for the new pesticide. The process from nomination to promulgation of MRLs takes from 4 to 8 years. During those years, the farmers and exporters are confronted with a dilemma. The pesticide may be used in accordance with the national labels (registrations) on crops for domestic production. However, it cannot be used on those crops intended for export to countries that rely upon the Codex MRLs for pesticide residue enforcement. The growers must risk rejection of their exports**,** use older pesticides that sometimes are less effective and/or more dangerous for the consumer from a health perspective, or pursue national import tolerances for the countries of interest. For the last option, not all countries have established import tolerance procedures, and such bilateral approaches require wasteful replication of effort in the preparation and review of the data packages.

This situation is more than an inconvenience to the growers and exporters. It strikes at the relevance of the Codex process. The Codex system for pesticide residues in food/feed is charged with the responsibilities of

[1] Prepared by the USA with assistance of Australia, Brazil, Canada, Chile, New Zealand, South Africa, European Community and CropLife International.

protecting human health and facilitating international trade in food and feed items. In a world of rapidly expanding international trade it is unreasonable and impractical to utilize a system that takes 4 to 8 years to establish the standards for a pesticide residue in internationally traded commodities. The lack of standards might cast the protection of human health into doubt and is counterproductive to trade. The Codex system must either modify its operations or risk losing its usefulness in the 21st century. If CCPR and the Codex Alimentarius Commission do not act to remedy the problem, national governments will seek remedy through bilateral arrangements and through existing or newly created regional and international organizations. On the other hand, action by CCPR to eliminate the window of trade vulnerability will encourage nations to utilize the Codex MRLs (CXLs).

The Meeting at its thirty-third session thoughtfully considered the issue and agreed that there is a problem, and requested the USA to chair a drafting group (Australia, Brazil, Canada, Chile, New Zealand, South Africa, European Community, and CropLife International) charged with exploring the problem and proposing solutions.

CURRENT PROCESS

The MRL standard creation process is a series of discrete sequential steps. The sponsor nominates the pesticide through a national delegation to the CCPR. The nomination includes certain specific information on the compound, including existing national MRLs. The Priorities Working Group of CCPR reviews the nomination and schedules the submission for review by the Joint Meeting on Pesticide Residues (JMPR), subject to the approval of the CCPR. The sponsor submits the complete toxicology and residue chemistry data packages to the WHO and FAO, respectively, with designated deadlines prior to the scheduled JMPR Meeting. The submissions are reviewed by the JMPR and recommendations are made in the JMPR Report. The JMPR Report recommendations are taken up at the CCPR meeting about 1.5 years after the JMPR, thereby affording member governments and other interested parties adequate time to review the findings. The CCPR may fast track MRL recommendations, sending the recommendation to the next Codex Alimentarius Commission (CAC) session for action, or using the conventional stepwise consideration which returns the proposed MRL to the CCPR in a future session. The CAC may meet in the same year as the CCPR or one year later. The CAC establishes the formal MRL (CXL).

This stepwise process through groups that meet only once per year has an inherent element that requires 4 years minimum to process an MRL request. A pesticide nominated in 2001 could theoretically be scheduled for JMPR review in 2002, provided the sponsor could rapidly submit all data packages to the WHO and FAO. (Given the logistics of assembling data packages and reviewing the material, the pesticide would most likely be scheduled for 2003.) The recommendations from the 2002 JMPR would be taken up by the 2004 CCPR. If agreeable to the CCPR, the proposed MRLs could be fast-tracked to the CAC in 2005. Under current procedures, the CAC would not meet in 2004. Thus, four years elapsed. Spinosad is a typical example. It was nominated to the CCPR in 1998 and scheduled for review by the JMPR in 2001 (toxicology and residue chemistry). The JMPR Report will be considered by the CCPR in 2003, and the CCPR could advance the proposed MRLs to the CAC in 2003. About five years will have elapsed.

The time gaps occur between nomination and JMPR review (1.4 - 4 years, a reflection of the workload of the JMPR and the time for sponsors to submit the data packages), between JMPR review and CCPR consideration (1.5 years, system requirement, but see Option 5 below), and between CCPR consideration and CAC action (1 year if the CAC does not meet, <0.5 year if the CAC meets).

The sequence of events and the associated time element may be summarized as follows:

Event	Interval Between Events (years)	Cumulative Time (years)
Nomination/Scheduling	0	0
JMPR Review	1.4 – 4	1.4 – 4
CCPR Consideration	1.5	3 – 5.5
CCPR Additional	1 - 2	3 – 5.5 fast track

Consideration (Step 5/6)		4 – 7.5 normal procedure
CAC Decision	0.5 – 1	3.5 – 6.5 fast track 4.5 - 8.5 normal procedure

CONSIDERATIONS

In response to the recognition of the problem by the 33rd Session of the CCPR and its request for possible solutions, a comprehensive list of options has been prepared. Options to reduce the time to promulgate new Codex MRLs generally fall into two categories: (1) changes that can be implemented with little additional resources, and (2) modifications that require substantial additional resources. Those in category one generally involve changing the timing of events or accelerating MRL Steps on a temporary basis, while those in category 2 infuse resources into the current or modified process. Elements of various options may be combined for maximum effect.

CATEGORY 1: CHANGES REQUIRING MINIMAL NEW RESOURCES

Option 1: National Government MRLs Become Interim Time-Limited Codex MRLs Pending JMPR Review

A national government would petition CCPR to recommend the establishment of interim MRLs for a new pesticide, i.e., a material not generally recognized as previously used in the agricultural industry. An interim MRL is defined as a time-limited MRL pending review of the data base by the JMPR. The pesticide would be introduced by the national government at CCPR and could be designated an interim MRL at the next annual CCPR Meeting. Upon introduction by the national government to CCPR , the pesticide nomination would be forwarded to the Priorities Working Group for scheduling for review by the JMPR. The pesticide MRLs would remain interim MRLs for no more than 4 years, during which interval the toxicology and chemistry data bases would be reviewed by the JMPR. During this interval the "List of Maximum Residue Limits for Pesticides in Food and Animal Feeds (At Various Steps of the Codex Procedure)" would have each interim MRL tagged (footnote) with its expiration date. Failing data review and/or appropriate recommendations by the JMPR within the four year period, the interim MRLs would be revoked**.** Upon introduction at Step 3 as a referral from the JMPR, the interim designation would be replaced by the Step 3 designation.

Before nomination, the subject national government would need to have ascertained acceptable dietary risk through both chronic and acute dietary risk analyses and would need to have MRLs in place for the pesticide. Upon nomination, the national government must supply dietary risk calculations for each of the regional diets based on the procedures of the JMPR, and make available to CCPR members the data base necessary for independent analyses. The national government would also be required to supply information on the probable extent of international trade of the treated commodities. At the time of nomination to CCPR, the sponsor (manufacturer(s)) would need to commit to supply to the JMPR Secretariat the complete toxicology and residue chemistry studies, and the national government would need to supply their detailed reviews of the residue chemistry, toxicology, and dietary intake considerations**.** The Secretariat would confirm to CCPR the sufficiency of the data base and the conclusions on dietary risk. The Secretariat would not be validating the accuracy of the report, but rather the completeness of the submission under current WHO/FAO data requirements.

Nomination at CCPR would be followed by consideration at the next CCPR, where any member nation could oppose establishment of the Interim MRL, based on an analysis of the scientific data base, including human dietary acute and chronic exposure concerns. The interim MRL would be approved by this CCPR meeting and subsequently by the CAC, and would automatically expire 4 years after acceptance by the CAC. The intervening period would provide the opportunity for JMPR to review the data and to make recommendations to the CCPR. The interim MRL would automatically be replaced by a Step 3 MRL upon favorable recommendation from the JMPR. If an unfavorable recommendation is issued by JMPR or if the four year period expires with no JMPR action, the interim MRL will be revoked.

Interim MRLs for a new pesticide could be established within one to two years of the national registration. The status of the interim MRL before the WTO would need to be defined/established.

Resources to conduct toxicology and residue chemistry reviews are not equally distributed among national governments. Governments might not be willing to accept data reviews and risk assessments of some countries on even an interim basis. The nominations of some national governments/sponsors might lack the robust data base needed by JMPR to estimate maximum residue levels, acute reference doses, and acceptable daily intakes.

The nomination presented by one country might adversely impact another country where a different national MRL has been adopted based on its field trial data. Also, the manufacturers may have significant data not made available to the nominating country.

The JMPR has not conducted a review of the science upon which the interim MRLs and dietary risk are based. The CCPR has effectively acted as both risk assessor and manager on a temporary basis.

Option 2: Recommendations of the JMPR Become Interim MRLs Pending CCPR Review

The pesticide would advance to the JMPR in the existing procedure, and the JMPR would conduct the review according to its established guidelines. Its recommendations for maximum residue levels would, upon publication in Annex 1 of the JMPR Report, become interim MRLs. Such interim MRLs would be clearly distinguished in Annex 1 by appropriate footnotes**.** Such MRLs could not be established for those commodities where the JMPR calculations show a potential acute and/or chronic dietary risk in one or more of the regional diets.

Interim MRLs would exist for no more than 1-2 years**,** being replaced by Step 3 MRLs**.**

The JMPR interim MRLs could be established within 1.4 - 4 years of nomination, given the historical backlog of the JMPR. This time could be reduced by additional actions (See Options 5 and 7), making interim MRLs available within 2 years of nomination.

The JMPR interim MRL would be based on a complete review of the science by JMPR. The interim MRL would be endorsed by an impartial international group where the science had been carefully reviewed. However, the risk management and decision-making functions of CCPR are circumvented temporarily.

The legal status of these interim MRLs would require definition for the WTO/SPS.

Option 3: Give Priority to New Pesticides

The Priorities Working Group would give priority to new pesticides, especially those new pesticides that are safer, i.e., replacements for existing pesticides with substantial dietary risk implications. Some progress has already been made. The Priorities Working Group recommended, and the CCPR concurred, at the 33rd Session (2001) that the priorities list would be 50% new/50% old pesticides, with the recognition that the ratio may require adjustment from time to time. Thus, at least 50% of the review schedule is reserved for new nominations. Additionally, preference will be given to new and safer pesticides with a potential to replace those with public health concerns. The nominating government would provide a rationale for any safer or reduced risk designation.

An extension of this policy would be to give new pesticide nominations absolute priority, with any vacancies in the schedule being filled with periodic review pesticides.

The waiting period from nomination to review would, with the gradual elimination of backlogs, be reduced to no more than two years. Under the 50/50 procedure, the pesticides nominated in 2001 will be reviewed in 2003 and 2005.

The backlog of periodic review compounds would expand, and their scheduling would be uncertain as the new pesticide nominations would exercise bumping privileges. Existing MRLs would remain intact, whereas a review of the data base might indicate a need to revise or eliminate some MRLs. The periodic review process would be substantially impeded.

Option 4: Revise the JMPR Segment of the MRL-Setting Process

Measures would be implemented to expedite the JMPR review process. This should reduce the time period from nomination to JMPR recommendations.

A. Use national/regional (EU, NAFTA) reviews in the consideration of new pesticides. The complete toxicological and residue chemistry data packages would be available to the reviewers, but the national review would form the basis for deliberations. Reviewers would conduct detailed evaluations only where inspection of the national review generated concerns or where the evaluation requires data more extensive than any one country or regional review would contain. For example, the MRL estimates are based on consideration of the field trials, and no single national or regional review would encompass worldwide data. National hazard assessments for endpoint determinations would be used, but the reference dose and ADI would be independently assessed. Likewise, the dietary risk assessment would be independently judged.

   Use of national reviews might reduce the amount of time required prior to the Meeting for participants to evaluate the submissions. Because national reviews have not used universally standardized formats and because readily available portions may be very summary in nature, they have not been very useful to the JMPR. Perhaps as nations and regional organizations adopt standardized formats and more definitive reviews this option will have merit. Under ideal circumstances, participants ought to be able to review an increased number of pesticides, but under current conditions the use of national reviews tends to elongate the review process.

   Assuming that the JMPR is to remain an independent body that carefully reviews the scientific facts, the time required at the Meeting to consider a pesticide is not dramatically affected by the source of the review. Some increase in the number considered is possible, but a dramatic increase ($\geq$100%) is not predicted unless additional resources are supplied at the meeting.

B. Establish virtual meetings of the JMPR panels prior to the annual session. Preliminary reviews and preliminary decisions could be decided prior to the official session. Major problems could be identified and addressed in advance.

   Issues can be resolved before the Meeting, and draft Evaluations will require less consideration and revision at the formal Meeting. More pesticides can be considered. However, virtual meetings will increase the preparation time for participants. The JMPR experts perform most of the preparation on their own time, not that of the employer, and it is unreasonable to expect additional efforts from them. There will be no additional time to prepare reviews of additional pesticides.

C. Use Work Sharing, whereby JMPR evaluations would be conducted in collaboration with national and regional (EU, NAFTA) authorities. The 2001 JMPR endorsed the concept of Work Sharing and requested the Joint Secretaries of FAO/WHO to explore the proposal. Work sharing is a long-term solution, and the actual increase in efficiency is unknown. The willingness of national or regional authorities to enter into work sharing schemes is unknown. See Option 6.

Option 5: Adjustments to the Timing of the Sequential Steps

The paper considered by the CCPR at the 33rd Session (2001) argued that the slowness of the process cannot be attributed to one element. There are delays at each step, with the net result being a 4 - 8 year time requirement to establish an MRL. Minor adjustments in schedules could yield some improvements in reducing the time needed to establish a pesticide standard.

Under current processes, the JMPR meets in September, and it recommendations are considered 18 months later, with one intervening CCPR Meeting. If the JMPR met in June, its Appraisals and Evaluations could be available by December, and the CCPR could consider the findings in its April meeting. About 0.8 year is removed from the time requirement. This would require increased diligence from WHO/FAO to issue the reports rapidly and from member governments to review the reports in a short time frame. .

The Codex Alimentarius Commision (CAC) and its Executive Committee meet in alternate years. Thus, MRL actions by the CCPR may be delayed for over one year for CCPR meetings in those years with no CAC meeting. The CAC is considering annual meetings, but delayed any decision on this issue until the 25th Session in 2003.

Option 6. Harmonize time of National and Codex submissions

The simultaneous submission to both National Government (s) and the JMPR of the full database (residue chemistry and toxicology) at the time of a pesticide=s proposed entrance into the marketplace would place the JMPR/Codex process on a parallel time path with the National Registration activity. This would require that registrants take an approach that is consistent with the multinational status of the pesticide companies. Under this option, work-share may then be better positioned as an enabling tool for JMPR. Of course the registrants would have to grant permission for sharing between National Governments and JMPR. Under this scenario contemporary national dietary risk assessments would be available for comparison with the JMPR regional dietary risk assessments. It can be envisioned, in many instances, that Codex MRLs would be in place at about the same time as national MRLs go into effect.

CATEGORY 2: CHANGES REQUIRING SIGNIFICANT NEW RESOURCES

*Option 7: **Strengthen** the JMPR Segment of the MRL-Setting Process*

Measures would be implemented to increase the review capacity of the JMPR and/or expedite it's review process. This should reduce the time period from nomination to review to 1or 2 years. Many of these options have been raised in the past but succumbed for lack of resources.

A. Increase the number of meetings of the JMPR from one to two or more per year. Different expert panel members would be used at the two or more meetings. One JMPR session would consider periodic revaluations and additional data for existing or proposed new uses. The other JMPR session(s) would consider only new pesticides.

   Both periodic review and new pesticides would be evaluated at an accelerated pace. The wait from nomination to review should be reduced to no more than one year. The WHO/FAO would need to find additional competent experts, obtain the use of their valuable time from their employers, and insure consistent evaluations between the two or more panels**.**

   Major food/feed trading nations and/or nations with extensive pesticide regulatory structures ought to be willing to provide (additional) experts to conduct reviews and serve on the Panel. Regarding the FAO policy of limiting the number of members from one nation or region, multiple experts from one nation/region could serve as technical consultants or temporary advisors, with the presentations being made through the appropriate Panel member. Alternatively, developed nations might consider funding the training of scientists from developing nations to serve on the JMPR panel.

B. Increase the time span of the annual JMPR meetings from the current two weeks to three or four weeks or more.

   Additional pesticides can be considered, possibly increasing the output.

   Additional preparation time will be required of the participants, many of whom find the current workload stressful. An elongated Meeting will lead to burn-out and will make it more difficult to

attract competent participants**.** Many employers will not be willing to donate experts for such long periods**.**

C. Contract reviews to recognized independent companies or consultants, with the JMPR performing a secondary review function.

Preparation time prior to the Meeting will be reduced, and participants will be able to handle an increased workload. As with the use of national reviews, a significant throughput increase at the Meeting is not predicted unless substantial additional resources are provided**.** A substantial increase in the budget would be required (both for contractors and for additional experts at JMPR), and great care would need to be exercised to insure that the primary review contractor had no conflicts of interest. Contractors acceptable to all members could be difficult to locate.

D. Retain the JMPR panel members as full-time consultants for a fixed period of years, with the concurrence of the permanent employer. As presently structured, the panel members generally conduct their preparations for the Meeting on time donated by the employer and on off-work time, such as weekends and evenings, during the two to four months immediately before the Meeting. The generosity of the employers has varied considerably. As fulltime workers, the experts could prepare an increased number of pesticide cases for consideration at the formal Meeting. Option A would be a critical part of this scheme. The length of the formal Meeting would constrain the number of pesticides that could be considered and funding requirements would be significant**.**

Perhaps national governments could be encouraged to contribute the fulltime consultants by offering an offset of national dues to the United Nations. Also, sponsors (manufacturers) might consider the establishment of a trust fund to pay for consultants.

Option 8: Change the Overall Process

The Codex Alimentarius Commission at its 24th Session (2001) "…requested FAO and WHO to convene a consultation to review the status and procedures of the expert bodies and to develop recommendations for consideration by the Directors-General on additional ways to improve the quality, quantity, and timeliness of scientific advice to the Commission."

The JMPR, acting as a risk assessor body, has been the main source of scientific input to the CCPR. The CCPR has been the risk manager, using the findings of the JMPR and making recommendations for standards to the CAC. Each group meets for two weeks and one week per year, respectively.

An option to increase throughput and reduce the time gap between national MRLs and Codex standards is to eliminate the JMPR and have fulltime staffs within FAO and WHO perform the review and evaluation processes. CCPR would continue to handle preliminary scheduling and to serve as risk manager.

The units within FAO and WHO would be the international equivalent of national regulatory authorities and would provide for the timely review and evaluation of data, the recommendation of MRLs, and the consideration of acute and chronic dietary risks. The resource requirement would be monumental compared to current expenditure levels.

Alternatively, the JMPR could be replaced by regional organizations, such as OECD. The regional organization would perform the review and evaluation processes on a continual basis, receiving priorities from CCPR and reporting to CCPR. However, regional public organizations may be perceived as biased by those nations not members of the organization. Cooperation and acceptance would be issues, and the resource requirement would again be very large.

Dramatic restructuring of the entire process does not seem warranted. Option 8 would replace the JMPR. Secretariat staff reviewer costs would be substantial. The JMPR has consistently performed quality independent scientific reviews with very limited resources. Comparisons of the efficiency of national

regulatory bodies to the tardiness of JMPR are not appropriate. National registration bodies exist 365 days per year, not 2 weeks per year, typically have very much in excess of 20 or 30 individuals, and possess regulatory power. The JMPR should be commended for its dedication and integrity, and resources must be provided to strengthen it.

SUMMARY

The options and their estimated time-saving effect upon the current process are summarized in the following table:

Option Number	Category	Description	Estimated Time for New Pesticide Standard (years)
0	1	Present system	4 - 8
1	1	Interim MRL by CCPR	1 - 2
2	1	Interim MRL by JMPR	2 - 4
3	1	Priority to New Pesticides	3 - 6
4A	1	JMPR Use of National Reviews	4 - 8
4B	1	JMPR Increased Use of Electronic Technology	4 - 8
4C	1	Work Sharing for JMPR	Long term (?)
5	1	Adjust Timing of Process Steps	3 - 6
6	1	Simultaneous submission to both National Government (s) and Codex	1 - 5
7A	2	Two JMPRs per year	2 - 4
7B	2	Increased Meeting Duration of JMPR	3 - 7
7C	2	Contract Primary Review Function. JMPR Secondary.	4 - 8
7D	2	Retain JMPR members fulltime	2 - 4
8	2	Replace JMPR	2 - 4

FURTHER OPTION COMPARISONS/RECOMMENDATIONS

The interim MRL (Option 1) temporarily by-passes the JMPR assessment process, substituting the assessment of a national government or group of governments. It offers the possibility of an MRL within one year of nomination, but the continued existence of the MRL is dependent upon the ability of the JMPR to review the pesticide in a timely manner.

The MRL from the JMPR (Option 2) temporarily by-passes the risk management function of the CCPR and reflects the greater degree of acceptability associated with an independent evaluation of the residue and toxicology data. However, this option is limited by the backlog of the JMPR. Without additional resources for the JMPR, 2 years is the minimal time for obtaining a JMPR MRL. This might be at the expense of periodic and miscellaneous reviews. The equivalent of the JMPR MRL could be achieved in approximately the same time by use of Option 5 (adjust JMPR Meeting time).

Giving absolute priority to new pesticides in scheduling for JMPR review (Option 3) is an extension of the current 50/50 split between new and periodic review. This will, with no other changes in the process, yield the possibility of an MRL within 3 years of nomination. This assumes that the CCPR fast-tracks the recommendation and that the CAC is meeting in the same year as the CCPR. Such a policy will lead ultimately to an extensive backlog of periodic review candidates.

Options 4A, 4B, and 4C without additional resources to the JMPR have little effect upon the length of time required to generate an MRL. Combined with other options, such as option 7, they could have a significant impact.

Option 5, adjusting the timing of the CAC to annual meetings and moving the JMPR to June, has the effect of reducing the MRL promulgation time by 1 or 2 years. This option certainly should be considered as an adjunct to any of the other options.

Option 6, requiring submission of data packages to Codex at the same time as petitioning the National Government(s), places the generation of Codex MRLs on a parallel path with creation of the national MRLs and presents the opportunity for work sharing between the national authority and the JMPR. Theoretically, the Codex MRLs could be advanced at Step 8 to the CAC at about the same time as issuance of the national MRLs. However, the establishment of national MRLs do not necessarily occur simultaneously in all nations or regions, and a parallel process between one or two nations and Codex will undoubtedly fail to reflect the uses in other nations. The work sharing effort would need to be a longterm, multiyear project, as data packages to national governments for new pesticides are submitted segmentally over several years, and reviews may lead to the need for additional data, creating an iterative process. Moreover, national pesticide petitions typically involve initial uses on two or three major commodities, with expansion to other commodities at later dates. Sometimes national registrations never occur, which would result in wasted efforts for Codex **.** Under current rules, a pesticide must have national registrations before it can be nominated for Codex consideration**.** Coordination of activities for a group meeting a few days per year (JMPR) with fulltime national regulatory authorities would be difficult.

The Category 2 options, numbers 7A – 7D and 8, require the acquisition of additional substantial resources and are thus probably less readily implemented. Category 2 consists of increasing the capacity of the JMPR, either through longer meetings, more meetings, or the use of contractors or full-time reviewers, or replacing the JMPR with a regional or international agency. The latter seems extreme and is certainly the most costly. The use of the 7A – 7D options could reduce the MRL promulgation time to 2 years, a period comparable to the interim MRL or JMPR MRL (options 1 and 2, respectively). The 2 year period assumes fast-tracking by the CCPR and a meeting of the CAC in the year of the CCPR action.

The Options are not mutually exclusive, and various combinations can be envisioned.

The combination that will most dramatically reduce the existing time interval is the CCPR-based interim MRL (Option 1) combined with the creation of a second annual JMPR (Option 7A). The interim MRL provides, for the sponsor with the prerequisite information and data, the possibility of an MRL within 2 years or less of the national registration(s). Creating a second JMPR panel with responsibilities for only new compounds provides for a speedy review of the data and thus a minimal life for the interim MRL. An additional panel will also facilitate periodic and miscellaneous reviews by the other panel, thereby relieving the current periodic reevaluation backlog and concomitant maintenance of inappropriate MRLs. Note that with the CCPR-based interim MRL a second JMPR panel is not essential, but the situation of interim MRLs expiring for lack of review by the JMPR can readily be envisioned. Instituting interim MRLs without increasing the capacity of JMPR is not prudent.

The combination of a JMPR-based interim MRL (Option 2) and creation of a second annual JMPR meeting (Option 7A) would also achieve a significant reduction in the time required to achieve a standard. An efficiently operating JMPR group dedicated only to new pesticides should be capable of considering 5 - 8 new pesticides per year. Interim MRLs ought to be available within 2 years of nomination, and the interim MRLs would then advance through the CCPR. For the process to be effective, the second JMPR unit must be implemented. This temporary MRL option has the strong advantage of providing an independent evaluation of the database being used and the default risk management safeguard of not establishing an MRL where exposure may be exceeded in any regional diet.

Other combinations, such as increasing the number of JMPR meetings (Option 7A)/using national reviews (Option 4A)/using virtual meetings (Option 4B)/contracting or retaining panel members fulltime (Options 7C

and 7D) and adjusting the timing of meetings (Option 5) could have a significant effect on the time requirement and would not involve the use of interim MRLs. Under perfect conditions the nomination to CXL status could be less than 4 years.

FURTHER ACTION

The next step is to bring this matter to the attention of the Codex Alimentarius Commission (CAC). It would be appropriate to include CCPR recommendations for possible solutions, as discussed above. As these solutions involve fundamental changes to the Codex process for standard-setting and require additional resources from WHO and FAO, the issue is most properly handled by the CAC.