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Minimum Data Requirements for Establishing Maximum Residue Limits (MRLs) including Import Tolerances

Recommendations from the Scientific Workshop held at the Pesticides Safety Directorate, York, UK on 6-8 September 1999

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Background

In March 1998, PSD was awarded a contract by the European Commission to develop guidance for establishing guidelines on the minimum or core data requirements for establishing MRLs, including import tolerances. The work remit was outlined in the proposal presented and agreed by the November 1996 OECD Pesticide Forum. The primary objective was to examine those areas of guidance which represent the greatest obstacles to the establishment of national import tolerances and the acceptance of international MRLs.

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 of import tolerances;

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

The programme was organised as a set of three preparatory meetings held in York (November 1998, January 1999 and April 1999). During these meetings, agreements were reached **at a scientific level** on which areas relating to the setting of MRLs that were most and least harmonised. A workshop held in York in September 1999 was attended by 38 delegates representing Member States (except Greece, Italy and Luxembourg), Commission officials, OECD member country representatives (Australia, Canada, New Zealand, Norway, Republic of Korea, Slovak Republic, Slovenia), OECD secretariat, FAO and GCPF representatives. A list of delegates is given in Annex 1.

The least harmonised areas (approaches to geographical/climatic regions for residue trials (‘zoning’), criteria for determining the minimum number of residue trials and acceptable extrapolation/mutual support of residue trials data between crops) formed the basis of the main presentations and the discussions in the small working groups and the plenary sessions. Other areas which are near harmonisation or where good commonality exists (plant metabolism, farm animal metabolism, farm animal feeding studies, processing studies, the effect of formulation types, residues over different years and glasshouse trials) were the subjects of short presentations and discussion generally in the plenary only.

Reports from the working groups were adopted during the workshop.

Summaries of discussions and recommendations

General

Comparisons of data requirements were carried out to determine where common requirements already existed. The main documents examined were those from FAO, Canada, USA, Australia, New Zealand and the EU [1-6]. These comparisons were used as the basis for discussions.

Where agreement could not be reached or further work is required, this is indicated in italics.

It was recognised that import MRL requirements should be consistent with the national registration requirements so that additional data were not unnecessarily required. It was hoped that the work on minimum data requirements for the setting of international MRLs could be used by national governments for a basis for import MRL data requirements.

The meeting noted the different perspective of Codex/JMPR, which does not have the registration function of national authorities or the economic interests of national governments, and evaluates data on a scientific basis, not taking into account economic matters. Codex/JMPR are able to set a MRL if there is a supported GAP where as governments need to set the MRL on the basis of the critical GAP.

Plant metabolism

A comparison of the data required for assessing metabolism in plants in the different countries showed a high degree of conformity. The minimum requirements were agreed as:

Information required: Identity and quantities of metabolites, and distribution of metabolites (surface, leaves, stems, edible root crops);

Number of studies required: one study for each crop group; extrapolation from 3 studies on different groups to all crops, provided that metabolism is similar;

Crop groupings: root vegetables; leafy crops; fruits; pulses and oilseeds; cereals;

Material used: radiolabelling (C-14, P-32, S-35);

Dosage rate: at least equal to intended use (normally up to a maximum of 10x);

Identification and characterisation: Residues should be characterised and identified if these are > 0.05 mg/kg or > 10% of TRR, characterised if these are between 0.01 and 0.05 mg/kg, normally neither characterised nor identified if these are < 0.01 mg/kg, in the case of unextractable residues neither characterised nor identified if these are < 0.05 mg/kg or < 25% TRR and a significant portion (> 75%) has been identified.

Residue definition: The “marker compound concept” should be used for enforcement and “toxicological relevant compounds” should be used for risk assessment.

These recommendations concur with the requirements laid down in the FAO manual [(1)].

Farm animal metabolism

The requirements for metabolism studies in farm animals are an area where good commonality exists. The differences between the data requirements in several OECD countries and the FAO manual were small.

Circumstances when studies required: when significant residues remain in crops or commodities used in animal feed, in forage crops or in any plant parts used in animal feed.

A definitive conclusion on when studies were required was not reached. It was noted that the trigger value expressed in terms of mg/kg feed on a dry matter basis would lead to a study being required in almost all circumstances especially where a low percentage dry matter commodity was being considered. It was recommended that a trigger value based on an animal intake per kg bw would be more appropriate but further work would be required to define these levels.

Species: ruminants (normally lactating goats, lactating cows acceptable) and poultry (chickens). Studies using pigs to be conducted if metabolism in rat is different from that of goat and/or chicken.

Duration of dosing: dosed daily for at least 3 consecutive days.

Information required: Milk, eggs, meat, liver, kidney (ruminants and pigs only) and fat should be collected. Residues should be characterised and identified if these are > 0.05 mg/kg or > 10% of TRR, characterised if these are between 0.01 and 0.05 mg/kg, normally neither characterised nor identified if these are < 0.01 mg/kg, in the case of unextractable residues neither characterised nor identified if these are < 0.05 mg/kg or < 25% TRR and a significant portion (> 75%) has been identified.

It was recommended that it was not necessary to analyse excreta in animal metabolism studies however it was noted that this may be important from an environmental perspective and if metabolism appears to be different in the rat.

Dose rate: at the level of expected exposure but in practice not normally lower then 10 mg/kg.

Material used: Normally parent compound should be used. In cases where parent compound is not detected in plant metabolism studies, the main plant metabolite(s) should be used. Where plant and animal metabolism differ, a study with a unique plant metabolite may be required if this unique plant metabolite is of toxicological significance.

Farm animal feeding studies

The requirements for livestock feeding studies are an area where good commonality exists. The differences between the data requirements in several OECD countries and the FAO manual are small.

Further work was considered necessary to harmonise an animal feed component table for calculation theoretical dietary burdens by animals. Consideration should be given to not including crops that do not contribute regularly to animal feedingstuffs.

Circumstances when studies required: when significant residues occur in crops or commodities fed to animals and livestock metabolism studies indicate that significant residues (above the LOQ) may occur in edible tissues. Potential for bioaccumulation should also be considered.

A definitive conclusion on when studies were required was not reached. It was noted that the trigger value expressed in terms of mg/kg feed on a dry matter basis would lead to a study being required in almost all circumstances especially where a low dry matter commodity was being considered. It was recommended that a trigger value based on an animal intake per kg bw would be more appropriate but further work would be required to define these levels.

Species: ruminants (normally lactating cows) and poultry (chickens). Trials with pigs are only required if metabolism differs significantly in the pig as compared to ruminants. Only those species where intake is significant should be studied.

Number of animals and duration of dosing: A minimum of 3 dairy cows and of 10 chickens should be dosed for at least 28 days or until plateau is reached in milk or eggs.

Information required: meat, fat, liver, kidney (ruminants and pigs only), milk and eggs should be collected and analysed.

Dose rate: use three dose groups (level of expected exposure (1X), 3 to 5 times the level of expected exposure (3-5X), 10 times the level of expected exposure (10X)) and control group.

Material used: usually parent compound. In cases where parent compound is not found in plant metabolism studies, the main plant metabolite(s) should be used. Where plant and animal metabolism differ, a study with a unique plant metabolite may be required if this unique plant metabolite is of toxicological significance.

It was noted that for lipophilic compounds, variable residues can occur in different fat depots and it was considered important to take this into account when taking fat samples.

Processing studies

The need for processing studies has become more important since changes in guidelines for predicting dietary exposure have indicated that adjustments for processing should be taken into account at the first stage of the NEDI or IEDI

calculations. In some cases, they are also taken into account for setting MRLs in traded, processed commodities such as oils. It was considered that current guidelines necessitate the generation of too many studies from too many crops/commodities. The requirements for processing studies is an area where less harmonisation of requirements exists. The USA uses standard concentration factors for some processes but it was unclear how these were derived.

It was agreed that there was a necessity to know the nature of the residue in processed commodities. Generally, data should be requested where residues in the raw agricultural commodity exceed 0.1 mg/kg. However, consideration should be given to the processes involved: where these do not involve heating and/or change of pH, assessment of the nature of the residue may not be required.

For some crops and commodities such as hops and beer, residue levels may be predictable by the use of dilution factors.

Data on the transfer of residues into processed commodities are required where residues exceed 0.1 mg/kg and the intakes based on the individual NEDI (STMR x consumption/body weight) for any one crop exceeds 10% of the ADI or the total NEDI exceeds 100% of the ADI.

A minimum of 2 studies/commodity would be required.

The recommendations for the minimum requirements were as shown in table 1.

Table 1 Minimum requirements for processing studies

Major crops	**Processed food**	**Extrapolation**
apple	peel, juice, wet and dried pomace	pome fruit
apricot/peach	preserves (jam, dried)	stone fruit
grape	juice, wine	soft fruit and berries
citrus*	peel, pulp, juice, dried	
sub tropical fruits*	peel, pulp, dried	
wheat	flour, bran, bread	rye, maize, sorghum, oats
rice	polished, flour	
carrot	peel, juice, preserved	others tubers, peel
tomato	juice, preserved	other vegetables
peas, beans	without pod	
oilseed**	meal, oil	all other oilseeds
olive**	virgin oil	
tea	brewed tea	

* studies not required where no detectable residues in pulp
** take account of fat solubility of residue

The need for studies on sugar beet was questioned. Whilst this would give useful information, it was considered that efforts should be concentrated on minimum requirements.

The effect of formulation type

Data were presented comparing residue levels from trials on identical plots and crops using different formulations. It was agreed that different formulations are equivalent in terms of residues if they are used in the same way, for example as a high volume foliar spray. Aerially applied and ground applied low-volume treatments were considered equivalent for residue purposes. Aerially applied ULV may not be the same as ground applied ULV. If the change in formulation leads to a changed application technique (e.g. from foliar to soil applied granular) then it should be decided on the basis of available information (e.g. bridging trials) whether residues would be lower or higher than the previously accepted use. If residues are higher, a full data package is required. Case-by-case decisions will be necessary. For example, in moving from foliar sprays to soil applied granular treatments, root vegetables are the crops likely to produce higher residues and should be examined first. It was agreed that it was not possible to extrapolate other formulation residue data to support the use of slow-release formulations, which will need bridging data as a minimum requirement.

Residues trials carried out over different years

Comparisons of residue levels from different years indicated that this did not significantly affect the ranges seen. If trials covered a range of geographic locations, data from more than one season would not be required.

Glasshouse trials

It was agreed that protected crops (glasshouse, plastic tunnel where the environmental conditions can be controlled) should be treated as a single zone for Europe. Since this is predominantly a European practice, little data are available to show that this was true for the rest of the world. Cultural conditions were essentially optimised to suit the protected crop and it should be possible with further work (comparison of crop/growing conditions) to consider whether glasshouses could be considered as a single zone on a world-wide basis.

Post-harvest treatments

Post-harvest treatments were considered as a "single zone" for the purposes of decisions on numbers of trials.

Post-harvest treatments on cereals should generally produce a homogeneous and predictable residue. Where the residue is persistent or where the required storage interval is small, the MRL may be set at the application rate without residue trials data. However, it is should be noted that processing studies with incurred residues were likely to be necessary as a result of post-harvest treatments.

Post-harvest treatments on potatoes should also produce a predictable residue, but much less homogeneous than for cereals and trials will be required. Post-harvest spraying or dipping of fruits and vegetables produces a less predictable residue, but possibly more homogeneous than for potatoes and trials will be required.

The trials requirements for post-harvest treatments except where the residue is predictable and homogeneous (cereals) were agreed and are shown in table 2.

Table 2 The trials requirements for post-harvest treatments except where the residue is predictable and homogeneous

	Insignificant in diet	**Significant in diet**
Insignificant in trade	3	6
Significant in trade	6	8

Significance of commodities in the diet

0.5% of the total diet was agreed as the trigger value to differentiate between significant and non-significant in the diet. The 'diet' is the relevant WHO Regional Diet (currently 5 diets; mean consumption for the whole population).

Significance in trade

A definition of significant in trade was not agreed. This was primarily due to the lack of availability of useable statistics. Economic indicators for crop importance were discussed and it was agreed that the most convenient would be the % of cultivation area per relevant zone. This factor was chosen because it is less likely to fluctuate, compared to factors such as tonnage of production. No information was available to choose a suitable trigger value; 0.5% was suggested but the value should only be finalised after checking to see what value differentiates major crops from others. It was noted that % cultivation area was probably not a good indicator for glasshouse production.

More work is required to define crops significant/insignificant in trade.

Minimum residue trial requirements

The report from the working group is given in Annex 2. The main recommendations were:

- the absolute minimum number of trials required should be 3;
- the minimum number of trials required would depend on the significance of the crop in the diet and in trade and also the number of zones where GAP exists; this would range from 3 to 16;
- decline studies are only required in those situations where the pesticide is applied late in the season and when the final crop commodity to be harvested has formed and developed into its final form;
- single composite samples are adequate for supervised trials;
- zero residues may be predicted in some cases from crop metabolism studies and the physico-chemical properties of the pesticide. In such situations, 3 trials are required for commodities significant in the diet and no trials are required for commodities insignificant in the diet.

Extrapolation

The report from the working group is given in Annex 3. The main recommendations were:

- it was agreed that the ± 25% rule could be used when comparing GAPs;
- the primary crops within a group/subgroup must have a robust database prior to an extrapolation or group tolerance being considered;
- the main criterion for extrapolation when the edible part of the crop had started to form was crop morphology;
- *consideration was given to the definition of comparability when differences are seen in the residue profile of the main crops within a group. No agreement could be reached in setting an appropriate factor;*
- for tropical and subtropical fruit GAPs, morphology and cultural practices for these crops are so dissimilar that it makes extrapolation difficult;
- no recommendations were made for feed items since there are very few in international trade. However, for the purpose of MRL setting for products of animal origin, animal feed crops and fodder are important and residues data are required.

Leafy vegetables were not considered. Further work is required to define acceptable extrapolations for this group.

The possibility of increasing recommendations for group tolerances was examined. It was noted that the main obstacle was often incompatible GAPs within the group. It was also noted that if groups were too large, difficulties may arise in estimating realistic levels of consumer exposure.

The meeting noted that it had only been possible to recommend a limited number of extrapolations for minor crops.

Zoning

The report from the working group is given in Annex 4. Whilst the benefits of using the concept of zoning were acknowledged, specific recommendations could not be made. However, the benefits, beneficiaries, key parameters for defining zones and a proposal for developing a global zoning concept were proposed.

Further work will be required before a global zoning concept can be developed.

Conclusions

A set of positive recommendations was made as a result of comparing and contrasting global data requirements. A high degree of similarity of requirements for plant and farm animal metabolism and farm animal residue studies was noted. Recommendations for a reduced set of core data for predicting the transfer of residues into processed products were made. Situations were identified where extrapolations could be made for foliar applied sprays using different formulation type. It was agreed that residues data were only required from one seasons studies where data covered a range of geographic locations. Glasshouses in Europe and post-harvest treatments were considered single zones. Where crops treated post-harvest give rise

to homogenous and predictable residues, residues data would not be required. Recommendations were made for developing a global zoning concept. Recommendations on the minimum number of residues trials and extrapolations were developed. These reduce requirements both nationally and internationally without affecting the reliability of the data sets.

Acknowledgements

The authors of this report gratefully acknowledge the contributions made by attendees and those preparing working papers for the preparatory meetings and workshop. The efforts of the chairs and rapporteurs in the Workshop are also gratefully acknowledged.

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Abbreviations/Glossary of terms

ADI	Acceptable daily intake
CCPR	Codex Committee on Pesticide Residues
EC	European Commission
EU	European Union
FAO	Food and Agriculture Organisation
GAPs	Good Agricultural Practice
GATT	General Agreement on Tariffs and Trade
GCPF	Global Crop Protection Federation
GIS	Geographic Information Systems
IEDI	international estimate of dietary intake
JMPR	Joint Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	Maximum Residue Limit
NAFTA	North American Free Trade Association
NEDI	national estimate of dietary intake
OECD	Organisation for the Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
PSD	Pesticides Safety Directorate

SPS Agreement	Sanitary and Phyto-sanitary agreement
STMR	supervised trials median residue
TRR	total radioactive residue
UK	United Kingdom
ULV	ultra low volume
UN	United Nations
USA	United States of America
WHO	World Health Organisation
WTO	World Trade Organisation

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Annex 2 Report from the Working Group on Minimum Residue Trial Requirements

The Working Group first agreed on a set of headings to cover the topic and then discussed each in turn and made recommendations.

Scientific basis for the required number of trials
The Working Group agreed that importance of a commodity in the diet was a scientific basis for influencing the required number of residue trials.

The importance of the commodity in trade was also discussed as influencing the required number of trials. Indicators of importance could be its area of production or area to be treated with the product, the tonnage produced or the monetary value of the trade.

The importance in trade is more of an economic basis than a scientific basis for the minimum number of residue trials, but is a legitimate concern of national governments. Some crops products such as processed animal feed, hop extract and sugar are minor in the diet but are major in trade.

The Working Group noted the different perspective of Codex/JMPR, which does not have the registration function of national authorities or the economic interests of national governments, and evaluates data on a scientific basis, not taking into account economic matters. Codex/JMPR are able to set a MRL if there is a supported GAP where as governments need to set the MRL on the basis of the critical GAP.

Trigger values
The Working Group chose 0.5% of the total diet as the trigger value to differentiate between significant and non-significant in the diet. The diet is the relevant WHO Regional Diet (currently 5 diets) which are the mean consumption for the whole population.

The Working Group discussed the economic indicators for crop importance and decided that the most convenient would be the % of cultivation area per relevant zone. This factor was chosen because it is less likely to fluctuate, compared to factors such as tonnage of production. No information was available to the Group to choose a suitable trigger value; 0.5% was suggested but the value should only be finalised after checking to see what value differentiates major crops from others. It was noted that % cultivation area was probably not a good indicator for glasshouse production.

Absolute minimum number of trials
The Working Group agreed that the absolute minimum number of required trials was 3. This requirement should be kept as low as possible to minimise the number of "minor crop" situations where it is uneconomic to produce the trials data.

Range of number of trials
The Working Group incorporated significance in diet, significance in trade and the geographic zone concept into a matrix of required number of trials. In this case the GAP in the different zones is the same.

Required residue trials
The minimum number of residue trials required was as shown in table 3.

Table 3 Minimum residue trials requirements

	Number of zones where GAP exists	**Insignificant in diet**	**Significant in diet**
Insignificant in trade	1 zone	3	6
	2-3 zones	4	8
	> 3 zones	5	10
Significant in trade	1 zone	6	8
	2-3 zones	8	12
	> 3 zones	10	16

Significance in diet and trade: see *Trigger values*.
If the GAP is significantly different from one zone to another, a full package may be required by the national authority for the maximum GAP situation.

Number of seasons necessary
The aim is to cover the range of possible production conditions occurring in practice. More than one year's trials are unnecessary if the aim can be realised by distributing trials in different zones, in the one zone at different locations with a possibility of different conditions, early season and late season variation and different growing seasons within the one year where this is possible.

Number of sampling occasions during residue trials
The Working Group broadened the scope of the original "decline trials" topic to take into account all the situations where sampling is needed on more than one occasion during a residue trial:

(a) *decline studies* – 4 sampling intervals, i.e. 5 samples.
Decline information (residue depletion half-life) is needed in residue evaluation to decide on the range of trial PHIs acceptably close to GAP PHI and to assist in determining the influence of numbers of applications on the final residue.

Decline studies are only required in those situations where the pesticide is applied late in the season and when the final crop commodity to be harvested has formed and developed into its final form.

The Working Group agreed that, in these situations, the number of trials required as decline trials would be 1, 2 or 3 as shown in table 4. Decline trials are required only in defined situations.

Table 4 Residue trials showing required totals and numbers of decline trials in brackets

	Number of zones where GAP exists	**Insignificant in diet**	**Significant in diet**
Insignificant in trade	1 zone	3 (1)	6 (2)
	2-3 zones	4 (1)	8 (2)
	> 3 zones	5 (1)	10 (3)
Significant in trade	1 zone	6 (2)	8 (2)
	2-3 zones	8 (2)	12 (3)
	> 3 zones	10 (3)	16 (3)

(b) forage commodities where immature crops are taken for feed – usually 2 samples during the growing of cereals and other field crops to provide information on residues when they are likely to be consumed by farm animals grazing the crop.

(c) *systemic pesticides* - tracing build-up and dissipation of systemic pesticides in the commodity resulting from soil or foliar treatment. Examples are translocation of a soil-applied pesticide to fruits and translocation of a foliar applied pesticide to peanuts. Information on the timing of residue build-up and decline is needed for proper MRL evaluation. Plant and soil metabolism studies should be examined to decide on the necessary sampling strategy in the residue trials, but the number of sampling occasions should be adequate to define the time when residues reach a maximum in the commodity.

The Working Group agreed that the number of such studies required for systemic pesticides used in the circumstances described is the same as defined for decline studies.

Necessity of replicates or multiple composite samples from an individual trial site
The Working Group agreed that single samples are adequate for supervised residue trials. However, the variation between replicate field composite samples from a trial may be used as an aid to defining unit-to-unit variation, where unit-to-unit variation information is needed for the purposes of acute dietary intake assessment.

Number of trials in the case of changes in formulation
The Working Group agreed that different formulations are equivalent in terms of residues if they are used in the same way, for example as a high volume foliar spray. Aerially applied and ground applied low-volume treatments were considered equivalent for residue purposes. Aerially applied ULV may not be the same as ground applied ULV.

If the change in formulation leads to a changed application technique (e.g. from foliar to soil applied granular), then we should decide on the basis of available information (e.g. bridging trials) if residues are lower or higher than the previously accepted use. If residues are higher, a full data package is required.

Case-by-case decisions will be necessary. For example, in moving from foliar sprays to soil applied granular treatments, root vegetables are the crops anticipated to perhaps produce higher residues and should be examined first.

The Working Group agreed that it is not possible to extrapolate other formulation residue data to support the use of slow-release formulations, which will need a full data package.

Number of trials in the case of a zero residue situation
Zero residues may be predicted in some cases from crop metabolism studies and the physico-chemical properties of the pesticide. Examples are:

- seed treatments where metabolism data show that no translocation occurs;
- early applications where plant metabolism data show rapid decline of residues with no residues at harvest;
- edible portion is not present at time of application and no translocation of residues into edible portion occurs.

The Working Group noted examples where residues were predicted not to occur from metabolism studies but still may occur because of the methods of production or harvesting. Residues of a non-translocated foliar applied pesticide may occasionally occur in potatoes because part of a potato may be exposed to the direct spray. Pesticide may be physically transferred from the outside of tree-nut shells to the kernels during the cracking process and similarly from the pods of peas to the peas themselves during shelling.

The Working Group agreed that 3 trials are needed for commodities significant in the diet and no trials are needed for commodities insignificant in the diet.

Number of trials where residues are below LOQ
This situation is distinguished from the zero residue situation in that residues are expected to be present but at levels too low for the analytical method. For example, the residues may be seen to decline below the LOQ by the time of harvest, or exaggerated application rates produce detectable residues.

The Working Group noted that it was difficult to know that residues would be below LOQ until the full data set was produced. However, if the situation was found to apply to a major crop it would assist in ready extrapolation to the group, i.e. relaxing requirements on subsequent commodities within the group. In general where it is an LOQ situation much broader extrapolations should be possible.

Number of trials necessary for group tolerances
Full data packages for two representative crops would be required before a group tolerance could be established. Precedence should be given to the recommendations from the extrapolation group.

Number of trials in the case of protected crops
The Working Group agreed that protected crops (glasshouse, plastic tunnel with controlled environmental conditions) should be treated as a single zone for Europe but there were no data available to show that this was true for the rest of the world. Conditions are essentially optimised to suit the protected crop and it should be possible with further work to define this as one zone for the world. When a pesticide has both a field use and a glasshouse use, a full data package is needed for the critical GAP. Examples where the glasshouse use is clearly the critical GAP are for relatively volatile pesticides and those subject to photolytic breakdown as the main degradation pathway.

Required residue trials for protected crops
The Working Group agreed that for protected crops, the minimum number of trials required would be 1 as shown in table 5. Decline trials are required only in defined situations.

Table 5 Minimum number of trials required for protected crops

	Insignificant in diet	**Significant in diet**
Insignificant in trade	3	6
Significant in trade	6	8

Significance in trade is defined as the significance of the whole crop (field + protected) in the region with the official glasshouse GAP. See "trigger values" for discussion on significance of crops.

Number of trials in the case of post-harvest treatments
The Working Group considered post-harvest treatments as a "single zone" for the purposes of decisions on numbers of trials.

Post-harvest treatments on cereals should generally produce a homogeneous and predictable residue. Where the residue is persistent or where the required storage interval is small the MRL may be set at the application rate without residue trials. The Working Group drew attention to the requirement for processing studies on aged residues, not to be confused with the treatment and storage of the raw commodity. It is likely however, that trials will be required to produce aged residues for use in processing studies.

Post-harvest treatments on potatoes should also produce a predictable residue, but much less homogeneous than for cereals and trials will be required.

Post-harvest spraying or dipping of fruits and vegetables produces a less predictable residue, but possibly more homogeneous than for potatoes and trials will be required.

The Working group agreed on the trials requirements for post-harvest treatments except where the residue is predictable and homogeneous (cereals) as shown in table 6.

Table 6 Minimum residues trials requirements for post-harvest treatments

	Insignificant in diet	**Significant in diet**
Insignificant in trade	3	6
Significant in trade	6	8

Significance in trade is defined as the significance of the crop in the region with the official post-harvest GAP. See "trigger values" for discussion on significance of crops.

Residue data not conforming with GAP

Residue data not conforming to GAP may be directly used under some circumstances. In the nil residue situation data from trials may be used to support a GAP where:

- application rates in the trials exceed the GAP rate;
- PHIs in the trials are less than the GAP PHI and residues are expected to decline with time;
- the numbers of treatments in the trials exceeds the maximum number specified by GAP.

Trials on the isomeric mixture of a pesticide should support the GAP for a single isomer, where it may be predicted that the residues of the single isomer will be proportional to the isomeric mixture, taking into account the residue definition or expression of residue.

Annex 3 **Report from the Working Group on Extrapolations**

Introduction

The group decided to accept the recommendations of the third preliminary meeting as a starting point for their discussions. The following items were discussed:

- pre-requisite for extrapolation (comparability of GAP);
- tabulating extrapolation when edible crop part has started to form;
- special attention was made to the tropical sub-tropical group;
- tabulating of post harvest extrapolations;
- considerations of extrapolation for animal feed items.

The tables should be considered as a starting point for extrapolations, which can be added to in the future.

Discussion and agreement on major points

It was agreed that the ± 25% rule could be used when comparing GAPs. This can be applied to either the application rate or the number of applications. To consider the affects of changing the pre harvest interval, decline curves should be utilised. Deviations from this rule can be considered on a case by case basis.

The group considered that extrapolation could be made between different formulation types such that all formulations (except encapsulated products) that are used as a spray will lead to comparable residues.

The primary crops within a group/subgroup must have a robust database prior to an extrapolation or group tolerance being considered. This was defined as having both quantitatively and qualitatively enough data at the GAP to set a MRL for the primary crop(s) in its own right.

It was agreed that the main criterion for extrapolation when the edible part of the crop has started to form was crop morphology. But it was also agreed that other parameters such as the physical and chemical properties of the active substance could be of importance.

The Codex crop groupings were used as a starting point and modified where necessary. Only the crops considered significant in international trade were included in the list. In addition to this their importance in the diet was also considered.

Consideration was given to the definition of comparability when differences are seen in the residue profile of the main crops within a group. No agreement could be reached to set a factor.

When the group considered the tropical and subtropical fruit it became clear that the GAPs, morphology and cultural practices for these crops are so dissimilar that it makes extrapolation difficult. The group also considered extrapolation into this group from other fruit and vegetable categories but again this was difficult due to GAP, morphology and cultural practice differences and of course climatic conditions.

For feed items the group considered that there were very few in international trade. However, for the purpose of MRL setting for products of animal origin feed animal feed crops and fodder are important and residues data are required. No recommendations were made by the group.

Leafy vegetables were not considered due to time constraints.

Table 7 Commodity groups and proposal for extrapolations and group tolerances for applications after the consumable part of the crop has started to form.

Commodity	Group tolerance	Other extrapolations
Citrus		
Oranges *Grapefruits* Lemons Limes *Mandarins* (including clementines and similar hybrids) Others	Oranges/grapefruit and mandarins/lemons to the whole citrus group on a case by case basis. The commodities were picked to cover the large and the small fruit in the group.	Oranges to grapefruit. Mandarins to limes, lemons, clementines. Again these extrapolations are based on fruit size.
Pome fruit		
Apples *Pears* Quinces Crab apples Medlars Nashi Others	Apples and pears up to 50 % of the trials can be on pear. The justification for this is that apple and pears are by far the major commodities in trade and in the diet.	Apples and pears to whole group
Stone fruit		
Peaches *Apricots* *Plums* Nectarine (and similar hybrids) Cherries* Others	Peach or apricot or plum with a minimum of 50 % peach trials. 'Group' tolerance for peach, apricot, nectarine and plum.	
Berries and small fruit		
*Strawberry**	Data on strawberry will be required, as there are no other crops with a similar morphology.	
*Grapes**		Wine grapes to and from table grapes
Cane fruit *Blackberry* Loganberries *Raspberries*	Any *Rubus* spp. to any other *Rubus* spp.	

Table 7 continued

Commodity	Group tolerance	Other extrapolations
Other small fruit Bilberries Cranberries *Currants* *Blueberries*	Currants or blueberry to the crops listed.	-
Cereals		
Wheat *Barley* Rye Oats Triticale	Wheat and barley, at least 50 % barley but no more than 70 %. To wheat, barley, rye, oats and triticale.	
Millet *Sorghum* Rice* Maize*	-	Sorghum to millet.
Oilseeds		
Oilseed rape (canola) Linseed Poppy* Sesame* Sunflower Cotton* Mustard Safflower Peanut*	-	Oilseed rape to mustard and linseed. Sunflower to safflower.
Bulb vegetables		
Fennel Garlic Leek Bulb onion Shallot Spring onion		Bulb onions to garlic and shallots. Leek to spring onion.

Table 7 continued

Commodity	Group tolerance	Other extrapolations
Fruiting vegetables		
Solanacea		
Peppers (sweet and chilli) Aubergine Okra *Tomato* (including cherry tomatoes)		Tomato and peppers to aubergine or okra. If chilli pepper or cherry tomatoes consideration should be given to possible residues, due to the difference in surface area to weight ratio.
Sweetcorn		Immature maize to sweetcorn.
Cucurbits edible peel		
Cucumber *Courgette (zucchini)* Gherkin Summer squash Others	Cucumber and courgette with a minimum of 50 % cucumber trials to the group.	
Cucurbits inedible peel		
Melons Watermelon Winter squash Pumpkins Others	Melon to the group.	
Pulses		
Beans *Peas* Lentils Soyabean*	Beans and/or peas to the group (excluding soyabean).	
Legume vegetables		
Pea (with pod) Pea (without pod) Bean (with pod) Bean (without pod)	Peas and beans to the group	Pea (with pod) to and from bean (with pod) Pea (without pod) to and from bean (without pod)

Table 7 continued

Commodity	Group tolerance	Other extrapolations
Root and tuber vegetables		
Beetroot Carrot Cassava Celeriac *Potato* Radish Sweet potato Yams	Carrot and potato to the group.	
Tropical and sub-tropical fruit		
Edible peel		
Carambola* Date* Fig* Kumquats* Olives* Persimmon*		
Inedible peel		
Avocado Banana* Cherimoya* Durian* Guava* Kiwifruit* Litchi* Tamarillo* Mango Papaya* Passion fruit* Pineapple* Pomegranate*		Avocado to mango *It was considered that there could be no extrapolation to these crops.

i) The major crops in each group are in Italics.
ii) * = crops where there are no extrapolations.
iii) When ‘or’ is used in the tables it means that the data can be provided on either of the crops in any proportion unless otherwise stated.
iv) ‘Others ‘ refers to unlisted crops in the Codex crop group. The ‘Others’ category has been included where possible.

Table 8 Extrapolations and group tolerances for post harvest applications.

Commodity	Group tolerance	Other extrapolations
Citrus		
Oranges Grapefruit Lemons Limes *Mandarins* (including clementines and similar hybrids) Others	Oranges, mandarins or lemons to the whole group. At least 50 % of the trials should be on smaller fruits.	
Pome fruit		
Apples Pears Quinces Crab apple Medlar Nashi Others	Apples to the whole group.	-
Stone fruit		No extrapolation necessary since post harvest treatment is only applicable to peaches.
Berries and small fruit		Not applicable.
Cereals		
Wheat Barley Rye Oats Triticale Millet *Sorghum* Rice (unpolished) Maize Others	Any one commodity to the group.	
Oilseeds		Not applicable
Bulb vegetables		Not applicable
Fruiting vegetables		Not applicable
Pulses		
Beans *Peas* Lentils Soyabean	Beans or peas to the group.	

Table 8 continued

Commodity	Group tolerance	Other extrapolations
Legume vegetables		Not applicable
Root and tuber vegetables		Not applicable
Tropical and sub-tropical fruit		
Edible peel		
Carambola Date Fig Kumquats Olives Persimmon		Extrapolations may be made on a case by case basis and will mainly depend on the surface area to weight ratio of the fruit.
Inedible peel		
Avocado Banana Cherimoya Durian Guava Kiwifruit Litchi Mango Tamarillo Papaya Passion fruit Pineapple Pomegranate		Extrapolations may be made on a case by case basis and will mainly depend on the surface area to weight ratio of the fruit.
Nuts	From one type of nuts to all others except coconut. The justification for this was that it will be the nature of the commodity (i.e. high oil content) that will influence the residue and not the individual commodity.	

Table 8 continued

Commodity	Group tolerance	Other extrapolations
Dried fruit	Dried fruit to other dried fruit. It was considered that the moisture content of dried fruit was important. It was concluded that the fruit that will be treated would normally have the same moisture content. If the moisture content is very low then treatment would be unnecessary anyway.	

i) The major crops in each group are in Italics.
ii) When ‘or’ is used in the tables it means that the data can be provided on either of the crops in any proportion unless otherwise stated.
iii) ‘Others ‘ refers to unlisted crops in the Codex crop group. The ‘Others’ category has been included where possible.

Annex 4 **Report from the geographic zoning working group**

Introduction

The Working Group considered the utility and possible approaches to mapping the world into geographic zones within which pesticide residue behaviour would be expected to be comparable. This would allow the scientific comparison of data from residue trials within a particular zone to be considered equivalent and could support GAP for any country or region containing the same zone. This should help in assessing data in support of the establishment of MRLs and import tolerances.

When considering the reports of the Preliminary Meetings, the group noted that this zoning concept was already operating in a number of countries, either on a formal basis (e.g. NAFTA, EU) or more informally at an operational level (e.g. Australia, New Zealand), and that the opportunity existed to extend and harmonise these approaches into a single global zoning system.

In discussing possible approaches to zoning, the group noted the points made at the Preliminary Meetings:

- on the importance of climatic data (with other relevant data also being taken into account);
- that the use of the powerful GIS technique may not be strictly necessary;
- the need to keep the number of zones to a minimum necessary for the purposes of residue trial comparability.

Benefits

The group supported the zoning concept as a means of:

- promoting mutual acceptance of residue data from trials conducted within a particular zone;
- improving confidence in the supporting data reflecting potential residues in food, and thus the enhancement of food safety assurances based on these data;
- reducing the duplication of data on a world-wide basis (fewer trials required);
- facilitating international trade by supporting the establishment of Import Tolerances based on data developed anywhere within the same zone;
- increasing the opportunity to establish MRLs for minor crops by accepting data from the same zone that has been produced in a different part of the world;
- providing an incentive for manufacturers to develop (where possible) a common GAP for all countries within a particular zone and to generate a single supporting data package for all of these countries.

Beneficiaries
The working group agreed that the proposed zoning scheme would have advantages for:

- Manufacturers: potential for fewer trials world-wide; more rapid approvals through the mutual use of regulatory reviews; opportunity for a greater number of uses across a wider geographic area;
- Producers: greater range of pesticides available, particularly for minor crops; more rapid access to pesticides as a result of more rapid approvals; enhanced trade opportunities arising from more Import Tolerances being granted;
- Regulators: improved confidence that the supporting data are more representative; greater opportunity to accept regulatory reviews from other countries and thus more efficient assessments;
- Consumers: improved confidence in the scientific assessments underlying the establishment of MRLs;
- International Organisations: greater acceptance of Codex MRLs by national authorities because of increased confidence in the supporting global data set; increased number of MRLs, particularly for minor crops.

Approach
The Working Group considered a number of approaches towards designing global zone maps. These included the simple overlaying of publicly available maps as well as the complex computerised GIS system.

Key Parameters for Defining Zones
The Working Group considered the key parameters worthy of consideration in defining geographic zones with equivalent biophysical conditions relevant to the residue behaviour. It agreed that climate (predominantly rainfall, sunshine and temperature), altitude and to a lesser extent soil characteristics should be the major components to be investigated, and that crop distribution data would be of benefit in confirming or refining the boundaries between the different zones.

Proposal for developing the global zoning concept
Proposed approach
The Working Group suggested that to develop a global zoning system, the following steps would be necessary:

1. identify and collect available national and/or global data on the 'key' parameters used in the NAFTA approach. Data gaps should be identified;
2. develop a preliminary set of global geographic zones using the NAFTA approach to the extent possible. Identify those zones/areas where the full data sets are not available;
3. assess the relative importance/impact of the various data sets used in determining the different zones.

Rationale: It is anticipated that not all the data sets will be available globally. It would therefore be useful to know the relative importance/impact of the different data

sets in determining the zones, and whether a simpler approach, using fewer parameters would be acceptable.

4. Compare the results of Steps 2 and 3 with the other existing zoning schemes already in operation (e.g. EU, Australia, New Zealand), i.e. the number and location of zones, and refine the approach as necessary.

Rationale: The Working Group recognised the need for the zoning approach to be as simple as possible but as complex as necessary, such that the total number of zones are kept to the minimum needed for the purpose of residue trial comparability. It was considered that a system that resulted in more than 20-30 zones world-wide would not be acceptable. Difficulties would also arise if a system identified many more zones in a particular country or region than those already in use. For example, the EU currently use 2 zones, and the introduction of many more would not be practicable.

5. Conduct a verification study of the proposed zoning approach developed in Step 4 by comparing residue trial data summaries for a selection (e.g. 6?) of pesticide/commodity combinations. This would involve a comparison of (1) residue data from trials conducted within the same zone, but at different locations around the world, and (2) residue data from trials conducted in different zones. JMPR Monographs and/or manufacturers' registration submissions could be used in this study.

Rationale: It was agreed that the zones should be selected such that the anticipated variation in residue levels between zones is likely to be significant relative to factors affecting the variation in residue levels within a zone.

6. From the outcome of Step 5, revise the proposed approach as necessary.

   Propose a global zoning system for approval and use by interested parties (e.g. OECD, EC, JMPR, Codex, NAFTA countries).

7. Review the approach in 5-10 years time by conducting a further verification study based on all data available which should be considerably more than that available during the earlier verification described in Step 5. At this time, modifications to the zone map could be considered.

Rationale: The group agreed that continued support for the zoning system at the national and international level would depend on verification of the approach, and considered that an ongoing verification would be an integral part of the development process.

Proposed mechanism

It is proposed that the development of the global zoning system be done as a joint activity of OECD and FAO.

It is proposed that an OECD/FAO Steering Group be established to manage the development of the system. The Steering Group should include representatives from

interested countries, relevant international organisations and industry. For the outcome of the project to be widely accepted and applied, the involvement of key players from an early stage is vital. However, the Steering Group should not be too large (e.g. 10-15 persons maximum).

The Steering Group should include people with policy and/or technical expertise in pesticide registration, cropping systems and in MRL setting. Since much of the work, particularly in the early phases, will be of a very technical nature (i.e. GIS, mapping, agronomy etc.), it will be necessary for the Steering Group to identify and use additional expertise (e.g. consultants).

The Steering Group would report on progress to OECD, EC, JMPR, and Codex.

Constraints
The group recognised that the development and adoption of the zone concept has significant resource implications, particularly in the collection and analysis of the biophysical data underpinning the delineation of the various zones and may take a number of years.

Special Factors
The working group agreed there could be a number of instances where the use of the proposed geographic zoning system may not be appropriate. Examples included:

- greenhouse/protected crops ;
- post-harvest treatments;
- seed treatments (non-systemic);
- very close-to-harvest treatments;
- pre-harvest desiccation.

Related activities
The Working Group recommended that any further work in this area should take account of other environmental data gathering initiatives involving collection of similar data e.g. EUROSEISMIC, contractor. This should avoid duplication of effort and reduce costs.