A SURVEY REPORT TO FOLLOW-UP

THE DEVELOPMENT OF THE CONCEPT OF MINIMUM DATA REQUIREMENTS FOR ESTABLISHING MAXIMUM RESIDUE LIMITS (MRLs) INCLUDING IMPORT TOLERANCES FOR PESTICIDES

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

Rome, 2004

A Survey Report to Follow-up the
DEVELOPMENT OF THE CONCEPT OF MINIMUM DATA REQUIREMENTS FOR ESTABLISHING MAXIMUM RESIDUE LIMITS (MRLs) INCLUDING IMPORT TOLERANCES FOR PESTICIDES

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Executive Summary

In response to a further consultation on minimum data requirements for setting MRLs/import tolerances for pesticides, thirteen countries offered comments and observations. The geographic spread of the recipients indicates that most regions of the world have participated in this project.

The use of MRLs derived by JMPR has a different end use compared with those set by national governments. Whilst national MRLs can be used as a measure of GAP compliance and consumer safety as well as a trading standard, the way in which JMPR-recommended MRLs are derived means that they can only be used, as intended, as standards to aid international trade. This is a fundamental difference in the use of the MRL and therefore whilst any JMPR-recommended MRL should be set at a level, which should not give rise to adverse health effects, its end use is limited in comparison to national MRLs.

The principle of zoning appears to be already used by many national regulatory authorities but trials from outside of their immediate geographic areas would not be considered as applicable. However, national authorities appear unlikely to accept the recommendations of the zoning report due to the limited nature of the study. The value of performing further validation of these recommendations is questionable due to the likely underlying reluctance to accept data submitted under the terms of this initiative.

Throughout the world, major crops, requiring a higher number of residue trials to secure MRLs/import tolerances, are defined generally using area of cultivation and consumption. The actual percentage of cropped area used in the definition varies and therefore the extensive list of crops that may be defined as minor has been recommended based on only their consumption patterns. The underlying difficulties in accepting JMPR MRLs/import tolerances appear to be due to the fact that they do not meet the national government evaluation standards/criteria rather than to a fundamental disagreement with the principle of setting these limits on a reduced data set. It was recommended that the minimum number of residue trials that could be accepted is 3; however, lesser requirements could be accepted where other supporting data indicate a non-detectable residue situation usually at or below the limit of quantitation.

Additional possibilities for extrapolation of residue data resulting from a comparison of recommendations made by Australia, the European Union and the USA were considered

Processing data were not considered necessary or required in all situations. Triggers could include situations where concentration occurs in a processed commodity. Many concentration factors are predictable based on mass transfers of RAC to processed commodity and therefore the possibility exists that these data (US EPA standard values) should only be requested in the situation that refinement of a theoretically unacceptable consumer exposure occurs.

Eight specific recommendations for the evaluation of data are made; an expert consultation in also recommended.

Recommendations

1. Since the recommendations of the zoning project do not appear to be readily acceptable to respondents, additional criteria to increase their potential for acceptability should be put in place. Where residue data based on foliar applications are submitted from outside of the immediate geographic area where GAP exists, data should be supplemented with discussions on the relevance of climate, GAP and cultivation technique addressing the applicability of these data.

2. This report should be updated to reflect the 2004 JMPR's findings where compounds have been assessed using the zoning project guidelines.

3. In line with the recommendations of the York meeting, residues data for glasshouse treatments should be considered representative of any geographic area where the GAP (including application technique) and crop cultivation techniques are comparable.

4. In line with the recommendations of the York meeting, residues data for seed treatment uses would not be required to support an MRL/import tolerance if other data existed e.g. crop metabolism data which could be used to confirm a non-residue situation. If such data where not available then a minimum number of trials (3) would be acceptable to confirm a group tolerance MRL/import tolerance with groups being defined in line with the degree of extrapolation permitted for metabolism studies (e.g. root crops, fruit etc). Where MRLs are set on a lower number of residues trials, wider limits may be required in setting the MRL to account for the limited spread of data.

5. Where applications are made at a very early stage of crop development, residues data should be considered with respect to a group tolerance or wider extrapolations where this is applicable to GAP.

6. Additional recommendations have been made to define minor crops, such as requiring only 3 residue trials to set an MRL/import tolerance based solely on very low contribution to the diet. Since the value of 7.5g/person/day accounts for <1% of the total GEMS diet based mainly on fruit and vegetable consumption, this recommendation would not lead to an increase in consumer exposure/risk.

7. Recommendations on extrapolations have been made for a number of crops. These are based on comparable national regulations/guidelines and therefore should not lead to difficulties in acceptance of MRLs/import tolerances without further validation being required.

8. Where a government or regulatory body puts forward new, national extrapolations scenarios, these should be passed to the FAO panel of JMPR to assess whether these would also be suitable for the setting of international MRLs.

9. Since this report includes recommendations which would result in changes to the current guidelines for setting MRLs/import tolerances, it is recommended that an expert consultation is held to discuss the scientific acceptability of these proposals and to ensure that these can be practically and effectively implemented and would not compromise acceptance of Codex MRLs/import tolerances in the future.

Background

In a project jointly funded by the European Commission and OECD in 1998-1989, existing national and international practices and data were examined in order to develop internationally agreed guidelines for establishing maximum residue limits (MRLs) including import tolerances for pesticides. The aims of the project were to:

- Underpin the work of the JMPR in proposing international MRLs and to support the scientific and technical basis of Codex MRLs as reference limits within the SPS agreement;

- Facilitate work of national registration authorities in granting import tolerances:

- Facilitate the work of national regulatory authorities in granting of national registrations and MRLs.

As a result of this project, guidelines were developed recommending the minimum number of supervised residue trials required to support the setting of an MRL or import tolerance (Harris and Pim, 2000). The numbers of trials were based on the crop's significance in the diet, its significance in trade and the number of 'zones' where GAP exists. The minimum number of trials ranged from 3 to 16 but definitions on 'significance' were not agreed.

Since 1999, there has been follow-up work only in the area of global zoning. This work resulted in the development of the Zoning Report, which was adopted together with the full report of the 1999 York Meeting by the "OECD-Working Group on Pesticides" at its meeting in November 2002. The meeting concluded that the impact of climate on the behaviour of residues of some foliar applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless of the geographical location of the trials (OECD, 2002).

In September 2003, the FAO/JMPR also formally adopted the outcome of the 1999 York Meeting and the OECD Zoning Report (FAO, 2003).

However, although these two projects made a great deal of progress, further work was required to ensure these guidelines provided clear information which would result in import tolerances and MRLs that were mutually acceptable to governments around the world. Exponent International Ltd was commissioned by the FAO to investigate the progress made so far and help move forward the acceptance of MRLs recommended by JMPR. In order to achieve this, a questionnaire (Appendix 1) was prepared on behalf of the FAO/JMPR. It was sent to all Codex contact points, the members of the OECD Working Group on Pesticides, and the CCPR secretariat. The responses from the questionnaires form the basis of this report. Consultation on this report will take place by the FAO panel of JMPR at its 2004 meeting and it will serve as a basis for an international expert consultation on the issues that still require international harmonization.

Results

Replies to the questionnaire were received from 13 countries covering North and South America (4), Asia (3), Australasia (2) and Europe (4) (Argentina, Australia, Canada, Costa Rica, Germany, Indonesia, Japan, Netherlands, New Zealand, Portugal, Thailand, UK and USA).

The responses has been summarised to represent a definitive answer or, where this was not possible, the general trend of replies with details of objections or differences.

Zoning Project

Q1: Is the principle of zoning for the acceptance of residues trials enshrined in your national legislation? If so, how many and what zones are defined?
A1: Seven countries accepted the principle of zoning as part of their national legislation. The countries that did not accept this principle were Australia, Costa Rica, Japan, New Zealand and Thailand. The numbers of zones range from 2 (Europe; Northern and Southern) to 13 for the USA and NAFTA countries (Canada, Mexico, US). For the USA, the principle of geographic zoning for the acceptance of residue trials is a cornerstone of US guidelines and is included in NAFTA guidance. The zones are intended to represent the major growing regions for crops and reflect the range of climatic, geographic, and soil conditions and cultural practices under which a given crop might be grown. The assumption is that all major growing regions must be tested to obtain information on the highest likely residue under GAP. A similar philosophy is also covered by the New Zealand guidelines, which specify that 'trials should be designed to cover representative growing or storage conditions', with sites and trial conditions selected 'to reflect common commercial practice'. In practice, while no specific 'zones' have been defined, depending on the crop involved, trials are usually submitted from one or two major production areas.
Q2: What are your views on the conclusions of the zoning report, i.e. the impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless of the geographical location of the trials?
A2: Most responses focussed on the limited nature of the zoning report assessment making it difficult to accept the recommendations. In particular it was noted that only limited geographic areas and GAPs were actually considered. Notable omissions included data from tropical climate. The adverse condition of tropical climate, i.e. high temperature, heavy rain can have much effect on residue behaviour. In the report, influence of geography was observed for a limited number of pesticide/crop combinations. Generally it was felt that it would be more appropriate to state the report conclusion as 'the impact of climate is negligible, in comparison to other factors such as application technique, cultivation practices and variation of residues within a zone.' However there was some support expressed for a 'semi-zoning' type approach by considering similar GAPs and similar growing conditions and crop management systems (regardless of geography) as possible situations where this approach had been demonstrated to be reliable. Australian experience with residue data for orchard and vine crops generated in different countries has been that broad zones are applicable,

with Europe in one zone/region and Australia, New Zealand, USA and South Africa in another zone/region. This has in part to do with cultivation practices. It has also been shown in drift modelling experiments in different countries that orchard sizes, cropping densities and spray equipment make a difference with respect to spray deposition.
Q3a: How would your authority/agency implement these recommendations into their national guidelines? i.e. would your authority be prepared to accept residue trials data from countries/regions outside of your own?
A3a: Only a limited number of authorities (3; Australia, Argentina and Portugal) would accept all residue trials conducted in other countries with similar GAPs. New Zealand would accept 50% conducted under local conditions, which could be reduced if a non-detectable residue situation can be demonstrated. The majority of replies said that data would be accepted if the trials were conducted under conditions of similar climate, similar GAPs and similar cultivation practices but the definition of 'similar' was not addressed.
Q3b: From which other countries/regions would you be prepared to accept residue data to support an MRL/import tolerance?
Q3b: Australia - data from any other country, providing the proposed GAP is similar. This is determined by using the principles as published in the FAO Manual (2002). Costa Rica – from Central America. Germany/Netherlands - National/EU-MRL: data from European countries according to zones. Indonesia/Thailand - member countries of ASEAN (South-east Asian region) New Zealand - any country where the crop under consideration is grown commercially and the crop production systems and crop management techniques reflect their national situation (currently data from some states of Australia and USA, parts of Europe and occasionally from South Africa have been accepted) Portugal/UK - Countries of origin or similar climatic region. Import tolerances: data from the exporting country or region. USA: regions from which imports to the US are planned
Q4: What are your criteria for accepting supervised residue trials data from outside your country/region?
A4: 1. similar GAPs – 8 replies of yes 2. similar climate – 6 replies of yes 3. similar spray equipment– 6 replies of yes 4. similar agronomic factors – 7 replies of yes 5. Others: validated method of analysis required (Thailand); trials required where imports would represent ≥5% of US consumption.
Q5: The zoning group only made recommendations with respect to foliar sprays. What other application techniques should be evaluated to determine the effects of climatic zone on final residue levels?
A5: Generally it was felt that the data on foliar sprays were the most commonly used application technique but fumigation and seed treatments were also considered as candidates. Soil applied uses were also suggested but it was noted that the consideration of the soil type, soil temperature and rainfall interactions may be too resource intensive to warrant such action. Glasshouse/greenhouse/conservatory applications were also suggested.

Significance in Diet/Trade

Q6: Do you differentiate between major and minor crops in terms of residue data requirements?	
Eight responses indicated that a differentiation occurred. For New Zealand, there is no differentiation although data for a major crop can be used/extrapolated to cover a group tolerance/MRL.	
Q7: Is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops? Are other criteria established in your country (e.g. area of production)?	
Seven replies indicated that trade or diet was a suitable tool to determine major/minor crops. For Australia, Canada and Portugal, economic return and area under cultivation were the main drivers (Commonwealth of Australia Gazette No. 3, 5 March 2002; http://www.apvma.gov.au/gazette/gazette0203p39.pdf) with similar criteria for Thailand who also rely on quantity and value of crops in addition to diet and trade.	
Q8: How do you define major and minor crops in your region/country?	
A8: 1. by area/ hectarage (If so indicate % for minor and for major crops)	
Argentina	10 hectares (major crop)
Australia	volume of commodity production area under cultivation (ha) or numbers of trees or animals; dietary consumption (g/kg bw/day); value of crop or animal; export quantities. Can also be defined as a minor use on major crop (must not exceed 10% of the total area of crop, number of animals, or area of situation; or 10,000 hectares (whichever results in the least amount) per annum.
Canada	Unspecified
Costa Rica	Unspecified
Germany, Netherlands, Portugal, UK (standard EU criteria)	Major crop - cultivation area > 10 000 ha/year Minor crop – cultivation area <10 000 – 600 ha Very minor crop – cultivation area < 600 ha (less than 0.0035 % of the total cultivation area
Indonesia	Unspecified
Japan	No
New Zealand	No

USA	The 300,000 acres is considered the division between a major or minor use. A minor use means the use of a pesticide on a commercial agricultural crop or site where (1) the total acreages is less than 300,000 acres OR (2) "the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and (A) there are insufficient efficacious alternative registered pesticides; (B) the alternatives pose greater risks; (C) the minor use pesticide plays or will play a significant part in managing pest resistance; or (D) the minor use pesticide plays or will play a significant part in an integrated pest management program." Number of acres — Number of trials >10,000,000 — 16 >1,000,000 – 10,000,000 — 12 >300,000 – 1,000,000 — 8 >30,000 – 300,000 — 5 >2000 – 30,000 — 3 >200 – 2000 — 2 ≤200 — 1
A8.by consumption (If so, indicate for minor and for major crops)	
Argentina	Unspecified
Australia	No
Canada	Unspecified
Germany, Netherlands, Portugal, UK (standard EU criteria)	Major crop- consumption > 7.5 g/d for a person of 60 kg (equivalent to 0.5% of the consumption of this person) minor crop - consumption < 7.5 g/d for a person of 60 kg very minor crop - consumption < 1.5 g/d for a person of 60 kg
Indonesia	Unspecified
Japan	No
New Zealand	No
Thailand	Unspecified
USA	The number of trials is adjusted up or down by considerations of consumption. For commodities with acreage >300,000, the number of trials is increased one level (e.g., from 5-8 or 8-12) if consumption is ≥0.4% of total consumption for the general population, children, or nursing infants. A minimum of 16 trials is required for commodities with production greater than 300,000 acres and comprising greater than 1% of dietary consumption for the general population, non-nursing infants, or children. Likewise, a minimum of 12 field trials is required for commodities with production less than 300,000 acres and comprising greater than 1% of dietary consumption for the general population, non-nursing infants, or children

A8. Others (please specify)	
Australia	Economic return
Germany, Netherlands, Portugal, UK (standard EU criteria)	by production (necessary for some animal feeds): major crop - production > 200,000 tonnes per year minor crop - production < 200,000 tonnes per year
Japan	If the amount of the product of one crop is less than 30,000 metric tons per year, such a crop is defined as a minor crop
Thailand	By quantity and value of crops.
USA	The number of trials may also decrease if >90% of production is in one region.
Q9: What are (would be) your criteria for defining a crop as significant in trade or the diet?	
A9a: Significant in trade (e.g. % cultivation area, quantity of production, etc.)	
Australia	Production per region per annum; quantities traded on a per annum basis. There may be instances where a crop is defined as 'major' or 'significant' on the basis of production and consumption, however much of the production is used for domestic consumption only and not traded. These issues require further consideration if international definitions of a 'significant crop' are to be developed for the purposes of requesting residues data or setting MRLs.
Germany, Netherlands, Portugal, UK	By cultivation area, as specified under answers to Q8 (1) above. Germany – subject to confirmation by EFSA
Indonesia	% national income share of domestic and international trade
New Zealand	Not relevant
USA	Amount in international trade (a fixed number of metric tons). Quantity of production or % cultivation area may not be a good marker, for some items are consumed locally.
A9 b: Significant in diet (e.g. 0.5% of the total diet as the trigger value)	
Argentina	0.5%
Australia	Significance in the diet is difficult to gauge, as a major food (commodity) in one regional diet may not be a major food (commodity) in another. Therefore the data requirements for setting an MRL (or import tolerance) may be different in one region compared to another. For the purposes of this exercise, a threshold level would be required. However as stated above, where a crop is produced largely for domestic consumption and not traded, the data requirements will be different in one region compared to another.
Germany, Netherlands, UK	By threshold consumption (e.g. 0.5% of the consumption of 60kg person consuming > 7.5 g/d) as specified in answer A8 (2) above. Germany – subject to confirmation by EFSA
Indonesia	0.5%
New Zealand	Not relevant
Thailand	1%
USA	Based on US guidelines, 0.4% of the total diet for the general

	population or specific subgroups (children) would be appropriate
Q10: What source of dietary information do you use to carry out consumer risk assessments in your country/region?	
Argentina	IDA
Australia	The key data source is the detailed food consumption data that are contained in the large 1995 National Nutrition Survey of Australia
Canada	USDA dietary Longitudinal Food Survey
Costa Rica	Codex and US EPA
Germany	New German chronic and acute dietary intake models based on consumption data for children from
Indonesia	National statistical dietary consumption data published by National Statistic Agency
Japan	The food factor based upon the reports on national nutrition survey conducted annually by Ministry of Health, Labour and Welfare is applied in exposure assessment
Netherlands	Dutch food consumption survey, which was converted into raw agricultural products
New Zealand	'best estimate' of adult mean consumption values, based primarily on a 1997 National Nutrition Survey. For child (2-6 yr) mean consumption values and for all 97.5%ile consumption values, 'best estimates' are based primarily on Australian surveys (DIAMOND).
Portugal	National diet for chronic risk assessment and UK diet for acute risk assessment
Thailand	national consumption data (from national survey)
UK	National dietary surveys
USA	USDA/NHANES dietary consumption, which are surveys of dietary consumption (http://www.barc.usda.gov/bhnrc/foodsurvey/Products9496.html). USDA PDP, which is monitoring on target commodities obtained at the distribution level, near the market level (http://www.ams.usda.gov/science/pdp/redesign/quick.htm). Residue data are also obtained from market basket surveys conducted by industry or other interested parties and from FDA monitoring (http://www.cfsan.fda.gov/~dms/pesrpts.htm). Dietary intake analyses are performed in a tiered approach, with the first level being the use of field trial data. If a potential intake concern is found, survey and monitoring data are used in refinements of the calculations

Q11: Would you accept 3 as the minimum number of trials for establishing MRLs. If not, what would be the absolute minimum number of trials, without extrapolation, you would be prepared to accept in support of an MRL/import tolerance?
The majority of respondents (9) agreed that a minimum of 3 trials could be acceptable providing that certain criteria, e.g., (i) not for a major crop or (ii) the crop was insignificant in diet or (iii) insignificant in trade/production were met. UK, Netherlands and Portugal requested a minimum of 4 trials (Portugal could accept 3 trials if all residues were below the limit of quantitation) New Zealand proposed a stepped approach with 4 trials for one or more primary crops within a group, and 2 trials for subsequent 'secondary' crops, where measurable residues are expected at harvest, with a reducing number of trials being needed for 'other crops' in the group, or as the probability increases that no detectable residues will occur. (For example, no trials may be needed for non-systemic foliar pre-flowering sprays on apples, but perhaps 1-2 trials could be sufficient for pesticides of short persistence, applied at petal fall on apples).
Q12: Do your data requirements differ for setting National MRLs and for Import Tolerances i.e. based on uses outside of your country? If so, how?
A12: The majority of responding countries (8) indicated that they have the same standard requirements for import tolerances as for national MRLs. Where differences occurred (4 responses) these mainly related to where trials were carried out geographically or reduced data requirements in areas not relevant to the setting of an import tolerance such as worker exposure.

Extrapolation of residues data for one crop to another

Q13: **How do you implement the principle of extrapolation of residues data from one crop to another e.g. extrapolation of residues levels in tomatoes to estimate residue levels in aubergines? How do you decide what is an acceptable extrapolation?**	
A13:	
Argentina	If the residues level is different in the different crops. The distribution of residues is different in different fractions
Australia	Accepted crop extrapolations are available at: http://www.apvma.gov.au/guidelines/guidln24.shtml
Germany, Netherlands, Portugal, UK	EU guidelines detail acceptable extrapolations. These have been defined on the basis of criteria such as crop morphology, potential for residues and yield. For early applications, a large amount of extrapolation is tolerated whereas applications that are made close to harvest have less potential for extrapolation. Generally ±25% is tolerated on either the application rate or PHI.
Indonesia	Similar GAP (± 25% tolerances), crops within Codex crop groupings and crops having similar consumable part
Japan	Pesticide registration / establishing MRLs is made with the residue trial data of representative crop in the crop group, if it is confirmed by government that the residue level among these crops are similar and such a crop belongs to the group.

New Zealand	The above ± 25% (similar GAP) approach is used to determine the acceptability of all supporting residue trials, not just for extrapolation from one crop to another. The approach to crop group extrapolation is outlined above, involving 'primary', 'secondary' and 'other' crops within a group, with reducing number of trials (and the associated increase in the mutual support for the crops within a group)
Thailand	The ± 25% rule can be applied to either the application rate or the number of applications. Decline curves should be used to consider the affects of changing the pre harvest interval. Deviation from this rule can be considered on a case-by-case basis.
USA	The most common extrapolation is to a crop group, based on adequate data for the representative commodities (40CFR180.41). For example, sufficient data on tomatoes and Bell pepper and one type on non-bell pepper could provide a tolerance for all fruiting vegetables (except cucurbits), including aubergines. This extrapolation is based on a similar GAP and similar residue levels from the field trials (with the representative commodities). See: http://a257.g.akamaitech.net/7/257/2422/08aug20031600/edocket.access.gpo.gov/cfr_2003/julqtr/pdf/40cfr180.41.pdf. Additionally, some extrapolation among specific crops may be allowed where the pesticide is non-systemic, per 40CFR180.34 (d) and (e). See: http://a257.g.akamaitech.net/7/257/2422/08aug20031600/edocket.access.gpo.gov /cfr_2003/julqtr/pdf/40cfr180.34.pdf

Q14a: Can you accept extrapolation of data when there are similar GAPs only?
A14a: Eleven respondents could accept extrapolation of residues data between crops in situations beyond just similar GAP
Q14b: If not, what are your national/regional criteria to allow extrapolation of residues data? (e.g. comparability of GAPs, climate, geographical location, similarities in morphology of crops, crops within same groups, others.)
A14b: The criteria stated include extrapolation within crop groups, similar crop morphology, non-detectable residues, geographical location and the availability of statistical and analytical data.
Q15: Do you have an agreed list of extrapolations of residues data?
A15: Eight respondents (including 4 from the EU reported to have guidelines on extrapolation)
Q16: What data would you wish to have in order to agree to additional extrapolations?
A16: A majority of respondents requested residue data to support any newly proposed extrapolation. Important factors in consideration of this would include crop morphology/skin texture/size and dietary consumption. Two additional extrapolations were suggested as: extrapolation from rape seed to poppy seed, and extrapolation from spinach to whole group spinach and similar

Q17: Would you accept the principle of more extensive extrapolation of residue data to support minor crops?
A17: Eight respondents accepted the principle particularly in the situation for group tolerances Both the Australian government and IR-4 (USA) are currently assessing further extrapolations Portugal has a specific requirement related to lettuce up to the 8 leaf stage where data from this crop can be extrapolated to *Brassica rapa var. japonica* L. Mizuna), *Diplotaxis tenuifolia* L. (wild rocket), *Eruca sativa* L. (salad rocket), *Brassica juncea* (L.) Czern (red mustard).

Processing Data

Q18: Under what circumstances do you require the submission of data on processing i.e. data examining the distribution of residues between different fractions of processed foods?
A18: A common view on requirements included cases (i) where there are significant residues in the RAC e.g. ≥ 0.1 mg/kg, (ii) where foods are significantly consumed in the processed form, (iii) where consumption is more than 10% of ADI or (iv) where the possibility of concentration exists. In the US, MRLs for the RACs will not be recommended without sufficient/appropriate processing data.
Q19: What are the criteria for the extrapolation of processing data from one crop to another?
A19: Processing was generally considered to be a specific crop requirement. Extrapolations could be acceptable where the edible parts of the crop and the processing practices are similar or where the crop matrix has previously been shown to have little influence on the action of a specific process on the residue level. In addition, the UK felt that, additional extrapolations may be acceptable where there was a large margin of safety for consumers.
Q20: What information do you require from processing studies, e.g. do you require a balance study i.e. a full description of where residues remain in all parts of the processed foodstuff or just residue levels in final edible commodities?
A20: The majority of respondents only required data on residues in the RAC and the final edible commodities. However, in the EU, balance studies are required. The UK noted that consideration should be given to the pesticides' properties (e.g. volatility)
Q21: What is the minimum number of studies/trials required to determine a processing/transfer factor?
A21: There were a range of study numbers that were considered acceptable: 1 (4 responses), 2 (3 responses) and 3 (6 responses). The York meeting recommended a minimum of 2 studies.

Q22: Do you/would you permit the use of 'theoretical' processing factors i.e. factors based on water loss during the drying process – if not please provide a reason
A22: Seven respondents agreed that the use of theoretical processing factors was acceptable and 3 disagreed with this. Dehydration was noted as a suitable process for the use of theoretical values. In particular, the US noted such theoretical values were used in dietary intake calculations when no other data are available, but tolerances are set based on actual processing data. Such processes as loss of water during drying (grapes to raisins) represent the worst possible case and are not deemed appropriate for determining the need for a processed commodity tolerance. An exception is the occasional use of a drying factor to establish tolerances on hay (derived from forage). The practice most likely will not be used with a human food item.
Q23: Which data do you use to determine 'theoretical' processing factors?
A23: Data such as the ratio of weight of commodity in edible parts before and after processing such as where the concentration is based on the loss of water during processing, the theoretical concentration factor is the ratio of the percent of dry matter (DM) in the processed commodity to the percent of DM in the RAC. The second type of process is that in which a RAC is separated into components, such as the processing of corn grain into corn oil. In this case, the theoretical concentration factor can be derived as 100% divided by the percentage of the processed commodity in the raw commodity e.g. corn grain may contain as little as 4% corn oil. The theoretical concentration factor for processing of corn into oil then is 100/4, or 25X.

Discussion/Conclusions

In response to a further consultation on minimum data requirements, thirteen countries offered comments and observations. The conclusions of this report are based on these comments, supporting documentation supplied with the questionnaires, comparisons of national recommendations on extrapolation, and list of crops which make an 'insignificant' contribution to the diet. The geographic spread of the recipients indicates that most regions of the world have been covered but the comments cannot be considered to be representative of all governments in those areas.

MRLs derived by JMPR have a different end use compared with those set by national governments. Whilst national MRLs can be used as a measure of GAP compliance and consumer safety as well as a trading standard, the way in which JMPR-recommended MRLs are derived means that they can only be used, as intended, as international trading standards. This is a fundamental difference in the use of the MRL and therefore whilst any JMPR-recommended MRL should be set at a level which should not give rise to adverse health effects, its end use is limited in comparison to national MRLs.

Zoning Project

Zoning refers to the number of geographic 'zones' that determine the required number of residue trials to support an MRL/import tolerance. Agrochemical use is one of the criteria for zoning as originally defined at the York meeting. The zoning initiative indicated that for foliar applications, zoning is not a significant contributing factor affecting the levels of residues in crops and, therefore, any residue data can be used to support a further GAP/use in any country provided the GAP is comparable.

The principle of zoning appears to be already used by many national regulatory authorities but in general, trials from outside of their immediate geographic areas would not be considered as applicable. From the responses to the questionnaire, it is clear that national authorities would not accept the recommendations of the zoning report due to the limited nature of the study. It was felt that the conclusions could be most accurately represented, as 'the impact of climate is negligible, in comparison to other factors such as application technique, cultivation practices and variation of residues within a zone'. The value of performing further validation of these recommendations is questionable due to the likely underlying reluctance of governments to accept data submitted under the terms of this initiative.

The majority of replies said that data would be accepted if the trials were conducted under conditions of similar climate, similar GAPs and similar cultivation practices. However, the definition of 'similar' was not addressed. For JMPR whose function is to recommend MRLs for use as international standards, the recommendations of the zoning initiative may allow additional MRLs to be recommended. It is planned to evaluate the influence of this initiative if suitable data packages/GAP are available to the 2004 JMPR meeting. This report should be updated to reflect the JMPR's recommendations and conclusions.

It should be noted that the JMPR does not use the concept of 'critical GAP' i.e. the GAP likely to lead to the highest possible MRL, in recommending MRLs. Therefore as long as a minimum number of residue trials are available to support any geographically comparable GAP, an MRL will be proposed.

Other suitable application techniques for consideration were fumigation, seed treatment and glasshouse/greenhouse uses. Glasshouse uses were considered as parts of the York meeting where data were presented and analysed. The report recommended that residues data could be extrapolated from any glasshouse situation providing GAP was comparable (Harris and Pim, 2000). Similarly, seed treatments were considered; since seed treatments are unlikely to lead to detectable residues, the report recommended that there may be some occasions when no residues data would be applicable e.g. where metabolism data adequately demonstrated a non-residue situation or where a very limited data package (minimum 3 trials) covering a specific group of crops (rather then individual crops) may be suitable to recommend/set an MRL/import tolerance.

Significance in Diet/Trade

Originally in the York consultation, significance in diet and trade were criteria used for determining the number of trials necessary to support an MRL/import tolerance. Most countries differentiate between major and minor crops for determining the total number of residue trials necessary to support an MRL/import tolerance using criteria such as contribution to the diet, trade or production/area of cultivation to classify crops. Australia and the USA raised the question of whether production or area of crop is a suitable criterion for import tolerances as these criteria apply to all production including that used for national markets as well as international trade.

Classifications on area of cultivation for major crops are: Argentina: >10 ha; Europe: >10,000 ha; USA classifies >300,000 acres (*ca*. 121,406 ha). Consumption is used as a criterion to a lesser extent with both % of the diet and absolute consumption figures being used in the derivation. Despite many of the respondents having their own dietary survey information, from an international perspective, the GEMS/Food diet (WHO, 2003) is used for assessing chronic consumer exposure. These data only cover adult consumers and have the potential for 'double-counting' of consumption where some food commodities can by specified twice e.g. pome fruit

and apples and pears In this situation, using a percentage of the diet as a criterion for determining major and minor foodstuffs could be misleading due to double counting. Potential minor crops have been determined based on the criteria of a contribution of ≤ 2.0 g/person/day in all diets (approximately equal to 0.1-0.25% of the diet consumed as fruit and vegetables e.g. excluding meat, cereal and fish consumption) or ≤ 7.5 g/person/day in all diets (approximately equal to 0.4-0.9% of the diet consumed as fruit and vegetables. The following crops (Table 1) have been determined as minor based on these criteria:

Table 1 Minor crops derived from GEMS/Food consumption data

Codex Code	**Name**
	Minor crops (≤ 2g/person/day)
TN 0295	Cashew nut
TN 0660	Almonds
TN 0664	Chestnuts
TN 0666	Hazelnuts
TN 0672	Pecan
TN 0675	Pistachio nut
TN 0678	Walnuts
FP 0231	Quince
FS 0243	Cherry, sour
DF 0014	Prunes
FB 0019	Vaccinium berries (incl. Bearberry)
FB 0020	Blueberries
FB 0265	Cranberry
FB 0021	Currants, red, black, white
FB 0278	Currant, black
FB 0279	Currant, red, white
FB 0264	Blackberries
FB 0266	Dewberries, incl boysen- & loganberry
FB 4079	Boysenberry
FB 0268	Gooseberry
FB 0272	Raspberries, red, black
FT 0295	Date
FT 0297	Fig (fresh, dried)
FT 0297	Fig (fresh)
FT 0307	Persimmon, Japanese
FT 0312	Tree tomato
FI 0341	Kiwi fruit
FI 0351	Passion fruit
VR 0469	Chicory, roots
VR 0494	Radish
VR 0497	Swede
VR 0506	Turnip, Garden
VR 0574	Beetroot
VR 0583	Horseradish
VR 0588	Parsnip
VR 0591	Radish, Japanese
VR 0596	Sugar beet

Table 1 continued

Codex Code	Name
	Minor crops (< 2g/person/day)
VA 0380	Fennel, bulb
VA 0384	Leek
VC 0433	Winter squash
VO 0444	Peppers, chilli
VO 0442	Okra
JF 0448	Tomato juice
VB 0403	Cabbage, Savoy
VB 0405	Kohlrabi
VL 0464	Chard
VL 0466	Pak-choi or paksoi
VL 0469	Chicory leaves (green and red)
VL 0473	Watercress
VL 0476	Endive
VL 0480	Kale
VL 0485	Mustard greens
VL 0502	Spinach
VL 0506	Turnip greens
VL 0510	Cos lettuce
HH 0624	Celery leaves
HH 0740	Parsley
VP 0062	Beans, shelled (immature seeds)
VP 0522	Broad bean (green pods & immature seeds)
VP 0534	Lima bean (green pods & immature seeds)
VP 0541	Soya bean (immature seeds)
VP 0545	Lupin
VS 0469	Witloof chicory (sprouts)
VS 0621	Asparagus
VS 0624	Celery
VS 0627	Rhubarb
DV 0168	Dried vegetables
VD 0526	Common bean (dry)
SO 0090	Mustard seeds (collective name)
SO 0495	Rape seed
SO 0691	Cotton seed
OC 0691	Cotton seed oil, crude
SO 0693	Linseed
-d	Linseed oil, crude
-d	Linseed oil, refined
SO 0696	Palm nut
SO 0699	Safflower seed
SO 0700	Sesame seed
OC 0700	Sesame seed oil, crude
OR 0700	Sesame seed oil, edible
SO 0701	Shea nuts (karite nuts)
-	Shea nuts (karite nuts), butter
SO 0702	Sunflower seed, consumed fresh
DH 1100	Hops, dry
	Minor crops (≤ 7.5g/person/day)
JF 0004	Orange juice
FC 0203	Grapefruit
OC 0665	Coconut oil, crude
OR 0665	Coconut oil, refined
JF 0226	Apple juice

Table 1 continued

Codex Code	Name
	Minor crops (< 2g/person/day)
FS 0013	Cherries
FS 0244	Cherry, sweet
FS 0014	Plums (fresh, prunes)
FS 0014	Plums (fresh)
FS 0240	Apricot
DF 0269	Grapes, dried (= currants, raisins and sultanas)
FT 0305	Olives
FI 0326	Avocado
VA 0381	Garlic
VA 0388	Shallot
	Minor crops (< 7.5g/person/day)
VA 0389	Spring onion
VC 0424	Cucumber
VC 0425	Gherkin
VO 0450	Mushrooms
VB 0402	Brussels sprouts
VD 0523	Broad bean (dry)
VD 0541	Soya bean (dry)
VD 0524	Chick-pea (dry)
VD 0533	Lentil (dry)
SO 0089	Oilseed (except peanut)
SO 0697	Peanut
OC 0697	Peanut oil, crude
OR 0697	Peanut oil, edible
SO 0698	Poppy seed
DT 0171	Teas (tea and herb teas)
DT 1114	Tea, green, black (black, fermented and dried)

There were no major differences in the quality and quantity of residue data required by national authorities to support an import tolerance when compared to those required for a national MRL. The difficulties in accepting import tolerances or JMPR MRLs appear to be due to the fact they do not meet the national standards criteria rather than to a fundamental disagreement with the principle of setting these limits on a reduced data set. However, the Codex MRLs are the reference standards applied by the World Trade Organization (WTO) to protect health of consumers while ensuring fair trade practices and are of significant benefit to developing countries and net exporting countries. Whilst for national import tolerances, governments are entitled to set their own regulatory standards; lesser requirements could be accepted when:

1. crops make an insignificant contribution to the diet and do not lead to unacceptable consumer exposure in international scenarios; and
2. these crops are commodities traded internationally.

The minimum number of trials that could be accepted is 3; however, lesser requirements could be accepted where other supporting data indicate a non-detectable residue situation usually at or below the limit of quantitation e.g. very early applications such as before the edible part of the crop is present.

Extrapolation of Residues Data for One Crop to Another

The concept of extrapolation of residue data (in order to minimise the need for additional residue trials data in setting/proposing MRLs/import tolerances) was considered an acceptable tool in setting MRLs. Crop morphology was noted as an important factor for consideration and a number of responses indicated that any new recommendation on extrapolation of data should be supported by residue data. Greater possibilities were recognised for minor crops (due to their potentially small contribution to the diet) and also for extrapolating to crop groups although the latter would be of limited benefit in an international forum where MRLs are only recommended where GAP exists. A number of respondents indicated that they have programmes examining potentially new extrapolation scenarios.

Based on an exercise to compare and contrast the recommendations made in Australia, the European Union and the USA, extrapolations, which would be suitable for use in recommending MRLs/import tolerances are summarised in Table 2

Table 2 Extrapolations that can be used in situations of comparable GAP

crop	**recommendation**
Citrus fruit	Oranges and a small citrus to whole group
Tree nuts	Almonds plus one other nut (except coconuts) to whole group
Pome fruit	Apples and pears to whole group
Stone fruit	Peaches, nectarine and cherry or peaches, plum and cherry to whole group
Berries and other small fruit	Any berry and currant to whole group (excluding grapes)
Root and tuber vegetables	Potato, carrot and one other root crop to whole group Potato to tuber and corm sub group Sweet potato or yam to tuber and corm excluding potato sub group
Bulb vegetables	Onions green and dry to whole group
Fruiting vegetables (non-cucurbits)	Tomato and peppers to whole group
Fruiting vegetables (cucurbits)	Cucumber, melon and other cucurbit to whole group
Brassicas	Cauliflower or broccoli and cabbage and one other brassica to whole group
Leafy vegetables (also see stem vegetables)	head and leafy lettuce and spinach to leafy vegetables Cos lettuce to leafy Asian vegetables
Herbs	Two leafy herbs to whole group
Legume vegetables (fresh)	Beans green and peas green to whole group
Stem vegetables	Celery to leafy petioles sub group
Pulses	Any dried bean and dried pea to whole group
oilseeds	Any 3 oilseeds to whole group
Cereals	Rice plus any two other cereals to whole group including rice

Processing Data

Processing data were not considered necessary or required in all situations; however, the following could trigger a request for processing data: (i) significance of residues (identified as $\geq$ 0.1 mg/kg or >10% ADI) or (ii) where residues would be expected to concentrate in the processed commodity. Recently, recommendations were made by JMPR and CCPR that MRLs should also be set for processed commodities where a higher residue would be expected in the processed commodity compared to the RAC i.e. concentration occurs. This could also be used as a trigger for requesting processing data. However, many concentration factors are predictable based on mass transfers of RAC to processed commodity and therefore the possibility exists that these data should only be requested in the situation that refinement of a theoretically unacceptable consumer exposure occurs.

Standard transfer factors such as those derived by the US EPA should be applied to assess whether acceptable consumer exposure could be achieved if these refinements were supported by data in the future (EPA, 1996).

Recommendations

10. Since the recommendations of the zoning project do not appear to be readily acceptable to respondents, additional criteria to increase their potential for acceptability should be put in place. Where residue data based on foliar applications are submitted from outside of the immediate geographic area where GAP exists, data should be supplemented with discussions on the relevance of climate, GAP and cultivation technique addressing the applicability of these data.
11. This report should be updated to reflect the 2004 JMPR's findings where compounds have been assessed using the zoning project guidelines.
12. In line with the recommendations of the York meeting, residues data for glasshouse treatments should be considered representative of any geographic area where the GAP (including application technique) and crop cultivation techniques are comparable.
13. In line with the recommendations of the York meeting, residues data for seed treatment uses would not be required to support an MRL/import tolerance if other data existed e.g. crop metabolism data which could be used to confirm a non-residue situation. If such data where not available then a minimum number of trials (3) would be acceptable to confirm a group tolerance MRL/import tolerance with groups being defined in line with the degree of extrapolation permitted for metabolism studies (e.g. root crops, fruit etc). Where MRLs are set on a lower number of residues trials, wider limits may be required in setting the MRL to account for the limited spread of data.
14. Where applications are made at a very early stage of crop development, residues data should be considered with respect to a group tolerance or wider extrapolations where this is applicable to GAP.
15. Additional recommendations have been made to define minor crops, such as requiring only 3 residue trials to set an MRL/import tolerance based solely on very low contribution to the diet. Since the value of 7.5g/person/day accounts for <1% of the total GEMS diet based mainly on fruit and vegetable consumption, this recommendation would not lead to an increase in consumer exposure/risk.
16. Recommendations on extrapolations have been made for a number of crops. These are based on comparable national regulations/guidelines and therefore should not lead to difficulties in acceptance of MRLs/import tolerances without further validation being required.

17. Where a government or regulatory body puts forward new, national extrapolations scenarios, these should be passed to the FAO panel of JMPR to assess whether these would also be suitable for the setting of international MRLs
18. Since this report includes recommendations which would result in changes to the current guidelines for setting MRLs/import tolerances, it is recommended that an expert consultation is held to discuss the scientific acceptability of these proposals and to ensure that these can be practically and effectively implemented and would not compromise acceptance of Codex MRLs/import tolerances in the future.

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OECD (2002) Report of the OECD/FAO Zoning Steering Group http://www.fao.org/ag/agp/agpp/pesticid/jmpr/Download/zsg/zsg.doc
WHO (2003) GEMS/Food Regional Diets. Regional per Capita Consumption of Raw and Semi-processed Agricultural Commodities. Food Safety Department, WHO Health Organization Geneva, Switzerland.

Appendix 1 Questionnaire Used in the Consultation

Questions for consideration.
Please answer whenever possible and tick the answers if provided with choices

Zoning project

Q1: Is the principle of zoning for the acceptance of residues trials enshrined in your national legislation? If so, how many and what zones are defined?
A1: ***yes*** □ ***no*** □
Q2: What are your views on the conclusions of the zoning report[1], i.e. the impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless the geographical location of the trials?
A2:
Q3a: How would your authority/agency implement these recommendations into their national guidelines? i.e. would your authority be prepared to accept residues trials data from countries/regions outside of your own?
A3a: ***Your authority/agency accepts*** ***1. all trials conducted in other countries with similar GAPs*** ***yes*** □ ***no*** □ ***2. 50% conducted under local condition*** ***yes*** □ ***no*** □ ***3. Others (please specify)***
Q3b: From which other countries/regions do you currently accept residues data to support an MRL/import tolerance?
A3b:
Q3c: From which other countries/regions would you be prepared to accept residues data to support an MRL/import tolerance?
A3c:

Q4: What are your criteria for accepting supervised residue trials data from outside your country/region?					
A4:	***1. similar GAPs***	***yes***	□	***no***	□
	2. similar climate	***yes***	□	***no***	□
	3. similar spray equipment	***yes***	□	***no***	□
	4. similar agronomic factors	***yes***	□	***no***	□
	5. Others (please specify)				
Q5: The zoning group only made recommendations with respect to foliar sprays. What other application techniques should be evaluated to determine the effects of climatic zone on final residue levels?					
A5:					

Significance in diet/trade

Q6: Do you differentiate between major and minor crops in terms of residue data requirements?
A6: ***yes*** □ ***no*** □
Q7: Is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops? Are other criteria established in your country (e.g. area of production)?
A7: ***yes*** □ ***no*** □
Q8: How do you define major and minor crops in your region/country?
A8: ***1. by area/ hectarage (If so indicate % for minor and for major crops)*** ***yes*** □ ***no*** □ ***2. by consumption (If so, indicate for minor and for major crops)*** ***yes*** □ ***no*** □ ***3. Others (please specify)***
Q9: What are/would be your criteria for defining a crop as significant in trade or the diet?
A9a: Significant in trade (e.g. % cultivation area, quantity of production, etc.) ***A9 b: Significant in diet (e.g. 0.5% of the total diet as the trigger value)***

Q10: What source of dietary information do you use to carry out consumer risk assessments in your country/region?
A10:
Q11: Would you accept 3 as the minimum number of trials for establishing MRLs. If not, what would be the absolute minimum number of trials, without extrapolation, you would be prepared to accept in support of an MRL/import tolerance?
A11:
Q12: Do your data requirements differ for setting National MRLs and for Import Tolerances i.e. based on uses outside of your country? If so, how?
A12: ***yes*** □ ***no*** □

Extrapolation of residues data for one crop to another

Q13: How do you implement the principle of extrapolation of residues data from one crop to another e.g. extrapolation of residues levels in tomatoes to estimate residue levels in aubergines? How do you decide what is an acceptable extrapolation?
A13: ± 25% (similar GAPs) ***yes*** □ ***no*** □ ***Others (specify)***

Q14a: Can you accept extrapolation of data when there are similar GAPs only?
A14a: ***yes*** □ ***no*** □
Q14b: If not, what are your national/regional criteria to allow extrapolation of residues data? (e.g. comparability of GAPs, climate, geographical location, similarities in morphology of crops, crops within same groups, others.)
A14b:
Q15: Do you have an agreed list of extrapolations of residues data?
A15: ***yes*** □ ***no*** □
Q16: What data would you wish to have in order to agree additional extrapolations?
A16:
Q17: Would you accept the principle of more extensive extrapolation of residue data to support minor crops?
A17:

Processing data

Q18: Under what circumstances do you require the submission of data on processing i.e. data examining the distribution of residues between different fractions of processed foods?
A18:

Q19: What are the criteria for the extrapolation of processing data from one crop to another?
A19:
Q20: What information do you require from processing studies, e.g. do you require a balance study i.e. a full description of where residues remain in all parts of the processed foodstuff or just residue levels in final edible commodities?
A201:
Q21: What is the minimum number of studies/trials required to determine a processing/transfer factor?
A21:
Q22: Do you/would you permit the use of 'theoretical' processing factors i.e. factors based on water loss during the drying process – if not please provide a reason
A22: ***yes*** □ ***no*** □
Q23: Which data do you use to determine 'theoretical' processing factors?
A23:

Please provide the name and complete contact details including full address of a national expert who could be contacted if further discussion or clarification of answers is required.

Thank you for your input to this initiative.

Appendix 2 WHO GEMS/FOOD Consumption Data as an Indicator of Minor Crops Based on Diet

Codex Code	Name	Diets: g/person/day.					< g/person/day.				
		Mid-East	Far-East	African	Latin American	European	0.5	1	2	5	7.5
001	**CITRUS FRUITS**	-	-	-	-	-					
FC 0001	Citrus fruits	47.1	6.3	5.1	54.6	44.6					
FC 0002	Lemons and limes (incl. Citron)	3.8	0.3	0.0	10.8	4.8					
FC 0204	Lemon	1.9	0.2	0.0	5.4	2.4					x
FC 0205	Lime	1.9	0.15	0	5.4	2.4					x
FC 0003	Mandarins (incl. Mandarin-like hybrids)	8.8	0.2	0.0	6.3	6.0					x
FC 0206	Mandarin	8.6	0.2	0.0	6.3	6.0					x
FC 0004	Oranges, sweet, sour (incl. Orange-like hybrids)	31.5	4.0	4.8	31.0	29.8					
FC 0208	Orange, sweet	31.5	4.0	4.8	31.0	29.8					
FC 0005	Shaddocks or pomellos (incl. Shaddock-like hybrids)	3.0	1.8	0.3	6.5	4.0					x
FC 0203	Grapefruit	1.5	0.9	0.1	3.3	2.0				x	x
022	**TREE NUTS**	-	-	-	-	-					
TN 0085	Tree nuts	1.1	13.5	4.5	17.8	4.6					
TN 0295	Cashew nut	0.0	0.0	0.2	0.0	0.0	x	x	x	x	x
TN 0660	Almonds	0.5	0.0	0.0	0.1	1.8			x	x	x
TN 0664	Chestnuts	0.0	0.0	0.0	0.1	0.7		x	x	x	x
TN 0665	Coconut	0.3	13.5	3.3	17.5	0.5					
OC 0665	Coconut oil, crude	0.8	1.8	0.4	2.3	0.0				x	x
OR 0665	Coconut oil, refined	0.8	1.8	0.4	2.3	0.0				x	x
TN 0666	Hazelnuts	0.0	0.0	0.0	0.1	0.3	x	x	x	x	x
TN 0672	Pecan	0.0	0.0	0.0	0.0	0.3	x	x	x	x	x
TN 0675	Pistachio nut	0.3	0.0	0.0	0.0	0.0	x	x	x	x	x
TN 0678	Walnuts	0.0	0.0	0.0	0.0	0.5	x	x	x	x	x
-	Nuts NES	0.0	0.0	1.0	0.0	0.5		x	x	x	x
002	**POME FRUITS**	-	-	-	-	-					
FP 0009	Pome fruits	10.8	7.5	0.3	6.5	51.3					
FP 0226	Apple	7.5	4.7	0.3	5.5	40.0					
FP 0230	Pear	3.3	2.8	0.0	1.0	11.3					
FP 0231	Quince	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
003	**STONE FRUITS**	-	-	-	-	-					
FS 0012	Stone fruits	7.3	1.0	0.0	0.8	23.3					
FS 0013	Cherries	0.0	0.0	0.0	0.0	3.0				x	x
FS 0243	Cherry, sour	0.0	0.0	0.0	0.0	0.3	x	x	x	x	x
FS 0244	Cherry, sweet	0.0	0.0	0.0	0.0	2.7				x	x
FS 0014	Plums (fresh, prunes)	1.8	0.5	0.0	0.0	4.3				x	x
FS 0014	Plums (fresh)	1.8	0.5	0.0	0.0	3.8				x	x
DF 0014	Prunes	0.0	0.0	0.0	0.0	0.5	x	x	x	x	x
FS 0240	Apricot	3.0	0.0	0.0	0.0	3.5				x	x
-d	Peaches & nectarines	2.5	0.5	0.0	0.8	12.5					
FS 0245	Nectarine	1.3	0.3	0.0	0.4	6.3					x
FS 0247	Peach	1.3	0.3	0.0	0.4	6.3					x
004	**BERRIES AND OTHER SMALL FRUITS**	-	-	-	-	-					
FB 0018	Berries and other small fruits	16.0	1.0	0.0	1.6	23.5					
FB 0019	Vaccinium berries (incl. Bearberry)	0.0	0.0	0.0	0.0	0.8		x	x	x	x
FB 0020	Blueberries	0.0	0.0	0.0	0.0	0.5	x	x	x	x	x
FB 0265	Cranberry	0.0	0.0	0.0	0.0	0.3	x	x	x	x	x

Appendix 2 continued

Codex Code	Name	Diets: g/person/day.					< g/person/day.				
		Mid-East	Far-East	African	Latin American	European	0.5	1	2	5	7.5
FB 0021	Currants, red, black, white	0.0	0.0	0.0	0.0	0.3	x	x	x	x	x
FB 0278	Currant, black	0.0	0.0	0.0	0.0	0.0	x	x	x	x	x
FB 0279	Currant, red, white	0.0	0.0	0.0	0.0	0.3	x	x	x	x	x
FB 0264	Blackberries	0.0	0.0	0.0	0.0	0.0	x	x	x	x	x
FB 0266	Dewberries, incl boysen- & loganberry	0.0	0.0	0.0	0.0	0.0	x	x	x	x	x
FB 4079	Boysenberry	0.0	0.0	0.0	0.0	0.0	x	x	x	x	x
FB 0267	Elderberries	ND	ND	ND	ND	ND					
FB 0268	Gooseberry	0.0	0.0	0.0	0.0	0.5	x	x	x	x	x
FB 0269	Grapes (fresh, wine, dried)	16.1	1.0	0.0	1.6	16.1					
FB 0269	Grapes (fresh, wine, excluding dried grapes)	15.8	1.0	0.0	1.3	13.8					
-d	Wine only	0.5	0.0	0.8	19.8	97.8					
DF 0269	Grapes, dried (= currants, raisins and sultanas)	0.3	0.0	0.0	0.3	2.3				x	x
FB 0272	Raspberries, red, black	0.0	0.0	0.0	0.0	0.5	x	x	x	x	x
FB 0275	Strawberry	0.0	0.0	0.0	0.0	5.3					x
005	**ASSORTED (SUB)TROPICAL FRUITS - EDIBLE PEEL**	-	-	-	-	-					
FT 0292	Cashew apple	0.0	0.0	0.0	3.0	0.0				x	x
FT 0295	Date	41.8	0.3	0.0	0.0	0.3	x	x	x	x	x
FT 0297	Fig (fresh, dried)	2.8	0.0	0.0	0.3	0.5	x	x	x	x	x
FT 0297	Fig (fresh)	2.3	0.0	0.0	0.3	0.5	x	x	x	x	x
DF 0297	Fig, dried or dried and candied	0.5	0.0	0.0	0.0	0.0	x	x	x	x	x
FT 0305	Olives	1.3	0.0	0.0	0.3	2.8				x	x
OC 0305	Olive oil, crude	1.5	0.0	0.0	0.0	7.8					
OR 0305	Olive oil, refined	1.5	0.0	0.0	0.0	7.8					
FT 0307	Persimmon, Japanese	0.0	1.0	0.0	0.3	0.0		x	x	x	x
FT 0312	Tree tomato	0.0	1.9	0.1	1.5	0.1			x	x	x
006	**ASSORTED (SUB)TROPICAL FRUITS- INEDIBLE PEEL**	-	-	-	-	-					
FI 0326	Avocado	0.0	0.0	0.2	3.3	1.0				x	x
FI 0327	Banana	8.3	26.2	21.0	102.3	22.8					
FI 0341	Kiwi fruit	0.0	0.0	1.9	0.1	1.5			x	x	x
FI 0345	Mango	2.3	5.3	3.4	6.3	0.0					x
FI 0350	Papaya	0.0	0.2	0.0	5.3	0.0					x
FI 0351	Passion fruit	0.0	0.0	1.9	0.1	1.5			x	x	x
FI 0353	Pineapple (fresh)	0.0	9.3	2.6	15.5	1.3					
-	Pineapple, canned	0.8	0.8	0.5	0.3	2.0			x	x	x
FI 0354	Plantain	0.0	0.0	41.3	56.5	0.0					
016	**ROOT AND TUBER VEGETABLES**	-	-	-	-	-					
-d	Roots and tubers	61.8	108.5	321.3	159.3	242.0					
VR 0463	Cassava (fresh)	0.0	2.8	154.5	37.8	0.0					
-d	Cassava flour	0.0	3.7	11.0	7.0	0.0					
VR 0469	Chicory, roots	0.0	0.0	0.0	0.0	1.0		x	x	x	x
VR 0494	Radish	0.5	0.0	0.0	0.3	2.0			x	x	x
VR 0497	Swede	0.5	0.0	0.0	0.3	2.0			x	x	x
VR 0505	Taro	1.3	1.5	31.3	0.0	0.0					
VR 0506	Turnip, Garden	0.5	0.0	0.0	0.3	2.0			x	x	x

Appendix 2 continued

Codex Code	Name	Diets: g/person/day.					< g/person/day.				
		Mid-East	Far-East	African	Latin American	European	0.5	1	2	5	7.5
VR 0508	Sweet potato	1.5	81.3	14.3	13.8	1.3					
VR 0574	Beetroot	0.5	0.0	0.0	0.3	2.0			x	x	x
VR 0577	Carrot	2.8	2.5	0.0	6.3	22.0					
VR 0583	Horseradish	0.5	0.7	0.0	0.3	0.0		x	x	x	x
VR 0588	Parsnip	0.5	0.0	0.0	0.3	2.0			x	x	x
VR 0589	Potato	59.0	19.2	20.6	40.8	240.8					
VR 0591	Radish, Japanese	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
VR 0596	Sugar beet	0.5	0.0	0.0	0.3	2.0			x	x	x
VR 0600	Yams	0.0	0.0	89.5	46.0	0.0					
009	**BULB VEGETABLES**	-	-	-	-	-					
VA 0035	Bulb vegetables	25.6	13.9	7.5	14.4	32.9					
VA 0036	Bulb vegetables, except fennel, bulb	25.5	13.8	7.4	14.3	32.8					
VA 0380	Fennel, bulb	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
VA 0381	Garlic	2.0	2.2	0.0	0.5	3.0				x	x
VA 0384	Leek	0.5	0.0	0.0	0.3	2.0			x	x	x
VA 0385	Onion, bulb	23.0	11.5	7.3	13.8	27.8					
-d	Onions, dry	23.0	9.5	5.8	9.8	26.8					
VA 0388	Shallot	0.0	2.0	1.5	4.0	1.0				x	x
VA 0389	Spring onion	0.0	2.0	1.5	4.0	1.0				x	x
011	**FRUITING VEGETABLES, CUCURBITS**	-	-	-	-	-					
VC 0045	Fruiting vegetables, cucurbits	80.5	18.2	0.0	30.5	38.5					
VC 0046	Melons, except watermelon	16.0	2.0	0.0	2.8	18.3					
VC 4199	Cantaloupe	16.0	2.0	0.0	2.8	18.3					
-d	Cucumbers & gherkins	4.8	4.5	0.0	8.3	9.0					
VC 0424	Cucumber	2.4	2.3	0.0	4.2	4.5				x	x
VC 0425	Gherkin	2.4	2.3	0.0	4.2	4.5				x	x
VC 0429	Pumpkins	10.5	2.2	0.0	14.0	3.5					
VC 0431	Squash, summer	10.5	2.2	0.0	14.0	3.5					
VC 0433	Winter squash	1.5	0.3	0.0	2.0	0.5			x	x	x
VC 0432	Watermelon	49.3	9.5	0.0	5.5	7.8					
012	**FRUITING VEGETABLES OTHER THAN CUCURBITS**	-	-	-	-	-					
VO 0050	Fruiting vegetables other than cucurbits	92.3	12.6	27.0	33.9	91.6					
VO 0051	Peppers	3.4	2.1	5.4	2.4	10.4					
VO 0444	Peppers, chili	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
VO 0445	Peppers, sweet (incl. pim(i)ento)	3.3	2.0	5.3	2.3	10.3					
VO 0440	Egg plant	6.3	3.0	0.7	6.0	2.3					
VO 0442	Okra	0.8	0.0	0.0	0.0	0.0		x	x	x	x
VO 0448	Tomato (fresh, juice, paste, peeled)	81.5	7.0	16.5	25.5	66.6					
VO 0448	Tomato (fresh)	44.1	5.7	14.6	25.5	34.9					
VO 0450	Mushrooms	0.3	0.5	0.0	0.0	4.0				x	x
010	**BRASSICA**	-	-	-	-	-					
-d	Brassica vegetables (flowerhead, head & leafy brassicas, kohlrabi)	6.3	11.2	0.0	10.8	39.8					
-d	Cabbages (head & leafy brassicas, kohlrabi)	5.0	9.7	0.0	10.5	26.8					
VB 0403	Cabbage, Savoy	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x

Appendix 2 continued

Codex Code	Name	Diets: g/person/day.					< g/person/day.				
		Mid-East	Far-East	African	Latin American	European	0.5	1	2	5	7.5
VB 0402	Brussels sprouts	0.5	1.0	0.0	1.1	2.7				x	x
VB 0400	Broccoli	0.5	1.0	0.0	1.1	2.7					
VB 0404	Cauliflower	1.3	1.5	0	0.3	13					
VB 0405	Kohlrabi	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
013	**LEAFY VEGETABLES**	-	-	-	-	-					
VL 0053	Leafy vegetables	7.8	9.7	0.7	16.5	51.7					
VL 0464	Chard	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
VL 0466	Pak-choi or paksoi	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
VL 0469	Chicory leaves (green and red)	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
VL 0473	Watercress	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
VL 0476	Endive	0.5	0.0	0.0	0.3	2.0			x	x	x
VL 0480	Kale	0.5	0.0	0.0	0.3	2.0			x	x	x
VL 0482	Lettuce, head	2.3	0.0	0.0	5.8	22.5					
VL 0483	Lettuce, leaf	2.3	0.0	0.0	5.8	22.5					
VL 0485	Mustard greens	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
VL 0502	Spinach	0.5	0.0	0.0	0.3	2.0			x	x	x
VL 0506	Turnip greens	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
VL 0510	Cos lettuce	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
027	**HERBS**	-	-	-	-	-					
HH 0624	Celery leaves	0.5	0.0	0.0	0.3	2.0			x	x	x
HH 0740	Parsley	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
014	**LEGUME VEGETABLES**	-	-	-	-	-					
VP 0060	Legume vegetables	9.9	3.1	0.1	5.6	28.4					
VP 0061	Beans except broad bean & soya bean (green pods & immature seeds)	3.9	0.9	0.0	4.4	13.2					
VP 0062	Beans, shelled (immature seeds)	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
VP 0526	Common bean (green pods and/or immature seeds)	3.5	0.8	0.0	4.0	12.0					
VP 0522	Broad bean (green pods & immature seeds)	0.4	0.1	0.0	0.4	1.2			x	x	x
VP 0534	Lima bean (green pods & immature seeds)	0.4	0.1	0.0	0.4	1.2			x	x	x
VP 0541	Soya bean (immature seeds)	0.1	0.1	0.1	0.0	0.0	x	x	x	x	x
VP 0063	Peas (green pods & immature seeds)	5.5	2.0	0.0	0.8	14.0					
VP 0064	Peas, shelled (immature seeds)	4.0	0.5	0.0	0.2	10.1					
VP 0528	Garden pea (green pods & immature seeds)	5.5	0.7	0.0	0.3	14.0					
VP 0529	Garden pea, shelled (immature seeds)	4.0	0.5	0.0	0.2	10.1					
VP 0537	Pigeon pea (green pods & immature seeds)	0.0	1.3	0.0	0.5	0.0			x	x	x
VP 0545	Lupin	0.5	0.0	0.0	0.0	0.0	x	x	x	x	x
017	**STALK AND STEM VEGETABLES**	-	-	-	-	-					
VS 0469	Witloof chicory (sprouts)	0.5	0.0	0.0	0.3	2.0			x	x	x
VS 0620	Artichoke globe	2.3	0.0	0.0	0.0	5.5					x
VS 0621	Asparagus	0.0	0.0	0.0	0.0	1.5			x	x	x
VS 0624	Celery	0.5	0.0	0.0	0.3	2.0			x	x	x
VS 0627	Rhubarb	0.5	0.0	0.0	0.3	2.0			x	x	x

Appendix 2 continued

Codex Code	Name	Diets: g/person/day.					< g/person/day.				
		Mid-East	Far-East	African	Latin American	European	0.5	1	2	5	7.5
015	**PULSES**	-	-	-	-	-					
VD 0070	Pulses	18.9	14.5	17.5	20.3	9.4					
-	Beans (dry), including broad beans	6.8	6.8	0.0	13.5	4.3					
VD 0523	Broad bean (dry)	4.5	2.0	0.0	0.5	0.8				x	x
VD 0071	Beans (dry)	2.3	4.8	0.0	13.0	3.5					
VD 0526	Common bean (dry)	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x
VD 0534	Lima bean (dry)	4.5	2.0	0.0	0.5	0.8			x	x	x
VD 0541	Soya bean (dry)	4.5	2.0	0.5	0.0	0.0				x	x
-	Soya sauce	1.5	11.0	0.0	0.0	0.0					
OC 0541	Soya bean oil, crude	1.3	1.7	3.0	14.5	4.3					
OR 0541	Soya bean oil, refined	1.3	1.7	3.0	14.5	4.3					
VD 0072	Peas (dry)	0.5	1.7	5.1	1.3	1.8					x
VD 0527	Cowpea (dry)	0.0	0.0	5.1	0.3	0.0					x
VD 0561	Field pea (dry)	0.5	1.7	5.1	1.3	1.8					x
VD 0524	Chick-pea (dry)	3.3	2.5	0.0	0.0	1.0				x	x
VD 0533	Lentil (dry)	2.8	0.7	0.0	0.0	2.3				x	x
-	Pulses NES	1.0	0.8	11.9	5.5	0.0					
023	**OILSEED**	-	-	-	-	-					
SO 0088	Oilseed	5.4	1.4	5.4	0.8	6.1					x
SO 0089	Oilseed (except peanut)	5.1	1.2	3.1	0.5	3.1				x	x
-d	Melonseed (except watermelon)	0.8	0.0	0.8	0.0	0.0		x	x	x	x
SO 0090	Mustard seeds (collective name)	0.0	0.0	0.0	0.0	0.8		x	x	x	x
SO 0495	Rape seed	0.0	0.0	0.0	0.0	0.0	x	x	x	x	x
OC 0495	Rape seed oil, crude	4.5	2.7	0.0	0.3	7.3					x
OR 0495	Rape seed oil, edible	4.5	2.7	0.0	0.3	7.3					x
SO 0691	Cotton seed	0.0	0.0	0.0	0.0	0.0	x	x	x	x	x
OC 0691	Cotton seed oil, crude	3.8	0.5	0.5	0.5	0.0	x	x	x	x	x
OR 0691	Cotton seed oil, edible	3.8	0.5	0.5	0.5	0.0	x	x	x	x	x
SO 0693	Linseed	0.0	0.0	0.0	0.0	0.0	x	x	x	x	x
-d	Linseed oil, crude	3.8	0.5	0.5	0.5	0.0	x	x	x	x	x
-d	Linseed oil, refined	3.8	0.5	0.5	0.5	0.0	x	x	x	x	x
SO 0696	Palm nut	0.0	0.0	0.2	0.0	0.0	x	x	x	x	x
OC 0696	Palm oil, crude	7.8	4.3	12.4	0.0	0.0					
OR 0696	Palm oil, edible	7.8	4.3	12.4	0.0	0.0					
SO 0703	Peanut, whole	0.0	4.0	5.5	1.3	0.3					x
SO 0697	Peanut	0.3	0.2	2.3	0.3	3.0				x	x
OC 0697	Peanut oil, crude	0.0	1.8	3.5	0.5	1.8				x	x
OR 0697	Peanut oil, edible	0.0	1.8	3.5	0.5	1.8				x	x
SO 0698	Poppy seed	2.3	1.2	0.5	0.5	2.3				x	x
SO 0699	Safflower seed	0.0	0.0	0.2	0.0	0.0	x	x	x	x	x
SO 0700	Sesame seed	1.0	0.0	0.6	0.0	0.0		x	x	x	x
OC 0700	Sesame seed oil, crude	2.3	0.2	0.9	1.0	0.0		x	x	x	x
OR 0700	Sesame seed oil, edible	2.3	0.2	0.9	1.0	0.0		x	x	x	x
SO 0701	Shea nuts (karite nuts)	0.0	0.0	0.2	0.0	0.0	x	x	x	x	x
-	Shea nuts (karite nuts), butter	0.0	0.0	0.7	0.0	0.0		x	x	x	x
SO 0702	Sunflower seed, consumed fresh	1.0	0.0	0.6	0.0	0.0		x	x	x	x
OC 0702	Sunflower seed oil, crude	9.3	0.5	0.3	0.8	8.5					
OR 0702	Sunflower seed oil, edible	9.3	0.5	0.3	0.8	8.5					
066	**TEAS**	-	-	-	-	-					
DT 0171	Teas (tea and herb teas)	2.3	1.2	0.5	0.5	2.3				x	x

Appendix 2 continued

Codex Code	Name	Diets: g/person/day.					< g/person/day.				
		Mid-East	Far-East	African	Latin American	European	0.5	1	2	5	7.5
DT 1114	Tea, green, black (black, fermented and dried)	2.3	1.2	0.5	0.5	2.3				x	x
057	**DRIED HERBS**	-	-	-	-	-					
DH 1100	Hops, dry	0.1	0.1	0.1	0.1	0.1	x	x	x	x	x

Appendix 3 Comparison of national rules on extrapolation of residues data with respect to setting group tolerances

crop	Australia (NRA, 2002)	European Union (CEC, 2001) (minimum number of trials in parenthesis)	USA (EPA, 2000)	recommendation
Citrus fruit	Oranges and lemons or limes or mandarins to whole group	Oranges (8) and mandarins (8) to whole group	Sweet orange, lemon and grapefruit to whole group	Oranges and a small citrus to whole group
Tree nuts	Almonds and macadamia to whole group	Any two nuts (except coconuts) to whole group	Almond and pecan to whole group	Almonds plus one other nut (except coconuts) to whole group
Pome fruit	Apples and pears to whole group	Apples (4) and pears to whole group	Apples and pears to whole group	Apples and pears to whole group
Stone fruit	Peaches, nectarine and cherry or peaches, plum and cherry to whole group Peaches to nectarine and plums	Peaches (4) or apricots to nectarines, apricots or peaches Sweet (4) and sour cherries (4) to all cherries	Sweet or sour (tart) cherries, peach and plum to whole group	Peaches, nectarine and cherry or peaches, plum and cherry to whole group

Appendix 3 continued

crop	Australia (NRA, 2002)	European Union (CEC, 2001) (minimum number of trials in parenthesis)	USA (EPA, 2000)	recommendation
Berries and other small fruit	Grapes, strawberry and one other berry or currant to whole group Raspberry to blackberry, boysenberry or cranberry	Table grapes to wine grapes and reverse Raspberries (8) or two cane fruit (including raspberries (4) to whole group Blackberries (8) to two cane fruit (including blackberries (4) to whole group Any wild berry or wild fruit or any other wild berry or wild fruit	Any blackberry or raspberry and blueberry to whole group Any blackberry or raspberry to caneberry group Blueberry to bushberry group	Any berry and currant to whole group (excluding grapes)

Appendix 3 continued

crop	Australia (NRA, 2002)	European Union (CEC, 2001) (minimum number of trials in parenthesis)	USA (EPA, 2000)	recommendation
Root and tuber vegetables	Potato, carrot and beetroot to whole group Potato, carrot and swede to whole group Potato, carrot and radish to whole group	Carrots to parsley root, Salsify, parsnips and horseradish Sugar beet to beetroot, swedes, and turnips Fodder beet to sugar beet and reverse Swedes to turnips and reverse Carrots (8), potatoes (8) and sugar beet (8) to whole group Early and ware potatoes to tropical root crops Sweet potatoes and/yam to tropical root crops	Carrot, potato, radish and sugar beet to whole group Carrot, radish and sugar beet to root vegetables excluding potatoes Carrot and radish to whole group excluding sugar beet and potatoes Potato to tuber and corm sub group Sweet potato to tuber and corm excluding potato sub group	Potato, carrot and one other root crop to whole group Potato to tuber and corm sub group Sweet potato or yam to tuber and corm excluding potato sub group

Appendix 3 continued

crop	Australia (NRA, 2002)	European Union (CEC, 2001) (minimum number of trials in parenthesis)	USA (EPA, 2000)	recommendation
Bulb vegetables	-	Bulb onions to garlic and shallots Spring onions to Welsh onions	Onions green and dry to whole group	Onions green and dry to whole group
Fruiting vegetables (non-cucurbits)	Tomato and peppers to whole group	Tomatoes to aubergines Sweet peppers to peppers	Tomato. Bell pepper and one non-bell pepper to whole group	Tomato and peppers to whole group
Fruiting vegetables (cucurbits)	Rock melon, cucumber and zucchini to cucurbits Melons to marrow, pumpkin, and squash	Cucumbers or courgettes (8) to edible peel cucurbits Melons to inedible peel cucurbits	Cucumber, muskmelon and summer squash to whole group Cantaloupe to melons subgroup Squash and cucumber to squash/cucumber subgroup	Cucumber, melon and other cucurbit to whole group
Fruiting vegetables (Sweetcorn)	Maize to sweetcorn	Immature maize to sweetcorn	-	-

Appendix 3 continued

crop	Australia (NRA, 2002)	European Union (CEC, 2001) (minimum number of trials in parenthesis)	USA (EPA, 2000)	recommendation
Brassicas	Cauliflower or broccoli and cabbage and Brussels sprouts to whole group	Cauliflower (4) and broccoli (4) to flowering brassicas Kale to leafy brassicas	Cauliflower or broccoli and cabbage and mustard greens to whole group Broccoli and cauliflower and cabbage to head and stem brassica group Mustard greens to leafy brassica greens group	Cauliflower or broccoli and cabbage and one other brassica to whole group

Appendix 3 continued

crop	Australia (NRA, 2002)	European Union (CEC, 2001) (minimum number of trials in parenthesis)	USA (EPA, 2000)	recommendation
Leafy vegetables (also see stem vegetables)	Leafy lettuce, spinach and Chinese cabbage to whole group (including leafy brassica vegetables) Spinach or celery to silver beet Cos lettuce to leafy Asian vegetables (NRA, 2002)	Lettuce to lettuce and similar	Celery, head and leafy lettuce and spinach to leafy vegetables Head and leaf lettuce and spinach to leafy greens Celery to leafy petioles sub group	head and leafy lettuce and spinach to leafy vegetables Cos lettuce to leafy Asian vegetables
Herbs	Parsley and mint to whole group	Parsley, spinach or lettuce to whole group	Basil fresh and dry, black pepper, chive and celery seed or dill seed to whole group (herbs and spices) Basil fresh and dry and chives to herb subgroup	Two leafy herbs to whole group

Appendix 3 continued

crop	Australia (NRA, 2002)	European Union (CEC, 2001) (minimum number of trials in parenthesis)	USA (EPA, 2000)	recommendation
Legume vegetables (fresh)	Beans green and peas green to whole group	Beans green with pods to peas with pods	Bean (Phaseolus) fresh and dried, pea (Pisum) fresh and dried and soybean to whole group (legume vegetable succulent or dried) Bean (Phaseolus) fresh and pea (Pisum) fresh to whole group (edible podded legume vegetable)	Beans green and peas green to whole group
Stem vegetables	Celery, asparagus and artichoke to whole group Celery to rhubarb	-	Celery to leafy petioles sub group	Celery to leafy petioles sub group
Pulses	Field peas (dry) and lupins and faba beans (dry) or chickpeas or navy beans to whole group	Beans and/or peas to whole group	See legume vegetables Any dried bean and dried pea to whole group	Any dried bean and dried pea to whole group

Appendix 3 continued

crop	Australia (NRA, 2002)	European Union (CEC, 2001) (minimum number of trials in parenthesis)	USA (EPA, 2000)	recommendation
Oilseeds	Canola or safflower or linseed or linola, cottonseed and peanuts or sunflower or soybean to whole group Rapeseed to mustard seed, poppy seed, sesame seed and linseed	Any two from cotton seed (4), rapeseed (4), soybean seed (4), sunflower seed (4) to whole group Rapeseed to linseed and mustard	-	Any 3 oilseeds to whole group
Cereals	Barley, wheat and oats to triticale and rye Maize and sorghum to millet Wheat or barley to oats rye triticale durum wheat (treatments applied before GS32) Wheat to whole group except rice for post harvest treatment	Applications made during and post inflorescence emergence Barley to oats Wheat to rye and triticale Maize to millet and sorghum Before inflorescence emergence barley, oats, rye, triticale or wheat to any other mentioned cereal	Sweetcorn and field corn, rice, sorghum and wheat to cereal group	Rice plus any two other cereals to whole group including rice

Appendix 3 continued

crop	Australia (NRA, 2002)	European Union (CEC, 2001) (minimum number of trials in parenthesis)	USA (EPA, 2000)	recommendation
Cereal forage, fodder and straw	-	-	Corn, wheat and other cereal grain crop to whole group	-
Grass forage, fodder and straw	-	-	Bermuda grass, bluegrass and brome grass or fescues	-
Non-grass animal feed	-	-	Alfalfa and clover	-

Appendix 4 Responses to the Questionnaire

Argentina

REQUEST FOR COMMENTS TO THE QUESTIONNAIRE ON THE DEVELOPMENT OF THE CONCEPT OF MINIMUM DATA REQUIREMENT FOR ESTABLISHING MRLS INCLUDING IMPORT TOLERANCE
CX 4/40.2 CL 2004/5- PR

Argentina's answers to the questionnaire

Zoning project

Q1: Is the principle of geographical zoning for the acceptance of residues trials enshrined in your national legislation? If so, how many and what zones are defined?
A1: yes ?
Region pampeana, patagonia, mesopotamia, noroeste

Q2: What are your views on the conclusions of the zoning report1, i.e. the impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless the geographical location of the trials?
A2 they should be carried out another trials.

Q3a: How would your authority/agency implement these recommendations into their national guidelines? i.e. would your authority be prepared to accept residues trials data from countries/regions outside of your own?
A3a: N O
Your authority/agency accepts
1. all trials conducted in other countries with similar GAPs
   yes
2. 50% conducted under local condition
   yes ?
3. Others (please specify)

Q3b: From which other countries/regions do you currently accept residues data to support an MRL/import tolerance?
A3b:
codex
Q3c: From which other countries/regions would you be prepared to accept residues data to support an MRL/import tolerance?
A3c:codex

Q4: What are your criteria for accepting supervised residue trials data from outside your country/region?
A4: 1. similar GAPs yes ?

2. similar climate yes

3. similar spray equipment yes

4. similar agronomic factors yes

5. Others (please specify)

Q5: The zoning group only made recommendations with respect to foliar sprays. What other application techniques should be evaluated to determine the effects of climatic zone on final residue levels?
A5:pulverization high and low volume
Air fumigation
Significance in diet/trade

Q6: Do you differentiate between major and minor crops in terms of residue data requirements?
A6: yes
Q7: Is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops? Are other criteria established in your country (e.g. area of production)?
A7: yes

Q8: How do you define major and minor crops in your region/country?
A8: 1. by area/ hectarage (If so indicate % for minor and for major crops)
yes (10 Ha for major crops)

2. by consumption (If so, indicate for minor and for major crops)
yes

3. Others (please specify)

Q9: What are/would be your criteria for defining a crop as significant in trade or the diet?
A9a: Significant in trade (e.g. % cultivation area, quantity of production, etc.)yes

A9 b: Significant in diet (e.g. 0.5% of the total diet as the trigger value)yes

Q10: What source of dietary information do you use to carry out consumer risk assessments in your country/region?
A10:IDA

Q11: Would you accept 3 as the minimum number of trials for establishing MRLs. If not, what would be the absolute minimum number of trials, without extrapolation, you would be prepared to accept in support of an MRL/import tolerance?
A11:is necessary to carry out 3 minimum number of trials

Q12: Do your data requirements differ for setting National MRLs and for Import Tolerances i.e. based on uses outside of your country? If so, how?
A12: yes, in general the national MLRs more strict like the another country.in general depends on the crops
If yes, please explain.

Extrapolation of residues data for one crop to another

Q13: How do you implement the principle of extrapolation of residues data from one crop to another e.g. extrapolation of residues levels in tomatoes to estimate residue levels in aubergines? How do you decide what is an acceptable extrapolation?
A13: ? 25% (similar GAPs) yes ? no, because residues level is different in the different crops.the distrbution of residues is differnt i n different fractions

Others (specify)

Q14a: Can you accept extrapolation of data when there are similar GAPs only?

A14a: no

Q14b: If not, what are your national/regional criteria to allow extrapolation of residues data? (e.g. comparability of GAPs, climate, geographical location, similarities in morphology of crops, crops within same groups, others.)
A14b:is not posible the data extrapolation.

Q15: Do you have an agreed list of extrapolations of residues data?

A15: no

Q16: What data would you wish to have in order to agree additional extrapolations?
A16: analytical and statistical data

Q17: Would you accept the principle of more extensive extrapolation of residue data to support minor crops?
A17 :no

Processing data

Q18: Under what circumstances do you require the submission of data on processing i.e. data examining the distribution of residues between different fractions of processed foods?
A18:when one ignore the rule of action behavior
When one knows the influence of the process (i.e .miling process)in the level residues.
Q19: What are the criteria for the extrapolation of processing data from one crop to another?
A19:n o

Q20: What information do you require from processing studies, e.g. do you require a balance study i.e. a full description of where residues remain in all parts of the processed foodstuff or just residue levels in final edible commodities?
A201:is necesary know the behaviorr of the active component ,the climate of crops morfology equipment, agronomic fa ctor .

Q21: What are the minimum number of studies/trials required to determine a processing/transfer factor?
A21:3 as minimun

Q22: Do you/would you permit the use of 'theoretical' processing factors i.e. factors based on water loss during the drying process – if not please provide a reason
A22: yes
Q23: Which data do you use to determine 'theoretical' processing f actors?
A23:climate,aplications number, type operations.

Please provide the name and complete contact details including full address of a national expert who could be contacted if further discussion or clarification of answers is required.
Thank you for your input to this initiative.

Australia

Questions for consideration.
Please answer whenever possible and tick the answers if provided with choices

Zoning project

Q1: Is the principle of geographical zoning for the acceptance of residues trials enshrined in your national legislation? If so, how many and what zones are defined?
A1: ***yes*** □ ***no*** ✓□
Q2: What are your views on the conclusions of the zoning report[1], i.e. the impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless the geographical location of the trials?
A2: *Australia agrees with the general outcomes of the zoning report, noting that a limited number of crops were reviewed. It would be more appropriate to state that the impact of climate is negligible, in comparison to other factors such as application technique, cultivation practices and variation of residues within a zone.* *The Australian experience with residues data for orchard and vine crops generated in different countries has been that broad zones are applicable, with Europe in one zone/region and Australia, New Zealand, USA and South Africa in another zone/region. This is in part to do with cultivation practices and has also been shown in drift modelling experiments, where orchard sizes, cropping densities and spray equipment make a difference with respect to spray deposition in different countries.*
Q3a: How would your authority/agency implement these recommendations into their national guidelines? i.e. would your authority be prepared to accept residues trials data from countries/regions outside of your own?
A3a: ***Your authority/agency accepts*** ***1. all trials conducted in other countries with similar GAPs*** ***yes*** ✓□ ***no*** □ ***2. 50% conducted under local condition*** ***yes*** □ ***no*** □ ***3. Others (please specify)*** *Australia accepts residues data from other countries, firstly providing that GAP is*

similar. Cultivation practices should also be similar to those in Australia where possible. It is noted that residues data generated from trials in countries where cultural practices are different often lead to different residue profiles compared to those in Australia, even though GAP may be similar, see comments above.

Q3b: From which other countries/regions do you currently accept residues data to support an MRL/import tolerance?

A3b:

For the purposes of MRL setting, Australia accepts data from any other country, providing the proposed GAP is similar. This is determined by using the principles as published in the FAO Manual 2002.

As a general principle similar requirements apply for MRLs that have been set on third country uses ie. commonly referred to as import tolerances. These particular MRLs, incorporated into the Food Standards Code, would generally apply to both imported and domestically produced food ie. there would not be separate MRLs established for imports.

Q3c: From which other countries/regions would you be prepared to accept residues data to support an MRL/import tolerance?

A3c:

For the purposes of MRL setting, Australia accepts data from any other country, providing the proposed GAP is similar. This is determined by using the principles as published in the FAO Manual 2002.

As a general principle similar requirements apply for MRLs that have been set on third country uses ie. commonly referred to as import tolerances. These particular MRLs, incorporated into the Food Standards Code, would generally apply to both imported and domestically produced food ie. there would not be separate MRLs established for imports.

1/ Zoning report is posted on the FAO and OECD website:
http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Default.HTM

Q4: What are your criteria for accepting supervised residue trials data from outside your country/region?					
A4:	***1. similar GAPs***	***yes***	✓□	***no***	□
	2. similar climate	***yes***	✓□	***no***	□
	3. similar spray equipment	***yes***	✓□	***no***	□
	4. similar agronomic factors	***yes***	✓□	***no***	□
	5. Others (please specify)				
Q5: The zoning group only made recommendations with respect to foliar sprays. What other application techniques should be evaluated to determine the effects of climatic zone on final residue levels?					
A5: *No other application methods are proposed.*					

Significance in diet/trade

Q6: Do you differentiate between major and minor crops in terms of residue data requirements?
A6: ***yes*** ✓□ ***no*** □ *The Australian criteria for determining whether a crop is major or minor are available at the link below:* *http://www.apvma.gov.au/gazette/gazette0203p39.pdf*
Q7: Is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops? Are other criteria established in your country (e.g. area of production)?
A7: ***yes*** □ ***no*** □ *For the purposes of chemical product registration, major crops are defined on the basis of economic return for a registrant with respect to costs incurred for product registration (see reference above). Significance in trade and the diet will vary depending on the region concerned, as a major crop in one region may be a minor crop in another. Although area under cultivation is also given some consideration, it is used in relation to actual pesticide use for the crop concerned. For example, a crop may be defined as a major crop on the basis of economic return, however actual pesticide use within that crop (per annum) may be relatively small (see reference above).*
Q8: How do you define major and minor crops in your region/country?
A8: ***1. by area/ hectarage (If so indicate % for minor and for major crops)*** ***yes*** □ ***no*** □ *By hectarage only for limited use in a major crop (see link below).* ***2. by consumption (If so, indicate for minor and for major crops)*** ***yes*** □ ***no*** ✓□ ***3. Others (please specify)*** *As indicated above and in the document at:* *http://www.apvma.gov.au/gazette/gazette0203p39.pdf*
Q9: What are/would be your criteria for defining a crop as significant in trade or the diet?

A9a: Significant in trade (e.g. % cultivation area, quantity of production, etc.)

Production per region per annum; quantities traded on a per annum basis.
There may be instances where a crop is defined as 'major' or 'significant' on the basis of production and consumption, however much of the production is used for domestic consumption only and not traded. These issues require further consideration if international definitions of a 'significant crop' are to be developed for the purposes of requesting residues data or setting MRLs.

A9 b: Significant in diet (e.g. 0.5% of the total diet as the trigger value)

Significance in the diet is difficult to gauge, as a major food (commodity) in one regional diet may not be a major food (commodity) in another. Therefore the data requirements for setting an MRL (or import tolerance) may be different in one region compared to another. For the purposes of this exercise, a threshold level would be required. However as stated above, where a crop is produced largely for domestic consumption and not traded, the data requirements will be different in one region compared to another.

Q10: What source of dietary information do you use to carry out consumer risk assessments in your country/region?
A10: *The key data source is the detailed food consumption data that are contained in the large 1995 National Nutrition Survey of Australia. Further details of this and other food consumption data available to Food Standards Australia New Zealand have previously been provided to Exponent*
Q11: Would you accept 3 as the minimum number of trials for establishing MRLs. If not, what would be the absolute minimum number of trials, without extrapolation, you would be prepared to accept in support of an MRL/import tolerance?
A11: *Yes, provided the commodity was not defined as a major crop in Australia (see guidance document referenced above).*
Q12: Do your data requirements differ for setting National MRLs and for Import Tolerances i.e. based on uses outside of your country? If so, how?
A12: ***yes*** □ ***no*** □ *As a general principle similar requirements apply for MRLs that have been set on third country uses ie. commonly referred to as import tolerances. These particular MRLs, incorporated into the Food Standards Code, would generally apply to both imported and domestically produced food ie. there would not be separate MRLs established for imports.*

Extrapolation of residues data for one crop to another

Q13: How do you implement the principle of extrapolation of residues data from one crop to another e.g. extrapolation of residues levels in tomatoes to estimate residue levels in aubergines? How do you decide what is an acceptable extrapolation?
A13: ± 25% (similar GAPs) ***yes*** ✓□ ***no*** □ ***Others (specify)*** *Accepted crop extrapolations are available at:* *http://www.apvma.gov.au/guidelines/guidln24.shtml*

Q14a: Can you accept extrapolation of data when there are similar GAPs only?
A14a: yes ✓□ ***no*** □
Q14b: If not, what are your national/regional criteria to allow extrapolation of residues data? (e.g. comparability of GAPs, climate, geographical location, similarities in morphology of crops, crops within same groups, others.)
A14b: *Allowable extrapolations are available at:* *http://www.apvma.gov.au/guidelines/guidln24.shtml*
Q15: Do you have an agreed list of extrapolations of residues data?
A15: yes ✓□ ***no*** □ *See above (A14b).*
Q16: What data would you wish to have in order to agree additional extrapolations?
A16: *Some level of confirmatory residues data as specified by the Australian Pesticides and Veterinary Medicines Authority (APVMA).*
Q17: Would you accept the principle of more extensive extrapolation of residue data to support minor crops?
A17: *Yes, providing there were data available to justify the extrapolations. Australia is currently developing further crop extrapolations on the basis of local data.*

Processing data

Q18: Under what circumstances do you require the submission of data on processing i.e. data examining the distribution of residues between different fractions of processed foods?
A18: *The Australian requirements for the provision of processing data are available at: http://www.apvma.gov.au/guidelines/guidln7.shtml* *Although the document is dated, the principles for provision of data for human foods are still appropriate.*

Q19: What are the criteria for the extrapolation of processing data from one crop to another?

A19:

In the guideline that is referenced above, it is stated:

When a number of similar crops are to be included on the label, studies on one representative from each crop group will normally be acceptable.

In general, the issue is determined on a case-by-case basis, depending on the properties of the chemical and the range of processed commodities under consideration. For example, if the primary route of degradation on processing is by hydrolysis a combination of a processing study on one fruit together with studies on hydrolysis conducted over temperature ranges typically encountered in commercial production may suffice.

There are exceptions to the extrapolations on occasion, and these are usually discussed with the APVMA prior to registration of a chemical product. For example a wheat processing study may not be extrapolated to rice in the case of a grain protectant use.

Q20: What information do you require from processing studies, e.g. do you require a balance study i.e. a full description of where residues remain in all parts of the processed foodstuff or just residue levels in final edible commodities?

A201:

See guideline referenced above (A18).

Q21: What are the minimum number of studies/trials required to determine a processing/transfer factor?

A21:

Usually one or two depending on the use and nature of the chemical product.

Q22: Do you/would you permit the use of 'theoretical' processing factors i.e. factors based on water loss during the drying process – if not please provide a reason

A22: ***yes*** ✓□ ***no*** □

Q23: Which data do you use to determine 'theoretical' processing factors?

A23:

Guidance as set out in USEPA document OPPTS 860.1520:
http://www.epa.gov/opptsfrs/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/860-1520.pdf
with confirmation from local Australian processors for the commodity of concern.

Please provide the name and complete contact details including full address of a national expert who could be contacted if further discussion or clarification of answers is required.

For MRL setting:
Raj Bhula, Australian Pesticides and Veterinary Medicines Authority, P.O. Box E240 Kingston ACT 2604, Australia
Phone 61 2 6271 6551; fax 61 2 6272 3551. E-mail: raj.bhula@apvma.gov.au

For Import tolerances:
Paul Brent, Food Standards Australia New Zealand, PO Box 7186, Canberra BC ACT 2610. Tel. +62 (0)2 6271 2279. E-mail: paul.brent@foodstandards.gov.au

Thank you for your input to this initiative.

Canada

Canada , PMRA, Response to the FAO questionnaire January 28, 2004
Page 1 of 7
Questions for consideration

Zoning project

1. What are your views on the conclusions of the report? (the impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless the geographical location of the trials).
2.

Comment: The ZWG recognized the limitations of Dataset used in their analysis (many variables have not been covered (not measured and not in scope) e.g. pesticide range, crop range, region, treatment details missing from Dataset). These limitations meant that the outcome of the analysis has many limitation in both interpretation and ability to generalize . We disagree with the statement "...residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless the geographical location of the trials)."

In the ZWG project much of variation in the residues found was similar to the variation found in the residues sampled at Day 0 (Note that the data in all cases was not from the same residue trial). The statistician concluded that approximately 70 % of the variability was most likely unrelated to other factors, (not quantified in the data gathering exercise, therefore unknown).

The ZWG opinion was that temperature, rainfall contributed little to the overall variation in residues. Therefore variation at harvest was dominated by variation in application factors, however this is not the same as saying there was no difference in residues between locations (countries).

The ZWG showed that geographic zoning based **solely on climate** has not been demonstrated by this analysis, the link between climate and residue levels can not be quantified consistently. The ZSG confirm that application factors for 0 day PHI (as measured by the variation in the zero day statistical analysis) are the most important influence on pesticide residues at harvested on the same day the pesticide was applied.

Our experience , within PMRA for some pesticides, is that even with longer PHIs there is significant variation of residue levels across the Canadian Zones. Furthermore in our joint registrations in which we look at data from the US and Canada we see, on an individual pesticide basis, variation of residues from the North (Canada) to Southern (US) zones as well as Canadian Interzonal differences (East to West).

2. How would your authority/agency implement these recommendations into their national guidelines? i.e. would your authority be prepared to accept residues trials data from

PMRA already has a well established Science based zonal requirements for the registration of crops already embedded in its national guideline (Directive 98-02) . PMRA already accepts residue data carried out in common zones between the US and Canada. The

countries/regions outside of your own?

identification of these zones was determined by Statistics Canada under a NAFTA TWG project. The final classification was based on eight data sources selected for the delineation process. These sources included:
• Agricultural Ecumene of Canada (SAGA, Agriculture Division, Statistics Canada);
• Arable Land in Canada (SAGA, Agriculture Division, Statistics Canada);
• Terrestrial Ecozones and Ecoregions of Canada (Environment Canada);
• Ecoclimatic Regions of Canada (Environment Canada);
• Soils of Canada Map (Agriculture and Agri-Food Canada);
• Canada Land Inventory for Agriculture (Environment Canada);
• Crop Area Dot Maps (SAGA, Agriculture Division, Statistics Canada); and
• Climatic Characteristics of Canada (Natural Resources Canada).
The same methodologies developed by Statistics Canada has now been used to establish NAFTA approved crop zones in Mexico and has resulted in common zones between the Mexico and the US.

3. From which other countries would you be prepared to accept residues data to support an MRL/import tolerance?

For MRLs on imported commodities PMRA will accept data that is representative of the exporting country ‘s Gap (As captured on its Legal National Label). The normal evaluation process for Nation al Registration also apply to the data supplied (Quality, GLP, OC /QA) to ensure that they meet modern standards. PMRA does not maintain a positive list of countries for the acceptance of data.

4. What are your criteria for accepting residues data from outside your country/region?

Data in support of import MRLs must also meet the same standards as required for National registration and associated MRLs . These criteria are captured in detail in the Canadian RESIDUE CHEMISTRY GUIDELINES (Directive 98-02.)

5. Would you only accept trials data from countries/regions outside of your own only if they were accompanied by trials data generated in your own country/region?

For a Domestic registration of a pesticide we would use the data from the other countries or regions as supplemental data. The core national data requirement would still have to be met. In the circumstance where all residues are less then the level of detection of a validated method in several countries including the United States (in Zones common with Canada) a case can be made that residues above the level of determination is not likely . We do accept data from outside Canada for trial carried out at same GAP in zones Common to the US and Canada, thought the data was generated outside the Canadian territorial borders.

6. The zoning group only made
recommendations with respect to foliar sprays. What other application techniques should be evaluated to determine the effects of climatic zone on final residue levels?

PMRA is of the strong opinion that a haphazard collection of trials cannot be the basis for making scientific recommendations. It is noteworthy that foliar residues are quite often greater than those seen with ground application of pesticides. There is no compelling reason to pursue other application methods given the large number of gaps that the ZWG identified with the data it had available in doing its analysis. In oral discussion the ZWG acknowledged the difficulties it had with the data thsu to make recommendations about any other application method. The ZWG had to eliminate the other application methods from its dataset to make its reported assessment.

Again, it is necessary to remind the survey authrs that the ZWG showed that geographic zoning based **solely on climate** has not been demonstrated by the ZWG analysis. Any link between climate and residue levels could not be quantified consistently.

Significance in diet/trade

1. Why is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops?
2.

While the concept of significance in the diet is used in addition to other data in determining the number of trials for registration, PMRA has not used significance in trade i.e % import as a criteria in setting the trial requirements for domestic registrations, where the major exposure is from domestic sources. In 1998 the dietary share information from Nutrition Canada was used to adjust the number of Canadian field trials used the following critical levels adopted from the U. S.. Methodology (1.00%, 0.4%, 0.15 % qnd 0.02%) With regards to significance in trade it is difficult to guess at how this concept can used as a tool to determine major or minor crops. Consider that though there may not be an export market for a crop, this does not mean the crop is not traded extensively within national borders e.g between states, provinces . The crop may well be regarded as significant in trade under this scenario. It appears some criteria for classifying a crop as being significant in Global/domestic trade need to be arrived at before such an exploration is even possible. The ZWG final meeting did have a discussion on this topic however the question as asked does not capture the essence of this discussion.. Because there is significant variation in the diet across age groups e.g juices may be quite significant in the diet of an enfant, but not significant in the diet of an adult. Hence the Fao should clarify what it means by significant in the diet for which age group i.e ., which population is relevant for this consideration?

2. How do you define major and minor crops in your region/country?

Ths categorization of Crops into Major and Minor was done by as part of their analysis for PMRA. Statistics Canada, *Spatial Analysis and Geomatics Applications (SAGA), The Delineation of Canadian **Major** and Minor **Crop** Field Trial Regions*. Report prepared for the PMRA, HED, Health Canada, Ottawa, February 1996. The criteria revolved primarily around national production data In terms of registration of pesticides for minor uses the following need to be considered.

Minor use

A minor use of a pesticide is defined as a necessary use of a pesticide for which the anticipated volume of sales is not sufficient to persuade a manufacturer to register and sell the product in Canada. The definition emphasizes that it is the projected sales of the pesticide that is minor and not necessarily the size of the crop. A minor use may be registered on a major crop because the use may be needed only occasionally or is limited to a small percentage of the total area of the crop. Thus a crop may be treated with a pesticide in a large number of regions but be classified as minor base on this criteria.

3. What are/would be your criteria for defining a crop as significant in trade or the diet?

PMRA ‘s mandate does not cover trade of food commodities. Significant in the diet in Canadian Residue Chemistry Guidelines (Directive 98-02) was based on Nutrition Canada Food Consumption Patterns

4. What source of dietary information do you use to carry out risk assessments in your country/region?
USDA dietary Longitudinal Food Survey

5. What would be the absolute minimum number of trials you would be prepared to accept in support of an MRL/import tolerance?

The current minimum for a National registration is 3 . Also note that fewer than three trials may be conducted if the dietary consumption is very low e.g Boysenberries, low dietary intake, low acreage grown, results in a required number of trials of 2.

Extrapolation of residues data for one crop to another

1. How do you implement the principle of extrapolation of residues data from one crop to another i.e. how do you decide what is an acceptable extrapolation? Extrapolation is based on harmonization approach with the USEPA Health Evaluation Division.

Many Crops grown in the US and tropical countries are not grown in Canada, consequently for most domestic registrations extrapolation is not required beyond the established crop groups. . For imports if an exporting country has used extrapolation in setting their domestic MRLs PMRA will look at this on a case by case basis.

2. What are your national/regional criteria to allow extrapolation?

This is based on a scientific assessment and the expertise of the PMRA on a case by case basis. For crops with similar GAP the residue data for the representative crops for a crop group is extrapolated to encompass all other crops in the crop group.

3. Do you have an agreed list of extrapolations?

Yes

4. What data agree further extrapolations?

As crops are added to existing crop groups or new crop groups are established. Representative trial dats to facilitate consideration and discussion on the scientific merit for extension of limited data to a broader range of commodities for which the PMRA may not have any experience with . Note that this consideration only applies to crop groups.

Processing data
1. When do you require the submission of processing data?

Processing studies are required to determine whether residues in raw commodities may be expected to degrade, reduce or concentrate during food processing. If residues do concentrate in a processed commodity, a maximum residue limit (MRL) may be established. However, if residues do not concentrate in processed commodities, the MRL for the raw agricultural commodity (RAC) itself applies to all processed food derived from it. If residues concentrate in a processed commodity that is an animal feed, data on the transfer of residues to meat, milk, poultry, and eggs are required If the processing of the RAC may result in alteration of the residue, then a radiolabeled processing study to determine the nature of the residue in food, as it is consumed, may be needed. If significant alteration of the residue occurs, and the additional residue components are of toxicological concern, then the MRL should include the additional residue component It may be possible to waive the processing study based on the results of field trials conducted at exaggerated application rates. If exaggerated rate data are available and these field trials result in no quantifiable residues in the RAC, then no processing study is required, provided that the rate was exaggerated by at least the highest theoretical concentration factor among all the processed commodities derived from that crop, or 5X, whichever is less.

2. What are the criteria for the extrapolation of processing data from one crop to another?

For surface residues this may be possible however this is a case by case decision based on the totality of information available on the specific pesticide.

3. What are the minimum number of trials required to determine a processing/transfer factor?

Only one processing study is required for each crop. However, it is advisable to have multiple samples of the RAC and processed commodities in the study. If multiple processing studies are available for a given crop, the Pest Management Regulatory Agency (PMRA) may use the average concentration factor obtained across these studies. It may be possible to waive the processing study based on the results of field trials conducted at exaggerated application rates. If exaggerated rate data are available and these field trials result in no quantifiable residues in the RAC, then no processing study is required, provided that the rate was exaggerated by at least the highest theoretical concentration factor (Canadian RCG Dir 98- 02Appendix A) among all the processed commodities derived from that crop, or 5X, whichever is less.

4. Do you permit the use of ‘theoretical’ processing factors i.e. factors based on water loss during the drying process?

Yes. However PMRA prefersto receive actual data documenting the real world changes associated with the processing methodology representative of the commercial process.

5. Which data do you use to determine ‘theoretical’ processing factors?

There are two types of processes for which maximum theoretical concentration factors can easily be calculated. • The first type is where the concentration is based on the loss of water during processing, The theoretical concentration factor is the ratio of the percent of dry matter (DM) in the processed commodity to the percent of DM in the RAC. The second type of process is that in which a RAC is separated into components, such as the processing of corn grain into corn oil. • In this case, the theoretical concentration factor is 100% divided by the percentage of the processed commodity in the raw commodity. Corn grain may contain as little as 4% corn oil. The theoretical concentration factor for processing of corn into oil then is 100/4, or 25X.

To determine the theoretical concentration factors, the Agency examined a number of reference sources for the percent of DM in a commodity (or the percent of water), and the composition of raw commodities. In looking for these percentages, the Agency searched for the percentage that would yield the highest theoretical concentration factor. So, for percent of DM, the Agency looked for the highest percent of DM in the processed commodity, and the lowest percent of DM in the raw commodity. For the composition of raw commodities, the Agency looked for the lowest percentage of the processed commodity in the raw commodity.

Costa Rica

Cuestionario:
Por favor siempre que sea posible; en caso de que se le ofrezcan varias respuestas posibles, seleccione una

Proyecto de distribución por zonas geográficas

P1 ¿La legislación de su país acoge el principio de distribución geográfica para la aceptación de ensayos de residuos?. En caso afirmativo, ¿cuántas zonas se definen y cuáles son?
R1 ***sí*** ☐ ***no*** **X**
P 2 ¿Cuál es su opinión sobre las conclusiones del informe de distribución por zonas a saber, que las repercusiones del clima en el comportamiento de los residuos de algunos plaguicidas aplicados en determinados cultivos son insignificantes y que los datos de residuos procedentes de modalidades de uso similares (BPA similares) y condiciones de crecimiento análogas se pueden comparar, con independencia de la localización geográfica de los ensayos?

R2

ES TODO

P3a ¿De qué modo traspondría su organismo o su autoridad estas recomendaciones en las directrices nacionales? Es decir, ¿estarían las autoridades competentes de su país dispuestas a aceptar datos relativos a ensayos de residuos procedentes de países o regiones distintos del suyo?

R3a:

Su organismo/agencia acepta

1. ***Todos los ensayos realizados en otros países con BPA similares***

Sí ☐ ***no*** [X]

2. ***50% realizado en las condiciones locales***

Sí ☐ ***no*** [X]

3. ***Otros (sírvase especificar***

P3b: ¿De qué otros países o regiones aceptan en la actualidad datos de residuos que respalden un LMR o una tolerancia de importación?

R3b:

NINGUNO

P3c. ¿De qué otros países o regiones estarían dispuestos a aceptar datos de residuos que respalden un LMR o una tolerancia de importación?

R3c:

DE AMERICA CENTRAL

P4 ¿Qué criterios emplean para aceptar ensayos de residuos supervisados procedentes de otros países o regiones?.

R4 ***1. BPA similares*** ***Sí*** ☐ ***No*** [X]

2. Climatología similar	***Sí***		***No***	**X**
3. Equipo de pulverización similar	***Sí***		***No***	**X**
4. Factores agronómicos similares	***Sí***		***No***	**X**

5. Otros (sírvase especificar)

NO SE ACEPTAN ENSAYOS REALIZADOS FUERA DEL PAÍS.

P 5: El grupo de distribución por zonas sólo hace recomendaciones en relación con la pulverización foliar. ¿Qué otras técnicas de aplicación deben evaluarse a fin de determinar los efectos de la zona climática sobre los niveles finales de residuos?

R5:

APLICACIÓN AL SUELO, EN INVERNADEROS

Importancia en el comercio o en el régimen alimentario

P6 ¿Distinguen entre cultivos principales y secundarios en lo que respecta a los requisitos en materia de datos de residuos?

R6: ***Sí*** ☐ ***No*** **X**

P 7 ¿Consideran que la importancia de los alimentos en el comercio o en los regímenes alimentarios es una variable adecuada para identificar los cultivos principales y secundarios? ¿Se han establecido otros criterios en su país (por ejemplo, la superficie de producción)?

R7: ☐ ☐

Sí ***No***

P8 ¿De qué forma se definen los cultivos principales y secundarios en su región o país?

R8:

1. En función de la superficie/hectáreas (en caso afirmativo, indique el porcentaje para cultivos principales y secundarios?

Sí [X] ***No*** ☐

2. En función del consumo (en caso afirmativo, indique el porcentaje para cultivos principales y secundarios).

Sí ☐ ***No*** ☐

3. Otros (sírvase especificar

P9: ¿Qué criterios emplean o estarían dispuestos a emplear para afirmar que un cultivo es importante para el comercio o los regímenes alimentarios?

R9a: Importancia en el comercio (por ejemplo, porcentaje de superficie de cultivo, cantidad de producción, etc).

R9b: Importancia en el régimen alimentario (p.ej. 0,5 por ciento de la dieta total como valor determinante).

PRODUCTOS: ***Sensibles :*** ***Barreras para el comercio, importe canasta básica***

Competir en mercado

Exportación: ***Potencial exportable:*** ***Agricultura orgánica***
Frutas tropicales

P10: ¿Qué fuente de información alimentaria emplean para realizar evaluaciones de riesgos de los consumidores en su país o región?
R10 : ***CODEX ALIMENTARIUS*** ***EPA (USA)***
P 11: ¿Aceptaría tres ensayos como número mínimo para el establecimiento de LMR? En caso negativo ¿qué número absoluto de ensayos, sin extrapolación, podrían aceptar para fijar un LMR o una tolerancia de importación?

R11:

DEPENDE SI ES UN CULTIVO QUE SE SIEMBRA VARIAS VECES AL AÑO, ZONAS GEAGRÁFICAS O AGROCLIMATICAS DIFERENTES.

P12: ¿Varían sus requisitos de datos para el establecimiento de LMR nacionales y tolerancias de importación en caso de que los datos se basen en usos de otros países?

R12:

Sí ☐ ***No*** ☒ X

En caso afirmativo, sírvase aportar una explicación.-

Extrapolación de datos de residuos de un cultivo a otro

P13: ¿De qué forma aplican el principio de extrapolación de datos de residuos de un cultivo a otro (p.ej. extrapolación de los niveles de residuos en los tomates para estimar los niveles de residuos en las berenjenas? ¿Cómo deciden cuándo una extrapolación es aceptable?

R13: ***+/- 25% (BPA similares)*** ***Sí*** ☐ ***No*** ☒ X

Otros (sírvase especificar)

P14a: ¿Aceptarían extrapolaciones de datos únicamente en los casos de BPA?

R14a: ☒ X ***Sí*** ☐ ***No***

P14b: En caso negativo, ¿cuáles son los criterios que emplea su nación o región para permitir la extrapolación de datos de residuos (p.ej. semejanzas en las BPA, clima, localización geográfica, similitudes en la morfología de los cultivos, cultivos pertenecientes a los mismos grupos, otros)?

R14b:
P15: ¿Cuentan con una lista aprobada de extrapolaciones de datos de residuos?
R15 : ***Sí*** ☐ ***No*** [X]
P 16: ¿Qué datos desearían obtener para aceptar extrapolaciones adicionales?
R16: ***HABITOS ALIMENTICIOS DE LA POBLACIÓN, REFERENTE AL CULTIVO QUE SI TIENE LMR ESTABLECIDO. CONDICIONES AGROECOLOGICAS DE REGION DONDE SE SIEMBRA EL CULTIVO, QUE FUE MUESTREADO PARA RESIDUOS Y PRACTICAS AGRÍCOLAS EMPLEADAS.***
P17: ¿Aceptaría el principio de una extrapolación más amplia de datos de residuo en relación con los cultivos secundarios?
R17: ***SI.***
Datos de elaboración
P18: ¿En qué condiciones exigen la presentación de datos de elaboración (por ejemplo datos que examinen la distribución de residuos entre diferentes fracciones de alimentos elaborados)?.
R18: ***NO SE HACE.-***
P19: ¿Qué criterios emplean para la extrapolación de los datos de elaboración de un cultivo a otro?
R19 :

NO SE HACE.-
P 20: ¿Qué información procedente de estudios de elaboración exoge? Por ejemplo, ¿requieren un estudio que proporcione una descripción completa, indicando si permanecen residuos en cada una de las partes del producto alimentario elaborado, o únicamente los niveles del residuo en los productos comestibles finales?.
R20: ***NO SE HACE.-***
P21: ¿Cuál es el número mínimo de estudios/ensayos que consideran necesario para determinar un factor de elaboración/transferencia?
R21: ***3 - 4***
P22: ¿Aceptan o podrían aceptar el uso de factores "teóricos" de elaboración (por ejemplo factores basados en las pérdidas de agua durante el proceso de secado)?. En caso negativo, sírvase explicar el motivo.
R22: [X] ***Sí*** [ ] ***No*** ***SE VALORARIAN JUNTO CON OTROS FACTORES.-***
P23: ¿Qué datos emplean para determinar los factores "teóricos" de elaboración?
R23: ***NO SE DETERMINAN.***
Sírvase indicar su nombre y todos sus datos de contacto, incluida la dirección completa de un experto nacional con el que nos podamos poner en contacto en caso de necesitar comunicaciones o aclaraciones ulteriores sobre las respuestas.
madriga@hotmail.com

Eduardo Madrigal Abarca / Ministerio De Salud

rodríguezm@protecnet.go.cr
Ing. Marielos Rodríguez Porras / Ministerio Agricultura y Ganadería

Germany

Questions for consideration.
Please answer whenever possible and tick the answers if provided with choices

Zoning project

Q1: Is the principle of zoning for the acceptance of residues trials enshrined in your national legislation? If so, how many and what zones are defined?
A1: yes x no □ ***2 Zones outdoor: EU North, EU South*** ***1 zone in stored products and glasshouse***
Q2: What are your views on the conclusions of the zoning report[11], i.e. the impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless the geographical location of the trials?
A2: ***We agree with the conclusions, impact of climate is negligible, GAP and growing conditions are the important points***
Q3a: How would your authority/agency implement these recommendations into their national guidelines? i.e. would your authority be prepared to accept residues trials data from countries/regions outside of your own?
A3a: ***Your authority/agency accepts*** ***1. all trials conducted in other countries with similar GAPs*** ***yes □ no x*** ***2. 50% conducted under local condition*** ***yes □ no x*** ***3. Others (please specify)*** ***Depends from view of European Commission, EFSA***
Q3b: From which other countries/regions do you currently accept residues data to support an MRL/import tolerance?
A3b: ***National/EU-MRL: data from European countries according to zones*** ***Import tolerances: data from the exporting country or region***

1 Zoning report is posted on the FAO and OECD website:
http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Default.HTM

Q3c: From which other countries/regions would you be prepared to accept residues data to support an MRL/import tolerance?					
A3c: ***Field treatment:*** ***- For minor uses only: Data from a country/region with identical GAP (± 25%)and similar agricultural conditions.*** ***- For major uses: trials should be done in Europe according to European growing conditions*** ***- For import tolerance see A3b*** ***Glasshouse, seed treatment, storage etc:*** - ***Data from other regions with similar GAP(±25 %) accepted for major and minor uses*** -					
Q4: What are your criteria for accepting supervised residue trials data from outside your country/region?					
A4:	***1. similar GAPs***	***yes***	□	***no***	***x***
	2. similar climate	***yes***	□	***no***	***x***
	3. similar spray equipment	***yes***	***x***	***no***	***x***
	4. similar agronomic factors	***yes***	***x***	***no***	***x***
	5. Others (please specify)				
Q5: The zoning group only made recommendations with respect to foliar sprays. What other application techniques should be evaluated to determine the effects of climatic zone on final residue levels?					
A5: ***Soil treatment***					

Significance in diet/trade

Q6: Do you differentiate between major and minor crops in terms of residue data requirements?
A6: ***yes*** ***x*** ***no*** □
Q7: Is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops? Are other criteria established in your country (e.g. area of production)?
A7: ***yes*** ***x*** ***no*** □
Q8: How do you define major and minor crops in your region/country?
A8: ***1. by area/ hectarage (If so indicate % for minor and for major crops)*** ***yes*** ***x*** ***no*** □ ***Major crop - cultivation area > 10 000 ha/year*** ***Minor crop – cultivation area <10 000 – 600 ha*** ***Very minor crop – cultivation area < 600 ha*** (less than 0.0035 % of the total cultivation area) ***2. by consumption (If so, indicate for minor and for major crops)*** ***yes*** ***x*** ***no*** □ ***Major crop- consumption > 7.5 g/d for a person of 60 kg (equivalent to 0.5% of the consumption of this person)*** ***minor crop - consumption < 7.5 g/d for a person of 60 kg*** ***very minor crop - consumption < 1.5 g/d for a person of 60 kg*** ***3. Others (please specify)*** ***by production (necessary for some animal feeds):*** ***major crop - production > 200000 tonnes per year*** ***minor crop - production < 200000 tonnes per year***
Q9: What are/would be your criteria for defining a crop as significant in trade or the diet?
A9a: Significant in trade (e.g. % cultivation area, quantity of production, etc.) ***Depends from view of European Commission, EFSA*** ***A9 b: Significant in diet (e.g. 0.5% of the total diet as the trigger value)***

Depends from view of European Commission, EFSA
Q10: What source of dietary information do you use to carry out consumer risk assessments in your country/region?
A10: ***New German chronic and acute dietary intake models based on consumption data for children from 2 to under 5 years (VELS data 2002) will be available in September 2004***

Q11: Would you accept 3 as the minimum number of trials for establishing MRLs. If not, what would be the absolute minimum number of trials, without extrapolation, you would be prepared to accept in support of an MRL/import tolerance?
A11: ***insignificant in diet and insignificant in trade, one zone: 3*** ***significant in diet and significant in trade, one zone: 8*** ***significant in diet and significant in trade, two zone: 12***
Q12: Do your data requirements differ for setting National MRLs and for Import Tolerances i.e. based on uses outside of your country? If so, how?
A12: yes □ ***no*** ***x***

Extrapolation of residues data for one crop to another

Q13: How do you implement the principle of extrapolation of residues data from one crop to another e.g. extrapolation of residues levels in tomatoes to estimate residue levels in aubergines? How do you decide what is an acceptable extrapolation?
A13: ± 25% (similar GAPs) ***yes*** ***x*** ***no*** □ ***Others (specify)*** ***According to EU guidance document extrapolation Doc. 7525/VI/95-rev.7 12/3/2001***
Q14a: Can you accept extrapolation of data when there are similar GAPs only?
A14a: yes ***x*** ***no*** □ ***According to EU guidance document extrapolation Doc. 7525/VI/95-rev.7 12/3/2001***
Q14b: If not, what are your national/regional criteria to allow extrapolation of residues data? (e.g. comparability of GAPs, climate, geographical location, similarities in morphology of crops, crops within same groups, others.)
A14b: ***According to EU guidance document extrapolation Doc. 7525/VI/95-rev.7 12/3/2001***

Q15: Do you have an agreed list of extrapolations of residues data?
A15: yes x no □ ***According to EU guidance document extrapolation Doc. 7525/VI/95-rev.7 12/3/2001***
Q16: What data would you wish to have in order to agree additional extrapolations?
A16: ***Extrapolation from rape seed to poppy seed,*** ***extrapolation from spinach to whole group spinach and similar***
Q17: Would you accept the principle of more extensive extrapolation of residue data to support minor crops?
A17: ***yes***

Processing data

Q18: Under what circumstances do you require the submission of data on processing i.e. data examining the distribution of residues between different fractions of processed foods?
A18: ***According to EU guidance document processing Doc. 7035/VI/95-rev.5 22/7/1997***
Q19: What are the criteria for the extrapolation of processing data from one crop to another?
A19: ***According to EU guidance document extrapolation Doc. 7525/VI/95-rev. 7 12/3/2001***
Q20: What information do you require from processing studies, e.g. do you require a balance study i.e. a full description of where residues remain in all parts of the processed foodstuff or just residue levels in final edible commodities?
A201: ***According to EU guidance document extrapolation Doc. 7525/VI/95-rev. 7 12/3/2001***
Q21: What are the minimum number of studies/trials required to determine a processing/transfer factor?
A21: ***According to EU guidance document extrapolation Doc. 7525/VI/95-rev. 7 12/3/2001***
Q22: Do you/would you permit the use of 'theoretical' processing factors i.e. factors based on water loss during the drying process – if not please provide a reason
A22: yes x no □ ***In special cases only, i.e. water loss during drying. Not in general for all procedures.***
Q23: Which data do you use to determine 'theoretical' processing factors?
A23: ***Data from experimental processing studies only***

Please provide the name and complete contact details including full address of a national expert who could be contacted if further discussion or clarification of answers is required.
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Indonesia

Zoning Project

Q1: Is the principle of geographycal zoning for the acceptance of residue trials enshrined in your national legislation?
A1: yes
Q2: What are your views on the conclusions of the zoning report: 1. The impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible 2. Residue data deriving from similar GAPs and similar growing conditions may be compared regardless the geographical location of the trials
A2: *1.* **The variation of zero-days residues reported from comparable trials within the same climatic zone were high (at least 70%, annex 3), while statistical evaluation of residue data sets were mostly of temperate zone (78%), followed by cold and very few of tropical zones (table 1, annex 3). Therefore the impact of climate, which was represented by temperate and cold zones, could be overshadowed by contribution of the variation of zero-days residues. Since most crop application are carried out in the tropics or tropical weather, a better judgement to the climatic effect would be obtained if more tropical data sets were included in the statistical evaluation.** *2.* **Pesticide residues behavior in the environment and crops are determined by its physico-chemical characteristics and ecosystem where the pesticides are applied, while the level of pesticide residues remain in crops depend on the dose applied and pesticides behavior in the environment and in crops. Therefore, it is expected that more sound conclusion could be attained if the physico chemical characteristics of the pesticides are incorporated in the evaluation of the residue data sets, i.e. how is the effect of rainfall to water soluble or polar pesticides, both applied at certain PHI and at zero days.**

Q3a: How would your authority/agency implement these recommendations into their national guidelines? i.e. accept residue trials data from countries regions outside of your own
A3a: Our authority accept supervised residue trials in crops and plant product which follows the Guidelines on Producing Pesticide Residue Data from Supervised Trials, part 3 (FAO, 1990)
Q3b: From which other countries/regions do you currently accept residues data to support an MRL/import tolerance?
A3b: - Indonesia accept SPRT which follows the FAO Guidelines, therefore we adopt the CAC-MRLs - *Indonesia also accept the ASEAN harmonised SPRT, and adopt the ASEAN harmonised MRLs*
Q3c: From which other countries/regions would you be prepared to accept residues data to support an MRL/import tolerance?
A3c: -
Q4: What are your criteria for accepting supervised residue trials data from outside your country region?
A4: 1. Similar GAP: yes *2. Similar climate : no* *3. Similar spray equipment: yes* *4. Similar Agronomic factors: yes*
Q5: The zoning group only made recommendation with respects to foliar srays. What other application techniques should be evaluated to determine effects of climatic zone on final residue?
A5: -

Significance in diet/trade

Q6: Do you differentiate between major and minor crops in terms of residue data requirements?
A6: Yes
Q7: Is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops?
A7: Yes
Q8: How do you define major and minor crops in your region/country?
A8: 1. By % production ……. *2. By % consumed ……..…..…*
Q9: What are/would be your criteria for defining a crop as significant in trade or the diet?
A9a: Significant in trade: >…….% national income share of domestic and international trade A9*b*: Significant in diet: *>0.5%*
Q10: What source of dietary information do you use to carry out consumer risk assessment in you country/region?
A10: National statistial dietary consumption data published by National Statistic Agency
Q11: Would you accept 3 as the minimum number of trials for establishing MRLs.
A11: Yes
Q12: Do your data requirements differ for setting National MRLs and for Import Tolerances?
A12: No

Extrapolation of Residues data for one crop to another

Q13: How do you implement the principle of extrapolation of residue data from one crop to another
A13: Similar GAP (± 25% tolerances), crops within Codex crop groupings and crops having similar consumable part
Q14: Can you accept extrapolation of data when there are similar GAP only? If not , what are your national/regional criteria to allow extrapolation of residues data?
A14a : No *A14b : Similar GAP, comparable weather and geographycal location*
Q15: Do you have an agreed list of extrapolation of residue data?
A15: No
Q16: What data you wish to have in order to agree additional extrapolation?
A16: Confirmation by SPRT data
Q17: Would you accept the principle of more extensive extrapolation of residue data to support minor crops?
A17: If it is to support minor crops based on term of minor to local diets, it will be considered to accept the extrapolation.

Processing data

Q18: Under what circumstances do you require the submission data on processing, i.e. data examining the distribution of residue between different fractions of processed foods?
A18: When there is potential metabolites and degradation products of toxicological concern determined in the consumable food
Q19: What are the criteria for the extrapolation of processing data from one crop to another?
A19: Similar GAP, post harvest application, and growing condition, within the Codex crop groupings, crops having similar consumable part and similar food processing
Q20: What information do you require from processing studies, e.g. do you require a balance study i.e. a full description of where residues remain in all parts of the processed foodstuff or just residue levels in final edible commodities?
A20: Residue levels in final commodities, before and after processing
Q21: What is the minimum number of studies/trials required to determine a processing/transfer factor?
A21: 3 (three) replicates
Q22: Do you/would you permit the use of "theoretical processing factor" i.e. factor based on water loss during the drying process – if not please provide a reason
A22: No, because the dissipation processes and transformation of the pesticide into more toxic degradation products are influenced by many factors, such as physicochemical factors, biological factors, environmental factor, processing of the food and human factor
Q23: Which data do you use to determine 'theoretical' processing factors?
A23: The ratio of pesticide residues level determined in edible parts before and after processing

Please provide the name and complete contact details including full address of a national expert who could be contacted if further discussion or clarification of answers is required	
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Japan

Questions for consideration.
Please answer whenever possible and tick the answers if provided with choices

Zoning project

Q1: Is the principle of geographical zoning for the acceptance of residues trials enshrined in your national legislation? If so, how many and what zones are defined?
A1: no Tolerance for pesticide residue in Codex Alimentarius and overseas countries are referred to establish the tolerance under the Food Sanitation Law in Japan. In addition supervised trial data of crop residue made in other countries is accepted in the case that tolerance in food related to the pesticide used overseas is requested to establish newly or revise. But in the case of the registration of pesticide under the Agricultural Chemical Regulation Law overseas data of crop residue isn't accepted on the pesticide inspection with the standards for withholding of agricultural chemicals registration, because the application of the registered pesticide is limited in our country.
Q2: What are your views on the conclusions of the zoning report[1], i.e. the impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless the geographical location of the trials?
A2:
Q3a: How would your authority/agency implement these recommendations into their national guidelines? i.e. would your authority be prepared to accept residues trials data from countries/regions outside of your own?
A3a: ***Your authority/agency accepts*** ***1. all trials conducted in other countries with similar GAPs*** ***no*** ***2. 50% conducted under local condition*** ***no*** ***3. Others (please specify)***
Q3b: From which other countries/regions do you currently accept residues data to support an MRL/import tolerance?
A3b:

Q3c: From which other countries/regions would you be prepared to accept residues data to support an MRL/import tolerance?

A3c:

1/ Zoning report is posted on the FAO and OECD website:

http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Default.HTM

Q4: What are your criteria for accepting supervised residue trials data from outside your country/region?

A4:	***1. similar GAPs***	***yes***	□	***no***	□
	2. similar climate	***yes***	□	***no***	□
	3. similar spray equipment	***yes***	□	***no***	□
	4. similar agronomic factors	***yes***	□	***no***	□
	5. Others (please specify)				

Under the Food Sanitation Law tolerance for pesticide residue in food is established referring tolerance in US, Canada, EU, Australia and New Zealand based upon trial data which is enough to evaluate in JMPR and JECFA.

Q5: The zoning group only made recommendations with respect to foliar sprays. What other application techniques should be evaluated to determine the effects of climatic zone on final residue levels?

A5:

No interest

Significance in diet/trade

Q6: Do you differentiate between major and minor crops in terms of residue data requirements?
A6: yes
Q7: Is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops? Are other criteria established in your country (e.g. area of production)?
A7: yes
Q8: How do you define major and minor crops in your region/country?
A8: 1. by area/ hectarage (If so indicate % for minor and for major crops) ***yes*** □ ***no*** □ ***2. by consumption (If so, indicate for minor and for major crops)*** ***yes*** □ ***no*** □ ***3. Others (please specify)*** In Japan, in case that the amount of the product of one crop is less than 30,000 metric ton per year, such a crop is defined as minor crop.
Q9: What are/would be your criteria for defining a crop as significant in trade or the diet?
A9a: Significant in trade (e.g. % cultivation area, quantity of production, etc.) ***A9 b: Significant in diet (e.g. 0.5% of the total diet as the trigger value)***

Q10: What source of dietary information do you use to carry out consumer risk assessments in your country/region?
A10: The food factor based upon the reports on national nutrition survey conducted annually by Ministry of Health, Labour and Welfare is applied in exposure assessment.
Q11: Would you accept 3 as the minimum number of trials for establishing MRLs. If not, what would be the absolute minimum number of trials, without extrapolation, you would be prepared to accept in support of an MRL/import tolerance?
A11:
Q12: Do your data requirements differ for setting National MRLs and for Import Tolerances i.e. based on uses outside of your country? If so, how?
A12: yes ***If yes, please explain.*** In the case of establishing tolerance for pesticide residue on pesticide registration in Japan, domestic trial data of crop residue is required. When establishment or revision of tolerance for a pesticide residue in food is requested in consideration of overseas use of the pesticide, the overseas data of crop residue complied with GLP is accepted.

Extrapolation of residues data for one crop to another

Q13: How do you implement the principle of extrapolation of residues data from one crop to another e.g. extrapolation of residues levels in tomatoes to estimate residue levels in aubergines? How do you decide what is an acceptable extrapolation?
A13: ± 25% (similar GAPs) ***no*** ***Others (specify)*** Pesticide registration / establishing MRLs is made with the residue trial data of representative crop in the crop group, if it is confirmed by government that the residue level among these crops are similar and such a crop is grouped.

Q14a: Can you accept extrapolation of data when there are similar GAPs only?
A14a: no
Q14b: If not, what are your national/regional criteria to allow extrapolation of residues data? (e.g. comparability of GAPs, climate, geographical location, similarities in morphology of crops, crops within same groups, others.)
A14b: If residual values are similar between crops in systematic botany, these crops will be grouped by government, and the residue data of representative crop in the group will be used for the pesticide registration.
Q15: Do you have an agreed list of extrapolations of residues data?
A15: yes
Q16: What data would you wish to have in order to agree additional extrapolations?
A16: The trial data of crop residue under same GAP would be requested to agree additional extrapolations.
Q17: Would you accept the principle of more extensive extrapolation of residue data to support minor crops?
A17: Yes, If the similarity of crop residue is confirmed on minor crops, more extensive extrapolation of residue data to support them will be authorised.

Processing data

Q18: Under what circumstances do you require the submission of data on processing i.e. data examining the distribution of residues between different fractions of processed foods?
A18: ***Require*** Under Agricultural Chemicals Regulation Law, processing data isn't yet required for pesticide registration. When tolerance of pesticide residue is established under Food Sanitation Law, submission of processing data is desirable if there is a knowledge relating to reduction, translocation and concentration of pesticide through processing / cooking of crops especially oilseed and cereal.
Q19: What are the criteria for the extrapolation of processing data from one crop to another?
A19:
Q20: What information do you require from processing studies, e.g. do you require a balance study i.e. a full description of where residues remain in all parts of the processed foodstuff or just residue levels in final edible commodities?
A201:
Q21: What are the minimum number of studies/trials required to determine a processing/transfer factor?
A21:
Q22: Do you/would you permit the use of 'theoretical' processing factors i.e. factors based on water loss during the drying process – if not please provide a reason
A22: ***yes*** □ ***no*** □
Q23: Which data do you use to determine 'theoretical' processing factors?
A23:

Please provide the name and complete contact details including full address of a national expert who could be contacted if further discussion or clarification of answers is required.
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Agricultural Chemicals Office
Plant products Safety Division
Ministry of Agriculture, Forestry and Fisheries

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Standards and Evaluation Division
Department of Food Safety
Ministry of Health, Labour and Welfare

Thank you for your input to this initiative.

The Netherlands

Questions for consideration.
Please answer whenever possible and tick the answers if provided with choices

Zoning project

Q1: Is the principle of geographical zoning for the acceptance of residues trials enshrined in your national legislation? If so, how many and what zones are defined?
A1: yes ■ no □ ***2 zones; North and South Europe***
Q2: What are your views on the conclusions of the zoning report[1], i.e. the impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless the geographical location of the trials?
A2: ***We await the discussion in the EU, to form an opinion***
Q3a: How would your authority/agency implement these recommendations into their national guidelines? i.e. would your authority be prepared to accept residues trials data from countries/regions outside of your own?
A3a: ***Your authority/agency accepts*** ***1. all trials conducted in other countries with similar GAPs*** ***yes □ no □*** ***2. 50% conducted under local condition*** ***yes □ no □*** ***3. Others (please specify)*** ***We accept trials conducted in N-European countries, with similar GAPs***
Q3b: From which other countries/regions do you currently accept residues data to support an MRL/import tolerance?
A3b: ***See A3a***
Q3c: From which other countries/regions would you be prepared to accept residues data to support an MRL/import tolerance?

A3c:

For import tolerances we accept residue trials of the region(s) from which products are imported

Q4: What are your criteria for accepting supervised residue trials data from outside your country/region?

A4:

At the moment we do not accept trials from outside North Europe. In the future we could accept:

1. similar GAPs ***yes*** ■ ***no*** □

2. similar climate ***yes*** ■ ***no*** □

3. similar spray equipment ***yes*** □ ***no*** ■

4. similar agronomic factors ***yes*** ■ ***no*** □

5. Others (please specify)

Q5: The zoning group only made recommendations with respect to foliar sprays. What other application techniques should be evaluated to determine the effects of climatic zone on final residue levels?

A5:

We expect that foliar spray is the worst case application. However, the residues resulting from soil treatment could be influenced more strongly by climatic conditions than residues from foliar sprays, and could be worthwhile to evaluate

Significance in diet/trade

Q6: Do you differentiate between major and minor crops in terms of residue data requirements?
A6: ***yes*** ■ ***no*** □
Q7: Is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops? Are other criteria established in your country (e.g. area of production)?
A7: ***yes*** ■ ***no*** □ ***yes*** ■ ***no*** □
Q8: How do you define major and minor crops in your region/country?
A8: ***1. by area/ hectarage (If so indicate % for minor and for major crops)*** ***yes*** ■ ***no*** □ ***2. by consumption (If so, indicate for minor and for major crops)*** ***yes*** ■ ***no*** □ ***3. Others (please specify)*** ***Production per year***
Q9: What are/would be your criteria for defining a crop as significant in trade or the diet?
A9a: Significant in trade (e.g. % cultivation area, quantity of production, etc.) ***A9 b: Significant in diet (e.g. 0.5% of the total diet as the trigger value)*** ***We follow the European guidelines***

Q10: What source of dietary information do you use to carry out consumer risk assessments in your country/region?
A10: ***We use a diet based on a Dutch food consumption survey, which was converted into raw agricultural products***
Q11: Would you accept 3 as the minimum number of trials for establishing MRLs. If not, what would be the absolute minimum number of trials, without extrapolation, you would be prepared to accept in support of an MRL/import tolerance?
A11: ***At the moment we accept 4 as the minimum for minor crops.*** ***We await further discussions in the EU to form an opinion***
Q12: Do your data requirements differ for setting National MRLs and for Import Tolerances i.e. based on uses outside of your country? If so, how?
A12: yes □ ***no*** ■ ***If yes, please explain.***

Extrapolation of residues data for one crop to another

Q13: How do you implement the principle of extrapolation of residues data from one crop to another e.g. extrapolation of residues levels in tomatoes to estimate residue levels in aubergines? How do you decide what is an acceptable extrapolation?
A13: ± 25% (similar GAPs) ***yes*** ■ ***no*** □ ***Others (specify)***

Q14a: Can you accept extrapolation of data when there are similar GAPs only?
A14a: yes □ ***no*** ■ ***See A15: extrapolation from crop to crop should be possible***
Q14b: If not, what are your national/regional criteria to allow extrapolation of residues data? (e.g. comparability of GAPs, climate, geographical location, similarities in morphology of crops, crops within same groups, others.)
A14b: ***climate, geographical location (North European),*** ***similarities in morphology of crops, crops within same groups***
Q15: Do you have an agreed list of extrapolations of residues data?
A15: yes ■ ***no*** □ ***(List/table in EU Guidelines)***
Q16: What data would you wish to have in order to agree additional extrapolations?
A16: ***Some residue trials (bridging studies), to confirm that residue levels are similar***
Q17: Would you accept the principle of more extensive extrapolation of residue data to support minor crops?
A17: ***Yes***

Processing data

Q18: Under what circumstances do you require the submission of data on processing i.e. data examining the distribution of residues between different fractions of processed foods?
A18: ***We follow EU guidelines (amongst others more than 10% of ADI)***
Q19: What are the criteria for the extrapolation of processing data from one crop to another?
A19: ***If similar crop group and similar kind of processing extrapolation is possible***
Q20: What information do you require from processing studies, e.g. do you require a balance study i.e. a full description of where residues remain in all parts of the processed foodstuff or just residue levels in final edible commodities?
A201: ***both***
Q21: What are the minimum number of studies/trials required to determine a processing/transfer factor?
A21: ***Minimal 1, depending on the way of processing***
Q22: Do you/would you permit the use of 'theoretical' processing factors i.e. factors based on water loss during the drying process – if not please provide a reason
A22: yes ■ ***no*** □ ***Provided that no metabolism takes place***
Q23: Which data do you use to determine 'theoretical' processing factors?
A23: ***We normally do not determine theoretical processing factors***

Please provide the name and complete contact details including full address of a national expert who could be contacted if further discussion or clarification of answers is required.
Erica Muller, Plant Protection Service, E.Muller@minlnv.nl Lindy Messchendorp, Board for the authorisation of pesticides, L.Messchendorp@CTB.agro.nl

New Zealand

Questions for consideration.
Please answer whenever possible and tick the answers if provided with choices

Zoning project

Q1: Is the principle of geographical zoning for the acceptance of residues trials enshrined in your national legislation? If so, how many and what zones are defined?
A1: NO ***Residue data requirement guidelines exist, but are not enshrined in legislation.*** ***The Guidelines specify that 'Trials should be designed to cover representative growing or storage conditions', with sites and trial conditions selected 'to reflect common commercial practice'.*** ***In practice, while no specific 'zones' have been defined, depending on the crop involved, trials are usually submitted from one or two major production areas.*** ***Suggested residue decay trial numbers are listed in the above Guidelines for the major crops and crop groups, these ranging from 2-4 trials per crop, generally 6 trials per crop group and a minimum of 6 trials for major export crops (apples, wine grapes, kiwifruit).*** ***Where the proposed use pattern is not expected to leave detectable residues, lower trial numbers (0-4) are acceptable, if supported by a reasoned argument and in some cases, foreign trials alone could be sufficient.*** ***NOTE: 'Trials' in the context of this questionnaire relate to residue decay studies involving at least 4-5 sampling dates, preferably bracketing the intended PHI. Residue studies involving single (at harvest) samples are not generally encouraged, and a higher number of these trials would normally be requested (on a case-by-case basis).***
Q2: What are your views on the conclusions of the zoning report[1], i.e. the impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless the geographical location of the trials?
A2: ***Some support for the conclusion that climate may not influence residue degradation as much as was originally thought, but some hesitancy in accepting without validation, the assumptions as to what factors contribute to the variability in 'day-zero' residues (application, agronomic practices, sampling etc).***

The approach to consider similar GAPs and similar growing conditions and crop management systems (regardless of geography) is supported.
Q3a: How would your authority/agency implement these recommendations into their national guidelines? i.e. would your authority be prepared to accept residues trials data from countries/regions outside of your own?
A3a: ***For outdoor crops, up to 50% of the required residue trials can be sourced from other countries, while for protected crops and post-harvest uses, up to 75% of the required trials can also be sourced from other countries.*** ***The above '50%(75%) substitution' applies where finite residues can be expected in crops at harvest. Where no detectable residues expected, up to 100% substitution may be accepted.*** ***A review of these %substitutions will depend on the outcome of the proposed expert consultation.***
Q3b: From which other countries/regions do you currently accept residues data to support an MRL/import tolerance?
A3b: ***For MRL-setting, residue data from some states of Australia and USA, parts of Europe and occasionally from South Africa have been accepted, but in general, the source is dictated by where the manufacturer has conducted trials using the proposed GAP.*** ***For Import Tolerances, see A12 below***
Q3c: From which other countries/regions would you be prepared to accept residues data to support an MRL/import tolerance?
A3c: ***As a general rule, for MRL-setting, trials using the proposed GAP would be considered from any country where the crop under consideration is grown commercially and the crop production systems and crop management techniques reflect our national situation.*** ***For Import Tolerances, see A12 below***

1/ Zoning report is posted on the FAO and OECD website:

http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Default.HTM

Q4: What are your criteria for accepting supervised residue trials data from outside your country/region?	
A4:	***1. similar GAPs*** ***YES*** ***2. similar climate*** ***NO (see below)*** ***3. similar spray equipment*** ***YES□*** ***4. similar agronomic factors*** ***YES□ (including similar growing conditions and growing practices)*** ***5. Others (please specify)***
Q5: The zoning group only made recommendations with respect to foliar sprays. What other application techniques should be evaluated to determine the effects of climatic zone on final residue levels?	
A5: ***The applicability of the zoning group conclusions to systemic, foliar applied pesticides could be considered for evaluation.*** ***While the extension to soil applied pesticides (herbicides) may be possible, consideration of the soil type, soil temperature and rainfall interactions may be too resource intensive to warrant such action.***	

Significance in diet/trade

Q6: Do you differentiate between major and minor crops in terms of residue data requirements?	
A6:	***NO – not specifically*** ***No clear distinction between major and minor crops, as it is difficult to justify, from a dietary intake point of view, why a lesser data base (and hence a higher uncertainty) should be acceptable for some crops and not others.*** ***However, the crop group approach is used to extrapolate from the major crops in each group to the less widely consumed and/or grown crops.***

Q7: Is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops? Are other criteria established in your country (e.g. area of production)?
A7: See A6 above. ***Significance in trade or diet may not be a suitable tool for determining major/minor crops, particularly at the international level, as these will differ from country to country.*** ***At the national level, this significance will also change with time (as new crops expand), thus requiring ongoing adjustments to the number of trials required.*** ***For some crops, where production is mostly export oriented (e.g. apples, kiwifruit, wine grapes), 6 trials are considered the minimum, mainly to provide added confidence that MRLs set by our trading partners will not be exceeded.***
Q8: How do you define major and minor crops in your region/country?
A8: 1. by area/ hectarage (If so indicate % for minor and for major crops) ***Not defined – see A6 above*** ***2. by consumption (If so, indicate for minor and for major crops)*** ***Not defined – see A6 above*** ***3. Others (please specify)*** ***See A7 above***
Q9: What are/would be your criteria for defining a crop as significant in trade or the diet?
A9a: Significant in trade (e.g. % cultivation area, quantity of production, etc.) ***See A6-A8 above.*** ***A9 b: Significant in diet (e.g. 0.5% of the total diet as the trigger value)*** ***See A6-A8 above***

Q10: What source of dietary information do you use to carry out consumer risk assessments in your country/region?
A10: ***A 'best estimate' of adult mean consumption values, based primarily on a 1997 National Nutrition Survey.*** ***For child (2-6 yr) mean consumption values and for all 97.5%ile consumption values, 'best estimates' are based primarily on Australian surveys (DIAMOND).*** ***Where the consumption values in the above surveys were found to differ significantly from those reported in similar surveys in USA and UK, and appeared to be anomalies, they have been modified to reflect what is considered 'normal', hence the above qualifier of being a 'best estimate'.***
Q11: Would you accept 3 as the minimum number of trials for establishing MRLs. If not, what would be the absolute minimum number of trials, without extrapolation, you would be prepared to accept in support of an MRL/import tolerance?
A11: ***Reluctant to support any specific value for the minimum number of trials for MRL-setting.*** ***The ability to extrapolate data from one crop to another within a crop group, and to accept a reasoned argument for fewer trials where detectable residues are not expected, provides a degree of flexibility without compromising the robustness of the data base available to support an MRL.*** ***Possibly the concept of 4 trials for one or more primary crops within a group, and 2 trials for subsequent 'secondary' crops, could be considered where measurable residues are expected at harvest, with a reducing number of trials being needed for 'other crops' in the group, or as the probability increases that no detectable residues will occur. (For example, no trials may be needed for non-systemic foliar pre-flowering sprays on apples, but perhaps 1-2 trials could be sufficient for pesticides of short persistence, applied at petal fall on apples).*** ***For Import Tolerances, see A12 below***
Q12: Do your data requirements differ for setting National MRLs and for Import Tolerances i.e. based on uses outside of your country? If so, how?
A12: YES ***Imported food needs to comply with NZ MRLs, Codex MRLs or the current NZ 'default' limit of 0.1 mg/kg (whichever is higher).***

We are currently conducting an imported food review and Import MRL-setting will be part of this review.

Consideration is being given to acceptance of the MRL established in the country of origin, provided our national consumer risk assessment shows that the imported commodity would not create dietary intake concern.

To conduct this assessment, information on the toxicological end points (ADI and ARfD) and residue end points (STMP and HR) used in the country of origin may be sufficient.

The rationale for considering the exporting country MRL is that this should reflect national GAP in that country and has been assessed by the national regulatory authority. In such cases, it should not be necessary for us to re-evaluate the same full data-set in order to set an Import MRL.

Extrapolation of residues data for one crop to another

Q13: How do you implement the principle of extrapolation of residues data from one crop to another e.g. extrapolation of residues levels in tomatoes to estimate residue levels in aubergines? How do you decide what is an acceptable extrapolation?
A13: ± 25% (similar GAPs) ***YES – but see comments***□ ***The above ± 25% (similar GAP) approach is used to determine the acceptability of all supporting residue trials, not just for extrapolation from one crop to another.*** ***Our approach to crop group extrapolation is outlined in A11 above, involving 'primary', 'secondary' and 'other' crops within a group, with reducing number of trials (and the associated increase in the mutual support for the crops within a group)***

Q14a: Can you accept extrapolation of data when there are similar GAPs only?
A14a: NO□
Q14b: If not, what are your national/regional criteria to allow extrapolation of

residues data? (e.g. comparability of GAPs, climate, geographical location, similarities in morphology of crops, crops within same groups, others.)
A14b: ***Extrapolation within a crop group depends on similar GAPs, similar growing conditions and similar agronomic practices.*** ***Extrapolation across crop groups would be rare, but where no measurable residues could be expected, a reasoned argument could be sufficient to support such an extrapolation.***
Q15: Do you have an agreed list of extrapolations of residues data?
A15: YES – See the attached Guidelines. □
Q16: What data would you wish to have in order to agree additional extrapolations?
A16: ***Would prefer to await the outcome of the proposed Expert Consultation and note the recent CCPR initiative to review the Codex Classification of Foods and Feeds.***
Q17: Would you accept the principle of more extensive extrapolation of residue data to support minor crops?
A17: ***Would prefer to await the outcome of the proposed Expert Consultation, but would generally support any extrapolation that can be scientifically justified.***

Processing data

Q18: Under what circumstances do you require the submission of data on processing i.e. data examining the distribution of residues between different fractions of processed foods?
A18: ***Generally required for major processed foods where measurable residues are expected in the Raw Agricultural Commodity. Wine, apple and citrus juices, apple puree, tomato and cereal products are the commodities for which processing data are commonly provided. These data need not be generated locally.*** ***If not supplied, and residues not expected to concentrate, more conservative RAC residue levels used in the dietary intake calculations, until processing studies available.***

Q19: What are the criteria for the extrapolation of processing data from one crop to another?
A19: ***Extrapolation acceptable within crop groups provided the processing practices are similar.***
Q20: What information do you require from processing studies, e.g. do you require a balance study i.e. a full description of where residues remain in all parts of the processed foodstuff or just residue levels in final edible commodities?
A201: ***Residue levels in the final edible commodities.***
Q21: What are the minimum number of studies/trials required to determine a processing/transfer factor?
A21: ***While not specified in the Guidelines, two such studies are considered sufficient, unless a reasoned argument is provided to justify a single study (or none at all)***
Q22: Do you/would you permit the use of 'theoretical' processing factors i.e. factors based on water loss during the drying process – if not please provide a reason
A22: YES – if supported by a reasoned argument.
Q23: Which data do you use to determine 'theoretical' processing factors?
A23: ***Data is determined on a case-by-case basis, depending on the reasoned argument provided by the applicant.***

Please provide the name and complete contact details including full address of a national expert who could be contacted if further discussion or clarification of answers is required.
David Lunn Programme Manager (Residues – Plants) c/o ACVM Group New Zealand Food Safety Authority P.O. Box 2835 Wellington New Zealand Phone: +64 4 463-2654 Fax: +64 4 463-2675 E-mail: Dave.Lunn@nzfsa.govt.nz CC Debbie.Morris@nzfsa.govt.nz

Thank you for your input to this initiative.

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ACVM
DATA REQUIREMENTS FOR A FOOD OR FEED USE CLEARANCE

PLANT COMPOUNDS

This document may be altered at any time. It was current as at the date in the footer of each page of the document. It is recommended that anyone intending to use this document should contact the ACVM Group of NZFSA or check its website (http://www.nzfsa.govt.nz/acvm/) to confirm that it is the current version.

Endorsement:
Date:

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ACVM
DATA REQUIREMENTS FOR A FOOD OR FEED USE CLEARANCE

PLANT COMPOUNDS

1 INTRODUCTION

This document describes the minimum requirements for residue data and other information that must be supplied to enable assessment of the dietary intake risks associated with a proposed use of a plant compound on food or feed crops, the promulgation of an appropriate maximum residue limit (MRL) to support the proposed use, and the granting of a clearance for the use of a plant compound on a food crop, feed crop or other agricultural food or feed commodity.

Such a clearance must be obtained before registration (or a variation to the existing registration conditions) of a trade name product involving use on a food crop, feed crop or agricultural food or feed commodity can be finalised, unless a waiver has been granted by the Agricultural Compounds and Veterinary Medicines (ACVM) Group of the New Zealand Food Safety Authority (NZFSA).

It is important that these guidelines be followed. If you wish to vary the conditions outlined in the guidelines, then an information waiver must be obtained. Waivers may also be granted by NZFSA to reduce the number of studies or type of data that an applicant must submit.

Applicants should note that they are responsible for providing all the required information. Applications that do not contain the required information will be declined. If further advice is required, applicants are advised to contract the services of an appropriate consultant prior to submitting the application.

Additional guidance can be found in the guidelines for residue data developed by the FAO (JMPR), Australia (Australian Pesticides and Veterinary Medicines Authority), USA (Environmental Protection Agency) and the European Commission. However, where the information in these reference guidelines differs from specific requirements in this document, the New Zealand requirements take precedence.

1.1 Request for a food/feed use clearance

When applying for a clearance to use a plant compound on a new food crop, feed crop or agricultural food or feed commodity (i.e. both for a new plant compound or to extend the existing uses of a plant compound to include a new food crop, feed crop or agricultural food or feed commodity), the applicant must include a Supporting Data Package containing an Overview of the available data, together with the associated supporting data, with the application.

The Overview must identify the trade name product and the proposed use pattern. It must address each active ingredient and significant residue component in the formulation, with clear references to the appropriate studies or reports in the supporting data.

Where data for currently registered trade name products are cross-referenced, the data package summary must provide references to the previously submitted data.

1.2 Purpose

This document is intended as a guide for applicants on the data required to determine the acceptability of any proposed use of a plant compound on food crops, on crops grown for animal feed, and on stored food or feed.

1.3 Scope

These guidelines should be used when requesting a clearance to use a plant compound on a food or feed crop, or when requesting a variation to an existing plant compound food or feed crop use.

1.4 Definitions and abbreviations

Active ingredient
The substance or substances in a formulated product responsible for the biological or other effects that cause the product to meet the definition of an agricultural compound or veterinary medicine.

ACVM Group
The Agricultural Compounds and Veterinary Medicines Group, New Zealand Food Safety Authority.

ADI
Acceptable daily intake. The daily intake of a compound which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time of the evaluation of the chemical. It is expressed in milligrams of the compound per kilogram of body weight.

Acute Reference Dose (Acute RfD)
The estimate of the amount of a compound in food or drinking water, expressed on a body weight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer on the basis of all the known facts at the time of evaluation. It is expressed in milligrams of the compound per kilogram of body weight.

Agricultural compound
Any substance, mixture of substances, or biological compound, used or intended for use in the direct management of plants and animals, or to be applied to the land, place, or water on or in which the plants and animals are managed, for the purpose of:

- managing or eradicating pests, including vertebrate pests; or
- maintaining, promoting, or regulating plant or animal productivity and performance or reproduction; or
- fulfilling special nutritional requirements; or
- manipulating, capturing, or immobilising animals; or
- diagnosing the condition of animals; or
- preventing or treating conditions of animals; or
- enhancing the effectiveness of an agricultural compound used for the treatment of plants and animals; or
- marking animals;

and includes:

- any veterinary medicine, any substance, mixture of substances, or biological compound used for post-harvest pest control or disinfection of raw primary produce; and
- any substance, mixture of substances, or biological compound declared to be an agricultural compound.

Codex
Codex Alimentarius Commission.

Environmental fate data
Scientific data that characterise a plant compound's fate and distribution in the ecosystem, including the influence of factors associated with degradation (light, water, microorganisms), degradation pathways, and the resultant degradation products.

FAO
United Nations Food and Agriculture Organisation.

Feed
Any commodity intended for animal or livestock consumption and includes:

- pasture, lucerne and other forage crops that are grazed;
- harvested plant material (including fodder crops, hay, silage, grain);
- failed crop remains or stubble; and
- processed or manufactured stock feedstuffs.

Good Agricultural Practice (GAP)
The safe uses of a plant compound under actual conditions necessary for effective use. GAP may encompass a range of use patterns necessary to achieve the desired effect without excessive use, with the plant compound being applied in a manner that leaves a residue, which is the smallest amount practicable.

Good Laboratory Practice (GLP)
The system, process and conditions under which studies are planned, monitored, recorded and reported. GLP applies to both the field work associated with any residue trial and the laboratory work involved in analysing the samples. The requirements for GLP are provided in the following documents:
OECD GLP Guidelines:

- Number 1 The OECD Principles of Good Laboratory Practice.
  Environment monograph No. 45, Paris (1992, as revised in 1997).
- Number 6 GLP Consensus Document. The Application of the GLP Principles to Field Studies. Environment monograph No. 50, Paris (1992).

or

- Code of Federal Regulations section 40 part 160. (Good Laboratory Practice Standards), USA.

Limit of Detection (LoD)
The lowest concentration of a pesticide residue or contaminant that can be identified in a specified food, agricultural commodity or animal feed with an acceptable degree of certainty by a regulatory method of analysis.

Limit of Quantitation (LoQ)
The smallest concentration of the analyte that can be quantified. It is commonly defined as the minimum concentration of analyte in the test sample that can be determined with acceptable precision (repeatability) and accuracy under the stated conditions of the test. Generally, the LoQ of an analytical method for residues in specified substrates is the lowest level where satisfactory recoveries were achieved. Formerly known as the Limit of Determination.

Maximum residue limit (MRL)
The maximum concentrations of an agricultural compound residue legally permitted in or on food commodities, generally at the first point of sale. MRLs are based on Good Agricultural Practice (GAP), and residues in foods derived from commodities that comply with the respective MRLs are assessed to ensure they are toxicologically acceptable. MRLs are based on a toxicological assessment of the pesticide and its residue, a review of residue data from supervised trials reflecting GAP, and the subsequent assessment of the dietary residue intake, such that foods produced according to GAP are safe for human consumption.

Metabolism
The changes that occur to a chemical within an organism, including uptake and distribution, changes and elimination of the chemical and its metabolites.

National Estimate of Dietary Intake (NEDI)
A prediction of the long-term daily intake of a pesticide residue on the basis of the assumptions of average daily food consumption per person and median residues from supervised trials, allowing for residues in the edible portion of a commodity and including residue components specified in the residue definition. Changes in residue levels resulting from preparation, cooking, or commercial processing are included. When information is available, dietary intake of residues resulting from other sources is also included. The NEDI is expressed in milligrams of residue per person per day.

National Estimate of Short-Term Intake (NESTI)
A prediction of the short-term intake of a pesticide residue on the basis of the assumptions of high (97.5 percentile) daily food consumption per person and highest residues from supervised trials, allowing for residues in the edible portion of a commodity and including residue components specified in the residue definition. The NESTI is expressed in milligrams of residue per kilogram of body weight per day.

Plant compounds
Any substance, mixture of substances, or biological compound used or intended for use in the direct management of a plant. It also includes compounds used in the post-harvest treatment of unprocessed agricultural commodities of plant origin.

Pre-Harvest Interval (PHI)
The time interval between the last application of a pesticide to a crop and harvest. See also 'Withholding period' below.

Processing factor
The residue level in the processed product divided by the residue level in the starting commodity, usually a raw agricultural commodity. Also known as a concentration

factor (when residue levels increase) and a reduction factor (when residue levels decrease) as a result of processing.

Processed food
The product, resulting from the application of physical, chemical or biological processes to a primary food commodity intended for direct sale to the consumer, for direct use as an ingredient in the manufacture of food or for further processing. Primary food commodities treated with ionizing radiation, chopped, washed, sorted or submitted to similar treatments that do not result in a cellular change are not considered to be 'processed foods'.

Residue
Any specified substance in food, agricultural commodities or animal feed resulting from the use of a plant compound. The term includes any derivatives of a plant compound, such as conversion products, metabolites, reaction products and impurities considered to be of toxicological significance.

Residue definition (compliance)
The definition of a residue (for compliance with MRLs) is that combination of the pesticide and its metabolites, derivatives and related compounds to which the MRL applies. This definition is based on the results of metabolism and toxicology studies, supervised residue trials, analytical methods and its general suitability for monitoring compliance with GAP.

Residue definition (intake estimation)
The definition of a residue (for estimation of dietary intake) is that combination of the pesticide and its metabolites, derivatives and related compounds to which the STMR and HR (highest residue) apply. This definition is based on the results of metabolism and toxicology studies and its general suitability for estimating dietary intake of the residue for comparison with the ADI and acute RfD.

Significant residue components
Compounds other than the active ingredient(s) that are present in the trade name product which may be toxicologically significant.

Supervised residue trials
Scientific studies in which agricultural compounds are applied to target host species according to specified conditions intended to reflect commercial practice after which harvested crops or tissues of slaughtered animals are analysed for residues. Usually specified conditions are those which approximate existing or proposed GAP.

Supervised Trials Median Residue (STMR)
The expected residue level (expressed as mg/kg) in the edible portion of a food commodity when an agricultural compound for agricultural use has been used according to maximum GAP (i.e. the acceptable use likely to result in the highest residue at harvest). The STMR is estimated as the median of the residue values (one from each trial) from supervised trials conducted according to maximum GAP conditions.

Trade name product
An agricultural compound containing one or more active ingredient(s), normally mixed with non-active ingredients (such as surfactants, solvents, diluents, suspending agents), intended for application, with or without dilution prior to use, and which is labelled with directions for use.

WHO
World Health Organisation.

Withholding period (WHP)

Minimum permissible time between the last application of an agricultural compound to a crop (including pasture) and its harvesting for human or animal consumption or grazing with livestock.

1.5 References

OECD GLP Guidelines:
Number 1 The OECD Principles of Good Laboratory Practice. Environment monograph No. 45, Paris (1992, as revised in 1997).

Number 6 GLP Consensus Document. The Application of the GLP Principles to Field Studies. Environment monograph No. 50, Paris (1992).

FAO. 2002. Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. FAO, Rome.

FAO. 1990. Guidelines on producing pesticide residues data from supervised trials. FAO, Rome.

Code of Federal Regulations, Section 40, part 160: Good Laboratory Practice Standards.

European Commission. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market.

2 SUPPORTING DATA PACKAGE

The 'Supporting Data Package' must contain sufficient information about the plant compound and its residue characteristics in plants, animals and the environment for an assessment to be made on the composition and distribution of residues in food, and to estimate the potential dietary intake risks associated with these residues.

The data package should contain the full studies, detailed reports, or information waivers related to the submission; the Overview should contain data summaries and conclusions relating to the submission.

2.1 Overview

The Overview is a summary of the available information provided in the submission and the conclusions based on this information, referencing the relevant studies and preferably presented under the same section headings as used in the data package. Further details are included in Appendix 1.

Note that the submission of an electronic copy of the Overview, while optional, may facilitate the ACVM Group assessment process (in the preparation of assessment reports), and thus allow a more rapid response.

2.2 Supporting Data

The data provided in support of any submission should be compiled under the following headings, and must include the full studies, detailed reports, or information waivers relating to the requested food clearance.

Identity and Properties
Information on the identity, composition and properties of each active ingredient and significant residue component in the trade name product.

Proposed Use Pattern
The proposed use of the trade name product must be fully specified together with explanatory information on growing and husbandry practices, and production techniques. Supporting statements or documentation on the efficacy of the proposed use and its relevance to Good Agricultural Practice.

Methods of Analysis

Methods of analysis for both trial purposes and for compliance. Residue stability studies in stored analytical samples.

Animal and Plant Metabolism
Studies that elucidate the metabolism of the compound(s) in animals and plants.

Supervised Residue Trials
The reports of the New Zealand supervised residue trials undertaken in accordance with these guidelines; or, in the case of overseas trials, summary reports that provide sufficient information to permit an assessment of the quality and relevance of the trials.

Processing Studies
Studies relating to the nature and concentration of residues present in foods that are normally processed before consumption.

Animal Transfer Studies
Studies on the nature, distribution and decay profile of the compound(s) and metabolites in animal tissues and products.

Environmental Fate Studies
Studies on the fate and behaviour of the compound(s) in soil, water and water/sediment systems.

ADIs and Acute Reference Doses
Information on Acceptable Daily Intakes and any Acute Reference Doses established in New Zealand, by WHO or by other national regulatory agencies, together with a summary of the relevant toxicology studies from which these ADIs have been derived and the rationale for any safety factors that have been used.

National MRLs (optional)
MRLs that are established, pending or proposed in New Zealand, by Codex or by other regional or national authorities.

2.3 Good Laboratory Practice (GLP)

For supervised crop residue trials submitted after 1 January 2003, the ***analytical laboratory component*** must be GLP compliant (i.e. all analytical laboratory work must be carried out by a GLP accredited laboratory and be in accordance with GLP principles), and the ***field study component*** must comply with the *ACVM Research Standard*.

GLP compliance for the field study component of a supervised crop residue trial is not essential, but the study must be done to GLP principles and the documentation must be sufficient to provide an equivalent level of confidence in the accuracy of the study reports.

In the case of the other studies submitted as supporting data (see 2.2 above), similar conditions apply, with these studies either being GLP compliant or conducted according to GLP principles (i.e. containing sufficient documentation to give an equivalent level of confidence in the accuracy of the study reports).

In all cases, where a particular study does not meet the above requirements, an information waiver must be obtained from the ACVM Group.

3 IDENTITY AND PROPERTIES

A detailed chemical characterisation of the compound should be provided, together with information on selected physical properties.

Characteristics and properties that need to be addressed include:

3.1 Product composition

This information is required to determine the need to assess the residue characteristics of any impurities, manufacturing byproducts or other components in the formulated trade name product. These data should identify and quantify:

- the active ingredient and its concentration in the trade name product, together with a description of the product formulation type;
- a clear indication of the identity of the active ingredient (e.g. the ISO common name, the IUPAC chemical name, CAS Registry number) and its structural formula;
- any impurities present in the technical grade material at a concentration of more than 10 g/kg (1%), preferably with reference to their CAS numbers for impurities, if available. Impurities present at 10 g/kg (1%) or less, which may be toxicologically significant (e.g. dioxins, PCBs or N-nitrosamines), must be identified, and quantified if possible;
- other additives and excipients present in the formulated trade name product, identified by their chemical/common name, CAS Registry number and common trade names.

3.2 Physical and chemical properties

Selected properties of the active ingredient are required to provide indicative information on the behaviour of the plant compound during and after its application on crops or animals, and to assess its possible movement and fate in the environment. These properties include:

- vapour pressure;
- solubility in water and organic solvents;
- partition coefficient (octanol/water);
- hydrolysis;
- photolysis;
- reference to any FAO specifications relating to the active ingredient.

4 PROPOSED USE PATTERN

The use pattern of a trade name product influences the level and nature of residues that will occur in food. It is essential, therefore, that submissions include the complete, detailed use pattern proposed for the product, to supplement the proposed label directions.

Of particular importance is the provision of information on the maximum application rates likely to be used in the field, in terms of active ingredient concentration(s) and rate(s) per hectare as well as the maximum number of applications per season and an indication of the intended or common GAP spray volumes used in commercial practice.

4.1 Use situation

The proposed crop or use situation should be clearly identified, including an indication of the crop growth stage(s) involved (e.g. pre-emergent, mid-season foliar spray, post-harvest), where appropriate, using recognised growth stage coding systems (e.g. BBCH).

If the proposed label claim is for use on crop groups (e.g. 'citrus' or 'cucurbits'), this should be expanded to identify the individual crops within the proposed crop group and preferably identified by reference to the commodity description and code given in the *Codex Classification of Foods and Animal Feeds.*

4.2 Application method

The intended treatment must be given in sufficient detail (e.g. the type of apparatus used and its output, such as low or high volume sprayer etc.). There is often a link between the type of treatment and specific formulations developed for such applications. Where different application methods are likely, identify the predominant method in common use.

4.3 Application rate

The dose rates in amounts of active ingredient should be expressed in grams or kilograms active ingredient per hectare and as dilution rates (in grams or kilograms active ingredient per 100 litres). Where relevant, details of acid equivalent application rates should be provided. The amount of diluted spray mix likely to be applied per hectare should also be specified, particularly the maximum spray rates generally

recommended or in common practice. If there are likely to be significant regional or grower differences, these should be indicated, and the most common or predominant application practice should be noted.

Where the recommended application rates (dose rate per hectare or dilution) change during the crop life cycle, this should be specified.

Generally, for 'tall' crops such as orchard and vine crops, glasshouse tomatoes etc., for foliar-applied pesticides, where flat boom spraying is not common practice, the emphasis should be on the spray concentration (gai/100 litres) with a clear indication of the dilute spray rates being recommended per hectare at the various crop growth stages. For 'low' crops such as most vegetable crops, pasture and arable crops, where boom spraying predominates, application rates should relate to the rate of active ingredient applied per hectare, with supplementary information on anticipated water rates per hectare also being supplied.

Where the proposed use pattern is for spot treatment of weeds in pastures, it is recommended that the residue data be obtained for a broadcast rate equivalent to treating a hectare of the target weed using the necessary quantity of spray mix. For example, if the mixing rate is 10 g active ingredient per 100 L water and it takes 3000 L spray mix to treat 1 hectare of weed then the application rate for residue purposes is 300 g/ha. For the purpose of calculating animal intake of residues from treated pasture, information must also be provided on the anticipated maximum percentage of the pasture likely to be treated.

4.4 Application number and timing

In general most of the residues remaining at harvest are from the last one or two applications. The growth stages for each application should be recorded and any codes used to describe growth stages (e.g. BBCH, Zadoks) should be fully explained.

The minimum and maximum number of expected treatments per season, and the normal interval between applications in days should be stated. Because the treatment intervals are often linked to dose rates, any alternative treatment programmes should be indicated (e.g. dose A could be applied to a crop at 7 - 8 days interval or at a higher dose B at 10 - 14 days intervals).

4.5 Proposed Pre-Harvest Interval (PHI)

The proposed Pre-Harvest Interval(s) should be indicated for all food or feed commodities concerned. If different PHIs are proposed for the same or similar commodity (e.g. for glasshouse or outdoor grown crops, cereal grains for human consumption or green feed cereals intended for animal feed), the particular circumstances should be clearly indicated.

Where the proposed PHI is related to a specific crop growth stage (e.g. when recommended for use up to a particular stage of the crop development, such as petal fall in apple and pears, pre-emergence for weed control etc.), information should be provided on the range of PHIs likely to occur.

4.6 Good Agricultural Practice (GAP)

The assessment of whether a proposed use pattern is Good Agricultural Practice is dependant on the submission of sufficient information to show that the product will be effective for its intended purpose when used according to the label directions.

This information must be relevant to the proposed use pattern, be of sufficient quality and quantity to show that the proposed label claim will be effective (without the excessive use of the product) and should comment on the relationship between the proposed use pattern and existing good grower practices commonly in use.

5 METHODS OF RESIDUE ANALYSIS

5.1 Analytical methods for trial purposes

The applicant must provide complete details of the analytical method(s) used for the determination of residues in the residue trials.

The methods should:

- possess a high degree of specificity for the compound in question and be able to show selectivity for each of the residue components identified in the plant, animal and environmental studies as being of toxicological significance;

- be validated in compliance with GLP;

- be substantiated by adequate evidence to show that the method is effective for the determination of the residues in the substrates analysed, and at the levels under consideration.

Where the analytical method involves an instrumental determination such as spectrophotometry, HPLC, or gas-liquid chromatography, specimen output charts showing blank determination and recovery determinations should be provided to assist in the evaluation of the method.

The individual methods should be summarised and clearly outline the compounds determined, the commodities for which the method is recommended, specificity, repeatability of the method, the Limits of Detection and Quantitation and the range of residue levels for which the method has been validated, the mean recovery and the relative standard deviation of recoveries at each fortification level including the Limit of Quantitation.

It is important to relate the residue analytical procedures used in a particular residue trial to those provided in the supporting documentation. It is therefore essential to identify the detailed method of analysis clearly with a distinctive reference number and to specify the appropriate reference number in each residue trial report. Each trial report should describe any modifications made to the method of analysis.

Situations can arise where proof of the accuracy of the residue analytical method is not entirely demonstrated by the formal method validation document. This is because incurred residues may be less 'extractable' than the same analytes simply added to a sample for recovery purposes. In such situations demonstration of the accuracy of a method using, for example, labelled drug in a metabolism study will be required if the applicant cannot otherwise demonstrate that the method results accurately reflect true sample residue content.

5.2 Analytical methods for compliance purposes

In some cases, analytical methods used in the determination of residues in the trials conducted for the purposes of risk assessment may differ from those available for routine monitoring and for regulatory control.

Where specific analytical methods for compliance exist, these must be provided and must be capable of determining all residue components identified in the MRL residue definition.

The major residue components should be determined individually as far as technically possible and should preferably involve a multi-residue procedure even if the recovery rate is not as good as that of a specific individual 'trials' method.

Any analytical method used for compliance purposes should be sufficiently sensitive to determine whether an MRL is exceeded or not. Generally this means that any Limit of Quantification (LoQ) should be at least five times lower than the MRL. However, where an MRL is set at 0.1 mg/kg or less (but not at the LoQ), the associated LoQ should be half the MRL.

5.3 Storage stability tests for analytical samples

The results of stability tests for residues in stored analytical samples of representative substrates should be provided. Typical matrices should be selected to include predominantly water, oil, protein or starch-containing materials. In the case of animal products, sample storage stability tests should include animal tissues, milk and eggs.

5.4 Residue definitions

Residue definitions are required to clearly establish the compound or compounds of interest when estimating dietary intake risks associated with the use of a plant compound, and also to provide a basis for monitoring for GAP compliance.

The two requirements are sometimes not compatible and, as a compromise, various definitions of residues are possible. For some compounds it may be necessary to establish separate residue definitions for MRL enforcement and dietary intake purposes.

The residue definition for dietary intake purposes should include metabolites and degradation products of toxicological concern irrespective of their source, whereas the residue definition for compliance with MRLs needs to be a simple residue definition, i.e. indicator molecule suitable for practical routine monitoring and enforcement of the MRL at a reasonable cost.

Although metabolites, degradation products and impurities are included in the definition of pesticide residues, this does not necessarily mean that metabolites or degradation products should always be included in the residue definition for enforcement (MRLs) purposes or for estimation of dietary intake (STMR). Inclusion of transformation products (metabolites and degradation products) in the residue definition depends on a number of factors, and the decision on whether they should be included is very complex. Decisions have to be made on a case-by-case basis.

This issue is discussed in some detail in the FAO Guidelines (*JMPR Manual*). If in doubt about the suitability of the residue definition for use in New Zealand, please consult the ACVM Group prior to conducting residue trials.

6 PLANT AND ANIMAL METABOLISM

The purpose of conducting metabolism studies is to determine the metabolic fate of the active ingredient. Many agricultural compounds undergo change during and after application to plants, soil, water and livestock. The composition of the terminal residue must therefore be determined before the analytical methodology can be developed and residues can be quantified.

The information should include documentation on the identity of the metabolites and the quantities present. Distinction should be made about the presence of metabolites in the different plant parts (surface, leaves, stems etc.), in different animal tissues (fat, muscle, kidneys etc.), and in different soil types. The rate of the formation and disappearance of metabolites in plants, animals and soil must also be investigated.

6.1 Plant metabolism

Plant metabolism studies provide information on the approximate level of total residues, identify the major components of the total terminal residue, indicate the route of distribution of residues and its mobility (uptake from soil, absorption by plants or surface residue) and show the efficiency of extraction procedures for various components of the residue.

These studies are usually required for a minimum of three diverse plants (unless the plant compound is to be used on only one or two crops). If the metabolism in three diverse crops is similar, then the metabolism in other crops is normally assumed to be similar. However, if the metabolism is different in different types of plants, a metabolism study is required for each type of crop groups (e.g. root vegetables, leafy crops, fruits, pulses and oilseed, cereals) for which use is proposed.

6.2 Animal metabolism

Animal metabolism studies are required where there is a potential for livestock to be exposed to residues, such as when a plant compound is applied to animal premises or housing, or where significant residues remain in crops or commodities used in animal feed, in forage crops, or in any plant parts that could be used in animal feeds or fed to livestock.

If original detailed toxicokinetic studies are performed using laboratory animals, it will be necessary to show that similar metabolic pathways are followed in livestock exposed

to the chemical or its residues, and whose meat, milk and eggs are destined for human consumption.

Usually the most important metabolism studies are those involving ruminants and poultry. Normally lactating cows are used but, in the interest of economy, goats are acceptable alternatives. In the case of poultry, chickens are the animals of choice.

7 SUPERVISED CROP RESIDUE TRIALS

Supervised crop trials serve as the primary source of information for estimating maximum residue levels.

The FAO *Manual on the Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed (2000),* and the associated *Guidelines on Producing Pesticide Residues Data from Supervised Trials (1990*), are valuable references on the design and assessment of supervised residue trials. Both can be found on the FAO website(http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Default.htm). Click on the 'JMPR' link for the FAO manual (2002) and the 'FAO Pesticide Management Guidelines' for the link to the residue guidelines (1990).

7.1 Residue trial types

7.1.1 Residue decay studies

The most common type of residue trial in New Zealand is a residue decay study, where one or more (replicated) treatments are applied to a number of plots, with samples being taken at various intervals following the last treatment.

Decay curves for residues are valuable especially when a plant compound has been applied directly to the consumable part of a crop (e.g. to a half grown apple). In addition, decay studies allow a degree of interpolation to support use patterns (and Pre-Harvest Intervals) not directly equivalent to those used in the trials.

Samples should be taken at appropriate intervals after the last application, sufficient to demonstrate the decay profile of the plant compound. Generally this should involve s**ampling on at least 4-5 occasions, up to and including harvest.** It is essential to sample at the proposed Pre-Harvest Interval.

For example, with most fruit and vegetable crops, if the intended Pre-Harvest Interval is 14 days, the first sample would normally be taken between 0 and 3 days after the last application, with subsequent samples being taken 7, 14, 21 and 28 days after the last treatment, i.e. at the proposed Pre-Harvest Interval and 2 points either side of this date. If 'zero-day' samples are taken, information on the number of hours between application and sampling must be provided. Note that while 'zero-day' samples are not essential, they do provide valuable information on the magnitude of the initial residue, and can assist in determining the acceptability of comparable residue trials from different regions or countries.

If the samples are analysed in date order, and if two consecutive samples show no detectable residues (i.e. less than the LoD), it may be acceptable to stop further analysis at that point (although the retention of any untested samples is strongly recommended).

'Reverse decline trials', where a number of different plots are treated on different dates (to reflect the different Pre-Harvest Intervals) and all the plots are sampled on the same date, are also acceptable if these studies are more relevant to the proposed use pattern. Such trials are recommended where the crop is growing or maturing rapidly over the proposed treatment period, and the crop growth stage at the time of treatment is a significant factor influencing residue levels present.

7.1.2 Single point tests

An alternative method of collecting residue data, particularly in situations involving clearly defined treatment and harvest times, is to take residue samples at harvest from a number of different trial sites that have been treated in accordance with the proposed label claim. Instances where single point tests may be appropriate include pre-plant soil incorporation treatments, herbicides used before the crop has emerged, and pre-flowering applications to deciduous fruit trees.

Single point tests may be more appropriate than decay studies in cases involving single (early season) applications and a clearly defined harvesting date.

7.2 Design of residue trials

Residue trials should aim at giving as accurate as possible a measure of the residues likely to occur in edible portions of the crop or in other food commodities such as products of animal origin (meat, milk, milk products, eggs).

7.2.1 Treatment frequency and timing

The frequency of application, the interval between applications, and field conditions should be the same as those being specified on the label. If the trial conditions differ from those likely to occur in practice, this should be highlighted in the commentary, and a reasoned argument should be provided to support the extrapolation of the data to field use.

7.2.2 Formulation and treatment rates

Trials should include treatment of the proposed (or similar) formulation at the maximum proposed rate. While the inclusion of a double-rate treatment is not normally required, the inclusion of such treatments in some of the submitted trials does provide the ability to extrapolate the results in future, should there be a need to increase the label application rate. Treatments should reflect the 'worst case' situation associated with the

proposed use, i.e. the highest concentration or application rate and the shortest Pre-Harvest Interval.

Where commercial application equipment is not used, this should be noted. Comments on the relationship between the treatment method used in the trial and the method (equipment) commonly used in commercial practice should be explained.

7.2.3 Plot size and replication

Plot sizes should be sufficiently large to allow the use of application techniques that reflect commercial practice, and to provide representative crop samples for analysis, including duplicate samples that can either be bulked or analysed separately (see 7.6 below).

Because variations in residue levels between replicates at individual sites are generally less than the variability found in data from different sites, it is usually not necessary to replicate treatments at individual trial sites. However, it may be useful to include such replicate treatments (2-4) in at least one trial, in order to provide an estimate of 'within-site' residue variability.

7.2.4 Trial site selection

Trials should be designed to cover a representative range of growing or storage conditions. The sites of residue trials and the trial conditions (including, in the case of perennial crops, crop size and maturity) should be selected to reflect common commercial practice, so that the typical residue pattern likely to be encountered in the field may be determined. For crops with extended harvesting periods, more than 50% of the residue trials must involve early maturing varieties.

Where the crop management systems or growing conditions differ from region to region, the trial sites should be selected to reflect these different conditions and/or management practices.

7.2.5 Post-harvest trials

Where the product is applied to a harvested crop or a commodity in storage or transport, information is necessary on alterations to the amounts and nature of the residue that occur during the normal course of pre-sale storage and handling of the crop after treatment. In the case of a fumigant, for example, it is necessary to know how much is taken up by the foodstuff during treatment and whether and how quickly the plant compound is lost by ventilation.

Plant compounds used for pest control in stored products vary considerably in stability. In addition to the ambient temperatures, varying from tropical to temperate, moisture content and aeration can influence the rate of disappearance.

Application of plant compounds can vary from commodities stacked in sacks to automated systems in silos. In addition, the variability of residues within a store (i.e. intra-store variability) can be high, e.g. in situations such as fogged potatoes in box stores. For this reason, sampling procedures must be designed to obtain a sample representative of the lot.

7.3 Number of trials

The number of trials required (and the sampling methodology) is dependent on the variability of use conditions and the consequent scatter of the residue data.

Experience suggests that the minimum number of supervised crop residue trials listed in Appendix 2, spread over representative cropping areas or covering the predominant crop management practices and growing conditions, should be sufficient to provide an acceptable data base for a residue assessment.

Trials conducted at the same location will not normally be considered independent and thus 'separate' trials for the purposes of Appendix 2, unless there is convincing evidence that the additional trials are providing further independent information about the influence of the range of farming practices on residue levels.

7.4 Residue data from other countries

New Zealand residue data will normally be required for plant compounds. However, relevant data from residue trials carried out in other countries with similar crop management and growing conditions may replace some of the local trials, provided there is a clear rationale to show the relevance of the foreign data to the proposed New Zealand use pattern.

Factors that should be considered in this regard could include similarities in Good Agricultural Practice, crop production and management systems. However, in most cases, applicants will be expected to conduct confirmatory tests under typical conditions of use in New Zealand to indicate the levels of residues under local conditions, and to validate any extrapolation from the foreign data.

Appendix 2 provides more detailed guidance on the degree to which local trials can be replaced by foreign residue data and examples of where local trials may not be necessary.

7.5 Extrapolation within crop groups

Data on residue levels in one species of plant, or animal, do not necessarily represent the residue levels that might occur in distinctly different species.

Consideration will be given to the use of satisfactory data from several crops in a crop group to estimate the general residue behaviour for most, if not all, crops in that group, or even to a very similar crop in another group, provided use patterns are compatible.

The FAO publication *Codex Classification of Foods and Animal Feeds* provides guidance on crops and raw agricultural commodities considered essentially similar for the purposes of recommending MRLs.

Data on one crop within a crop group may be considered to represent the residue levels that can be expected to occur on crops within the same group, but in some cases, such as leaf (fancy) lettuce and head lettuce, such extrapolation may not be acceptable.

Residue data from other countries may also assist in the extrapolation from one crop when clearances are sought for an allied crop or a crop group. If these data show that residues are substantially similar for a number of crops within a crop group (as measured by the range of STMR values), this could provide a good case for extrapolating New Zealand data on one or two crops to all crops in that crop group.

Appendix 2 provides more detailed guidance on the trial data requirements needed to support a crop group extrapolation.

7.6 Sampling

Samples should be representative of the treated plot and the individual 'units' must be typical of those taken at harvest. Where immature or unripe samples have to be taken, these should be clearly noted in the trial report.

The FAO *Manual on the Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed (2000)* provides guidance on sampling methods in general, and includes advice on the number of units in a sample and the commodity portion to be analysed.

In addition, it is suggested that for crops having medium to large individual unit weights (e.g. more than 25 g/unit), at least three individual unit samples from at least one treated plot (preferably the one that approximates the proposed GAP label rate and Pre-Harvest Interval) should also be analysed and reported separately in order to provide some indication of the food unit variability within the composite sample.

Plot sizes should be sufficient to accommodate these multiple samples and provision should also be made for adequate sampling of controls or untreated crops.

7.7 Storage of samples

Samples should be analysed as soon as possible, but if it is necessary to store them before analysis then the method of storage and date of analysis should be given. In such cases it is recommended that the samples or subsamples be kept at -18 to -20 degrees C.

At most storage temperatures some changes in residues may still occur, so evidence should be provided on the stability of the residues in the sample under the storage condition used.

Where sample extracts have been stored for more than 24 hours prior to analysis, the stability of residues should be demonstrated with recovery studies performed under similar conditions.

7.8 Reporting of residue trials

In the full reports, all details of trial procedures must be provided, including data on variables that might influence the decline of residues. Each report must include details of the trial location, the specific trial site and design, together with comprehensive information on the application details, weather conditions, sampling methodology and analytical procedures and results. Any variations from documented protocols and methods must be identified.

The minimum data items that must be reported in any residue trial report are listed in Appendix 3, and the *FAO Guidelines on Producing Pesticide Residues Data from Supervised Trials (1990*) provides one example of a residue trial summary report.

8 PROCESSING STUDIES

The effects of industrial processing and household preparation on residues are required for commodities that may be further processed before consumption, in order to allow more realistic estimates of chronic or acute dietary intake of pesticide residues.

Processing studies are not normally required if:

- the plant or plant product is normally only eaten raw, e.g. head lettuce;
- only simple physical operations such as washing and cleaning are involved;
- significant residues (above 0.1 mg/kg) are not expected in the raw commodity (unless the pesticide concerned has a low acute RfD or ADI).

Processing studies should be conducted on representative commodities such as citrus fruits, apples, grapes, tomatoes, potatoes, cereals. By using core processing procedures and selecting representative crops, it should be possible to extrapolate to other crops processed by the same procedure. In cases where it is not possible to derive consistent processing factors or where a very low ADI is established, it may be necessary to conduct processing studies on every crop.

Procedures to be used in processing studies should correspond as closely as possible to those that normally occur in practice. Thus products of household preparation (e.g. cooked vegetables) should be produced using the equipment and preparation techniques normally used in households, whereas industrial items such as cereal products, preserves, fruit juices or sugar should be produced by procedures representative of commercial food technology. In some cases more than one commercial process may be routinely used (e.g. the different UK and US commercial practices in the production of potato chips). In such cases, reasons should be provided for the chosen process.

Processing studies should be designed so that processing factors can be derived. For consistent processing factors the results of more than one study are necessary.

The raw commodity used in the studies should be a field-treated commodity containing quantifiable residues, so that processing factors for the processed products can be determined. This may require field treatment at an exaggerated application rate to obtain sufficiently high residue levels. Processing studies with spiked samples are not acceptable unless it can be demonstrated that the residue in the raw commodity is entirely on the surface.

Generally, processing studies should be conducted on crops harvested at a reasonable interval after the last treatment (comparable with the proposed Pre-Harvest Interval) to allow ageing of the residue as expected in normal commercial practice.

9 ANIMAL TRANSFER STUDIES

In addition to the qualitative animal metabolism studies mentioned in 6.2 above, separate animal feeding studies (transfer studies), using unlabelled compounds, are required to establish the relationship between residue levels in feed and/or soil and the likely residues in food of animal origin (e.g. animal tissues, milk, honey and eggs).

These studies are required:

- if the chemistry or behaviour of an agricultural compound indicates a potential for residues to be transferred to livestock (e.g. fat-soluble pesticides); or

- where livestock metabolism studies indicate that significant residues (0.01 mg/kg or more) may occur in edible tissues and where significant residues (0.1 mg/kg or more in the total animal diet) occur in feed or feed crops (e.g. pasture, fodder crops, hay, silage), in crop wastes (e.g. kiwifruit, carrots, onions, potatoes, pumpkins and squash) or in the top 5 cm layer of soil; or

- there is a potential for bioaccumulation to occur; or

- where agricultural compounds are to be applied to livestock premises or other situations where there is a potential for residues to enter the animals (either by ingestion or skin contact).

Similar requirements exist where there is a potential for residues to occur in honey or propolis, generally from the presence of residues in pollen or nectar, or from the treatment of hives or honey extraction equipment.

Animal transfer studies may be necessary in both ruminants and poultry. The cow is the preferred ruminant species, but lactating goats are an acceptable model. Chickens are the preferred poultry species. A study on pigs may also be required if significantly different metabolites are present in ruminants, poultry and rats.

Further guidance on the conduct of animal transfer studies is provided in the FAO *Guidelines on Producing Pesticide Residue Data from Supervised Trials (1990)*, the FAO *Manual on the Submission and Evaluation of Pesticide Residues Data for the Estimation of Maximum Residue Levels in Food and Feed (2000)* or in the US EPA *Residue Chemistry (Subdivision O) Guidelines*.

10 ENVIRONMENTAL FATE

Environmental fate studies are required to provide an indication of the general behaviour and fate of the compound in soil and water, and thus permit the assessment of the potential for residues to transfer from these compartments into food, feed or other agricultural commodities.

Studies on environmental fate in soil and in water/sediment systems are normally required for all plant compounds except those with specific restricted use (e.g. post-harvest application in storage). The availability of relevant studies is essential for the assessment of potential residues in food, feeds and drinking water arising from soil uptake/ingestion, irrigation or groundwater contamination.

The submitted data should address:

- metabolism and degradation in soils, identification of metabolites and degradation products, and an indication of their levels;
- persistence of the parent compound and its metabolites or degradation products in soils under aerobic and anaerobic conditions;
- mobility and partitioning of the parent compound and its metabolites in soils;
- adsorption by various soils;
- hydrolysis rate and products;
- photolysis on soil and plant surfaces and its products;
- crop uptake, bioconcentration and bioavailability of the compound and its metabolites;
- residues in rotational (subsequent) crops representative of those in New Zealand cropping systems.

11 ADIs AND ACUTE REFERENCE DOSES

Information is required on Acceptable Daily Intakes (ADIs) and any Acute Reference Doses (ARfD) established in New Zealand, by WHO or by other national regulatory agencies.

These intake levels are an essential component of all dietary intake risk assessments.

The ADI is required to estimate dietary intake residue levels that should not be exceeded in long-term (chronic) diets for various subpopulations, and the ARfD is used for the same purpose but for estimating short-term intake risks (generally over one meal or one day).

Supporting studies, from which the ADIs and ARfDs have been derived, should be summarised and the toxicological end-points clearly identified. If any safety factors have been used to account for intra-species variability, inter-species variability, special sensitivities of any subpopulations etc., these should be clearly indicated.

Where different ADIs or ARfDs have been established by different organisations or regulatory authorities, the rationale for these differences should be outlined.

12 NATIONAL MAXIMUM RESIDUE LIMITS

National or Codex MRLs should be reported exactly as they are published. The portion of the commodity to which the MRL applies should be specified and the relevant residue definitions should be given. Copies or extracts from the appropriate national legislation should be provided.

APPENDIX 1:
SUPPORTING DATA PACKAGE - OVERVIEW CONTENT

RESIDUE DATA PACKAGE OVERVIEW FOR (TRADE NAME PRODUCT)

1. Identity and Properties

1.1 Product composition

- *A list of all active ingredients and impurities or contaminants present in the technical grade material/manufacturing concentrate at levels above 10 g/kg (1%), indicating their concentration and highlighting those considered to be of significance from a residue or toxicological point-of-view.*
- *A list of all compounds of toxicological significance (e.g. dioxins, HCBs, nitrosamines) present at levels of 10 g/kg (1%) or less, indicating their concentration and highlighting those considered to be of significance from a residue or toxicological point-of-view.*
- *A list of all other ingredients present at levels above 10 g/kg (1%) and their concentration in the trade name product.*

1.2 Physical and chemical properties

A description of the key properties of the active ingredient that are of relevance to its potential residue behaviour in plants, animal tissues, soil and water, and conclusions on the significance of these properties.

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2. Proposed Use Pattern

- *A comprehensive description of the proposed use pattern, with comments on its appropriateness with respect to current production practices, and on any specific aspects of the proposed use that are novel or at variance with similar compounds or current practices.*
- *A brief overview of the target crop production systems (including the timing of the major crop growth stages) and commonly adopted pest management systems.*
- *A summary of the information submitted to support the proposed use pattern as being Good Agricultural Practice.*

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3. Methods of Analysis

3.1 Analytical methods

- *Summarise the methods of analysis available for residue trial purposes, commenting on the specificity, limits of determination and quantitation, recovery rates and other method performance parameters.*

- *Summarise the methods of analysis available for compliance purposes, commenting on the specificity, limits of determination and quantitation, recovery rates and other method performance parameters.*

3.2 Storage stability tests

Summarise the available residue stability studies and indicate the degree to which residues in analytical samples are likely to decay during storage.

3.3 Residue definition

Indicate the proposed residue definitions for both compliance purposes (i.e. MRL-setting) and for dietary intake risk assessment purposes, together with the basis for proposing these definitions.

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4. Animal and Plant Metabolism

Provide a summary of each of the available metabolism studies on representative plant species, laboratory animals and on livestock, identifying the metabolic fate of the active ingredient and the nature and distribution of the terminal residues.

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5. Supervised Crop Residue Trials

- *In a table, summarise the results of each of the available crop residue trials data, including for each residue trial: the trial reference, application details, the Pre-Harvest Intervals and the associated residue levels found.*
- *Comment on the relevance of these trials to the proposed use and the level of consistency between the results.*
- *Identify and comment on any mitigating or confounding factors associated with the trials that may influence the assessment of the results.*

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6. Processing Studies

Summarise the available processing studies and indicate an appropriate processing factor(s) to reflect the degree to which residues decline, increase or metabolise as a result of processing.

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7. Animal Transfer Studies

- *Summarise the available animal feeding studies (transfer studies), indicating the nature and distribution of the parent compound and significant metabolites.*
- *Comment on the potential for residues to occur in animal tissues following the consumption of treated feeds or feed crops.*

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8. Environmental Fate

- *Summarise the available studies on environmental fate in soil, water and water/sediment systems with comments on their relevance.*

- *Taking into account the key chemical and physical properties of the active ingredient, indicate the potential for residues to occur in subsequent food and feed crops, and in animal tissues as a result of soil ingestion or from residues in stock drinking water.*

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9. ADIs and Acute Reference Doses

List any Acceptable Daily Intakes and/or Acute Reference Doses established in New Zealand, by WHO or other regulatory agencies, together with the toxicological end-points from which these have been derived and a reference to the related study and the rationale for any safety factors that have been used.

APPENDIX 2
SUPERVISED CROP RESIDUE TRIALS

National or Foreign Supervised Residue Trials

New Zealand residue data are required for agricultural compounds whose use patterns or conditions of use in New Zealand are different from other countries, where the commodity is a major component of the New Zealand diet or animal feed, or where significant quantities of the treated produce are likely to be exported.

In some cases relevant data from residue trials carried out in other countries with similar crop management practices and crop growth characteristics may be included in the supporting data package to supplement or, in some cases, replace the New Zealand trials. In most cases, applicants will be expected to conduct confirmatory tests under typical conditions of use in New Zealand to indicate the levels of residues under local conditions, and to validate any extrapolation from the data from other countries.

In all cases where foreign studies are submitted to supplement or substitute for the listed New Zealand residue trials, the following conditions should apply:

- the foreign studies should have been conducted under conditions that reflect New Zealand crop management practices and crop growth conditions (with these similarities being clearly explained in the submission);

- the treatment regime used in the foreign studies should not differ from the proposed New Zealand use pattern (e.g. application rates, frequency, timing, PHI etc.) by more than 25% in total;

- the results of the entire data-set of trials should show similar residue behaviour patterns as measured by the range of the STMR values.

Foreign Trial Substitution Rule

Up to 50% of the specified New Zealand supervised field crop residue trials, and up to 75% of the specified New Zealand supervised glasshouse crop residue trials can be replaced by 'foreign' studies.

Crop Groups and Representative Crops

Data on residue levels in one species of plant, or animal, do not necessarily represent the residue levels that might occur in distinctly different species.

Consideration will be given to the use of data from several crops in a crop group to estimate the general residue behaviour for most, if not all, crops in that group. The Codex crop grouping system, as described in the FAO publication *Codex Classification of Foods and Animal Feeds*, provides further information on this point.

Data on one or two 'representative' crops within the main group may be considered to represent the residue levels that can be expected to occur on crops within the same group but, in some cases, such as leaf lettuce and head lettuce, such extrapolation may not be acceptable.

Residue data from other countries may also assist in the extrapolation from one crop to another within a crop group. If these data show that residues are substantially similar for a number of crops within a crop group, this could provide a good case for extrapolating New Zealand data on one or two crops to all crops in that crop group. For example, if New Zealand data on cabbages show similar results to those from UK cabbage trials, and UK studies on Brussels sprouts and broccoli indicate a similar decay pattern, an argument could be made to extrapolate from the New Zealand cabbage data to include all horticultural brassica crops.

The listed crops within each crop group should be considered representative of the group, and a more extensive listing can be found in the *Codex Classification of Foods and Animal Feeds*. For specific crops not listed, the number of trials required should be based on the requirements listed under 'Other'.

Crop Group Extrapolation Rule

The number of residue trials needed to support crop group clearances are listed in column 2 of the following table. Trials to support crop group clearances must involve the 'representative' crops listed in column 1, in proportion to the numbers listed for each specific crop. However, up to 25% of the trials can involve other crops within the crop group. Where claims are being considered only for 'other' crops, the required number of trials needs to be increased to the highest number listed for the representative crop (see example below).

Example

In the case of Vegetable Brassicas, four Broccoli trials are required to support a claim for use on Broccoli, and four Cabbage trials would be needed for a Cabbage claim. Similarly, if Cauliflower were the only use being proposed, then four Cauliflower trials would be needed, even though this is not listed as a 'representative crop'. If a crop

group clearance is being considered, a minimum of six trials is recommended, covering both flowering and leafy/head Brassicas. These trials could include:

- 3 Cabbage and 3 Broccoli trials (i.e. in proportion to the number of 'representative crop trials'-4:4); or
- if the 25% replacement option is chosen, 2 Cabbage, 3 Broccoli and 1 Cauliflower, Broccoflower or Brussels sprouts ('other') trial; or
- 3 Cabbage, 2 Broccoli and 1 Cauliflower, Broccoflower or Brussels sprouts ('other') trial.

Table A2.1: Crop Residue Trials Required for Plant Compound Trade Name Products

Crop Group and Representative Crops	No of NZ SupervisedCrop Residue Trials	Notes and Comments
Residues less than the Limit of Detection	Reasoned argument plus 0-4 foreign trials at the proposed rate (or higher rates). Number of required trials decreases as the possibility of detectable residues decreases.	Situations where detectable residues would not normally be expected at harvest, but there is a small possibility that such residues could be detected at trace amounts. Examples could include the use of compounds on fruit crops just before or during flowering, use on immature vegetables (seedlings), early post-emergent soil treatments, treatment of food storage bins, packaging material, and food handling equipment, etc. The reasoned argument must include sufficient technical justification and relevant studies to support the conclusion that no residues will occur at harvest.
Vegetable Brassicas	6	The selected crops should include both flowering and leafy/head brassicas.
Broccoli	4	
Cabbages	4	
Other	2	
Bulb Vegetables	6	
Onions	4	
Spring Onions	2	
Other	2	
Cucurbits (edible skin)	6	For protected (e.g. glasshouse) crops, up to 75% of trials can be substituted by foreign trials.
Cucumbers	4	
Summer Squash	4	
Other	2	
Cucurbits (inedible skin)	4	For protected (e.g. glasshouse) crops, where trials on cucurbits (edible skin) have also been submitted, up to 100% of trials can be substituted by foreign trials, otherwise up to 75% substitution can be considered.
Melons	2	
Winter Squash	2	
Other	2	
Fruiting Vegetables (Solonaceae)	6	For protected (e.g. glasshouse) crops, up to 75% of trials can be substituted by foreign trials.
Peppers	2	
Tomatoes	4	
Others	2	
Leafy Vegetables	6	For protected (e.g. glasshouse) crops, up to 75% of trials can be substituted by foreign trials.
Lettuce (head)	3	
Lettuce (fancy, leaf)	3	

Crop Group and Representative Crops	No of NZ SupervisedCrop Residue Trials	Notes and Comments
Others	2	
Legume Vegetables	6	
Beans with pod	4	
Peas shelled	2	
Peas with pod	2	
Other	2	
Root and Tuber Vegetables	6	
Carrots	4	
Potatoes	4	
Other	2	
Stem Vegetables	6	
Asparagus	4	
Celery	4	
Others	2	
Citrus	6	
Mandarins	4	
Oranges	4	
Other	2	
Pome Fruit	6	
Apples	6	
Pears	4	
Other	2	
Stone Fruit	6	
Cherries	4	
Peaches	4	
Other	2	
Bush Fruit	4	
Blueberries	2	
Others	2	
Cane Fruit	4	Includes blackberries, boysenberries, loganberries, raspberries, youngberries or hybrids of these, alone or in any combination.
Others	See Notes	
Other Small Fruit	Not applicable	For protected (e.g. glasshouse) crops, up to 75% of trials can be substituted by foreign trials. Trials on wine grapes can be used as supporting data for field table grapes.
Grapes (wine)	6	
Grapes (table)	4	

Crop Group and Representative Crops	No of NZ SupervisedCrop Residue Trials	Notes and Comments
Strawberries	4	
Others	2	
Other Fruit	Not applicable	
Avocados	2	
Kiwifruit	6	
Passionfruit	2	
Persimmons	4	
Others	2	
Pulses and Oilseeds	6	
Soybeans	4	
Others	4	
Cereal Grain Crops	6	
Barley grain crops	4	
Wheat grain crops	4	
Other small grain crops	4	
Fungi	Not applicable	
Mushrooms	2	
Herbs	Not applicable	For protected (e.g. glasshouse) crops, up to 50% of trials can be substituted by foreign trials
Basil	2	
Chives	2	
Parsley	2	
Others	2	
Misc Crops	Not applicable	
Hops	2	
Maize/Sweetcorn	2	
Others	2	
Cereal Green Feeds	6	
Barley	4	
Maize	4	
Oats	2	
Wheat	4	
Other	2	
Fodder Beets	4	
Fodder beet	4	Can be replaced by any other fodder (root) brassica of regional significance.
Others	2	
Fodder Brassicas	4	
Swedes	4	Can be replaced by any other fodder (leafy)

Crop Group and Representative Crops	No of NZ SupervisedCrop Residue Trials	Notes and Comments
Others	4	brassica of regional significance.
Grasses	6	
Pasture	4	
Ryegrass	4	
Other	2	
Legume Feed Crops	6	
Clovers	4	
Lucerne	4	
Other	2	
Post-harvest and Premises Treatments	Not applicable	Up to 75% of trials can be substituted by foreign trials.
Stored grains	4	
Other	2	

APPENDIX 3
DATA ITEMS TO INCLUDE IN A SUPERVISED CROP RESIDUE TRIAL REPORT

1 Product identification

1.1 Active ingredient common name
1.2 Product trade name
1.3 Formulation and active ingredient content
1.4 Trial reference number
1.5 GLP status
1.6 Supervisor

2 Field data

2.1 Crop and variety/situation
2.2 Trial site and location
2.3 Plot size, layout and replication
2.4 Application details (dates, growth stages, dilution, area rates, intervals)
2.5 Application method and equipment
2.6 Other pesticide treatments
2.7 Climatic data

3 Sampling details

3.1 Sampling dates and growth stages
3.2 Field sampling codes
3.3 Days after last treatment
3.4 Days before/after normal harvest (or normal harvest date)
3.5 Number of units per sample and the weights per unit
3.6 Details of sampling (sample selection, field preparation), packing, storage and transport

4 Laboratory details

4.1 Laboratory name
4.2 Principle investigator
4.3 Date and state of samples received
4.4 Storage details (duration and condition)
4.5 Crop part analysed
4.6 Sample handling, subsampling and preparation
4.7 Residue extraction and cleanup
4.8 Analytical method summary
4.9 Analytical method reference
4.10 Components detected
4.11 Method recovery
4.12 Degradation in storage
4.13 Residues in control samples
4.14 Result correction factor
4.15 Method sensitivity (LoD, LoQ)

5 Results

5.1 Lab and field sample codes
5.2 Pre-Harvest Intervals

5.3 Range of residues found and number of analyses (if multiple analyses)
5.4 Mean residue found (uncorrected for recovery or control)
5.5 Residues found in control samples

6 Attachments

6.1 Chromatograms
6.2 Supplementary information on methods of analysis

Thailand

Questions for consideration.
Please answer whenever possible and tick the answers if provided with choices

Zoning project

Q1: Is the principle of geographical zoning for the acceptance of residues trials enshrined in your national legislation? If so, how many and what zones are defined?
A1: ***yes*** ☐ ***no*** ☒
Q2: What are your views on the conclusions of the zoning report[1], i.e. the impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless the geographical location of the trials?
A2: It is difficult to make a conclusion like that because of limitation of data in some area, i.e. data from tropical climate. The adverse condition of tropical climate, i.e. high temperature, heavy rain can have much effect on residue behaviour.
Q3a: How would your authority/agency implement these recommendations into their national guidelines? i.e. would your authority be prepared to accept residues trials data from countries/regions outside of your own?
A3a: ***Your authority/agency accepts*** ***1. all trials conducted in other countries with similar GAPs*** ***yes*** ☐ ***no*** ☒ ***2. 50% conducted under local condition*** ***yes*** ☐ ***no*** ☒ ***3. Others (please specify)*** - accept trials from other countries with similar climate conditions
Q3b: From which other countries/regions do you currently accept residues data to support an MRL/import tolerance?
A3b: No specific guideline. case-by-case consideration
Q3c: From which other countries/regions would you be prepared to accept residues data to support an MRL/import tolerance?
A3c: member countries of ASEAN (South-east asian region)

Q4: What are your criteria for accepting supervised residue trials data from outside your country/region?
A4: ***1. similar GAPs*** ***yes*** ☒ ***no*** ☐ ***2. similar climate*** ***yes*** ☒ ***no*** ☐ ***3. similar spray equipment*** ***yes*** ☒ ***no*** ☐ ***4. similar agronomic factors*** ***yes*** ☒ ***no*** ☐ ***5. Others (please specify)*** - validated method of pesticide residue analysis
Q5: The zoning group only made recommendations with respect to foliar sprays. What other application techniques should be evaluated to determine the effects of climatic zone on final residue levels?
A5: Foliar sprays are the most commonly used for group of pesticide associated with the presences of residues in food.

Significance in diet/trade

Q6: Do you differentiate between major and minor crops in terms of residue data requirements?
A6: ***yes*** ☐ ***no*** ☒
Q7: Is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops? Are other criteria established in your country (e.g. area of production)?
A7: ***yes*** ☒ ***no*** ☐
Q8: How do you define major and minor crops in your region/country?
A8: ***1. by area/ hectarage (If so indicate % for minor and for major crops)*** ***yes*** ☐ ***no*** ☒ ***2. by consumption (If so, indicate for minor and for major crops)*** ***yes*** ☒ ***no*** ☐ ***3. Others (please specify)*** - By quantity and value of crops.
Q9: What are/would be your criteria for defining a crop as significant in trade or the diet?
A9a: Significant in trade (e.g. % cultivation area, quantity of production, etc.) - Quantity and value of production/export ***A9 b: Significant in diet (e.g. 0.5% of the total diet as the trigger value)*** - 0.5% seem to be too low for diet in our region. We consider 1% to be more appropriate.

Q10: What source of dietary information do you use to carry out consumer risk assessments in your country/region?
A10: national consumption data (from national survey)
Q11: Would you accept 3 as the minimum number of trials for establishing MRLs. If not, what would be the absolute minimum number of trials, without extrapolation, you would be prepared to accept in support of an MRL/import tolerance?
A11: YES
Q12: Do your data requirements differ for setting National MRLs and for Import Tolerances i.e. based on uses outside of your country? If so, how?
A12: ***yes*** ☐ ***no*** ☒ ***If yes, please explain.*** - We have never set Import Tolerance.

Extrapolation of residues data for one crop to another

Q13: How do you implement the principle of extrapolation of residues data from one crop to another e.g. extrapolation of residues levels in tomatoes to estimate residue levels in aubergines? How do you decide what is an acceptable extrapolation?
A13: ± 25% (similar GAPs) ***yes*** ☒ ***no*** ☐ ***Others (specify)*** - The ± 25% rule can be applied to either the application rate or the number of applications. Decline curves should be used to consider the affects of changing the pre harvest interval. Deviation from this rule can be considered on a case-by-case basis.

Q14a: Can you accept extrapolation of data when there are similar GAPs only?
A14a: ***yes*** ☐ ***no*** ☒
Q14b: If not, what are your national/regional criteria to allow extrapolation of residues data? (e.g. comparability of GAPs, climate, geographical location, similarities in morphology of crops, crops within same groups, others.)
A14b: National criteria to allow extrapolation of residue data are: comparability of GAPs, crops within same groups or group tolerance, similarities in morphology of crops.
Q15: Do you have an agreed list of extrapolations of residues data?
A15: ***yes*** ☐ ***no*** ☒
Q16: What data would you wish to have in order to agree additional extrapolations?
A16: GAPs, crop groupings, crop morphology
Q17: Would you accept the principle of more extensive extrapolation of residue data to support minor crops?
A17: It depends, decision should be made on case-by-case basis.

Processing data

Q18: Under what circumstances do you require the submission of data on processing i.e. data examining the distribution of residues between different fractions of processed foods?
A18: - High level of residues found in raw agricultural commodity, e.g. $\geqslant$ 0.1 mg/kg - Probability of higher residue level in edible portion/processed foods.

Q19: What are the criteria for the extrapolation of processing data from one crop to another?
A19: Similarities in characteristics and processing of commodities.
Q20: What information do you require from processing studies, e.g. do you require a balance study i.e. a full description of where residues remain in all parts of the processed foodstuff or just residue levels in final edible commodities?
A20: Residue levels in final edible commodities are preferable. A balance study may be required on a case-by-case basis.
Q21: What are the minimum number of studies/trials required to determine a processing/transfer factor?
A21: A minimum number of two studies/trials would be required to determine a processing/transfer factor.
Q22: Do you/would you permit the use of 'theoretical' processing factors i.e. factors based on water loss during the drying process – if not please provide a reason
A22: ***yes*** ☒ ***no*** ☐
Q23: Which data do you use to determine 'theoretical' processing factors?
A23: processing studies of representative commodities of commodity group

Please provide the name and complete contact details including full address of a national expert who could be contacted if further discussion or clarification of answers is required.
Director Office of Commodity and System Standards, National Bureau of Agricultural Commodity and Food Standards, Ministry of Agriculture and Cooperatives, Rajadamnern Nok Avenue, Bangkok 10200, THAILAND Tel: +662 280 3887 Fax: +662 280 3899 E-mail: codex@acfs.go.th And, Director Agricultural Production Science Research Development Office, Department of Agriculture, Ministry of Agriculture and Cooperatives, Chatuchak, Bangkok 10900, THAILAND Tel: +662 579 3579 Fax: +662 561 4695

Thank you for your input to this initiative.

United Kingdom

Questions for consideration.
Please answer whenever possible and tick the answers if provided with choices

Zoning project

Q1: Is the principle of geographical zoning for the acceptance of residues trials enshrined in your national legislation? If so, how many and what zones are defined?
A1: yes ✓□ ***no*** □ ***EU guidelines – only trials from northern EU countries acceptable.***
Q2: What are your views on the conclusions of the zoning report[1], i.e. the impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless the geographical location of the trials?
A2: ***It is accepted that GAP is the most significant factor in determining residues.*** ***However, the conclusions of the project have to be taken in context:*** ***1. The project considered only a limited range of crops, pesticides and application techniques.*** ***2. Information on GAP was often limited.*** ***Despite these limitations, a small but significant influence of geography was observed for a limited number of pesticide/crop combinations.*** ***Hence, whereas the current EU guidelines for trial location may be unnecessarily restrictive, climatic factors should still be considered in determining the relevance of residue trials.***

Q3a: How would your authority/agency implement these recommendations into their national guidelines? i.e. would your authority be prepared to accept residues trials data from countries/regions outside of your own?

A3a:

Your authority/agency accepts

1. all trials conducted in other countries with similar GAPs

yes □ ***no*** ✓□

2. 50% conducted under local condition

yes □ ***no*** ✓□

3. Others (please specify)

Currently working to EU guidelines (See A1)

Q3b: From which other countries/regions do you currently accept residues data to support an MRL/import tolerance?

A3b:

Country of origin or similar climatic region.

Q3c: From which other countries/regions would you be prepared to accept residues data to support an MRL/import tolerance?

A3c:

Country of origin or similar climatic region.

Q4: What are your criteria for accepting supervised residue trials data from outside your country/region?

A4:	***1. similar GAPs***	***yes***	✓□	***no***	□
	2. similar climate	***yes***	✓□	***no***	□
	3. similar spray equipment	***yes***	✓□	***no***	□

4. similar agronomic factors ***yes*** ✓□ ***no*** □ ***5. Others (please specify)***
Q5: The zoning group only made recommendations with respect to foliar sprays. What other application techniques should be evaluated to determine the effects of climatic zone on final residue levels?
A5: ***Soil applied and seed treatments.***

Significance in diet/trade

Q6: Do you differentiate between major and minor crops in terms of residue data requirements?
A6: ***yes*** ✓□ ***no*** □
Q7: Is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops? Are other criteria established in your country (e.g. area of production)?
A7: ***yes*** ✓□ ***no*** □
Q8: How do you define major and minor crops in your region/country?
A8: ***1. by area/ hectarage (If so indicate % for minor and for major crops)*** ***yes*** ✓□ ***no*** □ ***Greater than 10,000 ha*** ***2. by consumption (If so, indicate for minor and for major crops)*** ***yes*** ✓□ ***no*** □

Greater than 7.5g per day.

3. Others (please specify)

Production greater than 200,000 tonnes per year.

Q9: What are/would be your criteria for defining a crop as significant in trade or the diet?

A9a: Significant in trade (e.g. % cultivation area, quantity of production, etc.)

See A8.

A9 b: Significant in diet (e.g. 0.5% of the total diet as the trigger value)

See A8.

Q10: What source of dietary information do you use to carry out consumer risk assessments in your country/region?

A10:

National dietary surveys.

Q11: Would you accept 3 as the minimum number of trials for establishing MRLs. If not, what would be the absolute minimum number of trials, without extrapolation, you would be prepared to accept in support of an MRL/import tolerance?

A11:

4 trials.

Q12: Do your data requirements differ for setting National MRLs and for Import Tolerances i.e. based on uses outside of your country? If so, how?

A12: yes □ ***no*** ✓□

If yes, please explain.

Extrapolation of residues data for one crop to another

Q13: How do you implement the principle of extrapolation of residues data from one crop to another e.g. extrapolation of residues levels in tomatoes to estimate residue levels in aubergines? How do you decide what is an acceptable extrapolation?
A13: ± 25% (similar GAPs) ***yes*** □ ***no*** □ ***Others (specify)*** ***EU guidelines on acceptable extrapolations.***
Q14a: Can you accept extrapolation of data when there are similar GAPs only?
A14a: yes □ ***no*** ✓□
Q14b: If not, what are your national/regional criteria to allow extrapolation of residues data? (e.g. comparability of GAPs, climate, geographical location, similarities in morphology of crops, crops within same groups, others.)
A14b: ***EU guidelines. Must be from Northern EU country and comparable GAP.***
Q15: Do you have an agreed list of extrapolations of residues data?
A15: yes ✓□ ***no*** □ ***EU guidelines.***
Q16: What data would you wish to have in order to agree additional extrapolations?
A16: ***GAP, geographic location, morphology/skin texture/size, dietary consumption,***

Q17: Would you accept the principle of more extensive extrapolation of residue data to support minor crops?
A17: ***Yes.***

Processing data

Q18: Under what circumstances do you require the submission of data on processing i.e. data examining the distribution of residues between different fractions of processed foods?
A18: ***Where there are significant residues in the RAC and where significantly consumed in the processed form.***
Q19: What are the criteria for the extrapolation of processing data from one crop to another?
A19: ***Generally a specific crop requirement. However, extrapolation may be accepted where there is a large margin of consumer safety or where the crop matrix has previously been shown to have little influence on the action of a specific process on the residue level.***
Q20: What information do you require from processing studies, e.g. do you require a balance study i.e. a full description of where residues remain in all parts of the processed foodstuff or just residue levels in final edible commodities?
A201: ***EU guidelines. Balance study required, but with consideration of the pesticide properties (e.g. volatility)***

Q21: What are the minimum number of studies/trials required to determine a processing/transfer factor?
A21: ***EU guidelines. One balance study. However, an additional 3 follow up studies required if consumption of the processed product is significant or if MRL is to be set on processed commodity.***
Q22: Do you/would you permit the use of 'theoretical' processing factors i.e. factors based on water loss during the drying process – if not please provide a reason
A22: yes ✓□ ***no*** □
Q23: Which data do you use to determine 'theoretical' processing factors?
A23: ***Unprocessed and processed weight.***

Please provide the name and complete contact details including full address of a national expert who could be contacted if further discussion or clarification of answers is required.
Donal Griffin PSD Email: donal.griffin@psd.defra.gsi.gov.uk Tel: 01904 455788

Thank you for your input to this initiative.

United States of America

Questions for consideration.
Please answer whenever possible and tick the answers if provided with choices

Zoning project

Q1: Is the principle of geographical zoning for the acceptance of residues trials enshrined in your national legislation? If so, how many and what zones are defined?
A1: yes X□ no □ *The principle of geographic zoning for the acceptance of residue trials is a cornerstone of US guidelines and is included in NAFTA guidance. Series 860 Guidelines, specifically 860.1500, define 13 geographic zones for the US. Zones are also defined for NAFTA (Canada, Mexico, US) which incorporates the 13 US zones. The zones are intended to represent the major growing regions for crops and reflect the range of climatic, geographic, and soil conditions and cultural practices under which a given crop might be grown. The assumption is that all major growing regions must be tested to obtain information on the highest likely residue under GAP. See http://www.epa.gov/opptsfrs/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/860-1500.pdf* *The concept of one worldwide zone is not acceptable to the US. Climate and geography are considered major factors in the magnitude of residue found on raw agricultural commodities, and these parameters are reflected in the diverse major growing regions for the various crops.*
Q2: What are your views on the conclusions of the zoning report[1], i.e. the impact of climate on the behaviour of residues of some applied pesticides on certain crops is negligible, and residue data deriving from similar use pattern (similar GAPs) and similar growing conditions may be compared regardless the geographical location of the trials?
A2: *The conclusions have not been proven. The study was based on available JMPR study data, and the studies were not specifically designed to measure variability among geographic or climatic zones. There was so much variability in the field trial conditions that meaningful conclusions could not be made. It is a classic example of output no better than the input.* *The US holds that climate (temperature, rainfall) and many other factors, such as soil type and local agricultural practices, impinge upon the magnitude of the residue in raw agricultural commodities. Crop field trials are therefore required from diverse geographic areas that represent the major growing regions for specific crops.*

Q3a: How would your authority/agency implement these recommendations into their national guidelines? i.e. would your authority be prepared to accept residues trials data from countries/regions outside of your own?

A3a:

Your authority/agency accepts

1. all trials conducted in other countries with similar GAPs

yes □ ***no*** ***X***□

2. 50% conducted under local condition

yes □ ***no*** ***X***□

3. Others (please specify)

Trials in support of a domestic registration (no import tolerance consideration) must be conducted in the NAFTA countries. Where a combination domestic and import tolerance situation exists, some of the trials may be conducted outside the US, provided the trials represent the regions with the use of the pesticide and from which exports will be made to the US. Substitution of foreign (non-NAFTA) trials for some US trials (for a domestic-only registration) may be considered on a case-by-case basis. Factors considered would be similarity of the foreign growing region to a US region (climate, soil, growing practices) and similarity of GAP. See A3c for more details.

Q3b: From which other countries/regions do you currently accept residues data to support an MRL/import tolerance?

A3b: *For import tolerance purposes, the trials are to be conducted in those regions from which imports to the US are planned. This response addresses only the import tolerance situation; see A3a for domestic registrations. Specific requirements for field trials for an import tolerance are given in the following tables. See http://www.epa.gov/fedrgstr/EPA-PEST/2000/June/Day-01/p13708.htm. Also see the NAFTA Import Tolerance Guideline Document http://yosemite.epa.gov/opp/naftatwg.nsf/7cc5a21cfecd6b46852565ab005d77be/ff1cbe90259cd6b985256d0900705b7e/$FILE/NAFTA%20Import%20Tolerances%20Document.PDF.*

Table 4. Number of Field Trials Required for an Import Tolerance (Less than 75% of Crop Available for Consumption Imported into U.S.)[1,2]

Required No. of Field Trials for a U.S. Registration	Percentage of U.S. Consumption Imported (Weight Basis)		
	0 - 10%	10 - 35%	35 - 75%
20	5	16	20
16,15	5	12	16
12	3	8	12
9,8	3	5	8
6,5	3 [3]	3	5
3	2 [3]	3 [3]	3

[1] The number of trials determined using this table may be reduced by 25% for crops needing 8 or more trials if metabolism studies and all the trials show residues less than the limit of quantitation of the analytical method and the crops are not being used as representative commodities to obtain crop group tolerances.

[2] Representative crops being used for crop group tolerances require 25% fewer trials than indicated in Table IV-1 if the latter specifies 8 or more trials for the individual crop. Therefore, the 15, 9, and 6 trials in the left hand column refer only to representative crops being used toward a crop group tolerance.

[3] Fewer than three trials may be conducted if the dietary consumption is very low **and** a relatively small amount of the commodity is imported into the U.S. Four independent samples must be collected from each test plot if less than three trials are conducted. Petitioners should either consult OPPTS Guideline 860.1500 or contact the Agency before proceeding if they believe that fewer trials are warranted.

Table 5. Number of Field Trials Required for an Import Tolerance (Greater than 75% of Crop Available for Consumption Imported into U.S.) [1]

Maximum Percent in U.S. Diet [2]	No. of Trials Required
0 - 0.05	3 [3]
0.05 - 0.2	8
0.2 - 1.0	12
>1.0	16

[1] The number of trials determined using this table may be reduced by 25% for crops needing 8 or more trials if metabolism studies and all the trials show residues less than the limit of quantitation of the analytical method and the crops are not being used as representative commodities to obtain crop group tolerances.

[2] Highest percentage in the U.S. Diet for any of the following subgroups: general population, children 1-6, and infants. Information on percentages in the diet may be found in Table IV-1 of this document.

[3] Fewer than three trials may be conducted if the dietary consumption is very low **and** a relatively small amount of the commodity is imported into the U.S. Four independent samples must be collected from each test plot if less than three trials are conducted. Petitioners should either consult OPPTS Guideline 860.1500 or contact the Agency before proceeding if they believe that fewer trials are warranted.

Q3c: From which other countries/regions would you be prepared to accept residues data to support an MRL/import tolerance?

A3c: Same as A3b. This response addresses data to support an import tolerance (no domestic registration). See A3a for the domestic registration only situation. The following information is supplied from the *US Guidelines for Import Tolerance.*
See http://www.epa.gov/fedrgstr/EPA-PEST/2000/June/Day-01/p13708.htm

Trials should be conducted in countries in relative proportion to the amount each country imports into the United States. **Only those countries in which the pesticide is marketed or proposed to be marketed need be represented**. **Trials will generally need to be conducted in all such countries which export at least 5% of the total amount of a commodity imported into the U.S**. The petitioner should seek Agency approval if substitution of data from one country to another is desired. All major growing areas within a country should be represented, as is required for U.S. registrations in 860.1500. At least two individually composited samples must be taken from each test plot and analyzed.

All major formulation classes should be represented. Petitioners are referred to the section on formulations in the residue chemistry OPPTS Test Guidelines, 860.1500(e)(2)(x). For the major classes a full set of trials must be conducted for each class. For later season uses, it will likely be necessary to conduct trials on the different formulations within a class. If a petitioner has a chemical with a 2-day PHI which is formulated as an emulsifiable concentrate and a wettable powder, a full set of trials would be required for both formulations, unless side-by-side plots at a few sites show comparable residues from such products. In the latter case some reduction of the total number of trials is warranted; petitioners are advised to consult the guidelines or Agency staff if a reduced number of trials is intended.

For crops requiring eight or more trials the number of trials may be reduced up to 25% if metabolism studies indicate residues are likely to be below the limit of quantitation. If some trials show quantifiable residues, then the full number of trials must be conducted. The limit of quantitation should be sufficiently low from an analytical chemistry standpoint and for risk assessment purposes. The 25% reduction in the number of field trials may not be applied to representative commodities used to support crop group tolerances. For additional information, the petitioner is advised to consult OPPTS Guideline 860.1500(e)(2)(viii).

Data generated in the United States or countries other than where the petitioner has existing or proposed uses may be substituted for up to half of the required number of foreign trials, but a minimum of three trials must be from the countries in which the pesticide is marketed. The petitioner should demonstrate that crop cultural practices, climatological conditions, and use patterns are substantially similar between the subject foreign regions and regions represented by the U.S. (or other) data. The burden of proof is on the petitioner.

In the case of tolerances to cover treated commodities imported from Canada or Mexico only, it may be acceptable for >50% of the trials to be conducted in the United States. As part of the harmonization process under the NAFTA, the crop field trial regions in the U.S. guidelines have been extended into Canada and efforts are in progress to do the same into Mexico. This would allow trials in the U.S. to support registration and tolerances in Canada and Mexico or vice versa. As a result, among these three countries, for certain crops most or all the field trials could be in a different country than the one in

which the tolerance is to be established. For example, if a tolerance is desired to cover the export of cranberries from Canada to the U.S., most of the trials could be conducted in the northern regions of the U.S. even though the pesticide is to be registered in Canada. Similarly, for certain crops being imported from Mexico, many of the trials could be done in the southwestern U.S. In the future, if other countries develop zone maps employing similar concepts as were used for the NAFTA countries, and the regions and cultural practices are demonstrated to be substantially similar to U.S. regions, then the Agency may consider substitution of U.S. data for those countries as well.

A minimum of three trials are required for any crop. In certain cases a petitioner may conduct fewer than three trials if there is a low dietary intake of commodity and if the amount imported is relatively small. In such cases a greater number of samples would be required from the test plot. Petitioners should consult OPPTS Guideline 860.1500 or submit a protocol for comment by the Agency.

1/ Zoning report is posted on the FAO and OECD website:
http://www.fao.org/WAICENT/FAOINFO/AGRICULT/AGP/AGPP/Pesticid/Default.HTM

Q4:	What are your criteria for accepting supervised residue trials data from outside your country/region?
A4:	***1. similar GAPs*** ***yes*** ***X*** □ ***no*** □ ***3. similar spray equipment*** ***yes*** ***X*** □ ***no*** □ ***4. similar agronomic factors*** ***yes*** ***X*** □ ***no*** □ ***5. Others (please specify)*** *Trials are required from countries exporting ≥5% of US consumption (import tolerance).*
Q5:	The zoning group only made recommendations with respect to foliar sprays. What other application techniques should be evaluated to determine the effects of climatic zone on final residue levels?
A5:	*Other possible considerations: glasshouse (greenhouse); soil; seed.*

Significance in diet/trade

Q6:	Do you differentiate between major and minor crops in terms of residue data requirements?
A6:	***yes*** ***X*** □ ***no*** □ *The amount of production is a factor in determination of the number of trials. Minor crops in terms of acreage (with little consumption) may require 3 trials (or less). Major crops may require up to 20 trials. See OPPTS 860.1500 (http://www.epa.gov/opptsfrs/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/860-1500.pdf).*
Q7:	Is significance of the foodstuff in trade or diet a suitable tool to determine major and minor crops? Are other criteria established in your country (e.g. area of production)?
A7:	***yes*** ***X*** □ ***no*** □ *Both significance in diet and production are criteria for determining the number of trials in the US. By extension, the amount of an item in international trade and its importance in the human diet would be appropriate parameters for recommending the number of trials needed.*
Q8:	How do you define major and minor crops in your region/country?
A8:	***1. by area/ hectarage (If so indicate % for minor and for major crops)*** ***yes*** ***X*** ***no*** □ *The 300,000 acres is considered the division (FQPA) between major and minor. According to FIFRA, Sec. 2 (ll), a minor use means the use of a pesticide on a commercial agricultural crop or site where (1)*

the total acreages is less than 300,000 acres OR (2) "…the use does not provide sufficient economic incentive to support the initial registration or continuing registration of a pesticide for such use and (A) there are insufficient efficacious alternative registered pesticides…; (B) the alternatives… pose greater risks…; (C) the minor use pesticide plays or will play a significant part in managing pest resistance; or (D) the minor use pesticide plays or will play a significant part in t an integrated pest management program."

Number of acres	*Number of trials*
>10,000,000	*16*
>1,000,000 – 10,000,000	*12*
>300,000 – 1,000,000	*8*
>30,000 – 300,000	*5*
>2000 – 30,000	*3*
>200 – 2000	*2*
≤200	*1*

2. by consumption (If so, indicate for minor and for major crops)

yes ***X***□ ***no*** □

The number of trials is adjusted up or down by considerations of consumption.
For commodities with acreage >300,000, the number of trials is increased one level (e.g., from 5 to 8 or 8 to 12) if consumption is ≥0.4% of total consumption for the general population, children, or nursing infants. A minimum of 16 trials is required for commodities with production greater than 300,000 acres ***and*** *comprising greater than 1% of dietary consumption for the general population, non-nursing infants, or children. Likewise, a minimum of 12 field trials is required for commodities with production less than 300,000 acres* ***and*** *comprising greater than 1% of dietary consumption for the general population, non-nursing infants, or children.*

3. Others (please specify)

The number of trials may also decrease if >90% of production is in one region.

Q9: What are/would be your criteria for defining a crop as significant in trade or the diet?

A9a: Significant in trade (e.g. % cultivation area, quantity of production, etc.)

Amount in international trade (a fixed number of metric tons). Quantity of production or % cultivation area may not be a good marker, for some items are consumed locally.

A9 b: Significant in diet (e.g. 0.5% of the total diet as the trigger value)

Based on US guidelines, 0.4% of the total diet for the general population or specific subgroups (children) would be appropriate.

Q10: What source of dietary information do you use to carry out consumer risk assessments in your country/region?

A10:

USDA/NHANES dietary consumption, which are surveys of dietary consumption (http://www.barc.usda.gov/bhnrc/foodsurvey/Products9496.html). USDA PDP, which is monitoring on target commodities obtained at the distribution level, near the market level (http://www.ams.usda.gov/science/pdp/redesign/quick.htm).
Residue data are also obtained from market basket surveys conducted by industry or other interested parties and from FDA monitoring (http://www.cfsan.fda.gov/~dms/pesrpts.htm).
Dietary intake analyses are performed in a tiered approach, with the first level being the use of field trial data. If a potential intake concern is found, survey and monitoring data are used in refinements of the calculations.

Q11: Would you accept 3 as the minimum number of trials for establishing MRLs. If not, what would be the absolute minimum number of trials, without extrapolation, you would be prepared to accept in support of an MRL/import tolerance?

A11:
3 is the minimum for a commodity of low production and low dietary intake. Those commodities with either higher consumption and/or greater production require up to 20 trials. See Q6.

Q12: Do your data requirements differ for setting National MRLs and for Import Tolerances i.e. based on uses outside of your country? If so, how?

A12: ***yes*** □ ***no*** ***X***□

If yes, please explain.
The requirements (toxicology and residue chemistry) are the same. For import tolerance, studies (toxicology) that relate to worker exposure (e.g., dermal and inhalation data) would not be required if the pesticide is not registered in the US. The number and location of field trials may differ, as explained elsewhere.

Extrapolation of residues data for one crop to another

Q13***:*** How do you implement the principle of extrapolation of residues data from one crop to another e.g. extrapolation of residues levels in tomatoes to estimate residue levels in aubergines? How do you decide what is an acceptable extrapolation?

A13: ± 25% (similar GAPs) ***yes*** ***X***□ ***no*** □

Others (specify)
The most common extrapolation is to a crop group, based on adequate data for the representative commodities (40CFR180.41). For example, sufficient data on tomatoes and Bell pepper and one type on non-bell pepper could provide a tolerance for all fruiting vegetables

(except cucurbits), including aubergines. This extrapolation is based on a similar GAP and similar residue levels from the field trials (with the representative commodities). See: http://a257.g.akamaitech.net/7/257/2422/08aug20031600/edocket.access.gpo.gov/ cfr_2003/julqtr/pdf/40cfr180.41.pdf. *Additionally, some extrapolation among specific crops may be allowed where the pesticide is non-systemic, per 40CFR180.34(d) and (e). See: http://a257.g.akamaitech.net/7/257/2422/08aug20031600/edocket.access.gpo.gov /cfr_2003/julqtr/pdf/40cfr180.34.pdf*
Q14a: Can you accept extrapolation of data when there are similar GAPs only?
A14a: yes □ ***no*** ***X***□ *Similar GAP's are necessary but not sufficient. See Q14b.*
Q14b: If not, what are your national/regional criteria to allow extrapolation of residues data? (e.g. comparability of GAPs, climate, geographical location, similarities in morphology of crops, crops within same groups, others.)
A14b: *Adequate data must be available for the representative crops of the appropriate group (or subgroup); or for the case of non-systemic pesticides adequate data on a morphologically related crop might be translated, e.g., blackberries to raspberries. Interested parties may always request an extrapolation on a case-by-case basis, and these will be considered by EPA.*
Q15: Do you have an agreed list of extrapolations of residues data?
A15: yes ***X***□ ***no*** □ *40CFR180.41, defines the representative crops for crop group or subgroup tolerance setting purposes. 40CFR180.1(h) provides some additional information on the extension of a general crop definition to closely related crops. For example, "peaches" covers both peaches and nectarines. Also, the attached (Appendix 1) "HED Standard Operating Procedure 2000.1" relates each crop to its representative commodity for purposes of dietary intake considerations, when using field trial data.*
Q16: What data would you wish to have in order to agree additional extrapolations?
A16: *For use at the international level, the crop grouping work, including the designation of representative crops, started at the York Workshops needs to be completed. This relates to the Classification updating being done by CCPR and to the efforts of IR-4 in crop grouping.*
Q17: Would you accept the principle of more extensive extrapolation of residue data to support minor crops?

A17: *Extrapolation via the crop grouping concept is strongly supported. Minor crops are supported in the USA via IR-4. Minimal data sets are required, and the pursuit of crop group or crop subgroup tolerances are encouraged. Extensive efforts are being made by EPA, in cooperation with IR4 and grower groups, to create more crop groups to address minor crops (e.g., tropical fruits).*

Processing data

Q18: Under what circumstances do you require the submission of data on processing i.e. data examining the distribution of residues between different fractions of processed foods?
A18: *Processing data are required wherever a pesticide is used on a crop with significant processed commodities, unless it can be clearly demonstrated that no residue is present on the RAC at exaggerated application rates, typically 5X, except mint and citrus oils (see OPPTS Test Guideline 860.1520, Table 1;* http://www.epa.gov/opptsfrs/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/860-1520.pdf*). Tolerances will not be established for RACs without the appropriate processing studies. See OPPTS 860.1000, Table 1, for a list of processed commodities (http://www.epa.gov/opptsfrs/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/860-1000.pdf).*
Q19: What are the criteria for the extrapolation of processing data from one crop to another?
A19: *Historically, the US has rarely considered the translation of processing data from one crop to another. In a very few instances, the translation of data from one oilseed crop to another has been considered, where the oil contents of the seeds were similar.*
Q20: What information do you require from processing studies, e.g. do you require a balance study i.e. a full description of where residues remain in all parts of the processed foodstuff or just residue levels in final edible commodities?
A201: *Data are required on only those processed fractions which are deemed significant foods or feeds. One measure of the soundness of a processing study is mass balance. While data on every fraction are critical to a determination of the mass balance, such data are often not available and the resulting inability to perform a mass balance is not considered a deficiency. For example, data are usually not available on the wash water used in the processing of tomatoes and apples. Likewise, data are not required on tomato pomace, an item no longer considered important in the animal diet. In the processing of oilseeds, data are not required on soapstock.*

Q21: What are the minimum number of studies/trials required to determine a processing/transfer factor?
A21: *One study is considered adequate for estimating a processing factor for a given processing procedure for a given crop. The study must simulate commercial practice and the RAC must contain quantifiable residues incurred in the field (not spiked). Multiple RAC and processed commodity samples are highly recommended*
Q22: Do you/would you permit the use of 'theoretical' processing factors i.e. factors based on water loss during the drying process – if not please provide a reason
A22: yes □ ***no*** ***X***□ *Such theoretical values are used in dietary intake calculations when no other data are available, but tolerances are set based on actual processing data. Such processes as loss of water during drying (grapes to raisins) represent the worst possible case and are not deemed appropriate for determining the need for a processed commodity tolerance. An exception is the occasional use of a drying factor to establish tolerances on hay (derived from forage). The practice most likely will not be used with a human food item.*
Q23: Which data do you use to determine 'theoretical' processing factors?
A23: *Experimental factors from drying and simple separation into components have been used to determine theoretical processing factors for dietary intake estimation and determination of the appropriate maximum factor required in conducting a field trial for processing. See OPPTS Test Guideline 860.1520. (*http://www.epa.gov/opptsfrs/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/Series/860-1520.pdf) *These factors generally are not deemed appropriate for establishing MRLs or tolerances. However, these factors are used for setting processed commodity tolerances when the concentration observed in a study* ***exceeds*** *the theoretical maximum.*
Please provide the name and complete contact details including full address of a national expert who could be contacted if further discussion or clarification of answers is required.
Stephen Funk US EPA/OPP/HED 1200 Pennsylvania Ave., NW, 7509C Washington, DC 20460 1-703-305-5430 funk.steve@epa.gov

APPENDIX 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE:9/12/2000

SUBJECT: Guidance for Translation of Field Trial Data from Representative Commodities in the Crop Group Regulation to Other Commodities in Each Crop Group/Subgroup, HED Standard Operating Procedure 2000.1 (9/12/2000)

FROM: Margaret Stasikowski, Director
Health Effects Division

TO: Health Effects Division Staff

Attached is SOP 2000.1 - "Guidance for Translation of Field Trial Data from Representative Commodities in the Crop Group Regulation to Other Commodities in Each Crop Group/Subgroup." This guidance is the latest HED Standard Operating Procedure; it was issued on August 4, 2000.

This SOP provides guidance to HED staff members who are performing dietary exposure analyses. The SOP should be used when field trial data are available for the representative commodities of a crop group or subgroup, but data are not available for all commodities of the crop group or subgroup. It establishes the pairing (for field trial data translation) between the representative commodities within a crop group and the specific members of that same group which are most similar to the representative commodity.

If you have any questions, please contact Bernard Schneider (305-5555), David Miller (305-5352), or Douglas Dotson (305-5351).

OVERVIEW:

Dietary exposure of an individual to a pesticide in a commodity is a function of both consumption and residue level in that commodity. The Office of Pesticide Programs is currently using Dietary Exposure Evaluation Model™ Software (DEEM™) to estimate the distribution of daily pesticide dietary exposures across the U.S. general population and 26 population subgroups. This software combines the distribution of daily consumption of foods by individuals (from USDA's Continuing Survey of Food Intake by Individuals) with a point estimate or a distribution of pesticide residues in those foods (generally obtained from registrant-conducted controlled experimental field trials or from monitoring data). When a registrant has proposed tolerances for a crop group or subgroup, OPP does not require registrants to perform controlled field trials for all raw agricultural commodities (RACs) in the group or subgroup, but instead permits field trials to be performed on only a limited number of "representative commodities" that are generally highly consumed and are designated by the Code of Federal Regulations (CFR). That is, registrants and other data submitters are not required to submit field trial data for ALL crops being registered, but are instead permitted to perform trials on a limited number of representative crops within a *crop group or subgroup* and use the measured residues in these crops to obtain a tolerance (and a registration) for all crops included in the crop group or subgroup. Specific crop groups and subgroups are designated in the CFR (40CFR §180.41) and generally include those crops which, based on similar plant morphologies, cultural practices, growing seasons, etc. would be expected to contain similar pesticide residues. In this way, registrants are able, if desired, to "leverage" their field trials and to include other (generally less consumed) crops within that same crop group (or family) provided that a full set of field trials is performed with the commodities which are designated to "represent" that group, and provided that the maximum residue levels in the represent-ative crops do not differ by more than a factor of five. There are currently 19 crop groups listed in the CFR. Examples include cucurbit vegetables, citrus fruits, and cereal grains.

A registrant has conducted 12 field trials on apples in six regions obtaining a total of 24 residue values. In addition, the registrant has conducted six field trials with pears in three regions obtaining a total of 12 residue measurements. As apples and pears are the two designated "representative commodities" for the POME FRUITS Crop Group (Crop Group 11), the registrant is able, if desired, to obtain a crop group tolerance for POME FRUITS in which the tolerance for apples and pears would be applied to all members of the CFR-designated POME FRUITS Group (i.e., apple, crabapple, loquat, mayhaw, pear, oriental pear, and quince).

If a crop group tolerance were requested and it was necessary to use field trial data in place of tolerance level residues, OPP would perform this dietary exposure assessment by applying the 24 residue measurements obtained from the apple field trials to the apples and crabapples; and the 12 residue measurements obtained from pears to loquats, pears, oriental pears, and quinces in accordance with the designations established

In the context of exposure and risk assessment, an issue arises when a registrant has submitted a petition for a crop group tolerance and has submitted field trial data for only the representative crops of that crop group (as required). Although the residues in the representative crops would generally be expected to be similar, it previously has not been clear exactly which of the available field trial data sets should be used for the remaining crops in the crop group or subgroup. In the past, OPP has generally used residues in the "worst-case" representative crop to extend to other members in the crop grouping, but selection of the "worst case" representative crop is occasionally ambiguous. For example, it can be unclear as to whether the worst case residue set is that which contains the highest residue, that which has the highest mean, that which has the highest median, or that which contains the highest 90^{th} (or other) percentile of exposure.

The purpose of the present memorandum is to present a scheme for performing these translations. Briefly, the scheme permits translation of field trial data from a representative commodity to other commodities in that same group or subgroup that are most similar to the representative commodity. This Standard Operating Procedure (SOP) establishes the pairing between the representative commodities within a crop group for which extensive residue data from field trials are available and the specific members of that same group that have been determined to be most similar to the representative commodity.

This SOP is applicable to both acute and chronic dietary exposure assessments. In general, the data translation will be used when tolerance level residues do not provide sufficient refinement of the data, and it is necessary to use field trial data in their place. This guidance is only applicable to data from field trials. A separate SOP (99.3, 3/26/99) exists that addresses translation of monitoring data. This SOP is applicable to refinement of risk during reregistration, but again, only when field trial data are being used. Several commodities appear in DEEM™ that are not present in the crop group lists in 40CFR §180.41. These commodities are listed in the SOP and the appropriate representative commodities are given. An example of how this data translation would be performed is given in the boxed area above.

The Crop Groups list (40CFR §180.41) for the Dietary Exposure Science Advisory Council will be divided into two parts. Part I is applicable in cases in which a registrant is requesting a full crop group tolerance. For example, to obtain a tolerance for Crop Group 9, Cucurbit Vegetables, the registrant has submitted residue data on all the representative commodities (cucumber, muskmelon, and summer squash) and the registrant is not requesting any crop subgroup tolerances for this crop group (Crop Subgroup 9A- Melon Subgroup and/or 9B- Squash/Cucumber Subgroup).

The list in Part II contains the crop subgroups, and which members of each crop subgroup are most similar to the representative commodities. This list is applicable when the registrant is applying for a crop subgroup tolerance only, such as for Crop Subgroup 9A- Melon subgroup, and/or Crop Subgroup 9B- Squash/Cucumber Subgroup. Residue data would be available for the representative commodities of these crop subgroups. For example, for Crop Subgroup 9A the

representative commodity is cantaloupe. For Crop Subgroup 9B, the representative commodities are one cultivar of summer squash and cucumber. Some subgroups have only one representative commodity and they will be listed only for continuity. When the crop subgroups were developed, the selection of the representative commodities was based on similar cultural practices, plant morphology, growing seasons, etc. Detailed explanations for each commodity, as well as the list of cultural factors necessary to determine a representative commodity, are available in the Crop Monographs from FOOD AND FEED CROPS OF THE UNITED STATES, by G. M. Markle, J. J. Baron, and B. A. SCHNEIDER, Meister Publishing Co., Willoughby, OH, (1-800-572-7740).

The attached draft does not conflict with the guidance in HED SOP 99.3 Translation of Monitoring Data.

PART I - THIS LIST CONTAINS THE NINETEEN CROP GROUPS AND WHICH MEMBERS OF THE CROP GROUP ARE MOST SIMILAR TO THEIR REPRESENTATIVE COMMODITIES

Crop Group 1: Root and Tuber Vegetables

Representative Commodities: Carrot, potato, radish, and sugar beet

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Arracacha	Potato
Arrowroot	Potato
Artichoke, Chinese	Potato
Artichoke, Jerusalem	Potato
Beet, garden	Sugar beet
Beet, sugar	Sugar beet
Burdock, edible	Radish
Canna, edible	Potato
Carrot	Carrot
Cassava	Potato
Celeriac	Radish
Chayote, roots	Potato
Chervil, turnip-rooted	Carrot
Chicory	Carrot
Chufa	Potato
Dasheen	Potato
Ginger	Potato
Ginseng	Carrot
Horseradish	Carrot
Leren	Potato
Parsley, turnip-rooted	Carrot
Parsnip	Carrot
Potato	Potato
Radish	Radish
Radish, oriental	Radish
Rutabaga	Radish
Salsify	Carrot
Salsify, black	Carrot
Salsify, Spanish	Carrot
Skirret	Carrot
Sweet potato	Potato
Tanier	Potato
Taro	Potato

Turmeric	Potato
Turnip, roots	Radish
Yam bean	Potato
Yam, true	Potato

Crop Group 2: Leaves of Root and Tuber Vegetables (Human Food or Animal Feed)

Representative Commodities: Turnip, forage; and garden beet or sugar beet

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Beet, garden	Beet, garden*
Beet, sugar	Beet, sugar*
Burdock, edible	Beet, garden*
Carrot	Beet, garden*
Cassava	Beet, sugar*
Celeriac	Beet, garden*
Chervil, turnip-rooted	Beet, garden*
Chicory	Turnip, forage
Dasheen	Turnip, forage
Parsnip	Beet, garden*
Radish	Beet, garden*
Radish, oriental	Beet, garden*
Rutabaga	Turnip, forage
Salsify, black	Beet, garden*
Sweet potato	Turnip, forage
Tanier	Turnip, forage
Taro	Turnip, forage
Turnip	Turnip, forage
Yam, true	Turnip, forage

* In lieu of garden beet, tops data sugar beet, tops can be substituted, as the registrant is free to choose between garden beet and sugar beet as the representative commodity.

Crop Group 3: Bulb Vegetables

Representative Commodities: Onion, green; and onion, dry bulb

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Garlic	Onion, dry bulb
Garlic, great-headed	Onion, dry bulb
Leek	Onion, green
Onion, dry bulb	Onion, dry bulb
Onion, green	Onion, green
Onion, Welsh	Onion, green
Shallot, bulb	Onion, dry bulb
Shallot, fresh leaves	Onion, green

Crop Group 4: Leafy vegetables (except Brassica vegetables)

Representative Commodities: Celery, head lettuce, leaf lettuce, and spinach

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Amaranth, leafy	Spinach
Arugula	Spinach
Cardoon	Celery
Celery	Celery
Celery, Chinese	Celery
Celtuce	Celery
Chervil, fresh leaves	Spinach
Chrysanthemum, edible leaved	Spinach
Chrysanthemum, garland	Spinach
Corn salad	Spinach
Cress, garden	Spinach
Cress, upland	Spinach
Dandelion	Spinach
Dock	Spinach
Endive	Spinach
Fennel, Florence	Celery
Lettuce, head	Lettuce, head
Lettuce-Unspecified	
Lettuce, leaf	Lettuce, leaf
Orach	Spinach
Parsley, leaves	Spinach
Purslane, garden	Spinach
Purslane, winter	Spinach

Radicchio	Lettuce, head
Rhubarb	Celery
Spinach	Spinach
Spinach, New Zealand	Spinach
Spinach, vine	Spinach
Swiss chard	Celery

Crop Group 5: Brassica (Cole) Leafy Vegetables

Representative Commodities: Broccoli or cauliflower; cabbage; and mustard greens

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Broccoli	Broccoli*
Broccoli, Chinese	Broccoli*
Broccoli raab	Mustard greens
Brussels sprouts	Cabbage
Cabbage	Cabbage
Cabbage-Savoy	
Cabbage, Chinese, bok choy	Mustard greens
Cabbage, Chinese, napa	Cabbage
Cabbage, Chinese mustard	Broccoli*
Cauliflower	Cauliflower*
Collards	Mustard greens
Kale	Mustard greens
Kohlrabi	Cabbage
Mustard greens	Mustard greens
Mustard spinach	Mustard greens
Rape greens	Mustard greens

* In lieu of broccoli data, cauliflower can be substituted or visa versa, as the registrant is free to choose between broccoli and cauliflower as the representative commodity.

Crop Group 6: Legume vegetables (Succulent or dried)

Representative Commodities: Bean (Phaseolus), succulent and bean, dried; pea (Pisum), succulent; and pea, dried; and soybean

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Bean (Lupinus):	
Lupin, grain	Any one dried cultivar of bean (Phaseolus)
Bean (Phaseolus):	
Bean, kidney, seed	Any one dried cultivar of bean (Phaseolus)
Bean, dry	Any one dried cultivar of bean (Phaseolus)
Bean, lima, succulent	Any one succulent cultivar of bean (Phaseolus)
Bean, navy, seed	Any one dried cultivar of bean (Phaseolus)
Bean, pinto, seed	Any one dried cultivar of bean (Phaseolus)
Beans-Dry-Great Northern	
Bean, runner, succulent	Any one succulent cultivar of bean (Phaseolus)
Bean, snap, succulent	Any one succulent cultivar of bean (Phaseolus)
Beans-Succulent-Green	
Beans-Succulent-Other	
Bean, tepary, seed	Any one dried cultivar of bean (Phaseolus)
Bean, wax, succulent	Any one succulent cultivar of bean (Phaseolus)
Bean (Vigna):	
Bean, adzuki, seed	Any one dried cultivar of bean (Phaseolus)
Bean, yardlong, succulent	Any one succulent cultivar of bean (Phaseolus)
Pea, blackeyed, succulent	Any one succulent cultivar of bean (Phaseolus)
Pea, blackeyed, seed	Any one dried cultivar of bean (Phaseolus)
Catjang, seed	Any one dried cultivar of bean (Phaseolus)
Cowpea, succulent	Any one succulent cultivar of bean (Phaseolus)
Cowpea, seed	Any one dried cultivar of bean (Phaseolus)
Bean, moth, succulent	Any one succulent cultivar of bean (Phaseolus)
Bean, moth, seed	Any one dried cultivar of bean (Phaseolus)
Bean, mung, seed	Any one dried cultivar of bean (Phaseolus)
Bean, rice, seed	Any one dried cultivar of bean (Phaseolus)
Pea, crowder, seed	Any one dried cultivar of bean (Phaseolus)
Pea, southern, succulent	Any one succulent cultivar of bean (Phaseolus)
Pea, southern, seed	Any one dried cultivar of bean (Phaseolus)
Bean, urd, seed	Any one dried cultivar of bean (Phaseolus)
Bean, broad, succulent	Any one succulent cultivar of bean (Phaseolus)
Bean, broad, seed	Any one dried cultivar of bean (Phaseolus)
Beans-Dry-Pigeon Beans	
Chickpea, seed	Any one dried cultivar of bean (Phaseolus)
Guar, seed	Any one dried cultivar of bean (Phaseolus)
Jackbean, succulent	Any one succulent cultivar of bean (Phaseolus)
Bean, lablab, seed	Any one dried cultivar of bean (Phaseolus)
Beans-Dry-Hyacinth	
Lentil	Any one dried cultivar of bean (Phaseolus)

Pea (Pisum):	
Pea, dwarf, succulent	Any one succulent cultivar of pea (Pisum)
Pea, edible-podded	Any one succulent cultivar of pea (Pisum)
Pea, English, succulent	Any one succulent cultivar of pea (Pisum)
Pea, field, seed	Any one dried cultivar of pea (Pisum)
Pea, garden, succulent	Any one succulent cultivar of pea (Pisum)
Pea, green, succulent	Any one succulent cultivar of pea (Pisum)
Pea, snow, succulent	Any one succulent cultivar of pea (Pisum)
Pea, sugar snap	Any one succulent cultivar of pea (Pisum)
Pea, pigeon, succulent	Any one succulent cultivar of pea (Pisum)
Pea, pigeon, seed	Any one dried cultivar of pea (Pisum)
Soybean, seed	Soybean, seed
Soybean, vegetable, succulent	Any one succulent cultivar of bean (Phaseolus)
Swordbean, succulent	Any one succulent cultivar of pea (Pisum)

Crop Group 7: Foliage of Legume Vegetables

Representative Commodities: Any Cultivar of bean (Phaseolus), field pea (Pisum), and soybean

The commodities in this crop group include plant parts of any legume vegetable included in the Legume vegetables group that will be used as animal feed only.

Crop Group 8: Fruiting Vegetables (except cucurbits)

Representative Commodities: Tomato, bell pepper, and one cultivar of non-bell pepper

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Eggplant	Bell pepper
Groundcherry	Tomato
Pepino	Tomato
Bell pepper	Bell pepper
Paprika	
Chili pepper	Nonbell pepper
Cooking pepper	Bell pepper
Pimento	Nonbell pepper

Sweet pepper	Bell pepper
Tomatillo	Tomato
Tomato	Tomato

Crop Group 9: Cucurbit Vegetables

Representative Commodities: Cucumber, muskmelon, and summer squash

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Chayote, fruit	Summer squash
Christophine	
Chinese Waxgourd	Cucumber
Citron Melon	Muskmelon
Cucumber	Cucumber
West Indies gherkin	Cucumber
Gourd, edible	Summer squash
Okra/Chinese (luffa)	
Momordica spp.	Cucumber
Balsam Pear	
Bitter Melon	
Muskmelon	Muskmelon
Casabas	
Crenshaws	
Melons-Cantaloupe	
Melons-Honeydew	
Melons-Persian	
Winter Melon	
Pumpkin	Summer squash
Squash, Summer	Summer squash
Squash, Winter	Summer squash
Watermelon	Muskmelon

Crop Group 10: Citrus Fruits

Representative Commodities: Sweet orange, lemon, and grapefruit

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Calamondin	Sweet orange
Citron, citrus	Sweet orange
Citrus hybrids	Sweet orange
Tangelos	
Grapefruit	Grapefruit
Kumquat	Sweet orange
Lemon	Lemon
Lime	Lemon
Orange, sour	Orange, sweet
Orange, sweet	Orange, sweet
Pummelo	Grapefruit
Mandarin, Satsuma	Sweet orange
Tangerine	Sweet orange

Crop Group 11: Pome Fruits

Representative Commodities: Apple and pear

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Apple	Apple
Crabapple	Apple
Loquat	Pear
Mayhaw	Pear
Pear	Pear
Pear, oriental	Pear
Quince	Pear

Crop Group 12: Stone Fruits

Representative Commodities: Sweet cherry or tart cherry; peach; and plum or fresh prune

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Apricot	Peach
Cherry, sweet	Cherry, sweet*

Cherry, tart	Cherry, tart*
Nectarine	Peach
Peach	Peach
Plum	Plum
Plum, Chickasaw	Plum
Plum, Damson	Plum
Plum, Japanese	Plum
Plumcot	Plum
Plum, prune, fresh	Plum

* In lieu of sweet cherry data, tart cherry can be substituted or visa versa, as the registrant is free to choose between sweet cherry and tart cherry as the representative commodity.

Crop Group 13: Berries

Representative Commodities: Any one blackberry; or any one raspberry; and blueberry

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Blackberry	Blackberry*
Boysenberry	
Dewberry	
Youngberry	
Blueberry	Blueberry
Currant	Blueberry
Elderberry	Blueberry
Gooseberry	Blueberry
Huckleberry	Blueberry
Loganberry	Blackberry*
Raspberry, black	Raspberry*
Raspberry, red	Raspberry*

* In lieu of blackberry data, raspberry can be substituted or visa versa, as the registrant is free to choose between blackberry and raspberry as the representative commodity.

Crop Group 14: Tree Nuts

Representative Commodities: Almond and pecan

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Almond	Almond
Beech nut	Almond
Brazil nut	Pecan

Butternut	Pecan
Cashew	Pecan
Chestnut	Almond
Chinquapin	Almond
Filbert	Pecan
Hickory nut	Pecan
Macadamia nut	Pecan
Pecan	Pecan
Pistachio	Almond
Walnut, black	Pecan
Walnut, English	Pecan

Crop Group 15: Cereal Grains

Representative Commodities: Corn, sweet and corn, field; rice; sorghum, grain; and wheat

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Barley	Wheat
Buckwheat	Wheat
Corn, field	Corn, field
Corn, sweet	Corn, sweet
Millet, pearl	Sorghum, grain
Millet, proso	Sorghum, grain
Oat	Wheat
Popcorn	Corn, field
Rice	Rice
Rye	Wheat
Sorghum, grain	Sorghum, grain
Teosinte	Wheat
Triticale	Wheat
Wheat	Wheat
Wild rice	Rice

Crop Group 16: Forage, Fodder and Straw of Cereal Grains

Representative Commodities: Corn, wheat, and any other cereal grain crop

The commodities in this crop group consist of the forage, stover, and straw of all commodities included in the cereal grains group as applicable. All cereal grains are livestock feed items.

Crop Group 17: Grass Forage, Fodder, and Hay Group

Representative Commodities: Bermudagrass; bluegrass; and bromegrass or fescue

Any grass, Gramineae family (either green or cured) except sugarcane and those included in the cereal grains group, that will be fed to or grazed by livestock, all pasture and range grasses and grasses grown for hay or silage.

Crop Group 18: Nongrass Animal Feeds (Forage, Fodder, Straw, and Hay)

Representative Commodities: Alfalfa and clover

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Alfalfa	Alfalfa
Bean, velvet	Clover
Clover	Clover
Crownvetch	Clover
Kudzu	Clover
Lespedeza	Alfalfa
Lupin	Clover
Sainfoin	Alfalfa
Trefoil	Clover
Vetch	Clover
Vetch, milk	Clover

Crop Group 19: Herbs and Spices

Representative Commodities: Basil, leaves; basil, dried leaves; black pepper; chive; and celery, seed or dill, seed

CROP GROUP COMMODITY	REPRESENTATIVE COMMODITY
Allspice	Black pepper
Angelica	Basil
Anise, seed	Dill, seed
Anise, star	Black pepper
Annatto, seed	Black pepper
Balm	Basil
Basil	Basil
Borage	Basil
Burnet	Basil
Camomile	Basil

Caper buds	Dill, seed
Caraway, seed	Celery, seed*
Caraway, black	Celery, seed*
Cardamom, seed	Black pepper
Cassia	Black pepper
Catnip	Basil
Celery, seed	Celery, seed*
Chervil, dried leaves	Chive
Chive	Chive
Chive, Chinese	Chive
Cilantro, leaf	Basil
Cinnamon	Black pepper
Clary	Basil
Clove	Black pepper
Coriander seed	Dill, seed*
Costmary	Basil
Culantro, leaf	Basil
Culantro, seed	Dill, seed*
Cumin	Black pepper
Curry, leaf	Basil
Dillweed	Basil
Dill, seed	Dill, seed*
Fennel, seed	Celery, seed*
Fennel, Florence, seed	Celery, seed*
Fenugreek	Black pepper
Grains of paradise	Black pepper
Horehound	Basil
Hyssop	Basil
Juniper berry	Black pepper
Lavender	Basil
Lemongrass	Basil
Lovage, leaves	Basil
Lovage, seed	Celery, seed*
Mace	Black pepper
Marigold	Basil
Marjoram	Basil
Oregano	
Mustard, seed	Dill, seed*
Nasturtium	Basil
Nutmeg	Black pepper
Parsley, dried	Basil, dried leaves
Pennyroyal	Basil
Pepper, black	Black pepper
Pepper, white	Black pepper
Poppy , seed	Dill, seed*
Rosemary	Basil

Rue	Basil
Saffron	Black pepper
Sage	Basil
Savory, summer	Basil
Savory, winter	Basil
Sweet bay	Basil
Tansy	Basil
Tarragon	Basil
Thyme	Basil
Vanilla	Black pepper
Wintergreen	Basil
Woodruff	Basil
Wormwood	Basil

* In lieu of celery, seed data dill, seed data can be substituted and visa versa, as the registrant is free to choose between celery, seed and dill, seed as the representative commodity.

PART II- THIS LIST CONTAINS THE CROP SUBGROUPS AND WHICH MEMBERS OF THE CROP SUBGROUP ARE MOST SIMILAR TO THE REPRESENTATIVE COMMODITIES IN THE CROP SUBGROUP.

CROP SUBGROUPS:

Crop Subgroup 1A: Root vegetables subgroup

Representative Commodities: Carrot, radish, and sugar beet

CROP SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Beet, garden	Radish
Beet, sugar	Sugar beet
Burdock, edible	Radish
Carrot	Carrot
Celeriac	Radish
Chervil, turnip-rooted	Carrot
Chicory	Carrot
Ginseng	Carrot
Horseradish	Carrot
Parsley, turnip-rooted	Carrot
Parsnip	Carrot
Radish	Radish
Radish, oriental	Radish
Rutabaga	Radish
Salsify	Carrot

Salsify, black	Carrot
Salsify, Spanish	Carrot
Skirret	Carrot
Turnip, roots	Radish

Crop Subgroup 1B: Root vegetables, except sugar beet subgroup

Representative Commodities: Carrot and radish

CROP SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Beet, garden	Radish
Burdock, edible	Radish
Carrot	Carrot
Celeriac	Radish
Chervil, turnip-rooted	Carrot
Chicory	Carrot
Ginseng	Carrot
Horseradish	Carrot
Parsley, turnip-rooted	Carrot
Parsnip	Carrot
Radish	Radish
Radish, oriental	Radish
Rutabaga	Radish
Salsify	Carrot
Salsify, black	Carrot
Salsify, Spanish	Carrot
Skirret	Carrot
Turnip, roots	Radish

Note: Beet, garden; rutabaga; and turnip are represented by radish in this subgroup only.

Crop Subgroup 1C: Tuberous and corm vegetables subgroup

Representative Commodity: Potato

CROP SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Arracacha	Potato
Arrowroot	Potato
Artichoke, Chinese	Potato
Artichoke, Jerusalem	Potato
Canna, edible	Potato

Cassava	Potato
Chayote, roots	Potato
Chufa	Potato
Dasheen	Potato
Ginger	Potato
Leren	Potato
Potato	Potato
Sweet potato	Potato
Tanier	Potato
Taro	Potato
Turmeric	Potato
Yam bean	Potato
Yam, true	Potato

Crop Subgroup 1D: Tuberous and corm vegetables, except potato subgroup

Representative commodity: Sweet potato

CROP SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Arracacha	Sweet potato
Arrowroot	Sweet potato
Artichoke, Chinese	Sweet potato
Artichoke, Jerusalem	Sweet potato
Canna, edible	Sweet potato
Cassava	Sweet potato
Chayote, roots	Sweet potato
Chufa	Sweet potato
Dasheen	Sweet potato
Ginger	Sweet potato
Leren	Sweet potato
Sweet potato	Sweet potato
Tanier	Sweet potato
Taro	Sweet potato
Turmeric	Sweet potato
Yam bean	Sweet potato
Yam, true	Sweet potato

Crop Subgroup 4A: Leafy greens subgroup

Representative Commodities: Head lettuce, leaf lettuce, and spinach

CROP SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Amaranth, leafy	Spinach
Arugula	Spinach
Chervil	Spinach
Chrysanthemum, edible-leaved	Spinach
Chrysanthemum, garland	Spinach
Corn salad	Spinach
Cress, garden	Spinach
Cress, upland	Spinach
Dandelion	Spinach
Dock	Spinach
Endive	Spinach
Lettuce, head	Lettuce, head
Lettuce-Unspecified	
Lettuce, leaf	Lettuce, leaf
Orach	Spinach
Parsley	Spinach
Purslane, garden	Spinach
Purslane, winter	Spinach
Radicchio	Head lettuce
Spinach	Spinach
Spinach, New Zealand	Spinach
Spinach, vine	Spinach

Crop Subgroup 4B: Leaf petioles subgroup

Representative Commodity: Celery

CROP SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Cardoon	Celery
Celery	Celery
Celery, Chinese	Celery
Celtuce	Celery
Fennel, Florence	Celery
Rhubarb	Celery
Swiss chard	Celery

Crop Subgroup 5A: Head and Stem Brassica subgroup

Representative Commodities: Broccoli or cauliflower; and cabbage

CROP SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Broccoli	Broccoli *
Broccoli, Chinese	Broccoli *
Brussels sprouts	Cabbage
Cabbage	Cabbage
Cabbage-Savoy	
Cabbage, Chinese, napa	Cabbage
Cabbage, Chinese mustard	Broccoli *
Cauliflower	Cauliflower
Kohlrabi	Cabbage

* In lieu of broccoli data, cauliflower can be substituted or visa versa, as the registrant is free to choose between broccoli and cauliflower as the representative commodity.

Crop Subgroup 5B: Leafy Brassica greens subgroup

Representative Commodity: Mustard greens

CROP SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Broccoli raab	Mustard greens
Cabbage, Chinese, bok choy	Mustard greens
Collards	Mustard greens
Kale	Mustard greens
Mustard greens	Mustard greens
Mustard spinach	Mustard greens
Rape greens	Mustard greens

Crop Subgroup 6A: Edible-podded legume vegetables subgroup

Representative Commodities: Any one succulent cultivar of edible-podded bean (Phaseolus) and any one succulent cultivar of edible-podded pea (Pisum)

SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Bean (Phaseolus) includes: runner bean; snap bean; (green bean); wax bean	Any one succulent cultivar of edible-podded bean (Phaseolus).
Bean (Vigna) includes: asparagus bean; Chinese longbean; moth bean; yardlong bean; jackbean	Any one succulent cultivar of edible-podded bean (Phaseolus).
Pea (Pisum) includes: dwarf pea; edible-podded pea; snow pea; sugar snap pea; pigeon pea; soybean, vegetable; sword bean	Any one succulent cultivar of edible-podded pea (Pisum).

Crop Subgroup 6B: Succulent shelled pea and bean subgroup

Representative Commodities: Any succulent shelled cultivar of bean (Phaseolus) and garden pea (Pisum)

SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Bean (Phaseolus) includes: lima bean, green; broad bean, succulent	Any succulent shelled cultivar of bean (Phaseolus).
Bean (Vigna) includes: blackeyed pea; cowpea; southern pea	Any succulent shelled cultivar of bean (Phaseolus).
Pea (Pisum) includes: English pea; garden pea; green pea; pigeon pea	Garden pea (Pisum).

Crop Subgroup 6C: Dried shelled pea and bean, except soybean subgroup

Representative Commodities: Any one dried cultivar of bean (Phaseolus) and any one dried cultivar of pea (Pisum)

SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Dried cultivars of bean (Lupinus)	Any one dried cultivar of bean (Phaseolus).
Bean (Phaseolus) includes: field bean; kidney bean; lima bean, dry; navy bean; pinto bean (Beans-Dry-Great Northern); tepary bean	
Bean (Vigna) includes: adzuki bean; blackeyed pea; catjang; cowpea; crowder pea; moth bean; mung bean; rice bean; southern pea; urd bean	Any one dried cultivar of bean (Phaseolus).
Broad bean, dry	Any one dried cultivar of bean.

Beans-Dry-Pigeon Beans	
Chickpea	Any one dried cultivar of bean or pea.
Guar	Any one dried cultivar of bean.
Lablab bean	Any one dried cultivar of bean.
Beans-Dry-Hyacinth	
Lentil	Any one dried cultivar of pea.
Pea (Pisum) includes field pea	Any one dried cultivar of pea (Pisum).
Pigeon pea	Any one dried cultivar of pea

Crop Subgroup 9A: Melon subgroup

Representative Commodity: Cantaloupe

CROP SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Citron melon	Cantaloupe
Muskmelon	Cantaloupe
Casabas	
Crenshaws	
Melons-Cantaloupe	
Melons-Honeydew	
Melons-Persian	
Winter Melon	
Watermelon	Cantaloupe

Crop Subgroup 9B: Squash/Cucumber subgroup

Representative Commodities: One cultivar of summer squash and cucumber

CROP SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Chayote, fruit	Summer squash
Christophine	
Chinese waxgourd	Cucumber
Cucumber	Cucumber
West Indies Gherkin	Cucumber
Edible Gourd	Summer squash
Okra/Chinese (luffa)	
Momordica spp.	Cucumber
Balsam Pear	
Bitter Melon	
Pumpkin	Summer squash

Summer squash	Summer squash
Winter squash	Summer squash
Spaghetti Squash	

Crop Subgroup 13A: Caneberry (blackberry and raspberry) subgroup

Representative Commodities: Any one blackberry or any one raspberry

CROP SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Blackberry	Blackberry
Boysenberry	
Dewberry	
Youngberry	
Loganberry	Blackberry
Red raspberry	Raspberry
Black raspberry	Raspberry

Crop Subgroup 13B: Bushberry subgroup

Representative Commodity: Blueberry, highbush

CROP SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Blueberry	Blueberry
Currant	Blueberry
Elderberry	Blueberry
Gooseberry	Blueberry
Huckleberry	Blueberry

Crop Subgroup 19A: Herb subgroup

Representative Commodities: Basil, fresh and basil, dried leaves; and chive

SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Angelica	Basil
Balm	Basil
Basil	Basil
Borage	Basil
Burnet	Basil
Camomile	Basil

Catnip	Basil
Chervil, dried leaves	Chive
Chive	Chive
Chive, Chinese	Chive
Cilantro, leaf	Basil
Clary	Basil
Costmary	Basil
Culantro, leaf	Basil
Curry, leaf	Basil
Dillweed	Basil
Horehound	Basil
Hyssop	Basil
Lavender	Basil
Lemongrass	Basil
Lovage, leaves	Basil
Marigold	Basil
Marjoram	Basil
Oregano	
Nasturtium	Basil
Parsley, dried	Basil, dried leaves
Pennyroyal	Basil
Rosemary	Basil
Rue	Basil
Sage	Basil
Savory, summer	Basil
Savory, winter	Basil
Sweet bay	Basil
Tansy	Basil
Tarragon	Basil
Thyme	Basil
Wintergreen	Basil
Woodruff	Basil
Wormwood	Basil

Crop Subgroup 19B: Spice subgroup

Representative Commodities: Black pepper; and celery seed or dill seed

SUBGROUP COMMODITY	REPRESENTATIVE COMMODITY
Allspice	Black pepper
Anise, seed	Dill, seed*
Anise, star	Black pepper
Annatto, seed	Black pepper

Caper buds	Dill, seed*
Caraway, seed	Celery, seed*
Caraway, black	Celery, seed*
Cardamom, seed	Black pepper
Cassia	Black pepper
Celery, seed	Celery, seed*
Cinnamon	Black pepper
Clove	Black pepper
Coriander seed	Dill, seed*
Culantro, seed	Dill, seed*
Cumin	Black pepper
Dill, seed	Dill, seed*
Fennel, seed	Celery, seed*
Fennel, Florence, seed	Celery, seed*
Fenugreek	Black pepper
Grains of paradise	Black pepper
Juniper berry	Black pepper
Lovage, seed	Celery, seed*
Mace	Black pepper
Mustard, seed	Dill, seed*
Nutmeg	Black pepper
Pepper, black	Black pepper
Pepper, white	Black peppper
Poppy , seed	Dill, seed*
Saffron	Black pepper
Vanilla	Black pepper

* In lieu of celery, seed data dill, seed can be substituted and visa versa, as the registrant is free to choose between celery, seed and dill, seed as the representative commodity.