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Agenda Item 13

CX/PR 05/37/13-Add.1
March 2005

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

Thirty-seventh Session

The Hague, The Netherlands, 18 - 23 April 2005

PILOT PROJECT ON ESTABLISHMENT OF NATIONAL GOVERNMENT MRLS AS CODEX INTERIM MRLS FOR SAFER PESTICIDES: WORKING GROUP ON PRIORITIES PROPOSALS TO THE 2005 CCPR ON INTERIM MRLS FOR BIFENAZATE, FLUDIOXYNIL AND TRIFLOXYSTROBIN AND REVISIONS TO THE INTERIM MRL PROCESS

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A collation of the comments from member states on the pilot project on establishment of national government MRLs as Codex interim MRLs for safer pesticides was distributed to member countries for their information. The next step in the process agreed to at the 2004 CCPR called for the Working Group on Priorities to *analyze* the comments from member countries and the JMPR and prepare a preliminary appraisal of technical issues for consideration at the 2005 CCPR. The 2005 Working Group on Priorities was instructed to address and seek to resolve technical issues and make recommendations to the CCPR on advancement or deletion of proposed interim MRLs. It was also tasked with seeking to resolve issues related to the process and making recommendations on process improvements (ALINORM 04/27/24, paragraphs 220 – 234). CCPR will then decide on the advancement or deletion of the proposed interim MRLs and consider recommendations on the process. The CCPR will decide whether to continue with development of interim MRLs and determine any necessary revisions to the process.

The following is a *draft* analysis and *draft* proposals, for consideration by the Working Group on Priorities (WGP). It is divided into two main sections. First, is an analysis of the comments received on the proposed interim MRLs together with responses from the nominating country, and draft proposed recommendations to the 2005 CCPR for the WGP's consideration. Second, is an analysis of the comments received on the *process*, including a draft proposal on a revised process to be presented to the 2005 CCPR, again for the WGP's consideration. The third and final section discusses next steps.

I. Analysis of Comments on the Proposed Interim MRLs and Draft Recommendations to the CCPR on Advancement or Deletion

Seven member states and the JMPR provided written comments. The member states were Australia, Canada, Iran, Japan, Lithuania, Mexico, and New Zealand. Australia, Canada, and Mexico supported the proposed Codex interim MRLs for all three chemicals based on the finding that the intake values are appropriate and the dietary intake assessments are satisfactory and show low risk. All of the comments are summarized in Attachment I. The United States, as the nominating country, has provided additional technical information in response to these comments. Attachment II, which is a complete copy of JMPR comments, is provided for reference purposes.

Those comments which did not definitively support advancement of the MRLs fell into the following categories:

1. Commenters made general (or specific) comments without explicitly stating if they support or do not support each specific proposed interim MRL.
2. Commenters stated what the corresponding MRLs are in their country and indicated that these should be the interim MRLs (no data were provided to support the suggested values except, in some cases, the ranges of residue values from trials conducted in their country were reported)
3. A proposal that MRLs at or about the Limit of Determination be excluded from the scope of the Interim MRL process
4. A proposal that rejection of interim MRLs can only be on the basis of dietary intake concerns; i.e. objective evidence that the ADI or ARfD is exceeded
5. Technical issues fell into the following categories:
 - a. Questions about storage stability data (that were raised by the information provided in the package)
 - b. Adequacy of some of the field trial data provided in the package
 - c. Extrapolation of the data
 - d. Different interpretation of the residue data included in the package
 - e. Differing residue definitions
 - f. Use of residue data sets other than those provided in the information package

The following are proposed generic responses to these comments. The principles described here were used to determine the specific response to the comments for each interim MRL. These specific responses for each interim MRL are given in Tables 1-3 in Attachment I.

1. The revised process needs to make it explicitly clear what comment is being sought on the proposed interim MRLs. In general, it is not necessary to list the MRLs established in the commentator's country. It is important that the commentator be explicit about supporting or not supporting advancement of each of the proposed interim MRLs.
2. The revised process needs to make it clear that, just as with a standard JMPR review, many countries will have different MRLs established, but the highest proposed JMPR or Interim MRL that is supported by an adequate set of field trial data and that is *demonstrated to be safe*, is generally available for consideration by CCPR to be the selected as the Codex MRL (or interim Codex MRL). Thus, suggestions that a proposed interim MRL be lowered based on lower values in a particular country have not been considered.

However, the revised process should allow for the possibility that a country may need a higher MRL value (than the MRL proposed by the nominating country) to cover the use in their country. This needs to be an "up-front" addition to the process so that the intervening country can provide the required data to the nominating country for inclusion in the detailed information package.

Comments requesting higher interim MRLs at the end of the interim MRL process cannot be dealt with in this expedited (single year) process, because there is no allowance for re-review of the data by member states. Also, such requests must be accompanied by supporting data. Thus, suggestions that the MRL be higher based on higher values in a particular country were not considered due to lack of a process to consider them at this late date and lack of residue data.

3. Propose discussion of the suggestion that MRLs at or about the Limit of Determination be excluded from the scope of the Interim MRL process. As noted by New Zealand, there would seem to be little benefit (from a trade facilitation point-of-view) in proposing such MRLs. However, the proposed interim MRLs that are at the Limit of Determination have been retained in the draft proposal.
4. Propose that the concept behind Australia's proposal that rejection of interim MRLs can only be on the basis of dietary intake concerns; i.e. objective evidence that the ADI or ARfD is exceeded be given prominence in the new process. The key concern must be whether the proposed MRL's are *safe*. It must be recognized that the exact proposal for the interim MRLs will vary depending on the data considered and certain differing technical interpretations, but that this should not matter as long as all participants agree that they had an opportunity for their data to be considered, the MRLs are reasonable from a technical perspective, *and they are safe according to dietary intake calculations performed in accordance with JMPR procedure*.

5. Propose that the nominating country address the specific technical issues that commenters have made on specific proposed interim MRLs. These responses and resulting draft proposals on the interim MRLs will be reviewed by the Working Group on Priorities at their pre-CCPR meeting on April 16, 2004. This group will make the final recommendations to the 2005 CCPR on each interim MRL. Thus, the technical issues listed have been addressed by the United States (as the nominating country) in Attachment I, Tables 1-3, for each proposed MRL.

In addition, the process should make it clear that technical comments cannot reference residue data that have not been included in the detailed information package. Thus, all technical comments that were based on residue data not included in the detailed information packages have not been considered. Comments on the interpretation of the data provided have been considered. The exception to this is recommendations from JMPR. For this pilot process, it is proposed that in those cases where JMPR's recommendations differed from the proposed interim MRLs that the JMPR recommendations be adopted as the interim MRL recommendations. Many of the differences in the JMPR recommendations and the proposed interim MRL recommendations resulted from JMPR's consideration of larger data sets than were considered for the interim MRL process. It should be noted that this exception will not occur in normal practice, because JMPR recommendations and Interim MRL recommendations would not normally be available to the CCPR in the same session.

II. Comments on the Interim MRL Process and Draft Recommendations to the CCPR on a Revised Process

The comments on the process focused mainly on four areas:

1. If different (higher) MRLs than those proposed by the nominating country are to be considered, how will that occur?
2. What data are really necessary for member states to conduct their review?
3. Several commenters noted the data packages were long and not enough time was given for their review
4. How can the process be made efficient, transparent, and clear to all participants?

The following analysis and response incorporates member country comments and some additional comments from the nominating country in this pilot process (the United States), which is very familiar with the logistical and other problems encountered in the pilot process.

1. The revised process should allow for the possibility that a country may need a higher MRL value (than the MRL proposed by the nominating country) to cover the use in their country. This needs to be an "up-front" addition to the process so that the intervening country can provide the required data to the nominating country for inclusion in the detailed information package. Comments requesting higher interim MRLs at the end of the interim MRL process cannot be dealt with in this expedited (single year) process, because there is no allowance for re-review of the data by member states.

The process proposed at the 2004 CCPR called for the nominating country to nominate the highest MRL value currently established and obtain the relevant information from the country where that MRL was established. It was noted at the 2004 CCPR meeting that the manufacturer could help to facilitate this process. This process did not work for a variety of reasons including:

- o In some cases neither the companies nor the nominating country were able to obtain the information;
- o The member state information for fludioxinil was deemed not useful because the EU was in the midst of considering the chemical and the individual member state MRLs would soon be replaced by the EU values, therefore, the detailed information package proposed interim MRLs only for those MRLs proposed by the manufacturer that are supported by MRLs established in the US. In addition some of these MRLs were lower than the ones proposed by the manufacturer, if the US MRL is lower;
- o There were issues with using data supplied only by the company. In one instance, bifenazate on tea, the nominating country had only the data supplied by the company. The nominating country called Japan and confirmed that the information supplied by the manufacturer was

- correct. This confirmation was then passed on to member states in the summary materials included in the detailed information package;
- In one case, trifloxystrobin on barley, the originally envisioned process did work. This interim MRL was proposed based on the MRL established by the EU. The manufacturer provided, for inclusion in the detailed information package, the published document which contained the relevant information.
 - The amount of time and effort, on both the part of the manufacturer and the nominating country, to obtain even this limited amount of success, indicates that this is not a workable process.

It is suggested that the process be changed to address the difficulty in obtaining national government materials from national governments as well as to allow for any possible additions/changes for an approved chemical that member states wish to make after the nomination has been approved (but before the detailed information package goes out to member states for review). The proposed process change includes the following elements. Nominating countries, in conjunction with the manufacturers, will continue to list all of the established MRLs for nominated commodities in the countries where the chemical is registered during the initial nomination of the chemical to the CCPR. However, during the nomination of the chemical to the CCPR, the nominating country will only propose interim MRLs which are established in their country (or established in other countries from which they have *already obtained* the relevant national government information).

After nomination to the CCPR and approval, for a given chemical, other national governments will have two months to supply the nominating country the relevant materials to nominate other uses of the approved chemical for interim MRLs or higher MRLs for commodities already nominated. The nominating government will include these additional (or higher) interim MRL proposals in the detailed information package it sends to all member states for review. This is the only opportunity to add MRLs for an approved chemical or increase the MRL previously nominated for a commodity. No additional MRLs or higher MRLs will be considered at the end of the process (unless it is believed that a higher MRL is justified by the data *included* in the detailed information package).

2. The comments received concerning what data are really needed to conduct the review came from Australia, Canada, and New Zealand. All recommended that less information was needed than was supplied in the Pilot Process. New Zealand essentially said that the information prepared by the nominating country in the Pilot Process was sufficient—implying that the information supplied by the companies was not needed. Australia and Canada suggested that even less information was needed. The nominating country in the pilot process notes that it would be extremely difficult to get scientific reviews prepared specifically for the interim MRL process. Rather it is likely that the original review/decision material prepared for the registration of the chemical in the nominating country will need to be provided for the toxicology and residue chemistry information. This will likely mean that the information required will be supplied in different formats, depending on which country is the nominating country. The following proposal is based on the above comments.

The following information would be necessary (at a minimum):

For the original nomination to the Working Group on Priorities (WGP) and CCPR (except where noted these documents are the product of and are supplied by the nominating country and not the manufacturer):

- The nomination form, which is the same form that is submitted to the Working Group on Priorities in the standard process.
- List of all of the established MRLs for nominated commodities in the countries where the chemical is registered (this may be the product of the manufacturer), together with the proposals for interim MRLs.
- Dietary intake calculations based on the nominating country's ADI or ARfD, the nominated interim MRLs, and the JMPR methodology.
- Justification for qualification as a safer pesticide.

For the member countries wishing to add uses to the original list or support higher MRLs than those in the nominating country (except where noted these documents are the product of and are supplied by the nominating country and not the manufacturer):

- A summary table of the health intake values (ADI or ARfD) used in their country
- A summary of residue trial data (not raw data) and an explanation of how the MRL was determined for the nominated commodities (see below for the type of residue data required)
- Chronic and acute dietary intake assessments performed in their country

For the complete detailed information package sent out for review and comment by member states (except where noted these documents are the product of and are supplied by the nominating country and not the manufacturer):

- Summary of the information contained in the package and where it was obtained; noting, for example, if any additional or higher MRLs had been added by member states since the original nomination to the WGP and approval by the CCPR.
- Summary of the reduced risk justification.
- List of all the established MRLs for nominated commodities in the countries where the chemical is registered (this may be the product of the manufacturer), together with the proposals for interim MRLs.
- A summary table of the calculated dietary intake values from all countries where the chemical has been evaluated (this may be the product of the manufacturer).
- Summary reports of the toxicology (equivalent to OECD Tier II summaries). These summary reports of the toxicology database should also contain “summary” and/or “discussion” sections which explain how the health intake values (ADI and ARfD) were set, document the safety factors used, and comment on whether they are likely to be conservative or not. For example, was the ARfD based on an endpoint in a repeat-dose study because there was no adequate acute study in the toxicological database? Or was the endpoint a critical endpoint from a developmental toxicity study? Discuss whether (a) a LOAEL is used instead of a NOAEL and thus warranted the application of an additional factor and (b) indicate when the endpoint selected originated from a developmental neurotoxicity study or from a study which shows sensitivity of the young.
- Summary reports of the residue chemistry. This would include summary evaluations for plant and animal metabolism, analytical methods (for enforcement), field trials (commodity, GAP, residue values in ranked order), and processing studies (as applicable), and a reasoned definition of residues for dietary intake calculation and for MRL enforcement.
- The nominating national government’s assessment of the data in support of the interim MRLs. This would include the nominating national government’s dietary intake risk assessment and chronic and acute dietary intake assessments per JMPR methodology, using the nominating government’s health intake values and including all nominated commodities for all the regional diets considered by JMPR (FAO/WHO GEMS).
- In the case that other member states supplied additional information, this would also be included with the source clearly marked.

Note: As in the pilot, full reports should be available from the nominating country on request from a member state. In addition, in the case that a member state requests actual study data, the nominating country should work with the manufacturer to try and supply this information.

3. Agreement on a reduced amount of information required in the detailed information packages will help to address the first issue (length of data packages). However, the process needs to be altered and resources need to be committed to ensure that the detailed information packages can be made available to member countries for comment in a reasonable amount of time.

It is proposed that CCPR give clear direction to Codex to provide an interactive web space for the nominating country to post documents and for member states to post responses. FAO/WHO has done this in the past for other purposes, so it would appear that it can be done. In a process as streamlined as the interim MRL process, even small delays in providing materials can result in serious limitations on some member states ability to respond.

4. How can the process be made efficient, transparent, and clear to all participants?

It was clear from many of the comments that the interim MRL process used in the pilot was not as efficient and clear to many member states as it might have been. If CCPR chooses to continue consideration of interim MRLs, then the process needs to be made more efficient and clear. The product of the evaluation of the process by the WGP and CCPR needs to be a complete elaboration of the revised interim MRL process that is understandable and useful to all member states.

The process elaborated in Attachment III is proposed as the revised interim MRL process. In their comments on the pilot interim MRL process, Australia and Canada proposed a revised process. The process elaborated in Attachment III is based on Australia's and Canada's proposal, the comments received from other member states, and input from the nominating country in the pilot process.

Finally, in addition to the areas of concern discussed above, the JMPR noted concern over the definition of "safer"-- whether it refers to less toxic (hazard) or lower residue level (exposure) and whether it is limited to human health or also includes environmental effects. The definition of "new, safer, replacement pesticide" agreed to at previous CCPR meetings has been included in the process elaborated in Attachment III. The JMPR also cautioned that because the interim MRLs are limited to a period of 4 years, pesticides nominated in this process must be reviewed by the JMPR within this period. If there are many nominations for interim MRLs, the currently limited resources of the JMPR might result in the evaluations for some of the pesticides not being completed within the 4 years or other priorities, such as periodic reviews and evaluations, might have to be curtailed. This does not currently appear to be a major problem, however, it will need to be addressed if it becomes one.

III. Next Steps

The 2005 Working Group on Priorities, which will meet on April 16, 2005, has been tasked with addressing and seeking to resolve technical issues and making recommendations to the CCPR on advancement or deletion of proposed interim MRLs and with resolving issues related to the process and making recommendations on process improvements (ALINORM 04/27/24, paragraphs 220 – 234). The Working Group on Priorities may choose to use this *draft* analysis and *draft* recommendations as a starting point for their deliberations.

CCPR will then decide on the proposed interim MRLs and consider recommendations on the process. It will decide whether to continue with development of interim MRLs and determine any necessary revisions to the process.

ATTACHMENT I: ANALYSIS AND RECOMMENDATIONS ON PROPOSED INTERIM MRLS

**Note: Australia, Canada, and Mexico supported the proposed interim MRLs, however, clearly affirmative comments have not been included in Attachment I.*

Table 1: Analysis of the Proposed Interim MRLs for Bifenazate and Recommendations to the CCPR

Commodity	Proposed Interim MRL (mg/kg)	Comment/Objection	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
Interim residue definition for plant commodities: bifenazate + diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) Interim residue definition for livestock commodities: bifenazate + diazinecarboxylic acid, 2-(4-methoxy-[1,1'-biphenyl]-3-yl), 1-methylethyl ester (expressed as bifenazate) + 1,1'-biphenyl-4-ol + 1.1'-biphenyl-4-oxysulfonic acid (expressed as 1.1'-biphenyl-4-ol)					
Apple pomace, wet	2.0	NZ: Storage Stability	Surface residues stable for 224 days frozen. Apple pomace samples stored frozen up to 295 days.		2.0
Cottonseed SO 0691	1.0	NZ: Storage Stability	Field samples analyzed over an interval up to 56 days. Storage stability data showed bifenazate and D3598 unstable at 21 and 56 days (about 50% loss). Trials corrected with a factor of 0.57, which is the average recovery at 56 days. (1) Field samples analyzed in a reasonable interval. (2) Correction made for known lack of stability in arriving at MRL.		1.0
Pome fruits FP 0009	1.0				1.0
Grapes FB 0269	1.0				1.0

Commodity	Proposed Interim MRL (mg/kg)	Comment/Objection	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
Dried grapes (=currants, raisins and sultanas) DF 0269	2.0				2.0
Hops DH 1100	15	NZ: Storage Stability	Samples were stored frozen for up to 157 days. Storage stability was variable in other commodities; stable as a surface residue but unstable in mixed commodities. <i>Dried</i> hops more nearly resemble a surface residue situation.		15
Nectarine FS 0245	2.0				
Tree nuts TN 0085	0.2	NZ: Insufficient number of trials	14 pecan trials, 5 almond trials, more than adequate by any standard (US: 5 almond and 5 pecan). Maximum residues were 0.13 mg/kg on almond nutmeat and 0.02 mg/kg on pecan nutmeat.		0.2
Peach FS 0247	2.0				
Mint top HH 0738	25	NZ: Storage Stability	Samples were stored frozen for up to 98 days. Storage stability data on other commodities were variable, but surface residues were generally stable for over 100 days.		25
Plums FS 0014	0.3	NZ: 0.2, based on data	Seven trials, with residues ranging from 0.01 – 0.15 mg/kg. Either value would be acceptable, but 0.3 mg/kg provides a margin of error. All plum samples were analyzed		0.3

Commodity	Proposed Interim MRL (mg/kg)	Comment/Objection	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
			within the validated (peach) storage interval of 14 days.		
Strawberry FB 0275	2.0	NZ: Storage Stability	Samples were stored frozen for up to 175 days. No storage stability data to validate (metabolite unstable on peach at 14 days; parent and metabolite stable only 7 days in homogenized grapes; 50% loss at 14 days, <i>but stable 224 days as a surface residue- as strawberries were stored</i>).		2.0
Cucumber VC 0424	0.5	NZ: Storage Stability	Samples stored frozen for up to 14 days, which is within the 30 day period that does not require storage stability data.		0.5
Squash VC 0431	0.7	NZ: Storage Stability	Samples stored frozen for no more than 10 days, well within the 30 day period that does not require storage stability data.		0.7
Melons VC 0046	0.3	NZ: Storage stability	Samples stored frozen for no more than 14 days, well within the 30 day period that does not require storage stability data.		0.3
Watermelon VC 0432	0.3	NZ: Extrapolation not supported.	All trials (7) were on cantaloupe. The York Report (Minimum Data Base Requirements) recommends extrapolation of melon to watermelon, etc.		0.3
Pepper VO 0051	2.0	NZ: Storage stability	Samples were stored frozen for up to 16 days, within the 30 day period		2.0

Commodity	Proposed Interim MRL (mg/kg)	Comment/Objection	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
			that does not require storage stability data.		
Chili pepper VO 0444	2.0	NZ: Extrapolation not supported.	6 trials were conducted on bell peppers (max residue 1.3 mg/kg) and 3 trials on chili peppers (max residue 1.6 mg/kg). Adequate.		2.0
Okra VO 0442	2.0	NZ: Extrapolation not supported	Extrapolation from tomato and pepper, US representative commodities for fruiting vegetables. Also, York Report supports the translation of tomato and pepper to okra.		2.0
Tomato VO 0448	1.0	NZ: Storage stability	The samples were stored frozen for up to 14 days, within the 30 day period that does not require storage stability data.		1.0
Eggplant VO 0440	2.0	NZ: Extrapolation not supported.	Extrapolation from tomato and pepper, US representative commodities for fruiting vegetables. Also, York Report supports the translation of tomato and pepper to aubergine.		2.0
Tea DT1114	2.0	NZ: Insufficient number of trials	Based on two trials from Japan (MRL 2). Two trials meet the requirements of the US for tea.		2.0
Meat (from mammals other than marine animals) (fat) MM095	0.1	NZ: No animal feed items (if proposed deletions are approved).	Cottonseed and apple pomace are animal feed items.		0.1
Edible offal,	0.02	NZ: No animal feed items	Cottonseed and apple pomace are		0.01

Commodity	Proposed Interim MRL (mg/kg)	Comment/Objection	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
mammalian MO 0105		(if proposed deletions are approved).	animal feed items.		
Milks ML 0106	0.01	NZ: No animal feed items (if proposed deletions are approved).	Cottonseed and apple pomace are animal feed items.		0.01
Poultry meat PM110	0.01(*)	NZ: Do not propose MRLs at the LOQ No animal feed items (if proposed deletions are approved).	MRLs at the LOQ may not serve a purpose in trade for temporary standards. Cottonseed and apple pomace are animal feed items.		0.01(*)
Poultry, edible offal of 2PO110	0.01 (*)	NZ: Do not propose MRLs at the LOQ. No animal feed items (if proposed deletions are approved).	MRLs at the LOQ may not serve a purpose in trade for temporary standards. Cottonseed and apple pomace are animal feed items.		0.01(*)
Eggs PE112	0.01(*)	NZ: Do not propose MRLs at the LOQ No animal feed items (if proposed deletions are approved).	MRLs at the LOQ may not serve a purpose in trade for temporary standards. Cottonseed and apple pomace are animal feed items.		0.01(*)

Table 2: Analysis of the Proposed Interim MRLs for Fludioxonil and Recommendations to the CCPR

Commodity	Proposed Interim MRL (mg/kg)	JMPR Proposed MRL ¹ (mg/kg)	Comment/Objection ²	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
Interim residue definition for plant commodities: fludioxonil Interim residue definition for animal commodities: Fludioxonil and metabolites determined as 2,2-difluoro-1,3-benzodioxole-4-carboxylic acid, and calculated as fludioxonil. JMPR residue definition: Same						
Stone fruit FS12	5.0	5 (Po)				5 (Po)
Grapes FB269	2.0	2				2
Strawberry FB275	2.0	3				3
Raspberry FB272	5.0	5				5
Blackberry FB264	5.0	5				5
Blueberry FB20	2.0	2				2
Currants FB21	2.0	NONE	JMPR: No GAP available NZ: Extrapolation not supported	Blueberry to currant is an acceptable US extrapolation. The York Report suggested that blueberry and currant are representative for certain other small berry fruits.		NONE
Lychee FI343	1.0	NONE	JMPR: Trials exceeded GAP NZ: Insufficient number of trials	One extra application most likely did not significantly increase residues. Three trials adequate for US, where only 1 is required.		NONE

Commodity	Proposed Interim MRL (mg/kg)	JMPR Proposed MRL ¹ (mg/kg)	Comment/Objection ²	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
Longan FI342	1.0	NONE	JMPR: No data for longan; no extrapolation considered NZ: Insufficient number of trials (lychee); extrapolation not supported.	Extrapolation within US guidelines, if lychee acceptable		NONE
Pulasan FI357	1.0	NONE	JMPR: No data pulasan; no extrapolation considered NZ: Insufficient number of trials (lychee); extrapolation not supported.	Extrapolation within US guidelines, if lychee acceptable		NONE
Rambutan FI358	1.0	NONE	JMPR: No data for rambutan; no extrapolation considered. NZ: Insufficient number of trials (lychee); extrapolation not supported.	Extrapolation within US guidelines, if lychee acceptable		NONE
Spanish lime FI366	1.0	NONE	JMPR: No data for Spanish lime; no extrapolation considered.	Extrapolation within US guidelines, if lychee acceptable		NONE

Commodity	Proposed Interim MRL (mg/kg)	JMPR Proposed MRL ¹ (mg/kg)	Comment/Objection ²	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
			NZ: Insufficient number of trials (lychee); extrapolation not supported.			
Onion, bulb VA385	0.2	0.5				0.5
Cabbages, head VB41	2.0	2				2
Broccoli VB400	2.0	0.7	NZ: 0.7 or 1 mg/kg, based on data	2 is derived from the US tolerance for the brassica group, including cabbage. Data for broccoli only support 0.7. Highest broccoli residue is 0.53 mg/kg		0.7
Potato VR589	0.02(*)	0.02				0.02
Carrot VR577	1.0	0.7				0.7
Watercress VL473	10	10	NZ: Insufficient number of trials	Two trials are adequate for the US (and for JMPR, based on mutual support of mustard greens and watercress).		10
Mustard greens VL485	20	10		Maximum residue 7.1 mg/kg.		10
Herbs (fresh) HH726	10	10 basil HH0722 10	NZ: Extrapolation not supported	Compliant with US representative commodities, but York Report made no		10 basil HH0722 10

Commodity	Proposed Interim MRL (mg/kg)	JMPR Proposed MRL ¹ (mg/kg)	Comment/Objection ²	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
		chive HH0727		recommendations for an herbs crop group		chive HH0727
Herbs (dried) HH726	65	50 basil, dry VD0071 Chive, dry	NZ: Extrapolation not supported	Compliant with US representative commodities, but York Report made no recommendations for an herbs crop group		50 basil, dry VD0071 50 chive, dry (no Codex classification)
Rapeseed SO495	0.01(*)	0.02(*)	NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		0.02(*)
Cottonseed SO691	0.05(*)	0.05(*)	NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		0.05(*)
Sunflower seed SO702	0.01(*)	NONE	JMPR: No data available NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		NONE
Soya SO4723	0.01(*)	NONE	JMPR: No data available NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		NONE
Pistachio TN675	0.1	0.2				0.2
Wheat GC645	0.02(*)	0.05(*) Cereal grains GC80	NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		0.05(*) Cereal Grains GC80

Commodity	Proposed Interim MRL (mg/kg)	JMPR Proposed MRL ¹ (mg/kg)	Comment/Objection ²	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
Rye GC650	0.02(*)		NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		
Spelt GC4673	0.02(*)		NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		
Triticale GC653	0.02(*)		NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		
Barley GC640	0.02(*)		NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		
Oats GC647	0.02(*)		NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		
Maize GC645	0.02(*)		NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		
Popcorn GC656	0.02(*)		NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		

Commodity	Proposed Interim MRL (mg/kg)	JMPR Proposed MRL ¹ (mg/kg)	Comment/Objection ²	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
Sorghum GC651	0.02(*)		NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		
Sweet corn (corn-on-the-cob) VO447	0.02(*)	0.01(*)	NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		0.01(*)
Meat (from mammals other than marine) MM95	0.01(*)	0.01(*)	NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		0.01(*)
Edible offal (mammalian) MO105	0.05(*)	0.05(*)	NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		0.05(*)
Milks ML106	0.01(*)	0.01	NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		0.01
Poultry meat PM110	0.01(*)	0.01(*)	NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		0.01
Poultry, edible offal of PO111	0.05(*)	0.05(*)	NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary standards		0.05(*)
Eggs PE112	0.05(*)	0.05(*)	NZ: Do not propose MRLs at the LOQ	MRLs at the LOQ may not serve a purpose in trade for temporary		0.05(*)

Commodity	Proposed Interim MRL (mg/kg)	JMPR Proposed MRL ¹ (mg/kg)	Comment/Objection ²	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
				standards		

¹ Report of the JMPR(2004), Annex 1.

² See General Items from the Report of the JMPR (2004) for a detailed comparison of Interim MRL estimates and JMPR MRL estimates.

Table 3: Analysis of the Proposed Interim MRLs for Trifloxystrobin and Recommendations to the CCPR

Commodity	Proposed Interim MRL (mg/kg)	JMPR Proposed MRL ¹ (mg/kg)	Comment/Objection ²	Nominating Country Response	Working Group on Priorities Response	Working Group on Priorities Recommended MRL (mg/kg)
<p>Interim residue definition for plant and livestock commodities: trifloxystrobin and the free form of its acid metabolite CGA-321113, calculated as trifloxystrobin.</p> <p>JMPR residue definition for plant commodities: trifloxystrobin (for enforcement); trifloxystrobin and CGA-32113 for dietary intake.</p> <p>JMPR residue definition for plant and animal commodities: trifloxystrobin and the acid metabolite CGA-321113</p> <p>Difference in residue definition for plant commodities for enforcement: Inclusion of metabolite CGA-321113 is reasonable, given that it comprises about 30% of the residue in some plant commodities and that it forms from the parent in many processing operations. It must, as JMPR indicated, be included in dietary intake calculation. On the other hand, monitoring only the parent is adequate for enforcement.</p>						
Pome fruits FP9	1.0	0.7				0.7
Grapes FB269	3.0	3				3
Grapes, dried DF269	5.0	5				5
Barley GC640	0.3	0.5	NZ: 0.5mg/kg, based on data set (see data supplied by the manufacturer: German trial (BRD-2143-99). See page 1326, Table 1, of trifloxystrobin data package).	The highest residue was 0.19 mg/kg among trials recognized by the EC (Table B.7.50, page 1116 of trifloxystrobin data package). Reflects the MRL set by the EU 06/04. JMPR recommended 0.5 mg/kg based on the same data, but did not reject BRD-2143-99.		0.5
Meat (from mammals other than marine) MM95	0.04(*)	0.05 (fat)	NZ: No animal feed commodities. Address issue of fat basis.	Barley is an animal feed item. Feeding study (JMPR) indicated low level in		0.05 (fat)

				fat, no residue in meat. The log Pow 4.5 suggests fat solubility. Difference in values (LOQ vs quantifiable) is attributable to larger feed diet considered by JMPR, versus barley only for Interim. Considering <i>only barley</i> , the MRL would be (*) for meat or fat.	
Edible offal (mammalian) MO105	0.05	0.04(*) kidney MO98 0.05 liver MO99	NZ: No animal feed commodities	Barley is an animal feed item.	0.04(*) kidney MO98 0.05 liver
Milks ML106	0.02(*)	0.02(*)	NZ: No animal feed commodities Do not propose MRLs at the LOQ	Barley is an animal feed item. MRLs at the LOQ may not serve a purpose in trade for temporary standards	0.02(*)
Poultry meat PM110	0.04(*)	0.04(*) (fat)	NZ: No animal feed commodities Do not propose MRLs at the LOQ	Barley is an animal feed item. MRLs at the LOQ may not serve a purpose in trade for temporary standards	0.04(*) (fat)
Poultry, edible offal of PO 111	0.04(*)	0.04 (*)	NZ: No animal feed commodities Do not propose MRLs at the LOQ	Barley is an animal feed item. MRLs at the LOQ may not serve a purpose in	0.04(*)

				trade for temporary standards		
Eggs PE112	0.04(*)	0.04(*)	NZ: No animal feed commodities Do not propose MRLs at the LOQ	Barley is an animal feed item. MRLs at the LOQ may not serve a purpose in trade for temporary standards		0.04(*)

¹ Report of the JMPR(2004), Annex 1.

² See General Items from the Report of the JMPR (2004) for a detailed comparison of Interim MRL estimates and JMPR MRL estimates.

ATTACHMENT II: JMPR COMPARISON OF INTERIM MRL VALUES AND JMPR RECOMMENDATIONS (JMPR REPORT 2004, GENERAL CONSIDERATIONS)

Proposed Interim MRL and Corresponding JMPR Recommended MRLs¹

Commodity	Interim MRL Recommendation (mg/kg)	JMPR MRL Recommendation (mg/kg)	Comment on Difference
<p>Trifloxystrobin Interim Definition: Plant and animal, trifloxystrobin + CGA321113 or (E,E)-Methoxy-imino-{ -2-[1-(3-trifluoromethyl-phenyl)-ethylideneaminooxymethyl]-phenyl}-acetic acid. JMPR Definition: Plant, trifloxystrobin; animal, trifloxystrobin + CGA321113.</p>			
Barley GC640	0.3	0.5	High value from EU = 0.19 mg/kg. EC established 0.3 mg/kg. (Table B.7.49 and Table B.7.50) High value from JMPR = 0.40 mg/kg, based on. trial from Germany 1999.
Grapes FB269	3	3	
Grapes, dried DF269	5	5	
Pome fruit FP9	1	0.7	High value from European Commission, 0.44 mg/kg.
Edible offal (mammalian) MO105	0.05	Kidney MO98, 0.02 Liver MO99, 0.05	Interim, wide scope JMPR, narrow scope
Eggs PE112	0.04*	0.04*	
Meat (mammalian) MM95	0.04*	0.05 (fat)	Interpretation of feeding study. JMPR determined a maximum residue in fat of 0.038 mg/kg; 0.04 mg/kg is the LOQ (0.02 trifloxystrobin + 0.02 metabolite). Trifloxystrobin present in fat (0.05 mg/kg) at a feeding level of 20 ppm is approximately twice the US and JMPR calculated dietary intake of cattle. The 0.04 value is based on <i>one</i> feed item, barley, compared with the much greater intake of the total US and JMPR treated commodities.
Milks ML106	0.02*	0.0008* F	Equivalent, based on 4% fat in whole milk
Poultry, edible offal of	0.04*	0.04*	
Poultry meat	0.04*	0.04 (fat)	Interpretation of feeding study.
<p>Fludioxonil Interim Definition: Plant, fludioxonil. Animal, fludioxonil +metabolites determined as 2,2-difluorobenzo[1,1]dioxole-4-carboxylic acid, calculated as fludioxonil. JMPR Definition: Same</p>			
Herbs (fresh) HH726	10	Basil HH722, 10 Chives HH727, 10	JMPR restricted maximum residue levels to the specific herbs and did not extend them to the entire herbs group.
Herbs (dry) HH726	65	Basil, dry DH722, 50	JMPR considered two trials and a

Commodity	Interim MRL Recommendation (mg/kg)	JMPR MRL Recommendation (mg/kg)	Comment on Difference
		Chives, dry HH727, 50	drying factor of 8, yielding 15 and 24 mg/kg. The Interim approach considered dried basil and dried chives, one trial each, with residues of 23 and 31 mg/kg.
Blackberry FB264	5	5	
Blueberry FB20	2	2	
Broccoli VB400	2	0.7	Same data set (US Interim based on US brassica head and stem subgroup 5A (with higher residues for cabbage).
Cabbages, head VB41	2	2	
Carrot VR577	1	0.7	Same data set. Interim MRL based on US tolerance of 0.75 mg/kg rounded up under JMPR rules; highest residue was 0.46 mg/kg. JMPR reported highest residue 0.42 mg./kg from same data set.
Wheat GC643	0.02*	Cereal grains GC80, 0.05*	Interim based on seed treatments in the US, with an LOQ of 0.02 mg/kg. JMPR based on 71 trials in Europe and US, with LOQs ranging from 0.01 to 0.05 mg/kg.
Rye GC650	0.02*		
Spelt GC4673	0.02*		
Triticale GC653	0.02*		
Barley GC640	0.02*		
Oats GC647	0.02*		
Maize GC645	0.02*		
Popcorn GC656	0.02*		
Sorghum GC651	0.02*		
Cottonseed SO691	0.05*	0.05*	
Currants FB21	2		Interim based on translation of blueberry field trials (<0.05-1.4 mg/kg) to the US bushberry subgroup 13B. JMPR does not make this translation.
Grapes FB269	2	2	
Longan FI342	1	None	Based on lychee.
Lychee FI343	1	None	Same data (US). JMPR considered the three trials to be in excess of GAP.
Mustard greens VL485	20	10	Same data set. Interim maximum residue reported as 7.7 mg/kg;

Commodity	Interim MRL Recommendation (mg/kg)	JMPR MRL Recommendation (mg/kg)	Comment on Difference
			JMPR maximum residue reported as 7.1 mg/kg.
Onion VA385	0.2	0.5	Interim based on US data only with a maximum value of 0.11 mg/kg (0.06 mg/kg average for high field trial). JMPR included European data with a maximum value of 0.34 mg/kg
Pistachio TN675	0.1	0.2	Same data set (US). Although highest residue 0.08 mg/kg, JMPR estimated 0.2 mg/kg based on the small size of the set (n=3).
Potato VR589	0.02*	0.02	
Pulasan FI357	1	None	Based on lychee.
Rambutan FI358	1	None	Based on lychee.
Rapeseed SO495	0.01*	0.02*	Interim based on translation of other seed treatment data (wheat) with an LOQ of 0.01 mg/kg. JMPR based on 15 trials in Europe with an LOQ of 0.02 mg/kg.
Raspberry FB272	5	5	
Soya SO4723	0.01*	None	JMPR received no data. Interim based on seed treatment use and translation of data from wheat, lettuce, pea, cucumber, and radish (all below LOQ).
Spanish lime FI366	1	None	Based on lychee.
Stone fruit FS12	5	5	
Strawberry FB275	2	3	Interim based on US data only, with maximum value of 1.3 mg/kg. JMPR included European data, with maximum of 1.9 mg/kg.
Sweet corn (corn-on-the-cob) VO447	0.02*	0.01*	Interim based on LOQ for the cereal grain group. Codex does not consider sweet corn in the cereal grain group and evaluated data separately..
Watercress VL473	10	10	
Meat (from mammals other than marine) MM95	0.01*	0.01*	
Edible offal (mammalian) MO105	0.05*	0.05	
Milks ML106	0.01*	0.01	
Poultry meat PM110	0.01*	0.01*	

Commodity	Interim MRL Recommendation (mg/kg)	JMPR MRL Recommendation (mg/kg)	Comment on Difference
Poultry, edible offal of PO111	0.05*	0.05*	
Eggs PE112	0.05*	0.05*	

LOQ, limit of quantification; GAP, good agricultural practice.

¹ Reproduced from General Consideration 2.5 of the *2004 Report of the JMPR*

ATTACHMENT III: PROPOSED REVISED INTERIM MRL PROCESS (2005 CCPR)

Action 1. The proposed chemicals and associated Interim MRLs must be nominated to the Chair, Ad Hoc Working Group on Priorities (WGP) by February 1st, for consideration at the next WGP meeting. The chemical must already be scheduled for review by the JMPR or be nominated simultaneously for consideration by the WGP. The nomination package should include (except where noted these documents are the product of and are supplied by the nominating country and not the manufacturer):

- The nomination form, which is the same as the one submitted to the WGP in the standard process. The nominating country will only propose interim MRLs which are established in their country (or established in other countries from which they have *already obtained* the relevant national government information).
- List of all of the established MRLs for nominated commodities in the countries where the chemical is registered (this may be the product of the manufacturer), together with the proposals for interim MRLs.
- Dietary intake calculations based on the nominating country's ADI or ARfD, the nominated interim MRLs, and the JMPR methodology.
- Justification for qualification as a new, safer, replacement pesticideⁱ

Action 2. If the WGP (at its annual pre-CCPR meeting) agrees that the criterion for a new, safer, replacement pesticide is satisfied, then the nominations for Interim MRLs are to proceed to the CCPR for final decision.

Action 3. CCPR consideration and decision. CCPR may either decide to include the chemical on a list for consideration of interim MRLs at the next session or may decide to reject the chemical from further consideration in the Interim MRL Process.

Action 4. After the initial nomination process to the CCPR for a given chemical, and upon CCPR agreement, other national governments will have two months, until June 30, to supply the nominating country the relevant materials to nominate other uses of the approved chemical for interim MRLs or higher MRLs for commodities already nominated. Member countries wishing to add uses to the original list or support higher MRLs than those in the nominating country, should supply the nominating country with the following information, at a minimum (except where noted these documents are the product of and are supplied by the nominating country and not the manufacturer):

- A summary table of the health intake values (ADI and ARfD) used in their country
- A summary of residue trial data (not raw data) and an explanation of how the MRL was determined for the nominated commodities (see residue data requirements under Action 5 below)
- Chronic and acute dietary intake risk assessments performed in their country

Action 5. The nominating government would then include these additional (or higher) interim MRL proposals in the detailed information package it sends to all member states for review. The detailed information packages would be provided to the Codex Secretariat for posting on the webⁱⁱ no later than August 1. The packages would be posted on the web no later than September 1. The complete detailed information package sent out for review and comment will include, at a minimum (except where noted these documents are the product of and are supplied by the nominating country and not the manufacturer):

- Summary of the information contained in the package and where it was obtained; noting, for example, if any additional or higher MRLs have been added by member states since the original nomination to the WGP and approval by CCPR.
- Summary of the reduced risk justification.
- List of all of the established MRLs for nominated commodities in the countries where the chemical is registered (this may be a product of the manufacturer), together with the proposals for interim MRLs.
- A summary table of the calculated dietary intake values from all countries where the chemical has been evaluated (this may be the product of the manufacturer).

- Summary reports of the toxicology (equivalent to OECD Tier II summaries). These summary reports of the toxicology database should also contain “summary” and/or “discussion” sections which explain how the health intake values (ADI and ARfD) were set, document the safety factors used, and comment on whether they are likely to be conservative or not. For example, was the ARfD based on an endpoint in a repeat-dose study because there was no adequate acute study in the toxicological database? Or was the endpoint a critical endpoint from a developmental toxicity study? Discuss whether (a) a LOAEL is used instead of a NOAEL and thus warranted the application of an additional factor and (b) indicate when the endpoint selected originated from a developmental neurotoxicity study or from a study which shows sensitivity of the young. .
- Summary reports of the residue chemistry. This would include summary evaluations for plant and animal metabolism, analytical methods (for enforcement), field trials (commodity, GAP, residue values in ranked order), and processing studies (as applicable), and a reasoned definition of residues for dietary intake calculation and for MRL enforcement.
- The nominating national government’s assessment of the data in support of the interim MRLs. This would include the nominating national government’s dietary intake risk assessment and chronic and acute dietary intake assessments per JMPR methodology, using the nominating government’s health intake values and including all nominated commodities for all the regional diets considered by JMPR (FAO/WHO GEMS).
- In the case that other member states supplied additional information (as noted in Action 4 above) this would also be included with the source clearly marked.

Note: Full reports should be available from the nominating country on request. In addition, if a member state requests actual study data the nominating country will work with the manufacturer to try and supply this information.

Action 6. Comments by member states are to be posted on the web site by December 31. The interim MRL Groupⁱⁱⁱ will prepare and submit a report to the Chair of the WGP by February 1 for comment and subsequent distribution to member states for consideration at the next meeting of the WGP. Commentors should remember:

- The commentor should explicitly state whether they support or oppose each specific proposed interim MRL.
- As with a standard JMPR review, many countries will have different MRLs established, but the *highest nominated* Interim MRL that is *supported by an adequate set of field trial data* and that is *demonstrated to be safe*, would generally be selected as the interim Codex MRL. It is not necessary to list the MRLs established in the commentor’s country.
- Comments should not be based on residue data that are not included in the detailed information package. No additional residue data (and resulting alterations in the proposed interim MRLs) can be considered in the review of the detailed information packages. The only opportunity to provide additional residue data and propose different MRLs is in Action 4. Comments on the interpretation of the residue data provided in the detailed information packages and resulting suggested changes to interim MRLs are appropriate.

Action 7. The WGP, at its annual pre-CCPR meeting, will consider any technical issues raised and decide which Interim MRLs are proposed to CCPR for agreement at the plenary session.

Action 8. Proposed Interim MRLs agreed or refused by CCPR.

Action 9. Interim MRLs considered by the Codex Alimentarius Commission (CAC) for ratification at Step 8(I) or rejection.

Action 10. Upon CAC ratification, interim MRLs recognized as MRLs at Step 8(I), with the following conditions:

- The interim standard would have a four year lifetime. During the four years, the pesticide would be considered by the JMPR, and their recommendations would advance through the CCPR in the present Step fashion. The interim standard would be automatically withdrawn when the proposed standard in the normal process reaches Step 8.

- The interim values would continue until supplanted by the advancement of the JMPR values to Step 8 regardless of the values recommended by the JMPR.
- If JMPR makes unfavorable recommendations or cannot make MRL recommendations because of an insufficient data base, the subject interim MRLs will be automatically withdrawn at the next scheduled session of the CCPR.

Action 11. The adopted interim MRLs at Step 8(I) should be included in the annual listing (CX/PR) *Draft and Proposed Draft Maximum Residue Limits in Food and Feeds at Steps 7 and 4* or in whatever comprehensive, public listing that the Codex Secretariat may deem appropriate.

ⁱ A new, safer, replacement pesticide is defined (CX/PR 03/14) as a pesticide that usually would have never had one or more Codex MRLs; would be shown to be an alternative to an existing pesticide or pesticide type within the Codex system; and would have demonstrated reduced acute and/or chronic risk to humans via dietary intake compared to the pesticide that it would supplant or compared to many other pesticides in its classification (insecticide, herbicide, fungicide).

ⁱⁱ The CCPR must give clear direction to Codex to provide an interactive web space for the nominating country to post documents and for other countries to post responses.

ⁱⁱⁱ Membership of the Interim MRL Group, currently the Interim MRL Pilot Project Working Group, will need to be formalized if the pilot project is extended.