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FOOD AND AGRICULTURE
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Agenda Item 8

CRD 2

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON PESTICIDE RESIDUES

**Thirty-fourth Session
The Hague, The Netherlands, 13-18 May 2002**

CRITERIA FOR THE PRIORITISATION PROCESS FOR THE ESTABLISHMENT OF CODEX PRIORITY LISTS OF PESTICIDES

(Prepared by Australia)

Background

CCPR 33 agreed that a document should be prepared summarizing criteria for the prioritisation process including the criteria added in 2001 - ALINORM 01/24A paragraph 224.

New Chemicals

Before a new chemical can be considered for the Priority List it: must be available for use in a commercial product, and

- (a) must give rise to residues in or on a food commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.

The commodity for which the establishment of a Codex MRL (or EMRL in the case of persistent compounds no longer used as pesticides) is sought should:

- (a) form a component in international trade;
- (b) represent a significant proportion of the diet; and
- (c) contain chemical residues as evidenced in monitoring programmes

CCPR 33 agreed that the following procedures should apply when establishing priorities:

- chemicals identified by JMPR for acute toxicity evaluation are to be added to the priority list as candidate compounds for assessment of acute toxicity
- countries may nominate chemicals for assessment of acute toxicity; and
- acute toxicity is to be assessed for all new chemicals and those undergoing periodic re-evaluation.

CCPR 33 agreed to new chemicals and re-evaluations being prioritised on a 50:50 basis, with appropriate flexibility where required and taking into consideration the potential impact on health. It was agreed that the 50:50 prioritisation of new chemicals and re-evaluations would commence in 2003.

It was also agreed that when establishing priorities, preference should be given to those chemicals:

- the intake and/or toxicity profile of which indicate a high level of public health concern;
- that are new and safer with a potential to replace existing chemicals that present a public health concern;
- on which national reviews are available;
- that are related to chemicals (parent and metabolites used as pesticides) scheduled for evaluation so they can be reviewed concurrently; and
- that may be responsible for actual or potential losses owing to trade disruption (as evidenced by information provided to CCPR by national governments).

Prioritisation process for the chemicals tentatively scheduled in ALINORM 01/24A APPENDIX IX at CCPR 33

In establishing the Codex Priority List of Pesticides for CCPR 34, all sponsors of chemicals listed in ALINORM 01/24A APPENDIX IX at CCPR 33 were asked to complete questionnaires containing questions to satisfy the prioritisation criteria agreed at CCPR 33.

The criteria used for the prioritisation process for new chemicals and periodic review chemicals are summarised in the two questionnaires below. The questionnaires were compiled from the criteria agreed at CCPR 33 and other critical criteria such as the date the chemical was first proposed for evaluation or re-evaluation and the date data would be submitted.

Questionnaire A

Criteria for priority review of new chemicals

1. What was the year the chemical was proposed?	
2. Date of data submission commitment?	
3. Has the chemical been held over from a previous JMPR?	
4. Is it a safer chemical with a potential to replace existing pesticides of concern from a public health perspective?	
5. Does the intake and/or toxicity profile indicate a high level of public health concern?	
6. Is the chemical used on one or more high consumption crops?	
7. What is the volume and frequency of use on staple foods?	
8. Is there a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently?	
9. Does the same manufacturer have more than one new and/or periodic re-evaluation?	
10. Is a national review available or in progress and when could it be made available?	
11. Has the CCPR been advised by national governments that the chemical has been responsible for trade disruption?	

In prioritising the new chemicals (see tables 1, 2 and 3 below), the main criteria used from Questionnaire A (above) were:

- the year the chemical was proposed (criterion 1),
- the date of data submission commitment (criterion 2),
- whether the chemical been held over from a previous JMPR (criterion 3),
- whether it was a safer chemical with a potential to replace existing pesticides of concern from a public health perspective (criterion 4), and
- whether a national review was available (criterion 10).

Criterion 5, “ Does the intake and/or toxicity profile indicate a high level of public health concern?” does not appear to be relevant for new chemicals and should be deleted while retaining Criterion 4.

Criterion 6, “ Is the chemical used on one or more high consumption crops?” is important and has been required with new chemical nominations in the past.

Criterion 7, ” What is the volume and frequency of use on staple foods?” was poorly understood. Most answers provide details of how the chemical was applied. It is questionable whether this criterion is of value in prioritisation.

Criterion 8, “Is there a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently?” was used when required. For example when considering alpha and zeta-cypermethrin in 2004.

Criterion 9, “Does the same manufacturer have more than one new and/or periodic re-evaluation?” is important for the manufacturer who will be in the best position to judge if they can handle the data submission commitment. This criterion should be viewed in relation to the whole JMPR schedule for the particular year.

No respondent was aware that the CCPR been advised by national governments that any scheduled chemical had been responsible for any trade disruption in the past year (criterion 11).

Questionnaire B

Criteria for priority review of periodic re-evaluation chemicals

1. What was the first year the chemical was listed in Annex 1 –Candidate Compounds for Periodic Re-evaluation - Not Yet Scheduled?	
2. Has the chemical been held over from a previous JMPR?	
3. Is there commitment to review?	
4. If more than one manufacturer, are they all supporting periodic re- evaluation?	
5. What is the date of data submission commitment?	
6. Has a recently scheduled toxicological evaluation been completed? (for residues re-evaluation only)	
7. What is the date of last major re-evaluation?	
8. Has JMPR recommended re-evaluation?	
9. Does the intake and/or toxicity profile indicate a high level of public health	

concern?	
10. Is the chemical used on one or more high consumption crops?	
11. What is the volume and frequency of use on staple foods?	
12. Is there a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently?	
13. Does the same manufacturer have more than one new and/or periodic re-evaluation for re-evaluation?	
14. Is a national re-evaluation available or in progress and when could it be made available?	
15. Has a national re-evaluation resulted in the cancellation of many uses?	
16. Have there been substantial non-periodic evaluations completed?	
17. Has the CCPR been advised by national governments that the chemical has been responsible for trade disruption?	

In prioritising the chemicals for toxicological re-evaluation (see tables 4, 5 and 6 below) the main criteria used from Questionnaire B were:

- the year the chemical was added to Annex 1 (criterion 1),
- the date of the last major toxicological re-evaluation (criterion 7),
- the commitment to submit data (criteria 3 and 5),
- the public health concern (criterion 9),
- whether a national review is available (criterion 14), and
- whether the re-evaluation had been held over from a previous year (criterion 2).

Criterion 4,” If more than one manufacturer, are they all supporting periodic re-evaluation?” will be taken into consideration occasionally.

Criterion 8 “ Has JMPR recommended re-evaluation?” and criterion 11 “What is the volume and frequency of use on staple foods?” were poorly understood and do not appear to add any value to the prioritisation process. It is suggested that criteria 8 and 11 be deleted.

Criterion 9: In answering the question “does the intake and/or toxicity profile indicate a high level of public health concern?” the ratings of ‘low’, ‘moderate’ and ‘high’ in the tables below were provided by toxicological evaluators at the Australian Department of Health and Aged Care. The ‘yes’ and ‘no’ ratings in the tables have been provided via the company responses. This criterion has been used for prioritisation purposes only and is not the author’s opinion of the potential public health concerns associated with the chemicals tentatively scheduled for JMPR review.

Criterion 10 “Is the chemical used on one or more high consumption crops?” can provide useful information but adds little value to the prioritisation process.

Criterion 12 “Is there a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently?” has been used as appropriate. Examples in the tentative schedule are azocyclotin and cyhexatin and triadimefon and triadimenol.

Criterion 13, “Does the same manufacturer have more than one new and/or periodic re-evaluation?” is important for the manufacturer who will be in the best position to judge if they can handle the data submission commitment. This criterion should be viewed in relation to the whole JMPR schedule for the particular year.

The value of criterion 14, “Is a national re-evaluation available or in progress and when could it be made available?” needs to be discussed by the Ad Hoc Working Group on Priorities with input from the Joint Secretariat.

Criteria 15 and 16 may provide useful information.

No advice about trade disruption has been provided for this process (Criterion 17)

In prioritising the chemicals for residues re-evaluation (see tables 7, 8, 9 and 10 below) the main criteria used from Questionnaire B were:

- the year the chemical was added to Annex 1 (criterion 1),
- the date of the last major residues re-evaluation (criterion 7),
- the commitment to submit data (criteria 3 and 5),
- the public health concern (criterion 9),
- whether a recent toxicological re-evaluation had been conducted by JMPR (criterion 6), and
- whether the re-evaluation had been held over from a previous year (criterion 2).

Comments for criteria 4, 8, 10, 11, 12, 13, 15, 16 and 17 for residues re-evaluation are the same as for the comments made for the toxicological re-evaluation above with the exception of criterion 14.

Criterion 14, “Is a national re-evaluation available or in progress and when could it be made available?”

While the use of available national reviews may be possible for toxicological re-evaluation, it seems unlikely that national reviews will be used for residues re-evaluation in their entirety. It may be possible to use parts of a national residues review: for example, metabolism studies. The use of national residues reviews in the JMPR process needs to be discussed by the Ad Hoc Working Group on Priorities with input from the Joint Secretariat.

Pesticide Specifications

The 2000 CCPR approved in principle the recommendation of 1999 JMPR that pesticide specifications should be developed first before pesticides are evaluated within the Periodic Re-evaluation Programme of CCPR or for new Pesticides. Companies (sponsors) should indicate in their submissions of data to JMPR whether the pesticides used in their studies are in compliance with the new specifications. An FAO or WHO specification for the technical material should be required before establishing ADIs, acute RfDs or, where relevant, recommending MRLs. It was recognized that implementation of this proposal would take time.

The Ad Hoc Working Group on Priorities should consider an appropriate start date for a review of Specifications by the Joint Meeting on Pesticides Specifications (JMPS) allowing sufficient time for the companies to prepare the dossiers for specification and considering whether the Panel of the JMPS could accommodate all the scheduled pesticides for a particular year.

The 4-year rule for evaluations of extra data.

(See MRL Periodic Review Procedure Annex 1 CX/PR 02/6)

If insufficient data have been submitted to support a new MRL or to confirm the existing CXL, data submitters are advised by written notification from the FAO Joint Secretary and/or in the JMPR Report. On being advised of the data inadequacy data submitters may, by the next CCPR Meeting, provide to the FAO and CCPR

Secretaries a written commitment to generate and submit a complete dossier of required data for review within 4 years. The CXL is maintained for no more than 4 years following advice of data inadequacy unless the CCPR agrees to extend the

4-year period enabling the JMPR to schedule and complete the review of the available data.

Tables of data used in the prioritisation process for the chemicals tentatively scheduled in ALINORM 01/24A APPENDIX IX at CCPR 33

Table 1 New Chemicals 2003

	Year added	Data available for review	Safer Chemical	National review available	Held over previous year
cyprodinil	2000	T2003,R2003	yes	yes	no
methoxyfenozide	2001	T2002	yes	yes	no
famoxadone	2000	T2002	yes	yes	no
dimethenamid-P	2001	2000	yes	yes	no
pyraclostrobin	2002	2002	yes	EU Annex 1 listing	no

Note: The data submitter for both dimethenamid-P and pyraclostrobin has requested that pyraclostrobin, a chemical nominated for consideration at CCPR 34, be substituted for dimethenamid-P in 2003. Pyraclostrobin is a replacement chemical for quinclorac, tentatively scheduled for 2005 and no longer supported.

Table 2 New Chemicals 2004

	Year added	Data available for review	Safer Chemical	National review available	Held over previous year
zeta-cypermethrin	?	2002		?	
fludioxinil	2000	T2003,R2004	yes	yes	no
gentamicin sulfate	2000	yes	?	?	yes
oxytetracycline	2000	yes			yes
trifloxystrobin	2000	2004	yes	yes	no

Note: Acibenzolar-S-methyl is no longer supported.

Table 3 New Chemicals 2005

	Year added	Data available for review	Safer Chemical	National review available	Held over previous year
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dimethenamid-P	2001	2000	yes	yes	no
fenhexamid	2002	2004	yes	yes	no
indoxacarb	2002	2004	yes	yes	no
novaluron	2002	2003	yes	yes	no

Notes:

1. Fenhexamid, indoxacarb and novaluron are nominations for consideration at CCPR 34.
2. Quinclorac is no longer supported.
3. Dimethenamid-P has been moved from the 2003 tentative schedule.

Table 4 Chemicals listed in ALINORM 01/24A APPENDIX IX for 2003/2004 to be prioritised for toxicological re-evaluation.

	Year added to annex 1	Last major toxicological review	Commitment to submit data	Public Health concern	National review available	Held over from previous year
bendiocarb (137)	Not	supported				
carbosulfan (145)	?	1986	2002	low	yes EU 2002	1997
cyhexatin (067)/ azocyclotin (129)	?	1994	2002	high	yes	no
glyphosate (158)	1997	1986	T2003, R2004	moderate	yes	no
paraquat (057)	1998	1986	T2003,R2004	high	yes	no
phorate (112)	1998	1994,1996	2000	high	no	no
pirimicarb (101)	1996	1982	T2003, R2004	moderate	EU list 2, 2002	no
terbufos (167)	1999	1986, 1989	2000	high	yes	no
triadimefon (133)	?	1985	T2003,R2004	moderate	EU list 3	no

triadimenol (168)	?	1989	T2003, R2004	low	EU list 3	no
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Note: All entries in the Public Health Concern column in Table 4 have been provided by toxicological evaluators at the Australian Department of Health and Aged Care.

Table 5 Chemicals listed in ALINORM 01/24A APPENDIX IX for 2004/5 – toxicological re-evaluations.

	Year added to annex 1	Last major tox review	Commitment to submit data	Public Health concern	National review available	Held over from previous year
benalaxyl (155)	1999	1987	?		?	no
clofentezine (156)	1998	1986	?		?	2004
cyromazine (169)	2000	1990	2005	no	yes	no
flusilazole (165)	2001	1989	2006	no	yes	2004
profenofos (171)	2000	1990	2004	no	yes	no
propamocarb (148)	1998?	1986	2004	no	?	2004
propiconazole (160)	2000	1987	2004	no	EU process	2004

Note: The data submitter has requested that flusilazole be held over to 2006.

Table 6 Chemicals listed in Annex 1 ALINORM 01/24A APPENDIX IX for toxicological re-evaluation

	Year added to Annex 1	Last major tox review	Commitment to submit data	Public Health concern	National review available	Held over from previous year
azinphos-methyl	2001	1991	not before 2005	yes	yes	no
buprofezin	2001	1991	yes	no		no
bioresmethrin	2001	1991	yes	no	no	no
chlorpyrifos-methyl	2001	1992	2004	no	yes	no
cyfluthrin, beta-cyfluthrin	2001	1987	2007	possibly	EU List 1	no

fentin	2001	1991	2005	yes	no	no
hexythiazox	2001	1991	2004	no	EU - in progress	no
vinclozolin	2001	1995	yes	yes	yes	no

Table 7 Chemicals listed in ALINORM 01/24A APPENDIX IX in 2003 for prioritisation for residues periodic re-evaluation.

	Year added to Annex 1	Last major residues review	Commitment to submit residues data	Recent Tox evaluation by JMPR	High level Public Health Concern	Held over from previous year
acephate (095)	?	1994,96	?	2002	yes	no
ethoprophos (149)		1984	2004	1999	some	move to 2004 is requested
fenitrothion (037)	1996	1989	2003	2000	yes	no
lindane (048)	?	1989	?	due 2002	yes	no
metalaxyl-M	1997	1992	2003	due 2002	no	no
methamidophos (100)	?	1990	2003	due 2002	yes	no
methoprene(147)	?	1989		2001	no	no
paraquat (057)	1998	1981	2003	due 2003	yes	no
prochoraz (142)	1997	1990	2003	2001	some?	no
propineb	1999	1995	2003	no ,1992	no	no

Notes: The data submitter has requested that ethoprophos be moved to 2004.

Methamidophos can be reviewed with acephate.

Table 8 Chemicals listed in ALINORM 01/24A APPENDIX IX in 2004 for prioritisation for residues periodic re-evaluation.

	Year added to Annex 1	Last major residues review	Commitment to submit residues data	Recent Tox evaluation by JMPR	High level Public Health Concern	Held over from previous year
endosulfan (032)		1993	2004	1998	yes	2003

cypermethrin (118)		1990	undecided	1996 JECFA	yes	2004
cyhexatin (067) /azocyclotin (129)		1992/1991	?	2003	high	2004
glyphosate (158)		1994	?	2004	moderate	2004
phorate (112)		1994	2000	2004	high	2004
pirimicarb (101)	1996	1985	2004	2004	moderate	2004
propiconazole (160)		1994	2004	2005	low	2004
terbufos (167)		1990	2000	2003	high	2004
triadimefon (133)	1997	1985	2004	2004	moderate	2004
tridimenol (168)		1989	2004	2004	low	2004
triforine (116)		1978	undecided	1997	no	2004

Note: All entries in the Public Health Concern column in this table rated high, moderate or low have been provided by toxicological evaluators at the Australian Department of Health and Aged Care. Yes and no ratings have been derived from company responses.

Table 9 Chemicals listed in ALINORM 01/24A APPENDIX IX in 2005, 2006 and 2007 for prioritisation for residues periodic re-evaluation.

	Year added to Annex 1	Last major residues review	Commitment to submit residues data	Recent Tox evaluation by JMPR	High level Public Health Concern	Held over from previous year
clofentezine (156)	1998	1992	?	2005		2005
flusilazole (165)		1993	2006	2005	no	2005
permethrin (120)		1991	?	1999	?	2005
propamocarb (148)	1998?	1987	2006	2005	no	
benelaxyl (155)	1999	1993		2006		2006

cyromazine (169)	2000	1992	2005	2006	no	2006
cyhalothrin (146)						
procymidone (136)		1998	2007	2006		2007
profenofos (171)	2000	1995	2004 or later	2006	no	2005

Table 10 Chemicals listed in Annex 1 ALINORM 01/24A APPENDIX IX for prioritisation for residues periodic re-evaluation.

	Year added to Annex 1	Last major residues review	Commitment to submit residues data	Recent Tox evaluation by JMPR	High level Public Health Concern	Held over from previous year
azinphos-methyl (002)	2001	1995	2006	no	yes	no
buprofezin (173)	2001	1995	yes	no	no	no
bioresmethrin (093)	2001	1976	yes, in, principle	no	no	no
chlorpyrifos-methyl (090)	2001	1994	2005	no	no	no
cyfluthrin, beta-cyfluthrin (157)	2001	1992	2007	no	possibly	no
fentin (040)	2001	1994	2006	no	yes	no
hexythiazox (176)	2001	1991	2004	no	no	no
vinclozolin (159)	2001	1992	yes	no	yes	no