codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 11 **CX/PR 03/14**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES
Thirty-fifth Session
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DISCUSSION PAPER ON THE PILOT PROJECT FOR THE EXAMINATION OF NATIONAL MRLS AS INTERIM CODEX MRLS FOR SAFER REPLACEMENT PESTICIDES

Prepared by the United States of America

BACKGROUND

1. The Codex Committee on Pesticide Residues (CCPR) at its 34rd Session (The Hague, The Netherlands, May 2001) considered a paper on options to address the excessive time required to establish standards for new pesticides (CX/PR 02/11). From nomination to promulgation of the CXL can take up to eight years. During this interval of no international standards, growers cannot use the newer, often safer pesticides on crops that are destined for export to countries that rely upon the Codex standards, or national governments must negotiate bilateral arrangements. One of the options of interest to many of the CCPR attendees was the use of national MRLs as interim standards for a fixed period of time (Option 1 of CX/PR 02/11). During this time, the proposed standards would be considered by the JMPR and would subsequently advance through the standard Codex procedure. The Meeting decided to consider this proposal in detail at the 35th CCPR in 2003, and the United States agreed to chair a group to prepare a paper (ALINORM 03/24, paragraph 195; Annex 1). Other members of the drafting group included Argentina, Australia, Canada, Chile, Egypt, New Zealand, Senegal, South Africa, Sudan, European Community, Consumers International, and CropLife International. The paper was to include a proposed pilot project for *new safer replacement pesticides*.

INTERIM STANDARD - CRITERIA FOR CONSIDERATION BY CCPR

2. The interim standard would have certain distinct attributes. It could be used only for a new pesticide that is a safer replacement for an existing pesticide. *New* means not previously generally recognized as a pesticide chemical at the international level. This would usually be equivalent to never having had one or more Codex MRLs. The pesticide must be available for use as a commercial product. The commodities of interest must be in international trade, should be anticipated to contain residues of the pesticide, and should be significant in the human diet.

3. *Replacement* means a pesticide shown to be an alternative to an existing pesticide or pesticide type within the Codex system. This should not be confused with the "substitution principle" used by some authorities, whereby the registration for a relatively more toxic pesticide is canceled and replaced by the registration of a less toxic/less hazardous product. The deletion or retention of established pesticides within the Codex system would continue to be pursued through the Periodic Review process.

4. *Safer* means that the pesticide has demonstrated reduced acute and/or chronic toxicity risk to humans compared to the pesticide that it would supplant or compared to many other pesticides in its classification (insecticide, herbicide, fungicide).

4. Under this proposal, all three conditions (new, replacement, safer) must be met for a pesticide candidate to qualify for an interim standard.

5. The interim standard would have the status of a Step 8 proposal in the normal procedure. To distinguish it from Step 8 MRLs from the normal process, the standard would be designated “8(I)” in the List of Maximum Residue Limits for Pesticides in Food and Animal Feeds (At Various Steps of the Codex Procedure).

6. The interim standard at Step 8(I) would be anticipated to have the same status in the WTO as a Step 8 MRL arising from the JMPR and CCPR. Neither have full effect before adoption of the CXL by the Codex Alimentarius Commission, but would be taken into consideration by the WTO in trade dispute situations.

7. The CCPR will *not* need approval of the interim MRL concept by the Codex Alimentarius Commission before implementation. However, the Codex Alimentarius Commission should be consulted and informed of CCPR plans in this area. The steps in the Codex process have not been altered. The path to a Step 8 status has been modified as a temporary expedient. This change is the prerogative of CCPR.

8. The interim standard would have a *finite lifetime*. Upon recommendation by the CCPR, the interim standard would have a four year life. During the four years, the pesticide would be considered by the JMPR, and the latter’s recommendations would advance through CCPR in the present Step fashion. The interim standard would be automatically withdrawn when the proposed standard in the normal process reaches Step 8.

9. Should JMPR be unable to review the pesticide within the timeframe or should the JMPR make unfavorable or no recommendations, the interim standards would be withdrawn after the 4 year period or upon receipt of the unfavorable or no recommendations of the JMPR, whichever comes first. The CCPR could extend the four year period only to the extent necessary for the JMPR to schedule and complete review of available data. 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. This is analogous to the current process.

10. The Step 8(I) standards adopted by the CCPR would remain as interim standards for a fixed time period unless and until rejected by the Codex Alimentarius Commission (CAC). The CAC may reject the Step 8(I) status for specific MRLs.

INTERIM STANDARD PROCESS

11. The process is initiated by the nomination of a pesticide to the Priorities Working Group (PWG) of the CCPR. The nomination must be through a national government and most of the documentation, e.g., dietary exposure, would be the responsibility of the manufacturer. This is the current practice. The nomination must be accompanied by specific documentation, as follows:

1. “Pesticide Information for CCPR Working Group on Priorities”

   (Appendix VIII, *FAO manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed*, FAO, Rome, 2002, Second edition).

2. Summary toxicology information with emphasis upon the information used to estimate the acute reference dose and the chronic acceptable daily intake (ADI). This should, to the extent possible, be presented in tabular form. See Appendix III for an example, and also refer to the summary toxicology tables with pesticide reviews in the JMPR *Reports* and *Evaluations* (Toxicology)

3. Proposed interim MRLs (commodity and numerical value). These might be determined by consultation of the nominating governments and the manufacturer. The list might be limited to commodities of the trade interests of the nominating country and not as inclusive as the list ultimately submitted to the JMPR. All commodity names must be translated to terms of the Codex Classification System. Proposed MRL recommendations should follow the JMPR system of numbers (JMPR Report, General Consideration 2.3, 2001).

4. Summary residue information used to estimate the MRLs, e.g., field trial studies, animal feeding studies, metabolism studies, rotational crop studies . This should, to the extent possible, be presented in tabular form. See Appendix IV for an example. Also, consult the *FAO Manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed* (FAO, Rome, 2001)

5. Summary GAP information upon which the MRLs are based. See Appendix IV for an example and consult the *FAO Manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed* (FAO, Rome, 2001)

6. Residue definitions for MRL enforcement and for dietary risk considerations. The definitions must be consistent with the toxicology, metabolism, and analytical methods. Metabolites of significant toxicological concern would normally be included in the dietary intake calculation.

7. Summary description and reference for analytical methods validated for the enforcement of MRLs in the appropriate plant and animal commodities. See Appendix IV for an example.

8. Dietary intake exposure analysis, acute and chronic (as appropriate), based on the

   particular national methodology. The ADI and acute RfD selected would usually be that of the nominating country. A tabular presentation and calculation would suffice.

9. Detailed dietary intake exposure analysis, acute and chronic (as appropriate), based on the methodology of the JMPR. This would be the preferred methodology for consideration by the CCPR. See Appendix II for example calculations.

10. Detailed rationale for characterizing the subject pesticide as a safer replacement. This should include a comparison to the pesticide or pesticide class for which the nominee is considered a safer alternative.

12. The existing requirements for a new pesticide nomination continue. The pesticide must be available for use as a commercial product and must not have been previously accepted for consideration. For example, it would not be appropriate to nominate a pesticide considered and rejected by the JMPR. Nor would it be appropriate to nominate a pesticide/commodity combination for a pesticide with other commodity MRLs in the Codex system. The commodity or commodities for which the interim MRLs is/are proposed must be in international trade, must be a significant portion of the diet, and must be expected to contain pesticide residues.

13. The PWG will consider the completeness of the data package and forward its recommendation to the same session of the CCPR. The PWG will not judge the accuracy of the information submitted, but only the completeness. The PWG chairperson might give consideration to the use of a small advisory panel, perhaps virtual, to review the information and supply an opinion to the PWG. The PWG is providing only a screening mechanism and is not acting as a risk assessor. The PWG will also prioritize the pesticide for JMPR review. The CCPR will take note of the nomination and schedule the pesticide for full consideration of interim MRLs at the next annual session of the CCPR. The proposed 8(I) MRLs would be included in the Circular Letter (CL) requesting comments on MRL proposals from the JMPR.

14. In the intervening year, member governments and NGO's may review the information supplied to the PWG. It will be the responsibility of the nominating government in cooperation with the manufacturer(s) to supply any additional requested information and analyses to the members and interested parties, through the Codex Secretariat. Especial care must be taken to protect the proprietary nature of the manufacturer's data. At the next session of the CCPR, the interim MRLs will be presented as part of the discussions on pesticide proposals at Steps 3 and 6 in the standard Codex process. At that time any member country may

object to the proposed interim MRLs, based on its considerations of the scientific data base and the policy of CCPR. The member will also have had the opportunity to submit written comments prior to the Meeting in response to the appropriate CL issued prior to the Meeting. The rules that apply to proposed MRLs from the JMPR will apply to the proposed interim MRLs. For example, MRLs for animal feeds will not be considered if appropriate animal feeding studies have not been generated and appropriate animal commodity MRLs proposed. The Meeting will either recommend Step 8(I) interim MRLs or will reject the interim MRLs. Regardless of the CCPR decision, the scheduled JMPR review continues unabated.

15. Great care must be exercised in the preparation of interim MRL proposals for CCPR . The proposals must be complete and conclusions transparent. To prevent interim MRL proposals from becoming a time-consuming task for CCPR, it is suggested that an interim MRL proposal for a given pesticide/commodity combination be considered one time only. This would prevent stifling the system with repeat nominations and modified proposals. This would also encourage the nominating parties to provide a quality product.

16. The accepted interim MRLs will be published in the subsequent " List of Maximum Residue Limits for Pesticides in Food and Animal Feeds (At Various Steps of the Codex Procedure)" as MRLs at Step 8(I). Such MRLs will continue for a fixed time period, 4 years (with possible extension by the CCPR), unless rejected by the Codex Alimentarious Commission (CAC). The CAC has the option of rejecting the Step 8(I) status and returning the recommendations to the CCPR. Step 8(I) MRLs cannot be advanced to CXL status.

17. The situation might arise wherein a member government, not necessarily the original nominating government, wishes to increase an interim MRL or propose an additional MRL (for a new commodity) during the 4 year period or extension thereof. The government and cooperating manufacturer would need to supply detailed dietary exposure calculations to the Pesticide Working Group. The PWG would consider the request and forward it for consideration by the following year's CCPR. The PWG would also inform the FAO Joint Secretary of the JMPR of the potential expanded use, as the pesticide would be scheduled before the JMPR during this interim period.

18. Upon receiving favorable recommendations from the JMPR on the subject pesticide, the MRLs introduced at Step 3 will advance in the normal fashion, including the possibility of fast tracking. When the MRLs reach step 8, the Step 8(I) status will automatically be withdrawn. Should the JMPR review process require more than 4 years from the time of introduction of the interim MRLs, the CCPR may extend the life of the interim MRLs only to the extent necessary for the JMPR to schedule and complete review of available data.. If favorable recommendations arrive from the JMPR, the subject Step 8(I) MRLs remain in place until the JMPR recommendations advance to step 8. If the JMPR makes unfavorable recommendations, including the exceedence of the ADI in one or more regional diets or exceedence of the acute reference dose, the subject interim MRLs at Step 8(I) will be automatically withdrawn at the next scheduled session of the CCPR Likewise, if the JMPR cannot make MRL recommendations because of a faulty or insufficient data base, the subject interim MRLs will be subject to the same fate. This procedure recognizes the JMPR as the ultimate risk assessor.

19. The overall process is shown in Figure 1.

FIGURE 1: INTERIM MRL PROCESS

GOVERNMENT AND MANUFACTURER DEVELOP NOMINATION PACKAGE

↓

PWG Considers Nomination Package for Completeness

↓ YEAR 1

PWG Recommends Schedule for JMPR Review to CCPR

↓ YEAR 2 - 6

JMPR Reviews Toxicology and Residue Chemistry (Risk Assessment)

↓ YEAR 3 - 7

CCPR Considers JMPR Recommendations (Risk Management) at Step 3 or Step 6

↓ ↑ YEAR 4 - 8

CAC Reviews CCPR Decision at Step 5 or Step 8

↓ YEAR 4 - 8

CXL Standard Issued

↓ YEAR 1

PWG Informs CCPR of Interim MRL Proposal

↓ YEAR 2

CCPR Deliberates Interim MRLs (Risk Assessment/ Management)

↓ YEAR 2

Interim MRLs Issued at Step 8 (I)

↓YEAR 3 - 6(8)

Interim MRLs Continues☼

↓YEAR 4 - 6(8)

Interim MRLs Withdrawn when Step 8 Achieved

☼ *A finding by CCPR that an MRL for a subject pesticide cannot be advanced beyond Step 6 because of dietary exposure concerns will result in immediate withdrawal of the Step 8(I) status. A finding by CCPR that JMPR could not recommend MRLs because of a deficient data base will result in immediate withdrawal of the Step 8(I) status.*

SAFEGUARDS

20. The interim MRL may be based primarily upon the findings of one country and will not have had the review of the full data base by an independent international group. Thus, extra diligence must be exercised to avoid the introduction of new pesticides into the Codex system that would have significant deleterious health effects. National governments/manufacturers are cautioned to submit only nominations for pesticides with complete data bases. The efforts of the PWG and CCPR must not be expended on frivolous nominations.

21. The process is designed to prevent potentially dangerous pesticides from being granted interim MRLs. The nomination must be accompanied by both national and JMPR-type dietary risk analyses with sufficient detail *to permit an evaluation by the member countries of CCPR.* Summary residue and toxicology data must also be included, thereby allowing members to judge both the completeness of the data base and the interpretation of the data, for example, the selection of the appropriate toxicological endpoints.

22. One year will intervene between nomination and consideration, thereby affording ample opportunity for countries to review and investigate the proposed interim MRLs. Any member country or NGO finding faulty or insufficient data or potentially incorrect interpretations or having additional information not supplied may challenge the nomination before the CCPR.

23. The interim MRL is time-limited to four years, unless extended by specific act of the CCPR and only to accommodate the requirements of the JMPR. This provides the time for JMPR to conduct an independent review of the total data base and to make recommendations to the CCPR. Negative JMPR recommendations or the lack of recommendations resulting from an insufficient or deficient data base would result in immediate withdrawal of the Step 8 (I) MRLs at the next scheduled session of the CCPR. This would include adverse findings on the acute and/or chronic dietary intakes.

24. The Step 8(I) MRLs may be rejected by the intervention of the CAC. Note however that Ste p 8(I) MRLs will not routinely be considered by the CAC. Countries and other interested parties may object to specific Step 8(I) MRLs before the CAC. The CAC has the option of returning the proposals to CCPR. Of course, the maximum residue level proposals of the JMPR will advance via the CCPR to the CAC.

CRITERIA FOR SAFER OR REDUCED RISK PESTICIDE

25. Within the mandate of the CCPR, the term “reduced risk pesticide” is being used to mean a pesticide with *reduced risks to human health via dietary intake.* A reduced risk pesticide should exhibit minimal acute and chronic dietary intake risk concerns. The method of quantifying the concern is the calculation of the exposure in each of the dietary regions as a percentage of the acceptable daily intake (ADI) for chronic intake and is the calculation of exposure at the 97.5^{th} percentile for single commodities for the general population and children as a percentage of the acute reference dose (RfD) for acute intake, i.e., the current JMPR methodology. When compared to similar calculations for existing pesticides with similar function, the reduced risk pesticide should display lower percentages. The comparison of % ADI and % RfD between the proposed pesticide and the existing pesticide would be considered the primary differentiating factor. The existing pesticides must be in the Codex system and comparisons should use comparably derived ADI's and RfD's. For example, a new pesticide with no cholinesterase-inhibiting properties might be considered a replacement for an OP pesticide.

26. The ADI's and RfD's will be based on national methodology, as by definition the pesticide will have not been reviewed by the JMPR. The nominating government/manufacturer should provide an estimate of the ADI and RfD based on JMPR methodology. For example, national ADI's and RfD's are often adjusted by various safety factors not used in the Codex system. Differences in values should be carefully explained and the effects of the particular values used to calculate dietary exposure should be detailed.

27. Other reduced risk criteria, while very desirable, are not within the purview of the CCPR. These criteria are appropriate for use at the national and regional levels. These include:

- Reduced pesticide risks to non-target organisms
- Reduced potential for contamination of environmental resources
- Broadened adoption of or improved effectiveness of Integrated Pesticide Management (IPM).
- Reduced risks to pesticide handlers (occupational exposure).
- Reduced risks from non-agricultural uses (e.g., residential exposure).

PESTICIDES ON THE JMPR EVALUATION SCHEDULE: POSSIBLE CANDIDATES FOR INTERIM MRLS

28. The 34th CCPR charged the drafting group with the investigation of new pesticide nominations before the JMPR that might be candidates for the interim MRL approach. The following pesticides were scheduled by the 34th Session of the CCPR for consideration by the JMPR (ALINROM 03/24, Appendix VII):

2002

esfenvalerate
flutolanil
imidacloprid

2003

cyprodinil
famoxadone
methoxyfenozide
pyraclostrobin

2004

fludioxinil
trifloxystrobin

2005

dimethenamid-P
fenhexamid
indoxacarb
novaluron

29. It is proposed that pesticides from years 2003 – 2005 be considered as possible candidates for interim MRLs. The pesticides from the 2002 list will have been reviewed by JMPR and advanced to the CCPR for initial consideration at the same time as consideration of this paper. To be eligible for interim MRL consideration, a pesticide must first be classed as a reduced risk pesticide, as defined above. Classification as a reduced risk pesticide, possible MRLs, and acute and chronic dietary intake considerations are reviewed for each pesticide. Thereby, candidates for interim MRL considerations can be identified from the new pesticides currently scheduled for JMPR review.

30. Table 1 summarizes the status of the candidate compounds. The details of each pesticide are provided in Appendix I and Appendix II. For the purposes of this exercise the highest national MRL found was used as the proposed interim MRL. In the normal situation, the MRLs would most likely be from one country. The national ADIs and acute RfDs were combined with the proposed MRLs to calculate the theoretical maximum dietary intakes (chronic) and acute dietary intakes using the JMPR methodology.

Table 1: Evaluation of Scheduled New Pesticides for Interim MRL Status

Pesticide	Chronic			Acute			Candidate
	ADI (mg/kg bw/day)	Source of ADI	Intake as % ADI[1]	RfD (mg/kg bw)	Source of RfD	Intake as % RfD[2]	
Cyprodinil	0.0375	US	5 - 29	None	US	Not applicable	Yes
Famoxadone	0.012	EC		0.2	EC		No[3]
Methoxyfenoxide	0.10	US	1 - 38	None	US	Not applicable	Yes
Pyraclostrobin	Unknown	US		Unknown	US		No[4]
Fludioxonil	0.03	US	5-32	1.0 (female)	US	0 - 13	Yes
Trifloxystrobin	0.038	US	12 -51	2.5	US	0 - 6	Yes
Dimethenamid-P	0.05	US		2.15	US		No[5]
Fenhexamid	0.057[6] 0.2[7]	Canada US EC	1-11	None	Canada US EC	Not applicable	Yes
Indoxacarb	0.02	US	5-75	0.12	US	260 Brassica. 0-82	Yes, except Brassica vegetables
Novaluron	Pending	US		Pending	US		No[8]

[1] Using the JMPR methodology, not the national methodology. The maximum MRL of existing MRLs was used for a TMDI calulation. Actual exposure though the use of STMR values would most likely be less.

[2] Using the JMPR methodology, not national methodologies based on more realistic probabilistic estimates.

[3] Infomation on national MRLs is needed.

[4] The EU or a member state may have different information.

[5] Possible special concerns for infants and children. Also, an enriched isomer situation. Defer to JMPR.

[6] Includes a 3X safety factor that would most likely not be used by JMPR. Revised chronic intake, 0 - 4%.

[7] OECD endpoint, based on a 52 week dog study and a safety factor of 100.

[8] Most likely will be reduced risk, but data evaluations are incomplete.

CONCLUSION AND RECOMMENDATION

31. The interim MRL may provide a means to accelerate the setting of international standards for new pesticides. The current process requires up to 8 years with the stepwise methodology, and during that period growers and exporters cannot use the new pesticides on crops for export where appropriate MRLs have not been established by trading partners (bilateral negotiations, etc). The interim MRL provides a temporary international standard while the permanent standard is being considered through normal channels. Several safeguards are included to exclude potentially hazardous pesticides from the process. It is recommended that the 35th CCPR begin implementation of the interim MRL process as detailed herein.

32. Some of the new pesticides scheduled for consideration by the JMPR in 2003 - 2005 have been identified as potential interim MRL candidates. These include: cyprodinil, methoxyfenoxide, fludioxonil, trifloxystrobin, fenhexamid, and indoxacarb (except Brassica vegetables). As a pilot project to test the effectiveness of the proposed interim MRL process, it is recommended that the 35th CCPR invite the manufacturers to prepare the necessary nomination data packages for several or all of these nominees in

cooperation with the appropriate national governments. Manufactures may also wish to prepare such submissions for other new pesticides which they believe qualify as safer alternatives. These packages would include at a minimum the ten items specified under Interim Standard Process above. These nominations would then be scheduled for consideration by the Priorities Working Group for the 36th CCPR. Full consideration by the CCPR would occur no earlier than the 37th CCPR in 2005. In the year between the 36th and 37th CCPRs, the nominating country/countries would make the submissions available through FAO/WHO.

APPENDIX I: DETAILED CONSIDERATION FOR IDENTIFICATION OF CANDIDATE PESTICIDES

Cyprodinil

Cyprodinil, or 4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine, is a fungicide and has been designated as a reduced risk pesticide in the US. The acute toxicity data show that cyprodinil is not acutely toxic by oral, inhalation, or dermal routes of exposure. The technical material is a dermal sensitizer. The LD50 for rats via oral administration of the end-use product was >5000 mg/kg. Likewise, the chronic toxicity of cyprodinil is low. In a 24-month chronic toxicity rat study, the NOEL was 3.75 mg/kg/day based on degenerative liver lesions in males. The chronic reference dose (ADI) was set at 0.0375 mg/kg/day. Carcinogenicity studies showed no indication of carcinogenic potential at any dose level. Based on lower mean fetal weights and an increased incidence of delayed ossification in female rats, the developmental NOEL is 150 mg/kg/day. The NOEL for reproductive toxicity is 1000 ppm (81 mg/kg/day) based on decreased pup weights (rats). Results for mutagenicity were negative in all relevant studies. Neurotoxicity studies were not requested. Based on developmental toxicity studies and reproductive toxicity studies, the US concluded that infants and children are not more sensitive to exposure to this chemical than the general population.

Cyprodinil: National MRLs

<table>
<tr><td rowspan="3">Commodity</td><td colspan="12">MRL (mg/kg)</td></tr>
<tr><td colspan="12">Country</td></tr>
<tr><td>Australia</td><td>Austria</td><td>Belgium</td><td>Canada</td><td>France</td><td>Germany</td><td>Israel</td><td>Italy</td><td>Japan</td><td>Switzerland</td><td>USA[2]</td><td>Possible Codex</td></tr>
<tr><td>Almond</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>0.02</td><td>0.02</td></tr>
<tr><td>Caneberry</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>2 (black-berry, rasp-berry)</td><td>2 (blackberry, raspberry)</td><td>10</td><td>10</td></tr>
<tr><td>Pome fruit</td><td>0.05</td><td rowspan="2">0.05 (fruit)</td><td></td><td>0.1</td><td></td><td rowspan="2">0.05 (fruit)</td><td></td><td>1</td><td>5 (apple, pear) 0.1 (quince, loquat)</td><td>0.1</td><td>0.1</td><td>5</td></tr>
<tr><td>Stone fruit</td><td></td><td></td><td>2</td><td>0.5 (plum)</td><td></td><td>0.5[1]</td><td>2[1]</td><td>0.5</td><td>2</td><td>2</td></tr>
<tr><td>Apple, pomace, wet</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>0.15</td><td>0.5 (dry)</td></tr>
<tr><td>Grapes</td><td>2</td><td>2</td><td></td><td>2</td><td>1</td><td>2</td><td>2</td><td>5</td><td>5</td><td>3</td><td>2</td><td>5</td></tr>
<tr><td>Dried grapes, raisins</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>3</td><td>3</td></tr>
<tr><td>Onion (dry)</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>0.05</td><td>0.05</td><td>0.6</td><td>0.6</td></tr>
</table>

Onion (green)											4	4
Strawberry		1	0.5			1	1	2	1	0.5	5	5
Vegetables		0.05				0.05						
Cereal grains		0.05				0.05 (ex wheat)						
Barley grain			0.1						2	0.3		2
Corn grain									0.5			0.5
Rye grain									0.5			0.5
Wheat grain			0.2			0.3			0.5	0.3		0.5
Cucumber							0.05	0.5	0.5	0.5		0.5
Peppers							0.5	0.5				0.5
Tomatoes							0.5	0.5	0.5	0.5		0.5
Eggplant								0.5	0.5	0.5		0.5
Lettuce								2	1	1		2
Beans									0.1	0.1		0.1
Peas									0.1			0.1
Mandarins									0.1			0.1

1 apricots, cherries, nectarines, peaches, plums
2 The residue definition is cyprodinil.

The US chronic dietary intake risk analysis revealed no concerns. Exposure was greatest for infants, at 27% of the reference dose. The exposure for the general population was about 6% of the reference dose (ADI). Using the US chronic reference dose as an ADI and the suggested MRLs as residue levels, the chronic dietary exposure can be calculated using the JMPR procedure. See Appendix II. These calculations show that the dietary intake (TMDI) is 5 - 29% of the ADI.

Famoxadone

Famoxadone, or 5-methyl-5-(4-phenoxyphenyl)-3-(phenylamino)-2,4-oxazolidinedione, is not generally recognized as a reduced risk pesticide. The EC has established an ADI of 0.012 mg/kg bw/day based on a one year dog study and utilizing a 100X safety factor and has established an acute reference dose (RfD) of 0.2 mg/kg bw/day based on a 14 day oral study in the mouse and with a 100X safety factor. Information on national MRLs is necessary to perform a dietary risk evaluation.

Methoxyfenozide

Methoxyfenozide, or 3,5-dimethylbenzoic acid N-tert-butyl-N'-(3-methoxy-2-methylbenzoyl) hydrazide, is a diacylhydrazine. As an insecticide, it is a molt-accelerating compound that mimics the action of molting hormone of Lepidopterous larvae. The toxiocology database available to the US was judged extensive and complete. Methoxyfenozide is not acutely toxic, neurotoxic, carcinogenic, or mutagenic, and is not a developmental or reproductive toxicant. There is no evidence of increased susceptibility of infants or children. The US found that an acute reference dose in not required and selected a chronic RfD (ADI) of 0.10 mg/kg/day based on a NOAEL of 10.2 mg/kg/day and an uncertainty factor of 100. The ADI is based on the 2-year combined chronic feeding/carcinogenicity study in rats, in which the following effects were observed at the LOAEL of 411/491 mg/kg/day in male/females: hematological changes, liver toxicity, histopathological changes in the thyroid, and possible adrenal toxicity.

Methoxyfenozide: National MRLs

Commodity	MRL (mg/kg)	
	Country	
	USA[1]	Possible Codex
Almond hulls	25	25
Artichoke, globe	3	3
Brassica (cole or cabbage) vegetables	7	7
Cottonseed	2	2
Cotton, gin byproducts	35	N/A
Pome fruit	1.5	2
Apple, pomace, wet	7.0	20 (dry)
Fruiting vegetables, other than cucurbits	2	2
Grain, aspirated fractions	2	N/A
Grape	1	1
Grape, dried (raisin…)	1.5	2
Leafy vegetables	30	30
Longan	2	
Lychee	2	2
Maize grain	0.05	0.05
Maize, refined oil	0.2	0.2
Maize, stover (fodder)	125	130
Maize, forage	15	15
Plum	0.3	0.3
Tree nuts	0.1	0.1
Pistachio	0.1	N/A (see tree nut)
Pulasan	2	2
Rambutan	2	2
Soya bean	0.04	0.04
Soya, refined oil	1	1
Soya, hay	75	75
Soya, forage	10	10
Spanish lime	2	2
Stone fruit (except prune plum)	3	3
Sweet corn (kernel + cob, husks rem)	0.05	0.05
Sweet corn forage	30	N/A
Sweet corn stover	60	N/A
Meat, mammalian	0.02	0.5 (fat)
Offal, mammalian	0.02	0.02
Liver, mammalian	0.1	0.1
Fat, mammalian	0.1	
Liver, mammalian	0.1	0.1
Milk	0.1	0.1

Poultry meat	0.02	0.02
Eggs	0.02	0.02

[1] US tolerance is parent only for plant commodities and parent plus its glucuronide metabolite for animal commodities.

Chronic dietary risk analyses by the US have indicated no concerns, with the risk <10% chronic reference dose for children 1-6 and for the general population. Using the chronic RfD from the US as an ADI and the proposed MRLs, chronic dietary exposure can be calculated using the JMPR system. See Appendix II. These TMDI calculations show that the dietary intake is 1 - 38% of the ADI.

Pyraclostrobin

Pyraclostrobin, or [2-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl] methoxy carbamic acid methyl ester, is a fungicide. Pyraclostrobin is currently undergoing review in EPA. Some deficiencies in the toxicology data base were identified. Field trial data for numerous crops have been reviewed, and a multiresidue analytical method has been submitted. Registrations do exist, however, in Belgium, Denmark, Germany, and Great Britain, and the manufacturer may wish to pursue Interim 8(I) status via one of these countries**.**

Fludioxonil

Fludioxonil, or 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-1H-pyrrole-3-carbonitrile, is a pyrrole fungicide with significant registered uses around the world. In the USA, some uses include stone fruit, bushberry subgroup, caneberry subgroup, grapes, onions, strawberries, and seed treatment for a wide variety of crops. Fludioxonil has not been officially classified as a safer or reduced risk pesticide. This may result from its introduction before the enhanced interest in reduced risk pesticides. It does have low acute toxicity, and available data did not indicate a need for acute or subchronic neurotoxicity studies. It is not a dermal skin sensitizer. The acute reference dose, 1.0 mg/kg/day, was applicable to females 13-50 years old only, based on a NOAEL of 100 mg/kg/day from a developmental toxicity study in the rat. The chronic RfD of 0.03 mg/kg was based on a NOAEL of 3.3 mg/kg/day, reflecting decreased body weight gain in female dogs. It was decided that no special sensitivity of children to the pesticide was indicated. It is regarded as non-classifiable as to human carcinogenicity. In the US, acute dietary exposure (females 13 - 50) was <1% of the acute reference dose, and the chronic dietary exposures for the general population and all subgroups were below the chronic reference dose, infants (<1 year old) being the most exposed at 32%.

Fludioxonil: National MRLs

Commodity	MRL (mg/kg)												
	Country												
	Australia	Austria	Belgium	Canada	France	Germany	Israel	Italy	Japan	Netherlands	Switzerland	USA[1]	Possible Codex
Brassica vegetables		0.05				0.05				0.05		0.01	0.05
Cereal grains		0.05			0.02 (ex maize)	0.05		0.05 (barley, corn, wheat)	0.02	0.05	0.02	0.02	0.05
Cotton gin byproducts												0.05	
Cotton seed												0.05	0.05
Cucurbit vegetables		0.05				0.05	0.01 (cucum-ber)	1 (cucum-ber)	2 (cucum-ber)	0.05	0.5 (cucum-ber)	0.01	2
Legume vegetables									0.1 (beans, peas))	0.05	0.1 (beans)	0.01 (succulent and dry)	0.1
Foliage of legume vegetables												0.01	
Forage, fodder, and straw of cereal grains												0.01	0.01

Fruiting vegetables (except cucurbits)		0.05				0.05	0.3 (pepper, tomato)	1 (eggplant, tomato, pepper)	2 (eggplant, tomato)	0.05	0.5 (eggplant, tomato)	0.01	2
Grapes	2	2				2	1	2	5		3	1	5
Grass, forage, fodder, hay												0.01	0.01
Herbs and spices												0.02	
Leafy vegetables except Brassica		0.05				0.05		2 (lettuce)	1 (lettuce)	0.05	1 (lettuce)	0.01	2
Leaves and roots of tuber vegetables												0.02	
Non-grass animal feeds												0.01	
Onions, dry bulb		0.05				0.05			0.1	0.05	0.05	0.20	0.2
Onions, green		0.05				0.05				0.05		7	7
Peanut hay												0.01	0.01
Peanuts									0.1			0.01	0.1
Pulses									0.2				0.2
Flax seed												0.05	0.05
Rape forage												0.01	0.01
Rape seed												0.01	0.01
Root and tuber vegetables	0.05 (potato)			0.02 (potato)		0.05			0.02 (potato)			0.02	0.05
Strawberry		1	0.5			1	0.5	2	5		0.5		5

Sunflower seed												0.01	0.01
Fruit		0.05								0.05			
Stone fruit					0.5 (apricot, nectarine, peach)			0.5 (apricot, cherry, nectarine, peach, plum)	0.5 (apricot, cherry, nectarine, peach, plum)		0.5	5 Po (apricot, nectarine, peach, plum)	5
Maize					0.05								
Pear								0.5					0.5
Raspberry											1		1
Blackberry											1		1

[1] The residue definition is fludioxonil.

The US chronic reference dose (ADI) may be combined with possible Codex interim MRLs to generate TMDI's for the 5 GEMS food regions. See Appendix II. These calculations show that the dietary intake is 5 – 32% of the ADI. Acute dietary exposure calculations cannot be properly performed, as Codex does not have consumption data specific for females, the only group with an acute dietary exposure issue. An approximate calculation can be made by assuming that the consumption by females is the same as the general population. Thereby, the acute exposure for the general population is 0-13%.

Trifloxystrobin

Trifloxystrobin, or (E,E)-alpha-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl]ethylidene]amino]oxy]methyl]-benzeneacetic acid methyl ester, is a fungicide that functions by interfering with the respiration in plant pathogenic fungi. The site of action of strobilurin compounds is located in the mitochondrial respiration pathway. Trifloxystrobin is considered a reduced risk pesticide in the US due to the low acute toxicity. The acute toxicity endpoint in the USA is increased fetal skeletal anomalies from a developmental toxicity study with rabbits. The acute RfD was set at 2.5 mg/kg. The chronic toxicity endpoint is decreased pup body weights during lactation from a reproductive toxicity study with rats. The chronic RfD is 0.038 mg/kg/day. Trifloxystrobin has been classified as a not likely human carcinogen. It has an extensive list of registrations in the US and some in Australia, Israel, and Switzerland.

Trifloxystrobin: : National MRLs

Commodity	MRL (mg/kg)				
	Country				
	Australia	Israel	Switzerland	United States[1]	Possible Codex
Almond				0.04	0.05
Banana	0.1			0.1	0.1
Barley			0.2		0.2
Citrus group				0.3	0.3
Cucurbit veg		0.1 cucumber		0.5	0.5
Fruiting veg		0.2 tomato		0.5	0.5
Grapes	0.5	1	3	2	2
Hops, dried cones				11	15
Raisins	2			5	5
Maize				0.05	0.05
Maize forage				0.2	0.2
Maize stover				7.0	7
Nut group				0.04	0.04
Peanuts				0.05	0.05

Peanut hay				4.0	4
Pome fruit	0.3		0.5	0.5	0.5
potato				0.04	0.04
Rice				3.5	4
Rice straw				7.5	8
Rice hulls				8.0	8
Stone fruit		0.7 peach		2.0	2
Strawberry		0.2			0.2
Sugar beet root				0.1	0.1
Sugar beet top				4.0	4
Wheat			0.05	0.05	0.05
Wheat forage				0.3	0.3
Wheat hay				0.2	0.2
Wheat straw				5.0	5
Apple pomace, wet				5.0	12 (dry)
Milk	0.02			0.02	0.02
Meat, mammalian	0.05			0.05	0.05
Edible offal, mammalian	0.05				0.05
Egg				0.04	0.04

[1] Residue is trifloxystrobin and metabolite CGA-321113 (acid)

Chronic and acute dietary intake analyses may be performed, substituting Possible Codex Interim MRLs for the STMRs and High Residues, respectively. The calculations are in Appendix II. These show that the dietary intake is 12 – 51% of the ADI and that the acute reference dose is not exceeded for any commodity (0 – 6%).

Dimethenamid-P

Dimethenamid-P, or (S)-2-chloro-N-{(1-methyl-2-methoxy) ethyl}-N-(2,4-dimethyl-thien-3-yl) acetamide, has been reviewed by EPA as a reduced risk pesticide. Dimethenamid-P differs from racemic dimethenamid in that it is enriched in the S isomer. An acute reference dose for the general population of 2.15 mg/kg/day and an acute reference dose of 0.215 mg/kg/day for infants and children were determined from a rat developmental study, where the endpoint was early resorptions with a NOAEL of 215 mg/kg/day. An ADI for the general population of 0.05 mg/kg/day and an ADI of 0.005 mg/kg/day for infants and children were based on non-neoplastic alterations in a chronic rat study. The 10X factor was retained for calculation of the ADI and the Acute Reference Dose that apply to infants and children pending further investigation of the effects on children and further consideration by EPA. However, based on the rat and rabbit developmental toxicity studies as well as the reproduction study, there did not appear to be an increase in the sensitivity of fetuses or offspring in relation to either maternal or parental toxicity. Dimethenamid-P was also classified as a possible human carcinogen, Category C. There was increased tumor incidence in rats, but not in mice. Using the population adjusted acute reference dose, the acute dietary exposure for the general US population and all subpopulations was <1%. Using the population adjusted chronic reference dose (ADI), the chronic dietary risk was found to be greatest for children 1 - 6, 1.5%. These calculations were performed using the current MRLs for dimethenamid (mixed isomer) and assuming 100% crop treated.

Given possible issues surrounding the translation of field trial and other data from the racemic mixture to the S-enriched mixture, the consideration of Dimethenamid-P should be deferred to the JMPR. Moreover, dimethenamid-P may be of low risk primarily because of very low residue values; most MRLs are at the limit of determination of the analytical method, 0.01 mg/kg.

Fenhexamid

The USA has classified fenhexamid, or N-(2,3-dichloro-4-hydroxyphenyl)-1-methylcyclohexanecarboxamide, as a reduced risk pesticide. No adverse effects attributable to a single exposure were identified, and an acute reference dose was not established. A chronic reference dose of 0.17 mg/kg/day was set based on a NOAEL of 17 mg/kg/day from the chronic oral toxicity study in dogs. The endpoint was decreased red blood cell counts, hematocrit, and hemoglobin and increased Heinz bodies in RBC. A chronic population-adjusted dose of 0.057 mg/kg/day was adopted (3X factor) to account for possible increased sensitivity in children. There was qualitative evidence of increased susceptibility in rat pups compared to adults. Fenhexamid is classified as a not likely carcinogen. The core data base was reviewed jointly by Canada and the US.

Fenhexamid has registered uses in several countries, as summarized in the following table.

Commodity	MRL (mg/kg)				
	Country				
	Canada[1]	Israel	USA[1]	Japan	Possible Codex
Almond	0.02	0.02	0.02	0.02	0.02
Bushberry			5.0		5
Caneberry			20	3 raspberry	20
Cucumber		0.5		2	2
Eggplant		0.5		2	2
Plum	0.5				6 (see stone fruit)
Stone fruit	6 (apricot, cherry, peach, nectarine)		6.0 (incl cherry)	6 peach, nectarine, apricot, mume plum (excl cherry)	6
Cherry				10	10
Citrus				5 orange, lemon, grapefruit, lime, other	5
Grape	4	0.02	4.0	20	20

Kiwifruit				10	10
Onion				0.1	0.1
Raisin	6		6.0		6[2]
Pear			15.		15
Pistachio			0.02		0.02
Strawberry	3	4.0	3.0	5	5
Tomato		0.02		2	2

1 Residue is fenhexamide.

2 MRL for grape extends to raisin.

Chronic dietary exposure in the US was <10% of the chronic population-adjusted dose for general population and all subgroups. A chronic dietary exposure calculation can be conducted based on possible Codex interim MRLs and the US chronic population-adjusted dose (0.057 mg/kg/day). See the Appendix. These calculations (TMDI) indicate that the dietary intake is 2 – 31% of the ADI.

Indoxacarb

Indoxacarb, or (S)-methyl-7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4] oxadiazine-4a(3H)-carboxylate, is an insecticide belonging to the oxadiazine chemical family. The US has deemed indoxacarb a reduced risk pesticide and a replacement for the OPs, based on low acute and chronic toxicity and the lack of mutagenic, carcinogenic, developmental, and reproductive effects. Neurotoxicity effects do occur at the near-fatal dose level. There also is no evidence of increased susceptibility of infants and children to indoxacarb.

The US adopted an acute reference dose of 0.12 mg/kg for children and the general population, based on a NOAEL of 12.5 mg/kg/day and an uncertainty factor of 100. The reference dose was derived from an acute oral rat toxicity study where the observed effect was abnormal body weights. No factor was added for the susceptibility of children and infants. The chronic dietary RfD, or ADI, was set at 0.02 mg/kg/day based on a NOAEL of 2.0 mg/kg/day and an uncertainty factor of 100. This NOAEL is the lowest NOAEL of three studies: 90 day rat subchronic toxicity study; 90 day rat neurotoxicity study; chronic/carcinogenicity rat study. Effects were body weight variations, food consumption and efficiency, and decreased hematocrit, hemoglobin, and red blood cells (at 6 months). US dietary risk calculation procedures led to exposure at 12% of the acute reference dose for children 1-6 and 7.1% for the general population. The chronic dietary risk was 85% of the ADI for children 1-6 years old and 33% for the general population.

Indoxacarb: National MRLs.

Commodity	MRL (mg/kg)					
	Country					
	Australia	Israel	Italy	New Zealand	USA[1]	Possible Codex
Apple			0.3	0.5 (pome fruit)	1	1
Apple, pomace, wet					3	10

						(dry)
Pear			0.3	0.5 (pome fruit)	0.2	0.5
Brassica, head and Stem, vegetables	1	0.02 (cauliflower)	0.2	0.5	5	5[2]
Cottonseed					2	2
Cotton gin byproducts					15	[3]
Lettuce, leaf			2		10	10
Lettuce, head			2		4	4
Fruiting vegetables, except cucurbits		0.02 (pepper, tomato)	0.1 (eggplant, tomato)		0.5	0.5
Corn, sweet, kernel plus cob with husk removed					0.02	0.02
Corn, sweet, forage					10	10
Corn, sweet, stover					15	15
Grapes		0.02	0.5 (0.02 wine)			0.5
Maize grain		0.02				0.02
Meat (mammalian)					0.05	1.5 (fat)
Fat (mammalian)					1.5	
Offal (mammalian)					0.03	0.03
Milk					0.15	0.2 F

1 Indoxacarb plus its R-enantiomer.
2 See acute dietary intakes.
3 Not a Codex commodity.

The proposed MRLs and US ADI and acute RfD may be used as a basis for calculating chronic and acute dietary risks respectively with the JMPR system. The chronic TMDI and acute dietary intake analyses are given in Appendix II. The dietary intake ranges from 5 – 75% of the ADI. The acute reference dose is exceeded for children for brassica head and stem vegetables and for the general population for brassica head and stem vegetables, using cauliflower as the commodity. Thus, it would be inappropriate to consider an interim MRL for brassica vegetables. The calculations assumed that meat is 100% fat (1.5 mg/kg), as opposed to the JMPR Recommendation (2002 Report) of 20% fat (1.5 mg/kg) and 80% lean (0.05 mg/kg). This simplification exaggerated the dietary exposure from meat consumption.

Novaluron

Novaluron, or 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxy-ehtoxy) phenyl]-3-(2,6-difluorobenzoyl)urea, is an insect growth regulator (IGR). It disrupts the normal growth development of immature insects. Novaluron works primarily via ingestion and may be used in an integrated pest management system. It currently has no registered food/feed uses in the USA and is only used on ornamentals. It has been designated a reduced risk pesticide for non-food uses because IGRs are comparatively safer (e.g., OP pesticides) to beneficial insects and the environment. Novaluron was recently granted an alternative status for pending uses on cotton and pome fruit, but the evaluation of the toxicology and residue chemistry is incomplete. Data packages have also been submitted to Canada and are in the early stages of review. The following table indicates registered uses in several countries, but toxicology, residue chemistry, and reference dose information are needed.

Novaluron: National MRLs

Commodity	Argentina	Australia	Brazil	Bulgaria	Chile	Cuba	Hungary	Israel	Mexico	Peru	Ukraine	New Zealand	South Africa	Switzerland	Possible Codex
Alfalfa								2.0							2
Apple		1.0 (T)		0.5	0.5		0.2	0.02			0.1				See pome fruit
Apple Juice											0.1				
Artichoke								0.02							0.02
Bean								0.02		0.02					0.02
Broccoli														0.5	0.5
Cabbage					0.3			0.02		0.1				0.5	0.5
Cauliflower					0.05									0.5	0.5
Cottonseed		1.0 (T) 2.0 (T) \ oil	0.02					0.02	0.02 0.01 oil 0.01 by-products	0.02		0.1 (T)	0.05		1 2 oil
Maize	0.1		0.02				0.2	0.02	0.01 0.3 forage						0.1
Peach													0.05 (canned)		
Pear		1.0 (T)			0.5										1
Pome fruit														0.3	
Potato				0.01	0.01		0.2	0.02			0.05			0.01	0.2
Soya bean			0.02												0.02
Tobacco						10.0									
Tomato	0.5		0.02		0. 5			0.2		0.1			0.01	2	2

APPENDIX II: CALCULATION OF THE CHRONIC DIETARY AND ACUTE DIETARY INTAKES

The chronic dietary intakes for those pesticides on the Priorities list (ALINROM 03/24, Appendix VII) tentatively identified as safer replacements have been calculated using the current practices of the JMPR. Because field trial data have not been considered, the proposed interim MRLs have been used for the residue concentrations. Thus, the intakes calculated are in excess of those determined by the JMPR using the STMR or STMRP from field trial and processing studies and represent a Theoretical Maximum Dietary Intake. The chronic reference dose as determined by the US EPA, designated the ADI in the Codex system, has been used as the marker for maximum allowable daily intake.

The acute dietary intakes were also calculated where appropriate with the JMPR deterministic methodology. The acute reference dose or population-adjusted acute reference dose of the US EPA and the proposed interim MRLs were used. The MRLs may in some cases be greater than the HR (high residue) values used in the JMPR's calculations. Also, STMR and STMRP values were not available. Therefore, the MRL was used for the residue level in the large portion beyond the first unit. These alterations will lead to dietary exposures somewhat larger than those typically calculated by JMPR.

In all cases considered, except indoxacarb, the chronic and acute exposures were well below the allowable limits. For indoxacarb, the acute dietary exposure was unacceptable for both children and the general population for the Brassica vegetable group. Cauliflower was used in the calculation, as this commodity has the greatest consumption of the various Brassica vegetables.

Chronic Dietary. TMDI.	**CYPRODINIL**			ADI =	0.0375	mg/kg bw	or	2250	ug/person			
			Diets: g/person/day. Intake = daily intake:ug/person									
		MRL	Mid-East		Far-East		African		Latin American		European	
Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN660	almond	0.02	0.5	0.0	0	0.0	0	0.0	0.1	0.0	1.8	0.0
FB18	small berries	10	0	0.0	16	160.0	1	10.0	0	0.0	1.5	15.0
FP9	Pome fruit	5	10.8	54.0	7.5	37.5	0.3	1.5	6.5	32.5	51.3	256.5
FB269	Grapes	5	15.8	79.0	1	5.0	0	0.0	1.3	6.5	13.8	69.0
DF269	Dried grapes (=Currants .)	3	0.3	0.9	0	0.0	0	0.0	0.3	0.9	2.3	6.9
VA385	Onion, bulb	0.6	23	13.8	9.5	5.7	5.8	3.5	9.8	5.9	26.8	16.1
VA388	Onions and shallots green	4	0	0.0	2	8.0	1.5	6.0	4	16.0	1	4.0
FB275	Strawberry	5	0	0.0	0	0.0	0	0.0	0	0.0	5.3	26.5
GC 0645	Maize	0.5	48.3	24.2	31.2	15.6	106.2	53.1	41.8	20.9	8.8	4.4
GC640	Barley	2	1	2.0	3.5	7.0	1.8	3.6	6.5	13.0	19.8	39.6
OR 0645	Rye	0.5	0	0.0	1	0.5	0	0.0	0	0.0	1.5	0.8
GC654	Wheat	0.5	327.3	163.7	114.8	57.4	28.3	14.2	116.8	58.4	178	89.0
VC424	Cucumber	0.5	4.8	2.4	4.5	2.3	0	0.0	8.3	4.2	9	4.5
VO51	Pepper	0.5	3.4	1.7	2.1	1.1	5.4	2.7	2.4	1.2	10.4	5.2
VO448	Tomato	0.5	81.5	40.8	7	3.5	16.5	8.3	25.5	12.8	66	33.0
VO440	Eggplant	0.5	6.3	3.2	3	1.5	0.7	0.4	6	3.0	2.3	1.2
VL482	Lettuce	2	2.3	4.6	0	0.0	0	0.0	5.8	11.6	22.5	45.0
VD71	Beans	0.1	6.8	0.7	6.8	0.7	0	0.0	13.5	1.4	4.3	0.4
VP63	Peas	0.1	5.5	0.6	0.7	0.1	0	0.0	0.3	0.0	14	1.4
FI345	Mandarin	0.1	8.6	0.9		0.0	0	0.0	6.3	0.6	6	0.6
FS12	Stone fruit (peach+nectarine+plum+che)	2	4.3	8.6	1.0	2.0	0.0	0.0	0.8	1.6	19.8	39.6
		TOTAL =		401		308		103		190		677

		% ADI =		18%		14%		5%		8%		29%

Chronic Dietary. TMDI **METHOXYFENOZIDE**

ADI = 0.1 mg/kg bw/day or 6000 ug/day
Diets: g/person/day. Intake: daily intake in ug/person

CODE	COMMODITY	MRL	MIDD.EAST		FAR EAST		AFRICAN		LATIN AM.		EUROPEAN	
		mg/kg	Diet	Intake	Diet	Intake	Diet	Intake	Diet	Intake	Diet	Intake
VS620	Artichoke, globe	3	2.3	6.9000	0	0.0000	0	0.0000	0	0.0000	5.5	16.5000
VB40	Brassica (cole) veg	7	6.3	44.1000	11.2	78.4000	0	0.0000	10.8	75.6000	39.8	278.6000
VL53	Leafy veg	30	7.8	234.0000	9.7	291.0000	0	0.0000	16.5	495.0000	51.3	1539.0000
VO50	Fruiting veg (non-cucu)	2	92	184.0000	12.5	25.0000	22.5	45.0000	33.8	67.6000	78.5	157.0000
FB269	Grapes	1	15.8	15.8000	1	1.0000	0	0.0000	1.3	1.3000	13.8	13.8000
DF269	Grapes, dried (raisins)	2	0.3	0.6000	0	0.0000	0	0.0000	0.3	0.6000	2.3	4.6000
FI342	Longan	2		0.0000		0.0000		0.0000		0.0000		0.0000
LI343	Lychee (litchi)	2		0.0000		0.0000		0.0000		0.0000		0.0000
FP9	Pome fruit	2	10.8	21.6000	7.5	15.0000	0.3	0.6000	6.5	13.0000	51.3	102.6000
GC645	Maize (incl flour)	0.05	48.3	2.4150	31.2	1.5600	106.2	5.3100	41.8	2.0900	8.8	0.4400
OR645	Maize oil, edible	0.2	1.8	0.3600	0	0.0000	0	0.0000	0	0.0000	7.8	1.5600
FS14	Plum	0.3	1.8	0.5400	0.5	0.1500	0	0.0000	0	0.0000	3.8	1.1400
VD451	Soya	0.04	4.5	0.1800	2	0.0800	0.5	0.0200	0	0.0000	0	0.0000
OR541	Soya bean oil, refined	1	1.3	1.3000	1.7	1.7000	3	3.0000	14.5	14.5000	4.3	4.3000
FI366	Spanish lime	2		0.0000		0.0000		0.0000		0.0000		0.0000
FS12	Stone fruit (exc	3	2.5	7.5000	0.5	1.5000	0	0.0000	0.8	2.4000	15.5	46.5000

	plum)												
VO447	Sweet corn (kernel/cob)	0.05		0	0.0000	0	0.0000	3.3	0.1650	0	0.0000	6.2	0.3100
FI357	Pulasan	2			0.0000		0.0000		0.0000		0.0000		0.0000
FI358	Rambutan	2			0.0000		0.0000		0.0000		0.0000		0.0000
TN85	Tree nut	0.1		1	0.1000	13.5	1.3500	3.4	0.3400	17.5	1.7500	3.8	0.3800
OC691	Cotton seed oil, crude	2		3.8	7.6000	0.5	1.0000	0.5	1.0000	0.5	1.0000	0	0.0000
MO1280	Cattle liver	0.1		0.2	0.0200	0.0	0.0000	0.1	0.0100	0.3	0.0300	0.4	0.0400
ML106	Milks	0.1		116.8	11.6800	32.0	3.2000	41.8	4.1800	160.0	16.0000	294.0	29.4000
MO105	Edible offal mammalian	0.02		4.2	0.0840	1.4	0.0280	2.4	0.0480	6.1	0.1220	12.4	0.2480
MM95	Meat mammalian	0.5		37.0	18.5000	32.8	16.4000	23.8	11.9000	47.0	23.5000	155.5	77.7500
PM110	Poultry meat	0.02		31.0	0.6200	13.2	0.2640	5.5	0.1100	25.3	0.5060	53.0	1.0600
PE112	Eggs	0.02		14.6	0.2920	13.1	0.2620	3.7	0.0740	11.9	0.2380	37.6	0.7520
			.	.	.	.	.	.	.	.	.	.	.
			TOTAL		558		438		71.8		715.		2276
			% ADI		9.3	.	7.3		1.2		12		38

Chronic Dietary. TMDI **FLUDIOXONIL** ADI= 0.03 mg/kg bw or 1800 ug/person

		MRL	Diets: g/person/day. Intake: daily intake in ug/person									
			Mid-East		Far-East		African		Latin American		European	
Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
VB40	Brassica vegetables	0.05	6.3	0.3	11.2	0.6	0	0.0	10.8	0.5	39.8	2.0
GC80	Cereal grains	0.05	430.8	21.5	452.3	22.6	318.4	15.9	252.5	12.6	226.3	11.3

OC691	Cotton seed oil, crude	0.05	3.8	0.2	0.5	0.0	0.5	0.0	0.5	0.0	0	0.0
VC45	Cucurbits	2	80.5	161.0	18.2	36.4	0	0.0	30.5	61.0	38.5	77.0
VP601	Legume vegetables	0.1	9.5	1.0	1.5	0.2	0	0.0	4.3	0.4	26.	2.6
VO50	Fruiting vegetables, non-cucurbits	2	92	184.0	12.5	25.0	22.5	45.0	33.8	67.6	78.5	157.0
FB269	Grapes	5	15.8	79.0	1	5.0	0	0.0	1.3	6.5	13.8	69.0
VL53	Leafy vegetables	2	7.8	15.6	9.7	19.4	0	0.0	16.5	33.0	51.3	102.6
VA385	Onions, bulb	0.2	23	4.6	11.5	2.3	7.3	1.5	13.8	2.8	27.8	5.6
VA388	Onions and shallots green	7	0	0.0	2	14.0	1.5	10.5	4	28.0	1	7.0
SO697	Peanut	0.1		0.0		0.0		0.0		0.0		0.0
VD70	Pulses	0.2	24.6	4.9	19.8	4.0	17.8	3.6	23.1	4.6	12.1	2.4
VR75	Root and tuber vegetables	0.05	61.8	3.1	108.5	5.4	321.3	16.1	159.3	8.0	242	12.1
FB275	Strawberry	5	0	0.0	0	0.0	0	0.0	0	0.0	5.3	26.5
OR702	Sunflower seed oil	0.01	9.3	0.1	0.5	0.0	0.3	0.0	0.8	0.0	8.5	0.1
FS12	Stone fruit (peach+nectarine+plum+che)	5	4.3	21.5	1	5.0	0	0.0	0.8	4.0	19.8	99.0
FP230	Pear	0.5	3.3	1.7	2.8	1.4	0	0.0	1	0.5	11.3	5.7
FB272	Raspberry	1	0	0.0	0	0.0	0	0.0	0	0.0	0.5	0.5
FB264	Blackberry	1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
				0.0		0.0		0.0		0.0		0.0
		TOTAL =		498		141		93		230		580
		% ADI =		28%		8%		5%		13%		32%

Fludioxonil **IESTI General Population**

Acute RfD	mg/kg bw	1000	ug/kg bw	(females	13-50)	

Code	Name	MRL, mg/kg	Large portion diet Country	Body weight, kg	Large portion, g	Unit weight Unit weight g	Country	Unit weight, edible portion, g	Var factor	Case	IESTI, ug/kg bw/day	% acute RfD

VB40	Brassica vegetables (cauliflower)	0.05	UK	70	579	525	USA	224	7	2a	1.4	0
GC60	Cereal grains (wheat)	0.05	USA	65	383					1	0.3	0
VC45	Cucurbits (melon)	2.00	USA	65	606	552	USA	276	5	2a	52.6	5
VP60	Legume vegetables	0.10	NL	63	431				1	1	0.7	0
OR 0691	Cotton seed oil, edible	0.05	USA	65	9.10					1	0.0	0
V050	Fruiting vegetables, non-cucurbit (tomato)	2.00	USA	65	391.0	100	USA	100		2a	9.0	1
FB 269	Grapes	5.00	Aus	67	1004	125	FRA	118	7	2a	127.8	13
VL 53	Leafy vegetables (spinach)	2.00	NL	63	820	340	USA	245	10	2a	96.0	10
VR 75	Root and tuber vegetables (potato)	0.05	Nl	63	687	122	USA	98	7	2a	1.0	0
VA 385	Onions, bulb	0.20	Fra	62.3	300	164	UK	91	7	2a	2.7	0
SO697	Peanut	0.10	Fra	62.3	162				1	1	0.3	0
VD70	Pulses [VD72 dry pea]	0.20	Fra	62.3	446				1	1	1.4	0
FB 275	Strawberry	5.00	Fra	62.3	346	14	FRA	13	1	2a	27.8	3
OR 702	Sunflower seed oil	0	Fra	62.3	61				1	1	0.0	0
FS 12	Stone fruit (peach)	5.00	Jpn	52.6	626	98	USA	85	7	2a	108.0	11
FP 230	Pear	0.5	USA	65	671	166	USA	151	7	2a	12.1	1
FB 272	Raspberry	1.00	Fra	62.3	324					1	5.2	1
FB 264	Blackberry	1.00	Aus	65	138					1	2.1	0
											MAX IESTI =	13

Chronic Dietary. TMDI	**TRIFLOXYSTROBIN**		ADI=	0.038	mg/kg bw	or	2280	ug/person

MRL	Diets: g/person/day. Intake = daily intake:ug/person				
	Mid-East	Far-East	African	Latin American	European

Code	Commodity	Comment	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN660	Almond		0.05	0.5	0.0	0	0.0	0	0.0	0.1	0.0	1.8	0.1
FI327	Banana		0.1	8.3	0.8	26.2	2.6	21	2.1	102.3	10.2	22.8	2.3
GC640	Barley		0.2	1	0.2	3.5	0.7	1.8	0.4	6.5	1.3	19.8	4.0
FC1	Citrus fruits		0.3	54.3	16.3	6.3	1.9	5.1	1.5	54.8	16.4	49	14.7
VC45	Cucurbits		0.5	80.5	40.3	18.2	9.1	0	0.0	30.5	15.3	38.5	19.3
VO50	Fruiting vegetables, non-cucurbits		0.5	92	46.0	12.5	6.3	22.5	11.3	33.8	16.9	78.5	39.3
FB269	Grapes		2	15.8	31.6	1	2.0	0	0.0	1.3	2.6	13.8	27.6
DH1100	Hops, dry		15	0.1	1.5	0.1	1.5	0.1	1.5	0.1	1.5	0.1	1.5
DF269	Dried grapes (raisins)		5	0.3	1.5	0	0.0	0	0.0	0.3	1.5	2.3	11.5
GC645	Maize (incl flour)		0.05	48.3	2.4	31.2	1.6	106.2	5.3	41.8	2.1	8.8	0.4
TN85	Tree nuts		0.04	1	0.0	13.5	0.5	3.4	0.1	17.5	0.7	3.8	0.2
SO703	Peanut		0.05		0.0		0.0		0.0		0.0		0.0
FP9	Pome fruit		0.5	10.8	5.4	7.5	3.8	0.3	0.2	6.5	3.3	51.3	25.7
VR 0589	Potato		0.04	59	2.4	19.2	0.8	20.6	0.8	40.8	1.6	240.8	9.6
GC649	Rice		4	48.8	195.2	279.3	1117.2	103.4	413.6	86.5	346.0	11.8	47.2
FS12	Stone fruit(peach+nectarine+plum+che)		2	4.3	8.6	1	2.0	0	0.0	0	0.0	19.8	39.6
FB275	Strawberry		0.2	0	0.0	0	0.0	0	0.0	0	0.0	5.3	1.1
VR596	Sugar beet (root)		0.1	0.5	0.1	0	0.0	0	0.0	0.3	0.0	2	0.2
GC654	Wheat		0.05	327.3	16.4	114.8	5.7	28.3	1.4	116.8	5.8	178	8.9
ML106	Milks		0.02	116.8	2.3	32	0.6	41.8	0.8	160	3.2	294	5.9
MM95	Meat, mammalian		0.05	37	1.9	32.8	1.6	23.8	1.2	47	2	155.5	7.8
MO105	Offal, edible mammalian		0.05	4.2	0.2	1.4	0.1	2.4	0.1	6.1	0.3	12.4	0.6
PE112	Eggs		0.04	14.6	0.6	13.1	0.5	3.7	0.1	11.9	0.5	37.6	1.5
			TOTAL =		374		1158		440		432		269
			% ADI =		16%		51%		19%		19%		12%

Trifloxystrobin **IESTI General Population**

Acute RfD mg/kg bw 2500 ug/kg bw

Code	Name	MRL, mg/kg	Large portion diet Country	Body weight, kg	Large portion, g	Unit weight Unit weight g	Country	Unit weight, edible portion, g	Var factor	Case	IESTI, ug/kg bw/day	% acute RfD
TN660	Almond	0.05	Jpn	63	88					1	0.1	0
FI327	Banana	0.1	Usa	65	556	150	FRA	102	7	2a	1.8	0
GC640	Barley	0.2	Nl	63	378					1	1.2	0
FC1	Citrus fruits [orange]	0.3	Usa	65	564	190	FRA	134	7	2a	6.3	0
VC45	Cucurbits [melon]	0.5	Usa	65	655.00	700	FRA	420	5	2a	18.0	1
VO50	Fruiting veg [tomato]	0.5	Usa	65	390.0	105	FRA	102	7	2a	7.7	0
FB269	Grapes	2	Aus	67	1004	125	FRA	118	7	2a	51.1	2
DH1100	Hops, dry	15	Usa	65	6	125	FRA	118	7	2b	9.7	0
DF269	Dried grapes (raisins)	5	Fr	62.3	135					1	10.8	0
GC645	Maize	0.05	Fr	62.3	260					1	0.2	0
TN85	Tree nuts	0.04	Jpn	63	130					1	0.1	0
SO703	Peanut	0.05	Fr	62.3	161					1	0.1	0
FP9	Pome fruit [apple]	0.5	Usa	65	1350	110	FRA	100	7	2a	15.0	1
VR 0589	Potato	0.04	Nl	63	690	150	JPN	150	7	2a	1.0	0
GC649	Rice	4	Fr	62.3	310					1	19.9	1
FS12	Stone fruit [peach]	2	Jpn	63	750	150	Jpn	150	7	2a	52.4	2
FB275	Strawberry	0.2	Fr	62.3	350	15	Jpn	15	7	2a	1.4	0
VR596	Sugar beet (root)	0.1								1		
GC654	Wheat	0.05	Usa	65	380					1	0.3	0
ML106	Milks	0.02	Usa	65	2500					1	0.8	0
MM95	Meat, mammalian	0.05	Aus	67	521					1	0.4	0
Mo105	Offal, edible mammalian	0.05	Aus	67	459					1	0.3	0
PE112	Eggs	0.04	Fr	62.3	220					1	0.1	0

Trifloxystrobin **IESTI Children**

Acute RfD 2.5 mg/kg bw or 2500 ug/kg bw

Code	Name	HR, mg/kg	Large portion diet Country	Body weight, kg	Large portion, g	Unit weight g Unit weight g	Country	Unit weight, edible portion, g	Var factor	Case	IESTI, ug/kg bw/day	% acute RfD
TN660	Almond	0.05	Far	17.8	32					1	0.1	0
FI327	Banana	0.1	Jpn	15.9	312	150	FRA	102	7	2a	5.8	0
GC640	Barley	0.2	Aus	19	14					1	0.1	0
FC1	Citrus fruits	0.3	UNK	14.5	495	190	FRA	134	7	2a	26.9	1
VC45	Cucurbits	0.5	Aus	19	413.00	700	FRA	420	5	2b	54.3	2
VO50	Fruiting vegetables, non-cucurbits	0.5	USA	15	159.0	105	FRA	102	7	2a	25.7	1
FB269	Grapes	2	Jpn	15.9	388	125	FRA	118	7	2a	137.9	6
DH1100	Hops, dry	15	Jpn	15.9	1	125	FRA	118	7	2b	3.3	0
DF269	Dried grapes (raisins)	5	USA	15	60					1	20.0	1
GC645	Maize	0.05	Fra	17.8	150					1	0.4	0
TN85	Tree nuts	0.04	Aus	19	28					1	0.1	0
SO703	Peanut	0.05	USA	15	78					1	0.3	0
FP9	Pome fruit	0.5	USA	15	680	110	FRA	100	7	2a	42.7	2
VR 0589	Potato	0.04	UK	14.5	280	150	JPN	150	7	2a	3.3	0
GC649	Rice	4	Fra	17.8	222					1	49.9	2
FS12	Stone fruit [peach+nectarine+plum consumption]	2	Aus	19	316	150	Jpn	150	7	2a	128	5
FB275	Strawberry	0.2	Aus	19	176	15	Jpn	15	1	2a	1.9	0
VR596	Sugar beet (root)	0.1										
GC654	Wheat	0.05	Usa	15	151					1	0.5	0
ML106	Milks	0.02	Usa	15	1290					1	1.7	0
MM95	Meat, mammalian	0.05	Aus	19	260					1	0.7	0

MO105	Offal, edible mammalian	0.05	Fr	17.8	203	1	0.6	0
PE112	Eggs	0.04	Fra	17.8	134	1	0.3	0

Chronic Dietary. TMDI **Fenhexamid** ADI= 0.057 mg/kg bw or 3420 ug/person

Diets: g/person/day. Intake = daily intake:ug/person

		MRL	Mid-East		Far-East		African		Latin American		European	
Code	Commodity	mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
TN660	Almond	0.02	0.5	0.0	0	0.0	0	0.0	0.1	0.0	1.8	0.0
FB18	Berries	20	0	0.0	16	320	1	20	0	0.0	1.5	30
FS13	Cherry, sweet and sour	10	0	0.0	0	0.0	0	0.0	0	0.0	3	30.0
FC1	Citrus fruit	5	54.3	271.5	6.3	31.5	5.1	25.5	54.8	274.0	49	245.0
VC424	Cucumber	2	4.8	9.6	4.5	9.0	0	0.0	8.3	16.6	9	18.0
VO440	Eggplant	2	6.3	12.6	3	6.0	0.7	1.4	6	12.0	2.3	4.6
FI341	Kiwifruit	10		0.0		0.0		0.0		0.0		0.0
FS12	Stone fruit [peach+nectarine+plum]	6	4.3	25.8	1	6.0	0	0.0	0.8	4.8	16.3	97.8
FB269	Grape	20	15.8	316	1	20	0	0.0	1.3	26	13.8	276
DF269	Grape, dried (raisin)	(20)	0.3	6.0	0	0.0	0	0.0	0.3	6.0	2.3	46.0
VA385	Onion, bulb	0.1		0.0		0.0		0.0		0.0		0.0
FP230	Pear	15	3.3	49.5	2.8	42.0	0	0.0	1	15.0	11.3	169.5
FB275	Strawberry	5	0	0.0	0	0.0	0	0.0	0	0.0	5.3	26.5
VO448	Tomato	2	81.5	7.0	7	16.5	16.5	25.5	25.5	51.0	66	132.0
TN675	Pistachios	0.02	0.3	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		TOTAL =		698		451		72		405		1075
		% ADI =		20%		13%		2%		12%		31%

Chronic Dietary. TMDI **INDOXACARB** ADI= 0.02 mg/kg bw or 1200 ug/person

Code	Commodity	MRL	Diets: g/person/day. Intake = daily intake:ug/person									
			Mid-East		Far-East		African		Latin American		European	
		mg/kg	diet	intake	diet	intake	diet	intake	diet	intake	diet	intake
FP 0226	Apple	1	7.5	7.5	4.7	4.7	0.3	0.3	5.5	5.5	40	40.0
FP230	Pear	0.5	3.3	1.7	2.8	1.4	0	0.0	1	0.5	11.3	5.7
VB40	Brassica vegetables	5	6.3	31.5	11.2	56.0	0	0.0	10.8	54.0	39.8	199.0
OC691	Cotton seed oil, crude	2	3.8	7.6	0.5	1.0	0.5	1.0	0.5	1.0	0	0.0
VL482	Lettuce, head	4	2.3	9.2	0	0.0	0	0.0	5.8	23.2	22.5	90.0
VL483	Lettuce, leaf	10	2.3	23.0	0	0.0	0	0.0	5.8	58.0	22.5	225.0
VO50	Fruiting vegetables, non-cucurbit	0.5	92	46.0	12.5	6.3	22.5	11.3	33.8	16.9	78.5	39.3
VO447	Sweet corn (corn-on-the-cob)	0.02	0	0.0	0	0.0	4.4	0.1	0	0.0	8.3	0.2
FB269	Grapes	0.5	15.8	7.9	1	0.5	0	0.0	1.3	0.7	13.8	6.9
GC645	Maize (incl flour)	0.02	48.3	1.0	31.2	0.6	106.2	2.1	41.8	0.8	8.8	0.2
MM95	Meat (mammalian)[1]	1.5	37	55.5	32.8	49.2	23.8	35.7	47	70.5	155.5	233.3
MO105	Edible offal (mammalian)	0.03	4.2	0.1	1.4	0.0	2.4	0.1	6.1	0.2	12.4	0.4
ML106	Milks	0.2	116.8	23.4	32	6.4	41.8	8.4	160	32.0	294	58.8
		TOTAL =		214		126		59		263		899
		% ADI =		18%		11%		5%		22%		75%

[1] Dietary exposure from meat slightly exaggerated based on 100% fat rather than 80% muscle and 20% fat (2002 JMPR)

Indoxacarb

IESTI Children

Acute RfD 0.12 mg/kg bw or 120 ug/kg bw

Code	Name	HR, mg/kg	Large portion diet Country	Body weight, kg	Large portion, g	Unit weight Unit weight g	Country	Unit weight, edible portion, g	Var factor	Case	IESTI, ug/kg bw/day	% acute RfD
FP 0226	Apple	1	USA	15	679	110	FRA	100	7	2a	85.3	71
FP230	Pear	0.5	UK	14.5	279	100	FRA	89	7	2a	28.0	23
VB40	Brassica veg [cauliflower]	5	NL	17	209	1733	UK	780	5	2b	307.4	256
OR691	Cotton seed oil, edible	2	USA	15	6				1	1	0.8	1
VL482	Lettuce, head	4	USA	15	74.00	754	UK	558	5	2b	98.7	82
VL483	Lettuce, leaf	10	NL	17	102.0	10	USA	10	7	2a	95.3	79
VO50	Fruiting veg [tomato]	0.5	USA	15	159	105	FRA	102	7	2a	25.7	21
VO447	Sweet corn (corn-on-the-cob)	0.02	UK	14.5	161	371	UK	215	5	2b	1.1	1
FB269	Grapes	0.5	AUS	19	463	125	FRA	118	7	2a	30.8	26
GC645	Maize	0.02	FRA	17.8	148				1	1	0.2	0
MM95	Meat (mammalian)	1.5	AUS	19	260				1	1	20.5	17
MO105	Edible offal (mammalian)	0.03	FRA	17.8	203				1	1	0.3	0

ML106	Milks	0.2	AUS	19	1450				1	1	15.3	13
											MAX IESTI =	256

Indoxacarb **IESTI General Population**

Acute RfD 0.12mg/kg bw or 120 ug/kg bw

Code	Name	HR, mg/kg	Large portion diet Country	Body weight, kg	Large portion, g	Unit weight Unit weight g	Country	Unit weight, edible portion, g	Var factor	Case	IESTI, ug/kg bw/day	% acute RfD
FP 0226	Apple	1	USA	65	1348	110	FRA	100	7	2a	30.0	25
FP230	Pear	0.5	USA	65	693	100	FRA	89	7	2a	9.4	8
VB40	Brassica veg [cauliflower]	5	UNK	70.1	579	1733	UK	780	5	2b	206.5	172
OR691	Cotton seed oil, edible	2	USA	65	9					1	0.3	0
VL482	Lettuce	4	USA	65	213.00	754	UK	558	5	2b	65.5	55
VL483	Lettuce, leaf	10	NL	63	152.0	10	USA	10	7	2a	33.7	28
VO50	Fruiting vegetables [tomato]	0.5	USA	65	391	105	FRA	102	7	2a	7.7	6
VO447	Sweet corn (corn-on-the-cob)	0.02	USA	65	368	371	UK	215	5	2a	0.4	0
FB269	Grapes	0.5	AUS	67	1004	125	FRA	118	7	2a	12.8	11
GC645	Maize	0.02	FRA	62.3	260					1	0.1	0
MM95	Meat (mammalian)	1.5	AUS	67	520					1	11.6	10
MO105	Edible offal (mammalian)	0.03	FRA	62.3	277					1	0.1	0

ML106	Milks	0.2	USA	65	247				1	0.8	1

APPENDIX III: EXAMPLE OF TOXICOLOGY SUMMARY FOR STEP 8(I) NOMINEE PESTICIDES[1]

Summary Table of Toxicology Studies for XXXX (Technical)[1]

METABOLISM - XXXX

Absorption: With rats, radiolabeled. XXXX was rapidly and extensively absorbed in both sexes following single or repeat low-dose (0.97 mg/kg bw) administration and single high-dose (166 mg/kg bw) administration. Greater than 95% of the administered dose was absorbed following single or repeat low-dose administration and single high-dose administration. Data suggests that there was very little or no biliary absorption.

Distribution: The highest residues levels were observed in the fat, lungs, kidneys and liver, however, mean recovery of radioactivity in tissues/carcass at sacrifice (at 168 hours post-dosing) was less than 0.3% of administered dose for all dose groups indicating little potential for accumulation.

Metabolism: The major component in urine and faecal extracts was identified as XXXY, the free acid derivative of XXXX resulting from hydrolysis of the ester bond of the parent compound accounting for approximately 82.0-91.6% of the administered dose. The only other metabolite found (found in faecal extract only) was identified as the parent compound, XXXX, accounting for less than 0.1% of the administered dose.

Excretion: Excretion was rapid, with the majority of radioactivity being eliminated within 12 hours post-dosing via urine (greater than 85% of the administered dose at the low and high dose) and within 24 hours post-dosing via faeces (0.56-1.43 and 0.80-2.01% at the low and high dose, respectively). The major route of excretion was via urine, accounting for approximately 95% of administered dose at both dose levels. Faecal excretion accounted for approximately 1.0-2.4% of administered dose at both dose levels. By 72 hours less than 0.01% of the administered dose was recovered in expired air. Data suggests that there was very little or no biliary excretion

There were no significant qualitative differences in absorption, distribution, metabolism or excretion of XXXX between the sexes, between single and repeat low-dose administration or between single low-dose and high-dose administration.

STUDY	SPECIES/STRAIN AND DOSES	NOAEL and LOAEL mg/kg bw/day	TARGET ORGAN/ SIGNIFICANT EFFECTS/ COMMENTS
ACUTE STUDIES - XXXX Technical			
Oral	Sprague-Dawley rats 5 animals/sex/dose **Dose Level**: 3,500 (females only), 4,000, 4,5000 (males only) or 5,050 mg/kg bw	**LD50 (95% confidence limits)**: males: 4,610 (4,450-4,790) mg/kg bw females: 4,210 (3,450-5,140) mg/kg bw sexes combined: 4,460 (4,180-4,750) mg/kg bw	No mortalities at 3500 mg/kg bw or in males at 4000 mg/kg bw; 3 females at 4000 mg/kg bw died by d 2; at 4500 mg/kg bw 1 male died by d 2; at 5050 mg/kg bw/d 5 males and 4 females died by d 2. No treatment-related clinical observations, necropsy findings or changes in bw. **LOW TOXICITY**

Dermal	SPF hybrid albino rats 5 rats/sex/dose **Dose Level**: 4,000 mg/kg bw	LD50 greater than 4,000 mg/kg bw for both sexes	No mortalities and no treatment-related necropsy findings or changes in bw. Clinical signs included dyspnea, ruffled fur, abnormal body position and reduced spontaneous activity, completely resolved by d 10. **LOW TOXICITY**
Inhalation - Limit Test (4-hour nose-only)	Tif: RAI f (SPF) albino rats 5 rats/sex **Dose Level**: Analytical Conc.- 5.3 mg/L air Nominal Conc. - 9.84 mg/L air (MMAD - 2.1 µM; GSD - 2.7)	LC50 greater than 5.3 mg/L air	No mortalities and no treatment-related necropsy findings or changes in bw. Clinical signs included slight dyspnea and ruffled fur, completely resolved by d 7. **LOW TOXICITY**
Eye Irritation	New Zealand White rabbits 6 males and 3 females **Dose Level**: 0.1 mL undiluted test substance.	MIS: 5.33/110 at 1 hr for unwashed and washed eyes. MAS (for 24, 48 & 72 hrs): 0.67/110 for unwashed eyes and 0.89/110 for washed eyes.	Minimal (grade 1) conjunctival redness, chemosis and discharge in all animals (unwashed and washed) at 1 hour completely resolved by 72 hours. **MINIMALLY IRRITATING**
Skin Irritation	New Zealand White rabbits 3 males and 3 females **Dose Level**: 0.5 mL undiluted test substance.	MIS: 1.83/8 at 1 hour MAS (for 24, 48 & 72 hrs): 1.0/8	Very slight erythema in all animals at 1 hour, completely resolved by 72 hours. Very slight edema in 5 of 6 animals at 1 hour completely resolved by 7 days. **MILDLY IRRITATING**
Skin Sensitization (Optimization method)	Pirbright White guinea pigs 10 animals/sex in treatment and naive control group **Dose Levels**: <u>Intradermal Induction</u>: 0.1 mL of 0.1% solution of test substance in physiological saline (wk 1) or 0.1 mL of 0.1% solution of test substance in 1:1 formulation of physiological saline and Bacto Adjuvant (wk 2-3). <u>Intracutaneous Challenge</u>: 0.1 mL of 0.1% solution of test substance in physiological saline. <u>Epicutaneous Challenge</u>: 0.1 mL of 3% solution of test substance in vaseline.	No dermal reactions observed at 24 or 48 hrs after intradermal or epidermal challenge treatment.	**NOT A DERMAL SENSITIZER**
ACUTE STUDIES – XXXX Technical			
Oral	Sprague-Dawley rats 5 animals/sex **Dose Level**: 5,050 mg/kg bw	LD50 greater than 5,050 mg/kg bw for both sexes	One female found dead on day 1; no treatment-related necropsy findings or changes in bw; clinical signs included decreased activity, piloerection and sensitivity to touch, completely resolved by d 3. **LOW TOXICITY**

Dermal	New Zealand White rabbits 5 animals/sex **Dose Level**: 2,020 mg/kg bw	LD50 greater than 2,020 mg/kg bw for both sexes	No mortalities and no treatment-related necropsy findings or changes in bw; one female exhibited soft faeces two hrs after dosing, completely resolved by d 2. **LOW TOXICITY**
Inhalation	Sprague-Dawley rats 5 animals/sex **Dose Level**: Analytical Conc.- 2.57 mg/L air (MMAD - 2.1 □M; GSD - 2.3-2.4)	LD50 greater than 2.57 mg/L air for both sexes	No mortalities and no treatment-related necropsy findings or changes in bw; all animals exhibited fur coated with faeces/ urine upon removal from chamber and piloerection on d 1, completely resolved by d 2. **LOW TOXICITY**
Eye Irritation	New Zealand White rabbits 6 males and 3 females **Dose Level**: 0.5 mL undiluted test substance.	**Unwashed eyes**: MIS: 18.3/110 at 48 hrs. MAS (for 24, 48 & 72 hrs): 15.5/110 **Washed eyes**: MIS: 21.7/110 at 24 hrs. MAS (for 24, 48 & 72 hrs): 19.9/110	Mildly Irritating to eye based on MIS/MAS for washed eyes, however, due to persistence of ocular irritation up to and including d 7 in both washed and unwashed eyes (not all d 7 scores equal 0), classification is upgraded to **MODERATELY IRRITATING**
Skin Irritation	New Zealand White rabbits 3 males and 3 females **Dose Level**: 0.5 mL undiluted test substance.	MIS: 0.17/8 at 1 hr. MAS (for 24, 48 & 72 hrs): 0/8	Very slight (grade 1) erythema noted in 1 animal at 1 hour, dermal irritation completely resolved by 24 hours. **MINIMALLY IRRITATING**
Skin Sensitization (Buehler method)	Hartley albino guinea pigs 5 animals/sex in treatment and naive control group **Dose Levels**: 0.4 mL of undiluted test substance for both the induction and challenge treatments.	No dermal reactions observed at 24 or 48 hrs after challenge treatment.	**NOT A DERMAL SENSITIZER**
SHORT TERM - XXXX Technical			
90-day dietary - mouse	15 CD-1 [Crl: CD-1 (ICR)BR] mice/sex/dose **Dose Level**: 0, 10, 100, 1,000 or 10,000 ppm (equal to 0, 1.6, 15.4, 161 and 1,552 mg/kg bw/d in males and 0, 2.0, 19.8, 194 and 1,970 mg/kg bw/d in females).	**NOAEL**: 10,000 ppm (equal to 1,552 and 1,970 mg/kg bw/d in males and females, respectively) **LOAEL**: Not determined.	There were no treatment-related findings in either sex at dose levels up to an including 10,000 ppm, the HDT **Control wk 13 bw** males: 34.3 g females: 29.3 g **Control wk 13 daily food cons.**: males: 4.9 g/animal; females: 5.2 g/animal

90-day dietary - rat	15 Sprague-Dawley rats/sex/dose **Dose Level**: 0, 50, 500, 5,000 or 20,000 ppm (equal to 0, 3, 34, 346 or 1,350 mg/kg bw/d for males and 0, 4, 38, 395 and 1,551 mg/kg bw/d for females)	**NOAEL**: 500 ppm (equal to 34 and 38 mg/kg bw/d in males and females, respectively) **LOAEL**: 5,000 ppm (equal to 346 and 395 mg/kg bw/d in males and females, respectively)	5,000 ppm - increased cytoplasmic accumulation of hyaline droplets in kidney (M). 20,000 ppm - lower bw, bwg and food cons. (M/F); lower urinary pH (M/F); increased urinary SG and urine volume (M); increased incidence of tubular basophilia, cytoplasmic accumulation of hyaline droplets and tubular casts in the kidney (M). Kidney histopathological findings considered to reflect early onset of spontaneous senile nephropathy (severity considered minimal). **Control wk 13 bw**: males: 557 g females: 318 g **Control wk 13 daily food cons.**: males: 25.4 g/animal females: 18.9 g/animal
90-day dietary - dog	4 beagle dogs/sex/dose **Dose Levels**: 0, 50, 1,000, 15,000 or 30,000 ppm (equal to 0, 2.0, 34.9, 516 and 927 mg/kg bw/d in the males and 0, 1.9, 39.8, 582 and 891 mg/kg bw/d in females)	**NOAEL**: 15,000 ppm (equal to 516 and 582 mg/kg bw/d in males and females, respectively). **LOAEL**: 30,000 ppm (equal to 927 and 891 mg/kg bw/day in the males and females, respectively).	30,000 ppm: lower bwg (M/F)
12-month dietary - dog	4 beagle dogs/sex/dose **Dose Levels**: 0, 40, 1,000, 10,000 or 20,000 ppm (equal to 0, 1.6, 31.6, 366 and 727 mg/kg bw/d in males and 0, 1.4, 39.5, 357 and 784 mg/kg bw/d in females)	**NOAEL**: 1,000 ppm (equal to 31.6 and 39.5 mg/kg bw/d in males and females, respectively) **LOAEL**: 10,000 ppm (equal to 366 and 357 mg/kg bw/d in males and females, respectively)	10,000 ppm and above: mucoid or bloody faeces, increased serum cholesterol and mild focal bilateral vacuolation of the dorsal medial hippocampus and/or lateral midbrain, secondary to altered glucose metabolism (M/F). 20,000 ppm: sporadic emesis (M/F); reduced RBC counts and haematocrit (M/F); reduced haemoglobin (F): lower bwg (M).
4-week dermal - rabbit	5 New Zealand White rabbits/sex/dose **Dose Levels**: 0, 10, 100 or 1,000 mg/kg bw/d	**Systemic Toxicity** **NOAEL**: 1,000 mg/kg bw/d **LOAEL**: Not determined.	No adverse treatment-related systemic findings in either sex. **Local irritation**: marginal increased severity of acanthosis and minimal to moderate increased incidence of inflammation, hyperkeratosis and crust formation in both sexes at 100 and 1,000 mg/kg bw/d.

CHRONIC TOXICITY/ONCOGENICITY - XXXX Technical			
78-week dietary - mouse	70 CD-1 [Crl:CD-1 (ICR)Br] mice/sex/dose **Dose Levels**: 0, 7, 70, 1,000, 3,500 or 7,000 ppm (equal to 0, 0.9, 9.0, 131, 451 and 912 mg/kg bw/d in males and 0, 1.1, 10.7, 154, 539 and 1,073 mg/kg bw/d in females)	**<u>Chronic Toxicity:</u>** **NOAEL**: 7,000 ppm (equal to 912 and 1,073 mg/kg bw/d in males and females, respectively). **LOAEL**: Not determined.	There were no treatment-related findings in either sex at dose levels up to an including 7,000 ppm, the HDT No evidence to indicate any carcinogenic potential of XXXX at any dose level up to and including 7,000 ppm, the HDT.
2-year dietary - rat	80-90 Sprague-Dawley rats/sex/dose (10 /sex/dose interim sacrifice, 20/sex/dose chronic toxicity, 50/sex/dose terminal sacrifice; 10/sex recovery group for control and 20,000 ppm groups only) **Dose Levels**: 0, 10, 100, 3,000, 10,000 or 20,000 ppm (equal to 0, 0.4, 3.9, 116, 393 and 806 mg/kg bw/d in males and 0, 0.5, 4.9, 147, 494 and 1,054 mg/kg bw/d in females).	**<u>Chronic Toxicity</u>**: **NOAEL**: 3,000 ppm (equal to 116 and 147 mg/kg bw/d in males and females, respectively). **LOAEL**: 10,000 ppm (equal to 393 and 494 mg/kg bw/d in males and females, respectively).	<u>10,000 ppm and above</u>: decreased urinary pH (M/F) and brown pigmentation in renal tubular epithelium (F; partially reversible after recovery; not observed at 104 wks). <u>20,000 ppm</u>: lower bw, bwg and food consumption (M/F); increased incidence/severity hyaline droplets in kidneys and brown pigmentation in renal tubular epithelium (M,; reversible after recovery; not observed at 104 wks); bile duct hyperplasia (M); mammary gland galactoceles (F); acanthosis glandular stomach (F); low, but statistically significant, increased incidence of squamous cell carcinoma in non-glandular stomach (M), however, not considered to be biologically or toxicologically significant and likely not relevant to humans. Under conditions of this study, there was no biologically or toxicologically significant treatment-related increased incidence of tumours in the treatment groups compared to controls up to and including 20,000 ppm (HDT); therefore, under conditions of this study, trinexapac-ethyl not considered to be oncogenic. No treatment-related difference detected in total number of animals with tumours or in the total number of benign or malignant tumours at 52 or 104 weeks. No treatment-related effect on the time-dependent occurrence of tumour bearing animals.

REPRODUCTION / DEVELOPMENTAL TOXICITY - XXXX Technical			
Multi-generation - rat (1 litter/ generation)	30 Sprague-Dawley derived rats/sex/group Dose Levels: 0, 10, 1,000, 10,000 or 20,000 ppm (equal to 0, 0.6, 60, 594 and 1,212 mg/kg bw/d in males and 0, 0.9, 76, 751 and 1,484 mg/kg bw/d in females).	**Parental** NOAEL: 1,000 ppm (M = 60 mg/kg bw/d; F = 76 mg/kg bw/d) LOAEL: 10,000 ppm (M = 594 mg/kg bw/d; F = 751 mg/kg bw/d) **Offspring**: NOAEL: 10,000 ppm (M = 594 mg/kg bw/d; F = 751 mg/kg bw/d) LOAEL: 20,000 ppm (M = 1,212 mg/kg bw/d; F = 1,484 mg/kg bw/d) **Reproductive**: NOAEL: 20,000 ppm (M = 1,212 mg/kg bw/d; F = 1,484 mg/kg bw/d) LOAEL: Not determined.	**Parental**: 10,000 ppm: lower bw and bwg (F0/F1 males and females). 20,000 ppm: lower bw, bwg and food consumption (F0/F1 males and females). **Offspring**: 20,000 ppm: lower pup body weight (F1/F2 pups) and slight decreased pup survival (F1 pups). **Reproductive**: No adverse treatment-related effects on reproductive parameters up to & including 20,000 ppm (HDT).
Developmental toxicity - rat	24 sexually mature/nulliparous female Tif: RAIf (SPF) rats/dose **Dose Levels**: 0, 20, 200 or 1,000 mg/kg bw/d	**Maternal Toxicity**: NOAEL: greater than 1,000 mg/kg bw/d LOAEL: Not determined **Developmental Toxicity:** NOAEL: 200 mg/kg bw/d LOAEL: 1,000 mg/kg bw/d	**Maternal Toxicity** No treatment-related findings at any dose level up to & including 1,000 mg/kg bw/d (HDT). **Developmental Toxicity**: increased incidence of asymmetrically shaped vertebrae at 1,000 mg/kg bw/d. **Developmental toxicity**: No evidence of any treatment-related irreversible structural changes at any dose level up to & including 1,000 mg/kg bw/d (HDT); therefore, under the conditions of the study, XXXX did not show development toxicity.

Developmental toxicity - rabbit	16-17 sexually mature/ nulliparous female New Zealand White rabbits/dose **Dose Levels**: 0, 10, 60 or 360 mg/kg bw/d	**<u>Maternal Toxicity</u>**: NOAEL: greater than 360 mg/kg bw/d LOAEL: Not determined **<u>Developmental Toxicity:</u>** NOAEL: 60 mg/kg bw/d LOAEL: 360 mg/kg bw/d	**<u>Maternal Toxicity</u>** No treatment-related findings at any dose level up to & including 360 mg/kg bw/d (HDT). **<u>Developmental Toxicity</u>**: decreased live fetuses/litter and increased post-implantation loss at 360 mg/kg bw/d. **<u>Developmental toxicity</u>**: No evidence of any treatment-related irreversible structural changes at any dose level up to & including 360 mg/kg bw/d (HDT); therefore, under the conditions of the study, XXXX did not show developmental toxicity.
GENOTOXICITY - XXXX Technical			
STUDY	**Species/Strain or Cell Type**	**Dose Levels**	**Significant Effects / Comments**
Salmonella / Ames Test	*Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537	0, 20, 78, 313, 1,250 or 5,000 µg/plate. ± S9 metabolic activation.	**NEGATIVE**
Mammalian chromosomal aberration (*in vitro*)	mouse lymphoma L5178Y cells (at the TK locus)	0, 7.54, 30.16, 120.62, or 1930.00 µg/mL ± S9 metabolic activation.	**NEGATIVE**
Mammalian cytogenetics (*in vitro*)	Human lymphocytes	0, 62.5, 125, 250, 500 or 1,000 µg/mL ± S9 metabolic activation.	**NEGATIVE**
Micronucleus Assay (*in vivo*)	Male and female mouse bone marrow cells (erythrocytes)	0, 1,000, 2,000 or 4,000 mg/kg bw (sacrifice at 16, 24 and 78 hours)	**NEGATIVE**
Micronucleus Assay (*in vivo*)	Male and female mouse bone marrow cells (erythrocytes)	<u>Initial assay</u>: 0 or 3,000 mg/kg bw (sacrifice at 16, 24 and 48 hours) <u>Confirmatory Assay</u>: 0, 750, 1,500 or 3,000 mg/kg bw (sacrifice at 48 hours).	Significant increased frequency of MN-PCE's in males and sexes combined at 48 hours in the initial assay, however, values were within historical control range and not observed in the confirmatory assay at 3,000 mg/kg bw at 48 hours. In this study possible weak clastogen, however, weight-of-evidence suggest XXXX, not likely clastogenic.
UDS *in vitro*	Rat primary hepatocytes	<u>Preliminary cytotoxicity assay</u>: 0, 5, 10, 21, 41, 82, 164, 328, 656, 1,313, 2,625 or 5,250 µg/mL <u>Initial UDS assay</u>: 0, 0.8, 4, 20, 100, 200 or 400 µg/mL <u>Confirmatory UDS assay</u>: 0, 4, 20, 100, 150, 200, 300, 400 or 500 µg/mL.	**NEGATIVE**

Compound-Induced Mortality: There was no significant increased incidence of treatment-related mortalities in any short-term, long-term or special studies.

On the basis of the parental and offspring NOAEL's in the rat 2-generation reproductive toxicity study (one litter/generation) there was no indication that neonates were more sensitive than adults to the toxic effects of XXXX. However, the increased severity of the findings in the offspring compared to the severity of the findings in the dams at the respective NOAEL suggests that neonates may be slightly more sensitive to the toxic effects of XXXX. *On the basis of the maternal and developmental NOAEL's in the rat and rabbit developmental toxicity studies, there appears to an increased susceptibility of the fetus to in utero exposure to XXXX in both species.* *In rats, the increased sensitivity was indicated by an increased incidence of asymmetrically shaped vertebrae at 1,000 mg/kg bw/d, the highest dose tested (maternal NOAEL greater than 1,000 mg/kg bw/d; developmental NOAEL = 200 mg/kg bw/d).* *In rabbits, the increased sensitivity was indicated by decreased live fetuses/litter and increased post-implantation loss at 360 mg/kg bw/d, the highest dose tested (maternal NOAEL greater than 360 mg/kg bw/d; developmental NOAEL = 60 mg/kg bw/d).* *There was no evidence of any irreversible structural changes in either species; therefore, XXXX was not considered to show developmental toxicity.*

Recommended Acute RfD: Based on Endpoint:
Recommended ADI: Based on Endpoint:

[1] See also the summary tables at the end of the toxicology reviews of the JMPR *Report* and the *Evaluations* (Toxicology, ICPS). These may provide a simplified alternative in some cases.

Appendix IV: Example of Residue Chemistry Summary for Step 8(I) Pesticide Nominee

Table: Food residue chemistry summary

NATIONAL USE PATTERN							
Crop	Formulation	Method and timing	Rate	Number per season	Maximum rate	PHI (days)	Restrictions
Maize (Field corn)	Water dispersible granular, 55% a.i.	Post-emergence. Broadcast	x g a.i./ha	#	x g a.i./ha	x	Do not harvest silage within x days after application

ANIMAL METABOLISM
In goat and hen metabolism, the pesticide is rapidly excreted primarily as unchanged parent compound. Major compound identified is parent compound in urine, feces, liver and milk. Metabolites from Position 2 label were found in liver and feces. Major metabolite from Position 1 label is compound C in liver, feces and urine. Metabolic profile in plant and animal species suggest hydroxylation and conjugation of the rings; cleavage of the sulfonylurea bridge.

The residue for dietary exposure and enforcement is the parent.

Poultry metabolism (administration rate, method, no. of consecutive days, position(s) of radiolabel)		
Matrix	Identified Compounds or Components	Percent of TRR
Muscle (TRR, mg/kg)		
Fat (TRR, mg/kg)		
Eggs (TRR, mg/kg)		
Other (specify; TRR, mg/kg)		

Ruminant metabolism (specify goat or cow, administration rate, method, no. of consecutive days, position(s) of radiolabel)		
Matrix	Identified Compounds or Components	Percent of TRR
Muscle (TRR, mg/kg)		
Fat (TRR, mg/kg)		
Milk (TRR, mg/kg)		
Other (specify; TRR, mg/kg)		

CONFINED CROP ROTATION STUDIES 0.157 kg a.i./ha (5× gap); one foliar application post-emergent to maize (45 cm height)				
Crop	Crop fraction	Planting interval (DAT)	Harvest interval (DAT)	Equivalent to Position 1 ^{14}C-chemical X TRRs (mg/kg)
Winter wheat				
Corn				
Soybeans				
Sugar beets				

Leaf lettuce				

ANALYTICAL METHODS: PLANT AND ANIMAL MATRICES
HPLC method with UV detection at x nm; ILV . Example: Maize (field corn)

Residue: Pesticide parent *(or specify as indicated by metabolism studies and tox considerations)*

Matrix	Field corn				Corn processed fractions	
	Grain	Forage	Silage	Fodder	Oil	Presscake
LOQ (mg/kg)						
Recovery: mean ± SD (%)						
Matrix	Dairy cattle and Poultry					
	Milk	Muscle	Fat	Eggs	Liver	Kidney
LOQ (mg/kg)						
Recovery: mean ± SD (%)						

FREEZER STORAGE STABILITY TESTS FOR PLANT COMMODITIES
Stability of pesticide (parent) (*or specify as appropriate*) residues in corn substrates at –15°C
Field trial samples were stored for intervals consistent with these storage stability tests.

Storage interval (months)	Fortification level (mg/kg)	Freshly fortified % residues recovered			Stored fortified % residues remaining		
		Forage	Grain	Fodder	Forage	Grain	Fodder
0 day to x months							

FREEZER STORAGE STABILITY TESTS FOR ANIMAL COMMODITIES
Stability of pesticide (parent *or specify as appropriate*) residues in meat, milk and egg substrates at –15°C
Animal feeding study commodities and field trial residue samples were stored within the time periods studied

Storage interval (months)	Freshly fortified % residues recovered				Stored fortified % residues remaining			
	Beef liver (x mg/kg)	Milk (x ppm)	Poultry breast (x mg/kg)	Eggs (x ppm)	Beef liver (x mg/ kg)	Milk (x mg/ kg)	Poultry breast (x mg/kg)	Eggs (x mg/ kg)
0 day to XX months								

SUPERVISED RESIDUE TRIALS ON MAIZE (FIELD CORN)						
Commodity	Formulation	Application			PHI (days)	Residue (mg/kg)
		No.	Single rate (kg a.i./ha)	% GAP		
Forage (AF645)						
Fodder (AS645)						
Aspirated grain fractions						
Grain (GC645)						

PROCESSING STUDIES
Residue levels of pesticide parent *(or specify as appropriate)* in maize raw agricultural commodity (RAC) and processed fractions

Matrix and fraction	Rate (g a.i./ha)	PHI (days)	Residues (mg/kg)	Processing factor
Wet milling				
Maize grain (RAC)				
Oil, crude				
Oil, refined				
Milling by-product (specify)				
Dry milling				
Meal				
Oil, crude				
Oil, refined				
Milling by-products (specify)				

CATTLE FEEDING STUDY: Residues of (Specify) in Cattle Commodities
Dosed orally: 28 days
Maximum anticipated dietary burden: --- ppm (based on feed items, and consumptions per Appendix IX of FAO Manual…)

Feeding level (ppm in feed)	Maximum pesticide parent residues (mg/kg)			
	Milk	Muscle	Fat	Other

HEN FEEDING STUDY: Residues of (Specify) in Hen Commodities Dosed orally: 28 days Maximum anticipated dietary burden: --- ppm (based on feed items, and consumptions per Appendix IX of FAO Manual…)				
Feeding level (ppm in feed)	Eggs (mg/kg)	Muscle (mg/kg)	Fat (mg/kg)	Other (mg/kg)

PROPOSED MRLs *(examples; all categories may not apply)*			
Crop	Codex Classification	Proposed Interim Codex MRL (mg/kg)	MRL in submitting Country (mg/kg or ppm)
Maize (Field corn) grain	GC645		
Maize forage	AF645		
Maize fodder	AS645		
Maize processed commodity (specify)	CF1255 CF645 OC645 OR645		
Milk of cattle, goats and sheep	ML107		
Eggs	PE112		
Poultry meat	PM110		
Poultry, Edible offal of	PO111		
Meat of cattle, goats, hogs, horses, pigs and sheep	MM96		
Cattle, edible offal of	MO812		
Liver of cattle, goats, pigs and sheep	MO99		
Kidney of cattle, goats, pigs and sheep	MO98		