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Guidance Document on Crop Field Trials



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FOREWORD

This Guidance Document has been developed by the Residue Chemistry Expert Group of the OECD Working Group on Pesticides.

Crop Field Trials (also referred to as supervised field trials) are conducted to determine the magnitude of the pesticide residue in or on raw agricultural commodities, including feed items, and should be designed to reflect pesticide use patterns that lead to the highest possible residues. While the *OECD Guideline for the Testing of Chemicals on Crop Field Trial* (TG 509 published in September 2009) provides a harmonized approach to conducting and reporting crop field trials in OECD countries, this *Guidance Document on Crop Field Trials* will help in planning the trials in OECD countries and in interpreting the results.

After a second round of comments in May 2011 among the Working Group on Pesticides (WGP) and the Working Group of National Coordinators of the Test Guideline Programme (WNT), this document was approved by the WGP and WNT by written procedure which was finished in July 2011.

This document is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, which has agreed that it be declassified and made available to the public.

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Introduction

1. Crop field trials (also referred to as supervised field trials) are conducted to determine the magnitude of the pesticide residue in or on raw agricultural commodities, including feed items, and should be designed to reflect pesticide use patterns that lead to the highest possible residues. Objectives of crop field trials are:

- 1. to quantify the expected range of residue(s) in crop commodities following treatment according to the proposed or established good agricultural practice (GAP);
- 2. to determine, when appropriate, the rate of decline of the residue(s) of plant protection product(s) on commodities of interest;
- 3. to determine residue values such as the Supervised Trial Median Residue (STMR) and Highest Residue (HR) for conducting dietary risk assessment and calculation of the dietary burden of livestock; and
- 4. to derive maximum residue limits (MRLs).

2. The purpose of these trials is described in the OECD Guideline on Crop Field Trials. While the OECD Guideline on Crop Field Trials provides a harmonized approach to conducting and reporting crop field trials in OECD countries this Guidance Document on Crop Field Trials will help in planning the trials in OECD countries and in interpreting the results.

3. The document will discuss some aspects that need to be considered while evaluating crop field trials. Topics include:

- Principles of crop grouping and selection of appropriate representative crops as a prerequisite for extrapolation of results from residue trials used in national/regional approaches as well as in Codex;
- Proportionality, the relationship between application rate and resulting residues;
- Equivalency of formulations;
- Use of conversion factors that enable conversion of residues measured using the definition for residue enforcement to the equivalent residue using the definition for risk assessment;
- Conversion of residues in whole commodity to the residue in edible parts of the commodity;
- Geographical distribution of residue trials;
- The number of residue trials required using national/regional approaches, the Codex approach and comprehensive data submissions in OECD countries;
- The selection of residue data for MRL determination; and
- The Use of the OECD MRL Calculator.

1. Crop Grouping

Background

4. National authorities use targeted data sets and data extrapolation to provide sufficient data for exposure assessment or for setting MRLs for both individual major and minor crop commodities, and crop commodity groups. Data extrapolation provides the mechanism for extending field trial data from several (typically two or three) representative crop commodities to related crop commodities in the same crop group or subgroup. Crop grouping and the identification of representative crop commodities are also critical for maximizing the applicability of a targeted data set determined for representative crop commodities for minor uses. The representative crop commodity (within the group) has the following properties:

- 1. major in terms of production and consumption; and
- 2. most likely to contain highest residue.

5. Representative crops are those designated crops from which extrapolations of MRLs/tolerances can be made to one or more related crops or to an entire group of crops. Crop group schemes are intended to classify commodities into groups and subgroups that have similar characteristics and residue potential (Codex Alimentarius Commission, 1999). For example, the Codex pome fruit group contains apple, pear, crabapple, Japanese medlar, loquat, medlar, nashi pear, quince, and oriental pear. As an example for representative crops apple and pear would be suitable.

6. One use of the crop group is to establish a maximum residue limit (MRL, tolerance) for the entire group based on field trial data for several of the commodities, designated representative commodities, within the group. In the pome fruit group, residue data for apples and/or pears would be used to establish a MRL for pome fruit. This MRL would apply to all members of the group provided the GAP is comparable within the crop group.

7. The classification systems in North American Free Trade Agreement (NAFTA), European Union (EU), and Codex are currently under revision and expansion. NAFTA system is being revised and expanded based on petitions to EPA from Interregional Research Project No. 4 (IR4). IR4 creates the petitions based on work with the International Crop Grouping Consulting Committee (ICGCC), USDA, and EPA/OPP. The ICGCC is a voluntary association of international experts with interests in plant physiology, residue research, regulation, and the growth/export/import of minor crops. Simultaneously, Codex via a CCPR (Codex Committee on Pesticide Residues) workgroup chaired by the Netherlands is working on the revision of the Codex Classification of Foods and Feeds. The work of the ICGCC/IR4/EPA is being used as a basis for this revision.

8. The OECD Pesticide Residue Chemistry Expert Group (RCEG) will consider adoption of the groups as they become available at Step 7 in the Codex process.

9. This paper describes the current situation and contains a table of the groups, subgroups, representative commodities, and extrapolations in Codex, EU, Australia, Japan, and NAFTA (Appendix 1).

10. Like the EU, Codex will include crop and commodity codes to facilitate proper identification of crops/commodities. Note that in the classification there will be crops with multiple commodities (radish root and tops), and these commodities are in different classification groups. It may also happen, that one commodity belongs to different (sub) groups, e.g. blueberries (low bush) and blueberries (high bush) where

agricultural practice differs. If different MRLs are established for the (sub) groups, the higher level would prevail for enforcement purposes on blueberries.

11. Crop grouping in this guidance document will emphasize the criteria for classification, issues related to representative crops, and opportunities for additional extrapolations. Guidance will be provided on the use and combination of data sets for crop group MRLs.

Principles for Crop Grouping

National/Regional Approaches to Crop Groups

12. NAFTA has made extensive use of the crop group/subgroup MRL concept. The EU has tended to use extrapolations rather than the broader crop grouping. Extrapolations rely upon the data from one crop to support another, e.g., the MRL for tomato is extended to aubergine/eggplant. Upon closer examination, however, it seems that the EU extrapolations are often very similar to NAFTA crop sub groupings.

13. Subgroups are primarily indicative of form and growth habit, and normally at least one commodity would be needed from each subgroup to set a group MRL. For example, citrus are sometimes divided into large diameter (orange, grapefruit) and small diameter (lemon, lime, mandarin) subgroups. One commodity from each subgroup (e.g., orange and mandarin) would be needed for a group MRL. Therefore, orange may be extrapolated to grapefruit (same subgroup).

14. Consideration of form and growth habit can also lead to differences in subgroups among countries. For example, NAFTA subdivides fruiting cucurbit vegetables into melons and squashes/cucumbers. The EU and Australia subdivide into edible peel and inedible peel. However, similar crops are considered representative for the cucurbit vegetables (e.g. cucumber/zucchini, melon/watermelon/squash).

15. The commodity consumed may also be reflected in the sub grouping. For example, bulb vegetables are often grouped into subgroups 1. garlic, onion, shallot and 2. chives, spring onion, and leeks. The distinction is that only the bulbs of those in subgroup 1 are consumed, whereas the bulb and aerial portions of the subgroup 2 may be eaten. Different residue levels might be expected on the two sub groupings for most pesticide applications. Thus, it might be possible to extrapolate from bulb onion to garlic and/or shallot, but not from bulb onion to spring onion.

16. Some of the criteria used by Japan, NAFTA, Australia and the EU in developing crop groups are summarized in Appendix 2.

Codex approach to Crop Groups

17. For the revision of the Codex crop group/subgroup proposals the following principles were taken into account:

- 1. Botany and nomenclature of the commodity;
- 2. Geographical production and distribution of the commodity;
- 3. International trade in the commodity;
- 4. Cultural practices for the commodity;

- 5. Commercial importance of the commodity;
- 6. Possibilities of genetic improvement for the commodity;
- 7. Comparison of edible parts of the commodity;
- 8. If the commodity is used as a livestock feed item for beef and dairy cattle, poultry and swine;
- 9. If the commodity is used for processed products and/or fresh market as whole fruit/vegetable;
- 10. Comparison of pest problems of the commodity;
- 11. Comparison of potential residue levels on the commodity;
- 12. Existing classification of the commodity; and
- 13. Justification for a Crop Group/Subgroup Definition.

Representative commodities

National/Regional Approaches to Representative Commodities

18. When looking at national approaches for representative commodity (within the group) properties it seems that the following criteria are taken into account:

- major in terms of production and consumption; and
- most likely to contain the highest residue.

19. It is recognized that a major crop may not have the highest residue. Although, there may be no definite resolution as there are no supervised residue trials data on all minor crops of a crop group, it should not be acceptable that substantially higher residues in a minor crop commodity are ignored because residues of a major commodity from the same crop group support a lower MRL. In such cases, if appropriate data on the minor crop commodities are available, individual (higher) MRLs might be necessary. From a dietary exposure standpoint, using a major crop as representative of the group is acceptable because of the small consumption of minor commodities. Nevertheless, one should bear in mind that this mainly refers to chronic exposure while large portion consumption relevant for acute exposure assessment is often in the same magnitude for minor crops as for major crops. Using major crop residue situations which might not reflect highest residue in minor crops might therefore result in an underestimation of the acute intake. In addition to dietary risk issues, there may be impacts on compliance with MRLs. Therefore, a group/subgroup MRL may not reflect potential residues in one or more minor commodities. There exists the finite possibility of non-compliance for some commodities in the crop group. In such a case OECD countries have to take action on a case-by-case basis (a solution might be trials in some representative minor crops).

20. There may be some difference regionally in the desired representative commodity. For example, aubergine (eggplant) is a major fruiting vegetable in Asia but not in NAFTA. In these situations, the selection of alternative representative crops may be justified.

Codex approach to Representative Commodities

21. Following the proposals made in Codex (CCPR 2010) representative commodities within each commodity group and subgroup are selected and proposed, based on consideration of all available information. The following key principles are used for the selection of representative commodities:

- A representative commodity is most likely to contain the highest residues;
- A representative commodity is likely to be major in terms of production and/or consumption; and
- A representative commodity is most likely similar in morphology, growth habit, pest problems and edible portion to the related commodities within a group or subgroup.

22. On the basis of these criteria one representative commodity for each commodity group and subgroup may be sufficient. Nevertheless, to facilitate the global use of commodity groups for MRL setting, alternative representative commodities may be selected giving flexibility for use of residue tests conducted in different countries or regions that may vary due to regional differences in dietary consumption and/or areas of production for certain commodities.

23. The new proposed Codex crop groups and subgroups together with proposed representative crops and the principles for selection of representative crops were adopted at Step 5 in CCPR 2010 (April 2010, Alinorm 10/33/24). New Codex Crop groups and sub groups as well as representative crops are included in Appendix 1b.

Use of different representative commodities

24. Provided the GAP and production conditions (e.g. cultural practices) are comparable, crop trials which fulfil the data requirements of a regulatory authority may be used to replace up to 50% of the trials required by another regulatory authority. This concept may be applied to representative crops in crop groups as well, provided each authority uses the same representative crops. In those cases where the regulatory authorities in question have specified different representative crops, the application of the 50% reduction will be made on a case-by-case basis.

2. Extrapolation

National/regional approaches for extrapolation and establishment of crop group MRLs

25. In general, extrapolations and/or establishment of crop group MRLs in the EU occur only where there are registered uses for all members of the crop group or subgroup. It is based on a sufficient number of trials conducted on one or more representative crops from the crop group or subgroup. The basis can be seen in the role of the precautionary principle, known as the ALARA principle (<u>as low as reasonably achievable</u>).

26. Nevertheless, this approach might be too restrictive. In view of global trade nearly all crop groups or sub-groups include commodities not grown in the respective countries. Therefore a situation with all members of the group being covered by national GAPs is unlikely to occur. In this situation EU introduced the concept of related varieties or other products in Regulation (EC) No 396/2005. For example

the MRL for the commonly grown commodity radish also applies to Black radish, Japanese radish small radish and similar varieties and tiger nut, from which Japanese radish and tiger nuts are normally not covered by European GAPs).

27. The situation in NAFTA is slightly different. Extrapolations may be made for use on only a few crops when the registrant is not interested in registration on the entire crop group. For crop group MRLs, cases exist where not all the crops are registered due to the manufacturer having concerns over efficacy or phytotoxicity on particular plants. Therefore, although all necessary data may have been generated on all the representative commodities and regulatory authority may have established a crop group tolerance, the registrant may not permit use on certain members of the group. Extrapolations may also involve crops that do not belong to any group.

28. The original underlying assumption for extrapolation is having the same GAP for all crops of a crop group or subgroup. Nevertheless, in this context it should be read as similar GAP (within 25% variation) for all crops of a group or subgroup.

29. Appendix 1a contains a table of the groups, subgroups, representative commodities, and extrapolations in Codex, EU, Australia, Japan, and NAFTA.

30. In estimating crop group MRLs, two methodologies are possible. In the simplest and more common approach, the highest residue set for individual representative crops is used to estimate group/subgroup MRL. In some cases in Europe the data sets from the various crops of a group/subgroup are combined, and an MRL proposal is made from the combined data. Data sets for different commodities within a group/subgroup are considered for combination to estimate group MRLs only if residues are similar in magnitude (belonging to a similar residue distribution) and have similar GAPs (see paragraph 24). Otherwise, group MRLs may not be appropriate, or exceptions to the group may need to be specified. Different approaches are in place in countries on combining data for dietary risk assessments.

31. The single crop approach is utilized in NAFTA and also in the EU. Nevertheless, the EU Guidance Document SANCO 7525/VI/95 describes an approach to address the allowed variability in residues among crops for purposes of setting a group MRL. Using the proposed calculator model as described, residue levels for relevant different raw agricultural commodities are considered to be comparable:

- 1. if assuming a standard (normal) distribution of data the respective 'mean to one-sigma-limit' ranges overlap; and
- 2. if the resulting recommended maximum residue limits when calculated for each single crop according to the recommended calculation procedure fall into the same or a neighbouring MRL class after rounding up or down to the nearest MRL class.

32. The situation in NAFTA is different. The maximum residue limit for the representative crops should not differ by a factor of more than 5X in order to establish a crop group tolerance.

33. A statistical method for determining if data sets are from similar populations for possible combination is described in the FAO Manual 2009 (see paragraphs 41, 42) (FAO, 2009c).

Codex approach for extrapolation and establishment of crop group MRLs

34. Residue extrapolation is the process by which the residue levels on representative commodities are utilized to estimate residue levels on related commodities in the same commodity group or subgroup for which trials have not been conducted.

35. The establishment of commodity group MRLs as opposed to MRLs for individual commodities has long been considered an acceptable procedure since economics may not justify residue trials on all of the individual crops in a group. In principle the approach recognizes that adequate data for the major crops of a group may be sufficient to estimate maximum residue limits for the whole group.

36. Some pesticides may behave differently in different circumstances. Consequently, it is not possible to define precisely those commodities on which trials will always provide data that can lead to a group MRL. If the "highest residue" situation can be identified, however, the relevant data can be extrapolated to other crops with confidence, although it is recognised that this approach may result in an over-estimate of residues in some commodities. An acceptable example is extrapolation of residue data from gherkins to cucumber; however, the converse is not possible due to the higher residues that can be expected in gherkins as a consequence of the difference in surface/weight ratio.

37. Extrapolation requires a detailed knowledge of local agricultural practices and growth patterns. For example, wheat is generally grown under similar practices around the world, but grapes may be grown utilising widely varying practices. For the latter, care must be taken to ascertain if the relevant GAPs are comparable. In view of the large differences in commodity surface texture, shape, plant growth habits, rate of growth and seasonal cultivation and the significant role played by the surface/weight ratio, the JMPR has emphasized that decisions to extrapolate should be made on a case-by-case basis when adequate relevant information is available.

38. As a general precondition, for reliable estimation of residue levels an adequate number of independent trials are required. Under practical conditions the number of trials which can be performed for a given commodity is limited. On the other hand, a larger data set representing statistically not different residue population provides more accurate estimation of the selected percentile of residue population than a small data set derived from trials representing the critical GAP.

39. Provided that the GAPs are similar, data sets for a given commodity or commodity group may be combined. In deciding whether the results of trials reflecting different countries' GAPs give rise to different populations of residues data, the size of the database reflecting the different countries' GAPs should be taken into account. Statistical tools are available that can be used to ascertain if data sets come from populations characterized by similar median/mean and variance.

40. The field to field variation of residues skewed towards the high values may not follow normal distribution, even if this might be indicated by statistical tests based on small data sets. Consequently, distribution-free statistics should be used for comparing two or more residue data sets. Statistical tests are useful tools in the evaluation of pesticide residue trial data. However, due to the complexity of the task, which includes the consideration of several factors such as metabolism and rate of disappearance, such tests are not definitive and can only support expert judgement.

41. The question of comparable data sets was discussed during the JMPR meeting in 2001 (FAO, 2001) and again in 2008 (General Consideration 2.8) (FAO 2009a). It was proposed to use Mann-Whitney U-test for the comparison of residue populations. The principle is described in paragraph 42. The Mann-Whitney U-test can be used for the comparison of data sets from different regions, different representative crops, different use patterns or conditions of use or from different areas of applications (outdoor versus

glasshouse). It should be borne in mind, that this test is only valid for comparing two data sets. For cases where more than two data sets are to be compared the U-test is not applicable, in which case the Kruskal-Wallis H-test may be used. For more details see FAO Manual 2009.

42. The basic principle involved is that, if one type of pesticide use gives results that appear to be higher than those resulting from another type of use, there should be few instances in which individual results from the 'higher' population are exceeded by results from the 'lower' population. The sum of such cases is calculated, and the smaller is compared with the tabulated critical value. In making this comparison, the critical region, i.e. that in which the null hypothesis (the two median values are not different) can be rejected, is that in which the test statistic is less than or equal to the tabulated value; this is contrary to the criterion of many significance tests (e.g. Student t-test, F test, χ^2 -test). With the appropriate statistical table, a two-tailed test ($\alpha/2 = 5\%$) is usually applied and it is assumed that $n_1 \le n_2$, where n_1 and n_2 are the numbers of data points in populations 1 and 2, respectively. The test statistics, U₁ and U₂, are calculated as:

$$U_1 = n_1 n_2 + [n_1(n_1+1)]/2 - \sum R_1$$
(1)

$$U_2 = n_1 n_2 + [n_2(n_2+1)]/2 - \sum R_2$$
(2)

where $\sum R$ is the sum of ranks of the corresponding values. The correctness of a calculation can be checked from:

$$U_1 + U_2 = n_1 n_2$$
 (3)

An example for calculation is given in the JMPR Manual 2009.

43. It can be stated that the residue populations could be combined when the U test suggested that their medians were similar and to use the combined population for estimating maximum residue limits and STMR and HR values. For populations that are different, it can be stated that only that population which had the highest valid residue value should be used for both estimates or different estimations from the two distinct data sets on maximum residue limits and STMR and HR values should be made. The test should be applied with caution for residues below the LOQ in the populations to be compared.

44. Like other statistical methods it is crucial to properly define the aim before using the method. One should bear in mind that the described tests are less powerful than tests based on distributional assumptions, when that assumption is verified. It should be clear that if the tests show differences it is rather likely that the data sets do not belong to the same population and thus it will be inappropriate to combine the data sets.

Wider Extrapolations

45. The term 'wider extrapolations' (also referred to as 'cross group extrapolations') is used in this context for extrapolations that go beyond the bounds of a crop group or subgroup. Such extrapolations may be possible in special circumstances. Consideration on a case-by-case basis may be given to commodities with very similar shapes, volumes, and weights. For example in Australia, apple, peach, and nectarine may be extrapolated to persimmon.

46. Wider extrapolations may also be considered, on a case-by-case basis, for:

- Situations where residues are expected to be <LOQ (e.g pre-emergence herbicide uses, preflower treatments);
- Situations where the active substance is used early in the growing season (last application before consumable parts of the crop have started to form). (This kind of extrapolation should be used with caution since for some crops the edible part of the crop is always present either as a food or a feed item.);
- Seed treatments, if data from treatment of several different 'representative' seed types all report no detectable residues in the commodities from crops grown from the treated seed;
- Post harvest treatments for non-systemic pesticides (similar size & morphology) on the basis of the same treatment regimes; and
- Soil treatments with granules (with residue levels depending on plant morphology rather than on plant metabolism).

3. Proportionality

47. Proportionality means the direct relationship between application rate and residues.

Background

48. A proposal to predict the level of residues in plant matrices on the basis of the assumption that residues will increase linearly with the application rate may save time and resources. Residue studies in plants are usually not conducted as parallel trials using different application rates under otherwise identical conditions. The quantity of a pesticide initially deposited and retained on a crop surface depends upon many factors, including the physico-chemical properties of the active substance and especially the spray liquid, the nature of the (leaf) surface, growth stage and the application method used. The crop canopy is also important for determining spray deposits. Therefore, the interpolation of residues usually was not accepted as a waiver for residue trials in the past. A proposal on predicting residues was only recently considered.

Recent Developments

49. In a recent publication by Maclachlan and Hamilton (2010) a proposal was made to use day zero data and residue decline studies to estimate median and highest anticipated residues. This and other tools may be developed in the future to assist MRL estimation. The JMPR in 2010 dealt with the subject for the first time.

50. In the JMPR Report 2010 (FAO, 2011) a general item on proportionality is included. Here the results of an analysis by MacLachlan and Hamilton (submitted for publication) of a large number of sideby-side trials in which application rate was the variable were compared. The main conclusions were:

• principles of proportionality should not be used for herbicides and plant growth regulators applied to growing plants and not for granular applications;

- careful consideration should be given to residues in protected plant parts; and
- up-scaling of residues should be limited to a factor of 3, down-scaling to a factor of 5.

Recommendations

51. For the time being the calculation method based on zero day data proposed by Maclachlan and Hamilton (2010) is not recommended for regulators in the frame of authorization procedures as an alternative to residue trials. Its use should currently be restricted to well-justified individual cases. This is in line with the general consideration item in the JMPR Report 2010 saying that the tool might be suitable for use in 20% of cases.

52. Having noted the general consideration item in the JMPR Report 2010 (FAO, 2011) further discussion in Codex is necessary. This was announced in the Codex Committee on Pesticide Residues Meeting in 2010 and will be done in the CCPR Meeting in 2011 based on the JMPR considerations.

53. Further investigations are necessary using existing data from JMPR, OECD global joint reviews, EFSA conclusions and other sources. Ideally investigations should be made on different active substances from different categories with different uptake and distribution pattern covering crops from different crop groups using different application techniques. Results from residue trials to be compared should have the same GAP except the amount of active substance applied and each trial should have at least two data points: day zero and anticipated day of harvest. Trials to be directly compared should ideally be conducted in the same place while results for a given combination of crop/active substance could be widely spread. Having noted that these requirements were fulfilled for the residue trial data investigated by MacLachlan and Hamilton from reports of JMPR for the period 2000 through 2009, the usefulness of broadening the data base by using other sources should be discussed.

4. Conversion Factors

54. In some countries authorities responsible for enforcement have to fulfil two objectives:

- to enforce compliance with MRL legislation; and
- to assess consumer exposure.

55. The laboratories must analyse as many active substances as possible. Due to resource constraints they only can fulfil the first goal using up-to-date multi-residue methods since complex residue definitions which are normally set for risk assessment require more sophisticated work-up steps.

56. In order to reach the second goal, several factors must be taken into account:

- 1. Conversion from the residue definition for enforcement to the residue definition for risk assessment;
- 2. Residue in the edible part of the commodity; and
- 3. Processing factors.

57. The derivation of processing factors (PF) is described in OECD Guidance Document on Magnitude of Pesticide Residues in Processed Commodities.

Conversion of residue definition for enforcement to risk assessment

58. The conversion factor for the conversion from the residue definition for enforcement to the residue definition for risk assessment (CF_{risk}) should be assessed when supervised residue trials data are evaluated. In these trials both residue definitions have to be addressed by the applicant. Therefore they are the best source to derive CF_{risk} .

59. Plant metabolism studies give indications and can be used for the entire crop but should not be used on regular basis as their main purpose is to identify the nature rather than the magnitude of the residue which may vary from crop to crop. In most cases conversion factors should be calculated using data from supervised field trials supported by metabolism data.

60. In order to obtain the CF_{risk} the value of the measured residue for risk assessment is divided by the value of the measured residue for enforcement for each pair of residues for a set of residue trials data with a comparable GAP. From this set of individual CF_{risk} values, the mean is selected as the representative CF_{risk} . From a risk assessment perspective this approach is likely to be more conservative as compared to the median values.

Trial	Residue in compliance	Residue in compliance	Individual	
number	with residue definition for	with residue definition for	CF _{risk}	
	enforcement	risk assessment		
1	0,31	0,64	2,06	
2	0,15	0,28	1,87	
3	0,34	1,35	3,97	
4	0,32	0,56	1,75	
5	0,55	1,16	2,11	
6	7,80	9,55	1,22	
Mean value	e of individual CF _{risk}		2,16	

An example (Spinetoram in lettuce, FAO 2009b) to calculate CF_{risk} is given in the following table.

Conversion factor for edible parts

61. The conversion factor for the conversion from whole product to the edible product (CF_{edible}) should be assessed when supervised residue trials data are evaluated (based on the residue definition for enforcement). In order to obtain the CF_{edible} the value of the measured residues in the whole commodity is divided by the value of measured residues in the edible commodity for each pair of residues for a set of residue trials data with a comparable GAP. From this set of individual CF_{edible} values, the mean is selected as the representative CF_{edible} .

62. In case of residues below the LOQ the LOQ itself is used for the calculation.

5. Formulations (Equivalency of Formulations)

63. Most types of formulations can be divided into two groups — those which are diluted with water prior to application and those which are applied intact. Emulsifiable concentrates (EC) and wettable powders (WP) are examples of the first type whereas granules (GR) and dusts (DP) are the most common examples of the latter. Some special types of formulations are described in paragraphs 71 and 72.

Formulations diluted in water

64. The most common formulation types which are diluted in water prior to application include EC, WP, water dispersible granules (WG), suspension concentrates (SC) (also called flowable concentrates), and soluble concentrates (SL). Residue data may be translated among these formulation types for applications that are made to seeds, prior to crop emergence (i.e., pre-plant, at-plant, and pre-emergence applications) or just after crop emergence. Data may also be translated among these formulation types for applications directed to the soil, such as row middle or post-directed applications (as opposed to foliar treatments).

65. For late season foliar applications of formulations diluted in water, the decision on the need for additional data depends upon two factors: (1) the presence of organic solvents or oils in the product and (2) the pre-harvest interval. Wider extrapolation of data will generally be permitted for formulations that do not contain organic solvents or oils (e.g., WG, WP, SC). Provided the pre-harvest interval is longer than 7 days, such formulations will be considered equivalent for residue purposes. When the PHI is less than or equal to 7 days, bridging data will normally be needed to show residues are equivalent from these formulations. One exception to this point is that water dispersible granular formulations are sufficiently similar to wettable powders to allow translation of residue data between them regardless of the PHI.

66. In a recent publication by Maclachlan and Hamilton (2010) it was shown by evaluation of sideby-side trials with the same application rate and similar spray volumes that WP, EC, CS (capsule suspension) and SC formulations do not show a significant difference in day-zero residues after foliar treatment (JMPR data from 2000 to 2004). The evaluation includes trials with PHIs of less than 7 days. In light of this evaluation and experience gained, the above requirement for bridging studies (paragraph 65) could be reconsidered.

67. Data needs for formulations containing organic solvents or oils (e.g., EC, water in oil emulsions (EO)) differ depending upon the regulatory authority. Some authorities group such formulations with those discussed in paragraph 65. Therefore, if the PHI exceeds 7 days, data may be translated between formulations such as WG, WP, SC and EC. However, for other authorities crop field trial data for formulations such as EC or EO will normally not be translated to any other formulations unless the use is as described above in paragraph 64 (i.e., early season or soil applications). For mid to late-season uses of formulations like EC or EO, these authorities would require bridging data be provided to establish whether data from another formulation can be used to support their registrations.

Water soluble bags

68. Placing a formulation (typically WP) in a water soluble bag does not require additional residue data provided adequate data are available for the unbagged product.

Formulations applied intact

69. Granular formulations applied intact will generally require a complete data set regardless of what data are already available for other formulation types. This is based on several observed cases of residue uptake being quite different for granules versus other types of formulations of the same active ingredient.

Formulations designed for seed treatments

70. Some formulations are often designed specifically for seed treatment use such as DS powder for dry seed treatment use and ES emulsion for seed treatment. Residue data for seed treatment uses may be translated between such formulations.

Controlled release formulations

71. Controlled release formulations (e.g., certain microencapsulated products) normally require a complete data set tailored to that particular use. Since these formulations are designed to control the release rate of the active ingredient, increased residues are possible compared to other formulation types.

Formulations that contain active substances as nanomaterials

72. In general it is expected that if active substances were to be formulated as nanomaterial they would have different properties compared to normal sized material. At present no definitive statement can be made as to whether or not current data requirements are sufficient to carry out risk assessments for nanopesticides. For the time being a complete data set is needed for plant protection products containing nanomaterials in order to compare residue behaviour with conventional products.

6. Geographical Distribution of Residue Trials

73. In response to one of the recommendations of the workshop in York (1999) on "Developing Minimum Data Requirements for Estimating MRLs and Import Tolerances", the OECD Working Group on Pesticides and the FAO Pesticide Management Group invited a small group of residue experts from OECD and FAO Member countries to develop the concept of a global zoning scheme to define areas in the world where pesticide trials data could be considered comparable, and therefore where such trials could be used within each zone for MRL-setting purposes, irrespective of national boundaries.

74. On the basis of the underlying assumption that residues depend on climatic conditions a world map of four possible residue zones, i.e. cold, temperate wet, temperate dry, and tropical using the Köppen global climate classification was developed. An extensive database of residue trials data from the FAO/WHO Joint Meeting on Pesticide Residues (JMPR) Residue Evaluations was collected and then analysed by an independent statistician. Indications from this first statistical analysis suggested that the proposed zones, based on the Köppen global climate classification, were not appropriate. Furthermore, an analysis of the variability related to average pre-harvest climatic conditions (temperature and rainfall) for each residue trial location would not support a proposal for different temperature and rainfall 'bands', within which residue trials data could be considered comparable.

75. As the result of these analyses the available data were not sufficient to separate out the various climatic factors. This was mostly due to the high level of residue variability found within the proposed zones. In addition, data indicate that pre-harvest climate may not have such a strong influence as had been

previously thought. The data sets were re-analysed using additional data on residues reported at zero-days (the day of the final pesticide application, i.e. 0 days after the final application). The analysis indicates that a large part of the variability at harvest could be explained by variation in residues at 'zero-days' (assumed to be largely unaffected by pre-harvest climatic conditions).

76. It was noted that the analysis indicated considerable variations in zero-day residues for comparable trials (i.e. those with the same or similar Good Agricultural Practice), and suggested that much of this variability could be associated with residue sampling and laboratory analytical variability, as well as with differences in production systems and pesticide application techniques used in the trials.

- 77. The report concluded that:
 - there was sufficient information to indicate that a residue zoning scheme, based on climatic differences alone, could not be proposed because of the high variation in residues reported from comparable trials even within the same climatic zone;
 - pre-harvest climatic conditions were not major factors influencing residue variability in comparable residue trials;
 - most of the residue variability at harvest reported from comparable trials was associated with variability in residues at 'zero-days' (assumed to be largely unaffected by pre-harvest climatic conditions); and
 - many of the factors possibly contributing to residue variability in comparable residue trials have already been recognised, to a greater or lesser extent, in the MRL assessment procedures established at the national, regional and international level, with residue trials being designed to reflect the range of production systems and climate situations that might be expected during the commercial use of the product.

78. Unfortunately, the recommendations of this report were not considered further and the results were not used in any national or regional evaluation or legislation. One reason might be that only foliar applications were considered in the report. The only point addressed in the report was that national boundaries are not a barrier to acceptance of supervised field trials from other regions. This point was used by JMPR and some national/regional authorities at the time of publication.

Recommendation

79. The results of the above project were used to support the proposal that for comprehensive OECD submissions (see paragraphs 85 to 97) the number of residue trials can be reduced by 40 %. The EU will in future allow to a certain extent and to a maximum of 50% to replace the number of trials necessary by trials from outside Europe, provided that they correspond to the critical European GAP and that the production conditions (*e.g.* cultural practices) are comparable (GAP within the +/- 25% rule).

80. In order to make further progress in geographical distribution of residue trials it is recommended to revisit the above results in the light of OECD submissions. Five different major crops (e.g., grain, leafy vegetable, fruiting crop, root crop, oilseed) from different OECD countries/regions should be investigated laying emphasis not only on foliar applications but also take other applications techniques into account. Results from other application techniques should complete the project that examined foliar applications only. Different types of pesticides (insecticides, herbicides, etc.) with both systemic and non-systemic properties should be represented.

81. It might be useful to set up an expert consultation to discuss the results of the investigations in order to define a minimum and maximum number of trials for a submission in comprehensive OECD submission as well as to discuss the question on how to spread these trials over the different regions.

7. Number of Trials

National/regional approach to number of trials

82. National/regional requirements concerning number of residue trials per crop remain in place.

83. Due to the limited amount of information on possible zoning of residue trials, the only recommendation that will be used from the Report of the OECD/FAO Zoning Project is the acceptance of trials from other regions. A maximum of 50 percent of the total number of trials required by a regulatory authority may be replaced by trials required by another regulatory authority provided that these trials correspond to the critical GAP and the production conditions, i.e. the comparable cultural practices. Before combining residue data, the protocols should be studied carefully as to whether they met these criteria.

Codex approach to number of trials

84. JMPR performs the evaluation of the submitted information and estimates maximum residue limits if the database is considered sufficient, regardless of whether it represents worldwide use or is limited to a region. The number of trials (generally minimum 6-10) and samples is dependent on the variability of use conditions, the consequent variation of the residue data, and the importance of the commodity in terms of production, trade and dietary consumption.

Comprehensive data submissions

85. In the case of a comprehensive submission to all OECD countries where the desired GAP is uniform, a 40% reduction in the total number of trials is feasible, compared to the total number of trials determined by summation of individual country requirements. The residue trials chosen are those conducted independently. The assumption is that the number of trials specified in each crop production region reflects the economic (acreage) importance and/or dietary significance of the representative crop(s) within that production region.

86. The reduction in the total number of trials within any OECD country or crop production region is compensated for by the total number of crop field trials making up the comprehensive submission data set and the wider geographic distribution of these data. With this 40% reduction, regulatory authorities may receive fewer crop field trials in their specific country or region; however they will actually receive a greater number of trials in total with a more comprehensive geographical distribution. There are precedents in OECD countries and regions for this approach.

87. To qualify for this comprehensive submission approach, all crop field trials should meet the following criteria:

- 1. Field trials are conducted according to the *c*GAP (within +/- 25% of the <u>nominal</u> application rate, number of applications or PHI). For comprehensive submission at least 50% of the trials should be conducted at or above (within 25%) the *c*GAP. For this purpose, trials whose intended application rates match the cGAP but <u>actual</u> rates fall down to 10% below the cGAP (e.g., due to the normal variability in preparing spray solutions) are considered acceptable;
- 2. Some authorities request up to 50% of the trials to be decline studies;
- 3. The trials should cover a range of representative crop production practices for each crop including those likely to lead to the highest residues (e.g., irrigated vs. non-irrigated, trellis vs. nontrellis production, fall-planted vs. spring-planted, etc.); and
- 4. Trials that are substituted by trials from another country should not be used for across the board reduction.

88. The minimum total number of trials for any crop in a comprehensive submission is eight. In addition, the total number of trials to be conducted may not be less than the requirement for any given individual region. For example, upon calculation of the 40% reduction, some crops such as dried lima beans have fewer total trials (14) than required in one region (16 in the EU). Therefore, at least 16 trials are needed for dried lima beans in a comprehensive submission.

89. Any reduction in the number of crop field trials should be distributed proportionally among the crop production regions as shown in the example for a 40% reduction for barley below. A table with trial numbers for crops grown throughout OECD countries is given in Appendix 3. In the event that the number of required trials changes in any given region, the total number and reduced number can be calculated on the information given so far. Nevertheless, Appendix 3 should be adjusted accordingly.

90. In no case the number of trials in a given crop production region may be reduced below two. Thus, in the example given below the 40% reduction does not apply in Japan (required number of trials is two before and after reduction) and therefore the total number of trials is 33 rather than 32, which is the actual 40% reduction from 54.

Country or Region	NAFTA	EU	JP	AUS	NZ	Total
Number without reduction	24	16	2	8	4	54
Number with 40% reduction	14	10	2	5	2	33

91. It is important to keep in mind that this comprehensive strategy would only apply to an OECDwide submission. If, for example, the MRL submission is originally submitted to the US and Canada, the crop field trial guidelines, with respect to the number of trials, for those countries should be followed. Subsequently, if MRLs in additional OECD countries are pursued, the regulatory authorities in the additional countries should be consulted to determine what residue data are required. For example, following establishment of an MRL in the US and Canada, if an MRL for the same use is pursued in the EU, the applicant may consult with EU regulatory authorities about the possibility of using residue data from the US/Canadian data submission and performing fewer crop field trials in the EU.

92. The table of trial numbers in the Appendix 3 addresses only outdoor crop field trials and not greenhouse (glasshouse) or post-harvest treatments. For a comprehensive submission to OECD countries, with similar critical GAPs, a minimum of eight greenhouse trials is needed. For such greenhouse trials, geographic distribution typically is not an issue; however for active ingredients which are susceptible to

photodegradation, consideration should be given to locations at different latitudes and winter/summer periods.

93. The number of post-harvest trials on a commodity should be at least four, taking into consideration the application techniques, storage facilities, and packaging materials used. Changes in the mentioned conditions may require additional trials.

94. As stated in paragraph 81 further considerations are useful in the light of experience gained in future.

8. Results from Residue Trials to be used in MRL Estimations

95. In principle all data from residue trials conducted according to cGAP and considered valid should be taken into account for MRL setting. Nevertheless a few questions often arise and some of the main ones are discussed in the following paragraphs.

Handling of outliers

96. Residue values above the majority of the data population are always suspicious and therefore are often characterised as outliers. Nevertheless, before disregarding a result as an outlier the study should be carefully examined to see if there is adequate information and/or experimental evidence to justify their exclusion. At the time of evaluating the results, one should be careful when deciding that a result is invalid. The exclusion of an apparent outlier must be justified by agricultural practice or other evidence deriving from the experimental set up or analytical conditions. Statistical results, in and of themselves, are generally not sufficient to exclude data from the MRL-setting process.

Multiple component residues

97. In cases where the active substance and at least one metabolite, degradation or reaction product is included in the residue definition two cases have to be considered: either the components are converted to a single component or analyte by the analytical method or the components are determined separately.

98. In the first case the total residue is measured as a single compound and expressed as the parent compound or in some circumstances as a metabolite or degradation product. As in any other case the LOQ is usually determined by the lowest validated level of analyte. The MRL estimate is based on the measured residues for the total residue.

99. In the second case residue components are determined separately by the method of analysis. The concentrations of measurable residues are adjusted for molecular weight and summed, and their sum (normally parent equivalent residues) is used for estimating the maximum residue limit. Nevertheless, some guidance is necessary if the residues for some or all the components are at or below the LOQ. This is explained using the following example.

Example (based on FAO Manual for bentazone with values being fictive):

100. The residue definition is given as "bentazone, 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone". The LOQ of the method of analysis for the single components of the residue definition is 0.02 mg/kg. The different situations are described in the following table.

Example	Maximum lev	vels (mg/kg) detected	Recommended total residue (mg/kg)	
	bentazone	6-hydroxy-	8-hydroxy-	
		bentazone	bentazone	
(a)	< 0.02	< 0.02	< 0.02	< 0.06
(b)	0.04	< 0.02	< 0.02	0.08
(c)	0.04	0.03	< 0.02	0.09
(d)	< 0.02	0.04	0.05	0.11

101. This recommendation is based on the assumption that it might be possible to improve the method of analysis to achieve for example a LOQ of 0.01 mg/kg. Re-examination of the results may then give residues only slightly below 0.02 mg/kg for each of the single compounds and 0.06 mg/kg for the sum. The total recommended values should be used in MRL estimations. It should be considered whether <0.06 would be appropriate to be used for the MRL calculation since the individual components were all <LOQ and the number of censored data is relevant for the calculation.

102. The recommendation provided in the FAO Manual 2009 differs from this proposal. The problem is illustrated with the example of bentazone where the residues of bentazone in plant commodities are defined as the sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone, expressed as bentazone. The LOQs reported in supervised trials for each of the three components were generally 0.02 mg/kg, but the practical LOQs were regarded as 0.05 mg/kg for regulatory purposes. If an MRL for bentazone was set as the sum of the practical LOQs of the three components of the residue, it would have to be established at 0.15 mg/kg (3 times the practical limit of quantification to incorporate all three residue components and round it to the next MRL class). In this case, any part of the residue components could be present at 0.15 mg/kg, or all of the three at 0.05 mg/kg, without exceeding the MRL. Consequently, individual residue components could be respectively 7.5 and 2.5 times those which should arise from the recommended use of the compound but would be within the MRL. Similarly, if the sum of the LOQs achieved in the supervised trials was considered, an MRL of 0.06 mg/kg would be needed, which would still allow 3 times the residue that would arise from treatments complying with GAP.

103. In the FAO Manual 2009 it is recommended that the best option should be to select the appropriate LOQ on a case-by case basis taking into account the relative ratio of metabolites. From this point of view but also due to other reasons the best option for regulatory laboratories is to choose a simple enforcement residue definition, i.e., a single component if possible.

104. It is recommended that decisions on the levels of MRLs at or about the practical limit of quantification should particularly take into account the following factors:

• Toxicity of the active ingredient as indicated by the ADI or the ARfD. Normally, low ADIs or ARfDs should be accompanied by relatively low limits of quantification. The lower limit used may also have implications for risk assessment calculations;

- In principle, the lower the residue arising from GAP, the lower the limit of quantification should be;
- The limit used in the supervised residue trials is also a consideration which should be taken into account. A LOQ may not normally be established at a level lower than that used in the generation of the data. However, should other factors be considered determinant, regeneration of the data using a more appropriate lower limit may be required; and
- As analyses at lower levels will influence enforcement costs, the expenditure/benefit evaluation will influence the final decision on the appropriate limit of quantification.

Independent supervised residue trials

105. As a principle only one result from each residue trial that is within cGAP should be used for the estimation of MRLs. In addition selected results from residue trials should only be used from independent supervised residue trials. In this respect the FAO Manual is useful to consult. It is stated that the following trial conditions are usually recorded and are taken into consideration:

- Geographical location and site trials at different geographic locations are considered independent;
- Dates of planting (annual crops) and treatments trials involving significantly different planting dates or treatment dates are considered independent;
- Crop varieties some varieties may be sufficiently different to influence the residue;
- Formulations comparability or independence of trials with different formulations should be assessed (see also paragraphs 63 72);
- Application rates and spray concentrations trials at significantly different application rates and spray concentrations are counted as separate trials¹;
- Types of treatment, e.g., foliar, seed treatment, directed application different types of treatment on different plots at the same site are considered as separate trials;
- Treatment operations trials at the same site treated in the same spray operation are not counted as separate trials;
- Application equipment trials at the same site treated by different equipment, other things being equal, are not counted as separate trials; and
- Addition of surfactants a trial with the addition of surfactant may constitute sufficient difference to be treated as independent. It is expected that the level of residue will change when adding surfactants.

¹ This point should be reconsidered in the light of ongoing discussions on proportionality. If the principle of proportionality is applied, then only one residue result from each location should be used and in this case, trials at significantly different application rates or spray concentrations would not be counted as separate trials.

106. Only one field trial would normally be selected per trial site if multiple plots/trials are conducted in parallel, unless one or more of the conditions outlined above apply, e.g., significantly different varieties in the replicate plots. For trials at the same location there should be convincing evidence that additional trials are providing further independent information on the influence of the range of farming practices on residue levels.

Replicates

107. Various scenarios may apply when several residue values are described as "replicates" such as when there are:

- 1. replicate analysis samples from one laboratory sample (duplicate analysis);
- 2. replicate laboratory samples obtained with sub-division from one field sample;
- 3. replicate field samples analysed separately (each sample is taken randomly from a plot which was sprayed as a whole);
- 4. replicate plots or sub or split-plot field samples are analysed separately (the whole trial is subject to the same spraying operation, but it is divided into 2 or more areas that are sampled separately); and
- 5. replicate trial samples are analysed separately (trials from the same site that are not independent may be considered as replicate trials).

108. In all cases the type of replicate should be specified when assessing the data. The average or mean value of replicates should be used as the representative value for that field trial in exactly the same fashion that is done for analytical replicates of the same composite sample. From a statistical point of view, the mean or average residue value of replicate samples provides the basis for setting MRLs targeted at the p95 of the underlying distribution. However, there may be situations where single valid results from replicate samples may exceed the MRL estimated from the use of average or mean values. In such situations and in view of consumer safety, consideration may be given by some regulatory authorities to the use of these single values as the HR in dietary risk assessment.

Residues at harvest

109. Normally, the residue at the PHI specified in the cGAP should be used for the MRL estimation. Nevertheless, the residue trial data should be assessed carefully and higher residues at longer PHIs should be used instead of the residue at the cGAP as this safety interval is defined as the shortest possible meaning that harvest at later stages may take place.

110. In some cases the time of application is well defined by the growth stage (BBCH; a decimal code system, which is divided into principal and secondary growth stages²). In this case setting of a PHI is not necessary. The selection of the results from residue trials then depends on the use of the plant protection product at the correct growth stage and the normal harvest of the product.

² A description in German, English, French, or Spanish can be downloaded from http://www.jki.bund.de/en/startseite/veroeffentlichungen/bbch-codes.html

9. MRL Estimations

Calculations based on the use pattern of a plant protection product

111. One may consider two cases where MRL calculations based on the use pattern of a plant protection product is an option for theoretical worst case MRLs. The cases are the use of plant protection products in stored products and in seed treatments.

112. The post-harvest use of a persistent, non-volatile active substance in stored products will lead to residues that can be calculated on the basis of the amount used to treat the stored commodity for short waiting periods. The MRL could not be set at a higher level than the application rate equivalent, although MRL calculation may indicate higher maximum residue limits due to inhomogeneous distribution of the pesticide during application or due to problems in sampling (especially bulk commodities). Any variation in residues depends on the precision of the application especially concerning the deposition of the active substance on the surface of the treated commodity. Environmental and commodity related factors (like metabolism) will only have limited influence. Residue trials are necessary to reflect storage locations with variable conditions regarding temperature, humidity, aeration, etc. Once the relationship between application rate and residue level has been shown, additional trials with other application rates are not necessary.

113. For seed treatments a situation could be imagined, where the worst-case MRL based on the aicontent in the seed and the known yield of the commodity would be estimated being below the LOQ or below an already existing MRL. In that case and assuming that possibly formed metabolites are adequately covered, a waiver for additional residue trials with a new application rate might be acceptable.

Use of the OECD calculator

114. A statistical calculator has been developed by OECD for determination of MRLs from valid field residue data. The calculation process is based on "mean + 4sd" methodology. A White Paper and related user guide are available as additional resources (OECD 2010).

115. For the OECD calculator method of MRL calculation, it has been determined that the mean or average residue value, when replicate sample data have been generated per field site, should be used in the calculation process.

116. Several examples of criteria, used in selecting data to be considered in the MRL calculation, require expert judgement and consultation with national/regional authorities:

- Use of residue values between the validated Limit of Quantitation (LOQ) and the method Limit of Detection (LOD), i.e. censored data, if available. The default inputs to the calculator for these values are the respective LOQ values with an asterisk designation for censored data. The actual censored values, while less reliable, depending upon the type of analytical method, may be useful in the calculation process on a case-by-case basis;
- Combining of datasets from the same region (e.g. NAFTA) for the same crop commodity treated at the same GAP except, for example, indoor versus outdoor production (i.e. calculate the MRL for each dataset separately and compare results to determine highest residue population);

- Combining/separating datasets for the same ai/crop/GAP combination generated with different LOQs and containing censored data (i.e. calculate the MRL for each dataset for a respective LOQ separately and compare results to determine highest residue population). Where there are two or more data sets with different LOQ levels, the highest one serves for HR and MRL setting, while the lowest LOQ level is used for STMR setting;
- Small datasets are the locations independent enough to be valid for a set? If the dataset consists of less than 3 values the message "MRL calculation not possible. [Too small dataset]" is displayed at the bottom of the spreadsheet. The choice of 3 values was made based on the minimal requirement common among OECD countries. With a single residue value, it is impossible to compute an estimator for the standard deviation of the dataset, which is needed in the calculation procedure. If the dataset consists of 3-7 residue values, the message "High uncertainty of MRL estimate, [Small dataset]" is displayed to remind the user of the considerable level of uncertainty surrounding the calculation of any statistical quantity for such small datasets;
- Combining datasets from different regions (e.g. NAFTA and EU) for the same crop commodity treated at the same GAP (see paragraphs 40 43 in Extrapolation Chapter or alternatively calculate the MRL for each dataset separately and compare results to determine highest residue population);
- Combining of datasets from different crops for the same crop group treated at the same GAP (calculate the MRL for each dataset separately and compare results to determine highest residue population and crop group MRL); and
- Proposing MRLs lower than 0.01 mg/kg. The calculator lowest accepted residue value is 0.001 mg/kg. The calculator will work with values below 0.01 mg/kg and will display statistical values below 0.01 mg/kg including unrounded MRL. The proposed MRL will be always the lowest MRL class of 0.01 mg/kg. On the basis of these data it is possible to round the results to an appropriate MRL class below 0.01 mg/kg if warranted. Nevertheless, MRLs below 0.01 mg/kg are an exemption for the moment and routine MRL setting below this value should be discussed in the light of future developments in analytical methods.

117. The OECD calculator is useful to determine whether an MRL estimate is appropriate on the basis of a particular data set. However, a reviewer is aware of other factors which may influence the values at which MRLs are set. It is therefore important to note that although the calculator should be beneficial, the decision of the most appropriate MRL should be made by the reviewer, who is in possession of all the relevant information.

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APPENDIX 1

Appendix 1a: Existing Crop Groups and Extrapolations¹

Codex	NAFTA Crop	NAFTA Representative	EU Groups	EU Representative	Australia Commodity	Australia Rossible	Australia Possible
Group	Subgroup	Crop (for group	01 01 01 01 01 0	Crop	Crops	Extrapolation	Extrapolation
-		or subgroup)		and	Groupings	From	То
				Extrapolation ²			
FC Citrus fruits	10 Citrus Fruits	Sweet orange Lemon Grapefruit	1 Fruits (i) Citrus Fruits: Lemons Mandarin (including clementines and similar hybrids) Orange	Oranges or oranges and grapefruits (8 trials, with a minimum of four trials on oranges) and mandarins and/or lemons (8 trials)→ group	Subgroup 1 Lemon Lime Mandarin Subgroup 2 Grapefruit Oranges Tangelos	Oranges + Lemons Or Oranges + Limes Or Oranges + Mandarins	Whole group
FP Pome fruits	11 Pome Fruits	Apple Pear	1 Fruits (iii) Pome Fruit: Apple Pear	Apples OR Pears (with a minimum of 4 apple trials) → group	Apple Crab apple Loquat Nashi Pear Quince	Apples + Pears	Whole group
FS Stone fruits	12 Stone Fruits	Cherry (sweet or tart) Peach Plum (incl fresh prune)	1 Fruits (iv) Stone fruit: Apricot Cherry Peach (incl Nectarine) Plum	Peaches OR Apricots (with a minimum of 4 apricot trials) → nectarine, peach, apricot	Subgroup 1 Apricot Nectarine Peach	Peaches + Nectarines + Cherries Or Peaches + Plums + Cherries	Whole group

Codex Crop Group	NAFTA Crop Group/ Subgroup	NAFTA Representative Crop (for group or subgroup)	EU Groups of Crops	EU Representative Crop and	Australia Commodity Crops Groupings	Australia Possible Extrapolation From	Australia Possible Extrapolation To…
				Extrapolation ² Sweet cherries ↔ Sour cherries	Subgroup 2 Cherries Plums	Peaches	Nectarines, plums
FB Berries and other small fruits	13 Berries and Small Fruit	Blackberry Raspberry Highbush blueberry, elderberry, or mulberry Grape Fuzzy kiwifruit Strawberry	1 Fruit (v) Berries and small fruit		Prune Subgroup 1 Blackberry Boysenberry Cranberry Raspberry Subgroup 2 Blueberry Currants	Grapes + strawberry and one other from subgroups 1 or 2 Raspberry	Whole group Subgroup 1 Subgroup 2
	07D Small fruit vine climbing (07E except grape) [07F except kiwifruit]	Grape and fuzzy kiwifruit \rightarrow Grape, gooseberry, Amur river grape, kiwifruit, Maypop, schisandra berry (fuzzy kiwifruit \rightarrow above less grape) [grape \rightarrow above less kiwi]	(a) grapes (b) strawberries	Table ↔ Wine grapes	Other Grapes Strawberry	Currants	
	07G Low growing berry	Strawberry → strawberry, bearberry, bilberry, lowbush blueberry, cloudberry,					

Codex	NAFTA Crop	NAFTA	EU Groups	EU	Australia	Australia	Australia
Crop	Group/	Representative	of Crops	Representative	Commodity	Possible	Possible
Group	Subgroup	Crop (for group		Crop	Crops	Extrapolation	Extrapolation
		or subgroup)		and	Groupings	From	То
				Extrapolation			
		cranberry,					
		lingonberry,					
		muntries,					
		partingeberry					
				Raspberries (4			
	-07A Caneberry	Blackberry or	(c) cane fruit	trials) \rightarrow			
	,	Raspberry →		blackberries			
		blackberry,		Raspberries OR			
		raspberry,		two			
		loganberry,		representatives			
		(including		(6 trials) \rightarrow			
		nybrias,		whole group			
		cultivars, wild)					
				6 trials on			
	-07B Bushberry	Blueberry,	(d) Other	currants (black,			
		highbush $ ightarrow$	small fruits	red or white)			
		Currant,	and berries	alone or 6 trials			
		cranberry, salal,	(except wild)	on two			
		blueberry,		representatives			
		gooseberry,		(must also			
		ouner		minimum of 4			
	-07C Large shrub/	Elderberry or		trials on			
	tree	mulberry →		currants) or on			
		Bayberry,		grape and			
		chokeberry,		currant (must			
		elderberry,		also include a			
		Juneberry,		minimum of 4			
		mulberry,		trials on			
		others		W_{bole} aroun			
				vvilue group			
		cranberry.					

Codex Crop Group	NAFTA Crop Group/ Subgroup	NAFTA Representative Crop (for group or subgroup)	EU Groups of Crops	EU Representative Crop and	Australia Commodity Crops Groupings	Australia Possible Extrapolation From	Australia Possible Extrapolation To…
		bearberry, lowbush blueberry, cloudberry, lingonberry, muntries, partridgeberry		Extrapolation ²			
	(07H except strawberry)						
FT Assorted tropical and sub-tropical with edible peel	None		1 Fruits (vi)(a) Miscellaneous fruit – edible peel	table olives ↔ olives for oil production Cherries → Surinam cherries	Dates Figs Olives Persimmon Tamarillo Carambola Grumichan Jaboticaba	Olives + tamarillo (no extrapolation from one crop to another is possible although if data from these crops are consistent, a group MRL may be possible)	Whole group
FI Assorted tropical and sub-tropical with inedible peel	None		1 Fruits (vi)(b) Miscellaneous fruit – inedible peel, small (c) Miscellaneous fruit – inedible peel, large	none	Avocado Babaco Banana Custard apple Feijoa Guava Jackfruit Kiwifruit Litchi Longans Mango	Banana Avocado Kiwifruit Mango Papaw Pineapple (no extrapolation from one crop to another is possible although if	Whole group

Codex	NAFTA Crop	NAFTA	EU Groups	EU	Australia	Australia	Australia
Crop	Group/	Representative	of Crops	Representative	Commodity	Possible	Possible
Group	Subgroup	Crop (for group		Crop	Crops	Extrapolation	Extrapolation
		or subgroup)			Groupings	From	То
				Extrapolation			
					Mangosteen	data from	
					Pawpaw	these crops	
					Passion truit	are consistent,	
					Persimmon	a group MRL	
					Pineappie	may be	
					Sanadilla	possible)	
					Sapoto		
	2 Pulb vogotoblog	Onion hulh	2 Voqotablaa		Subgroup 1	Oniono +	Whole group
	3 Duib vegetables	Onion, buib			Garlic	Spring opions	whole group
vegetables	34 Onion bulb	Onion, green			Onions		
		Onion bulb	vegetables	Bulb onion \rightarrow	Shallots	Onions +	
		onion bulb		garlic shallots	Onanots	shallots	
		davlily pearl		garno, orianoto		Or	
		onion, shallot.				Onions +	
		others			Subaroup 2	Leeks	Subaroups 1.
	3B Onion, green			Spring/salad	Chives		2 and 3
	· · · , J · ·	Chive, leek,		onions \rightarrow	Spring	Onions	
		green onion,		Welsh onion,	onions	(green) or	
		Welsh onion,		chives		shallots	
		other			Subgroup 3		
				Leek ↔	Leeks		
				spring/salad			
				onions	Subgroup 4		
					Fennel bulb		
VB	5 Brassica (Cole)	Broccoli OR	2 Vegetables		Subgroup 1	Cauliflower +	Whole group
Brassica	Leafy Vegetables	Cauliflower	(iv) Brassica		Cauliflower	Cabbage +	
vegetables		Cabbage	vegetables		Broccoli	Brussels	
(excluding		Mustard greens				sprouts	
leaty)		Duralion			Subgroup 2	Or	
	5A Head and	Broccoll OR	(a) Flowering	Cauliflower,	Cabbage	Broccoll +	
	stem brassica	Caulifiower	brassicas.	DIOCCOII (4	Subaraun 2	Cappage +	
		Cabbage →		ulaiss each) \rightarrow	Subgroup 3	Brussels	
		DIUCCUII,		whole group	DIUSSEIS	sprouts	
		broccoli	(b) Hood	Brussole	sprouts		
		DIOCCOII,	(u) neau	DIUSSEIS			

Codex	NAFTA Crop	NAFTA	EU Groups	EU	Australia	Australia	Australia
Crop	Group/	Representative	of Crops	Representative	Commodity	Possible	Possible
Group	Subgroup	Crop (for group		Crop	Crops	Extrapolation	Extrapolation
		or subgroup)		and Extremelation ²	Groupings	From	10
		Bruccolo	braggiogo				
		Diusseis	Diassicas	sprouts, neau			
		sprouts,					
		Chinese		None			
		cabbage					
		Chinese	(d) kohlrabi	None			
		mustard					
		cauliflower.					
		caval broccolo,	(c) Leafy	Kale \rightarrow Whole			
		kohlrabi	brassicas	group			
	5B Leafy Brassica	Mustard greens					
	greens	\rightarrow					
		Broccoli raab,					
		bokchoy,					
		collards, kale,					
		aroone mustard					
		spinach rane					
		areens					
VC Fruiting	9 Cucurbit	Cucumber	2. Vegetables		Subgroup 1	Rock melon +	Whole group
vegetables	vegetables	Muskmelon	(iii) Fruiting		Cucumber	Cucumber +	-
cucurbit		Summer squash	vegetables		Chokos	Zucchini	
					Bitter melon		
	9A Melon	Cantaloupes \rightarrow	(b) cucurbit	Cucumber or	Zucchini		
		Citron melon,	edible peel	courgette (if			
		muskmelon,		courgettes	Subgroup 2	Melons	Subgroup 2
		watermelon		alone 8 trials)	Melons		
	OR	Summor		\rightarrow whole group	Rumpkin		
	Squash/cucumber	squash			Squash		
		Cucumber \rightarrow		Melons →	Oquasii		
		Chavote.	(c) cucurbit	Whole group	Subaroup 3		
		Chinese wax	inedible peel		Gherkin		
		gourd,			_		

Codex Crop	NAFTA Crop Group/	NAFTA Representative	EU Groups of Crops	EU Representative	Australia Commodity	Australia Possible	Australia Possible
Group	Subgroup	Crop (for group or subgroup)		Crop and Extrapolation ²	Crops Groupings	Extrapolation From	Extrapolation To
		cucumber, gherkin, gourd, pumpkin, squash	(d) sweet corn	Immature maize → sweet corn			
VO Fruiting vegetables noncucurbit	8 Fruiting Vegetables (except cucurbit) 8A Tomato 8B Pepper/eggplant 8C Nonbell	Tomato Bell pepper Non-bell pepper Tomato Bell pepper and one cultivar of nonbell pepper One cultivar of	 Vegetables (iii) Fruiting vegetables (a) Solanacea Tomatoes Peppers 	Tomato → Aubergine Sweet peppers → Peppers	Subgroup 1 Egg plant Tomato Subgroup 2 Fungi Mushrooms Other Peppers Chilies	Tomato + Capsicum (note it may be more appropriate to generate data as growing patterns and size vary widely) Maize	Whole group
	pepper/eggplant	small nonbell pepper or one cultivar of small eggplant			Cape gooseberry Sweet corn Okra Roselle (Rosella)		
VL Leafy vegetables (including Brassica)	4. Leafy Vegetables (except Brassica)	Celery Head lettuce Leaf lettuce Spinach	2. Vegetables (v) Leaf vegetables and fresh herbs		Subgroup 1 Lettuce Mustard Cress	Leafy lettuce + Spinach + Chinese cabbage	Whole group
	4A Leafy Greens (except watercress)	Head lettuce Leaf lettuce Spinach →	(a)Lettuce and other	Lettuce (8 trials on open leaf varieties)	Subgroup 2 Spinach Silverbeet	Spinach	Subgroup 2
		Amaranth; arugula; chervil; chrysanthemum, edible-leaved;	salad plants including Brassicacea	→ Whole lettuce and other salad plants group	Subgroup 3 Fennel Subgroup 4	Celery	Silverbeet

Codex	NAFTA Crop	NAFTA Representative	EU Groups	EU Roprosontativo	Australia Commodity	Australia Rossible	Australia Possible
Group	Subgroup	Crop (for group	0101093	Crop	Crops	Extrapolation	Extrapolation
		or subgroup)		and	Groupings	From	то
[see VS stalk and stem]	4B Leaf petioles	chrysanthemum, garland; corn salad; cress, garden; cress, upland; dandelion; dock; endive; lettuce; orach; parsley; purslane, garden; purslane, winter; radicchio (red chicory); spinach; spinach, New Zealand; spinach, vine. Celery → Cardoon; celery; celery, Chinese; celtuce; fennel, Florence; rhubarb; Swiss chard.	 (b) Spinach and similar (leaves) (c)vine leaves (grape leaves) (d)Water cress (e) Witloof 	Extrapolation ⁻ Spinach → (b) group Spinach → rocket, red mustard, leaves and sprouts of Brassica sp. Lettuce (8 trials, with a minimum of 4 trials on open leaf varieties) → group Spinach and similar None None	Chinese cabbage Kale		
vegetables	Vegetables (Succulent or	succulent and one dried)	 vegetables (vi) Legume vegetables 		Beans (green) Peas	вeans (green) + Peas (green)	vvnole group
	Dried)	Pea (one	(fresh)		(green)		

Codex	NAFTA Crop	NAFTA	EU Groups	EU	Australia	Australia	Australia
Crop	Group/	Representative	of Crops	Representative	Commodity	Possible	Possible
Group	Subgroup	Crop (for group		Crop	Crops	Extrapolation	Extrapolation
		or subgroup)		and	Groupings	From	То
				Extrapolation			
		succulent and					
		one dried)					
		Soybean (ury)					
	6A Edible-podded	Edible-podded	Beans, green	Beans, green			
	legume	bean	with pods	with pods \leftrightarrow			
	0	Edible-podded	•	Peas with pods			
		pea		Consideration			
		\rightarrow .		should be given			
	6B Succulent	snap bean, wax		to possible			
	snelled pea and	bean, Chinese		from			
	bean	nea sugar shan		mechanical			
		pea, pigeon		harvesting			
		pea, soybean					
		(immature					
		seed), sword					
		bean, etc					
	6C Dried shalled	aballad	Doog groop	None			
	nea and bean	succulent bean	without nod				
	(except sovbean)	garden pea \rightarrow	without pou				
	(0)(0)	lima bean,					
		broad bean					
		(succulent),					
		cowpea, pea					
		(garden), pigeon					
		pea, etc					
		dried bean.					
		dried pea					
		\rightarrow					
		dried grain lupin,					
		sweet lupin,					
		white lupin, field					
		bean, kidney					

Codex Crop	NAFTA Crop Group/	NAFTA Representative	EU Groups of Crops	EU Representative	Australia Commodity	Australia Possible	Australia Possible
Group	Subgroup	Crop (for group or subgroup)		Crop and Extrapolation ²	Groupings	Extrapolation From	Extrapolation
		bean, lima bean (dried), navy bean, pinto bean, cowpea, chickpea, lentil, pea (dried), pigeon pea, etc					
VD Pulses	See above 6C	See above 6C	3. Pulses, dry Beans, dry (including broad beans) Peas, dry (including chick peas)	Beans (dry) and/or peas (dry) → Whole group	Peas Beans Chickpea Lentils Lupin Soybean	Field peas (dry) + faba beans (dry) + lupins Or Field peas (dry) + chickpeas + lupins Or Field peas (dry) + navy beans + lupins	Whole group
VR Root and tuber vegetables	1. Root and Tuber Vegetables 1A Root vegetable	Carrot Potato Radish Sugar beet Carrot, radish, sugar beet → Garden beet, sugar beet, burdock, carrot.	 2. Vegetables (i)Root and tuber vegetables Carrots Sugar beet Fodder beet Swedes and turnips. (c)Other root and tuber vegetables except sugar 	Potato, carrot, and sugar beet (8 trials each) → Whole group (root and tuber vegetables) Carrots → Whole "other root and tuber vegetables except sugar	Subgroup 1 Carrot Parsnip Subgroup 2 Beetroot Swede Turnip Subgroup 3 Sweet potato Potato Yam	Potato + carrot + beetroot Or Potato + carrot + swede Or Potato + carrot + radish	Whole group

Codex	NAFTA Crop	NAFTA	EU Groups	EU	Australia	Australia	Australia
Crop	Group/	Representative	of Crops	Representative	Commoditv	Possible	Possible
Group	Subgroup	Crop (for group		Crop	Crops	Extrapolation	Extrapolation
		or subgroup)		and	Groupings	From	То
				Extrapolation ²			
		celeriac, chervil,	beet	beet"	Subgroup 4		
		chicory,	A		Radish		
		ginseng,	Carrot	Carrots \rightarrow	Horseradish		
		norseradisn,		roots of nerbal	Subaroup 5		
		narslev radish		iniusion, spices,	Chicory		
		oriental radish.		Sugar beet \rightarrow	onnoory		
		rutabaga.		Beetroot.			
		salsify, skirret,		Swedes, turnips			
		turnip					
				Swedes ↔			
	1B			turnips			
	Root vegetable	Carrot, radish \rightarrow		Curada ar turnin			
	(except sugar	1A except sugar		Swede or turnip			
	beel)	beel		\rightarrow Celefiac,			
				noiseiauisii			
				Potatoes			
				→tropical root			
		potato →		vegetables			
	1C	arracacha.					
	Tuberous and	arrowroot,	(a)Potatoes	Sweet potato			
	corm vegetables	Chinese		and/or yam →			
		artichoke,		tropical root			
		Jerusalem		vegetables			
		artichoke,	(b)Tropical				
		canna, cassava,	root and tuber				
		cnayote (root),	vegetables	Carrot or sugar			

Codex Crop Group	NAFTA Crop Group/ Subgroup	NAFTA Representative Crop (for group or subgroup)	EU Groups of Crops	EU Representative Crop and Extrapolation ²	Australia Commodity Crops Groupings	Australia Possible Extrapolation From	Australia Possible Extrapolation To…
		chufa, dasheen, ginger, leren, potato, sweet potato, tanier, turmeric, yam.	9. SUGAR PLANTS	beet → chicory roots			
	1D Tuberous and corm vegetables (except potato)	Sweet potato → 1C except potato					
	2. Leaves of root and tuber vegetables	Turnip Garden or sugar beet					
VS Stalk and stem vegetables [globe artichoke,	None	Celery- Group 4 Globe artichoke- no group Cardoon- Group 4	2. Vegetables (vii) Stem vegetables	Leek ↔ spring/salad onions	Artichoke Asparagus Celery Witloof Rhubarb	Celery, asparagus, artichoke Celery	Whole group

Codex Crop	NAFTA Crop Group/	NAFTA Representative	EU Groups of Crops	EU Representative	Australia Commodity	Australia Possible	Australia Possible
Group	Subgroup	Crop (for group or subgroup)		Crop and Extrapolation ²	Crops Groupings	Extrapolation From	Extrapolation To
asparagus, bamboo shoots, cardoon, celery, palm hearts, witloof chicory (sprouts)]		Red chicory (radicchio)- Group 4		Celery → Fennel (bulb), cardoon, rhubarb			
GC Cereal grains	15. Cereal grains	Corn (fresh sweet corn and dried field corn)	5. Cereals Barley	Barley \rightarrow oats Wheat \rightarrow rye Maize \rightarrow millet,	Subgroup 1 Wheat Triticale	Wheat + barley + oats	Subgroups 1 and 2
[Sweet corn = VO fruiting		Rice Sorghum Wheat	Maize Oats Rice	sorghum Immature wheat → immature	Cereal rye	Maize + sorghum	Subgroup 3
vegetables]			Rye Sorghum	spelt	Barley Oats	Rice	Subgroup 4
			Triticale Wheat	(treatments applied during inflorescence emergence and post- inflorescence	Subgroup 3 Maize Sorghum Millet Subgroup 4	Wheat or barley	Oats, rye, triticale, durum wheat, (treatments applied before GS32 only)
				emergence)	Rice	Wheat	Whole group except rice for post-harvest treatment only
GS Grasses for sugar or syrup production	None		None		Sugar cane		
TN Tree nuts	16. Tree nuts (except pistachio	Almond Pecan	1.Fruits (ii)Tree nuts	Any two representative	Almonds Cashew	Almonds + Macadamia	Whole group

Codex	NAFTA Crop	NAFTA	EU Groups	EU	Australia	Australia	Australia
Crop	Group/	Representative	of Crops	Representative	Commodity	Possible	Possible
Group	Subgroup	Crop (for group		Crop	Crops	Extrapolation	Extrapolation
		or subgroup)		and Extremeletion ²	Groupings	From	10
			(aballad ar		Chastauta		
	and coconut)		(snelled of	(Closed huls			
			unsnelled)		Macadamia		
				nute	Pecan		
				nistachios) with	Pistachios		
				the exception of	Walnuts		
				coconuts (6	V anato		
				trials) \rightarrow Group			
				Any "closed			
				nut"with the			
				exception of			
				coconuts (4			
				trials) \rightarrow			
				"closed nuts"			
SO Oilseed	20. Oilseed	Rapeseed	4. Oilseeds	Any two of:	Subgroup 1	Canola	Whole group
	(except peanut,	(canola varieties	and Oil fruits	Cotton seed,	Mustard	(sattlower,	
	soya)	ONIY), Supflower	(i) Oileanda	Rapeseed,	seed	linseed or	
		Surnower,	(I) Oliseeus	Supflowor	Dana sood		
		Collonseeu	Peanut	Minor unlisted	Nape seeu	in case of	
			Rapseed	oil seeds (oil	Subaroup 2	winter crops	
			Sova bean	seeds except	Poppy seed	depending on	
			Sunflower	those of	Safflower	use –pattern),	
				previous	seed	cottonseed,	
				column)	Sesame	peanut	
					seed	(summer	
				Rapeseed \rightarrow	Sunflower	crops,	
	20A. Rapeseed	Rapeseed \rightarrow		linseed,	seed	sunflower,	
		Borage,		mustard seed,	Cubara a	soybean may	
		Cuphon Flow		poppy seed,	Subgroup 3	replace	
		Cupilea, Flax		you or pleasure	reanul	depending on	
		nleasure Hare's		olives for oil	Subaroup 4	use-nattern)	
		ear mustard	(ii) Oil fruits		Sovbean	use-pattern).	
		Lesquerella.		table olives	coybour		

Codex Crop Group	NAFTA Crop Group/ Subgroup	NAFTA Representative Crop (for group	EU Groups of Crops	EU Representative Crop	Australia Commodity Crops	Australia Possible Extrapolation	Australia Possible Extrapolation
		or subgroup)		Extrapolation ²	Groupings	From	10
		Meadowfoam, Mustard seed, Oil radish, Poppy seed, Rapeseed, Sesame, Sweet rocket, echium, lunaria, and milkweed	Olives for oil production. Palm kernels		Subgroup 5 Olive Subgroup 6 Maize Subgroup 7 Cottonseed	Rape seed	Mustard seed, poppy seed, sesame seed, linseed
	20B. Sunflower	Sunflower → Castor oil plant, Chinese tallowtree, Euphorbia, Evening primrose, Jojoba, Niger seed, Rose hip, Safflower, Stokes aster, Sunflower, Tallowwood, Tea oil plant, and Vernonia.					
	20C Cottonseed	None					
SB Seeds for beverages and sweets [cacao,	None		6 Tea, coffee, herbal infusions, and cocoa		Coffee		
coffee, cola]			(i)Tea	None			
			(II) Cottee	None			

Codex Crop Group	NAFTA Crop Group/ Subgroup	NAFTA Representative Crop (for group or subgroup)	EU Groups of Crops	EU Representative Crop and Extrapolation ²	Australia Commodity Crops Groupings	Australia Possible Extrapolation From…	Australia Possible Extrapolation To…
			(iii)Herbal infusions (a)flowers (b)leaves (c)roots	Any single cultivated crop of (a), (b), or (c) \rightarrow (a), (b), OR (c) of herbal infusions and spices Carrots or any root and tuber vegetable \rightarrow Roots of herbal infusions and spices			
			(d)other herbal infusions	None			
			(iv)cocoa	None			
			(v) carbob (St Johns bread)	None			
HH Herbs	19. Herbs and Spices	Basil (fresh and dried) Black pepper Chive Celery seed OR Dill seed	2. Vegetables (v) Leaf vegetables and fresh herbs		Many	Parsley, mint (extrapolations to a group on a case-by- case basis)	Whole group
	19A. Herb	Basil (fresh and dried) Chive \rightarrow	(f)Herbs (fresh)	Any crop of the herbs group (except bay			

Codex Crop	NAFTA Crop Group/	NAFTA Representative	EU Groups of Crops	EU Representative	Australia Commodity	Australia Possible	Australia Possible
Group	Subgroup	Crop (for group	or crope	Crop	Crops	Extrapolation	Extrapolation
•		or subgroup)		and	Groupings	From	То
				Extrapolation ²			
		Angelica; balm;		leaves, sage,			
		basil; borage;		rosemary and			
		burnet;		thyme), spinach			
		camomile;		or lettuce (open			
		catnip; chervil		leaf varieties \rightarrow			
		(dried); chive;		Whole group			
		chive, Chinese,		(otner			
		(loof): continuer		extrapolations			
		(lear), costinary,		considered on a			
		curry (leaf):		case by case			
		dillweed:		basis)			
		horehound:					
		hyssop;					
		lavender;					
		lemongrass;		Any single			
		lovage (leaf);	6. (iii)Herbal	cultivated crop			
		marigold;	infusions	of (a), (b), or (c)			
		marjoram ((a)flowers	\rightarrow			
		Origanum spp.);	(b)leaves	(a), (b), OR (c)			
		nasturtium;	(c)roots	of herbal			
		parsiey (dried);		infusions and			
		pennyroyal,		spices			
		sage: savory		Carrots or any			
		summer and		root and tuber			
		winter: sweet		vegetable \rightarrow			
		bay; tansy;		Roots of herbal			
		tarragon; thyme;		infusions and			
		wintergreen;		spices			
		woodruff; and					
		wormwood.					
HS Spices	19B. Spice	Black pepper	8. Spices		Many	Ginger	Whole group
		Celery seed OR				(extrapolations	
		Dill seed	(i) Seeds:	Any single crop		to a group on	
		\rightarrow Allspice;	Anise,	of previous		a case-by-	

Codex	NAFTA Crop	NAFTA	EU Groups	EU	Australia	Australia	Australia
Crop	Group/	Representative	of Crops	Representative	Commodity	Possible	Possible
Group	Subgroup	Crop (for group		Crop	Crops	Extrapolation	Extrapolation
		or subgroup)		and Extremelation ²	Groupings	From	10
		anica (caad):	corowov				
		anise (seed); anise, star; annatto (seed);	celery, coriander, cumin, dill,	Whole group		,	
		caraway; caraway, black; cardamom;	fennel, fenugreek, lovage, pasturtium				
		cassia (buds); celery (seed); cinnamon; clove	nastuntum				
		(buds); coriander (seed); cilantro (seed); cumin; dill (seed);	(II)Fruits and berries	Any single cultivated crop → Fruits and berries of herbal infusions and spices			
		fennel, common; fennel, Florence (seed); fanugraak;	(iii)Bark	None			
		grains of paradise; juniper (berry); lovage (seed); mace; mustard (seed); nutmeg; pepper,	(iv) Roots or rhizome	Any single cultivated crop → roots of herbal infusions and spices			
		black; pepper, white; poppy (seed); saffron; and vanilla.		root and tuber vegetable \rightarrow roots of herbal infusions and spices			
[VO	21. Edible fungi	White button	2.Vegetables		See fruiting		

Codex Crop Group	NAFTA Crop Group/ Subgroup	NAFTA Representative Crop (for group or subgroup)	EU Groups of Crops	EU Representative Crop and Extrapolation ²	Australia Commodity Crops Groupings	Australia Possible Extrapolation From	Australia Possible Extrapolation To…
Fruiting Vegetables]		mushroom and Oyster mushroom Or Shiitake mushroom	(viii)Fungi (a)Cultivated	Any single cultivated mushroom species → All cultivated mushrooms	vegetable		
			(b) Wild	Any single wild mushroom species → All wild mushrooms			
DH Dried herbs	Hops	None	7.Hops [See 6 (iii) herbal infusions]	None			
DT Teas	Теа	None	6.Tea, coffee, herbal infusions and cocoa (i) Tea	None			

¹ The current situation is fluid. Revisions are occurring in Codex, EU, and NAFTA. The table attempts to represent the official situation at the moment.

² Late season use. Separate criteria for early season use and for postharvest use.

³ Only important crops are summarized in each group. Not all crops grown in Japan are classified in certain groups.

Appendix 1b: New Proposed Codex Crop Groups, Representative Crops and Extrapolations (April 2010)

Codex Crop Group ¹	Codex Subgroups ¹	Codex Boprosontativo Crop	Extrapolation ²
		(for group or	
001 Citrus fruits	001A, Lemons and	subgroup	
	Limes		
	001B, Mandarins		
	001C, Oranges,		
	Sweet, Sour		
	001D, Shaddock and Pomelos		
002 Pome fruits			
003 Stone fruits	003, A Cherries		
	003, B Plums		
	003, C Peaches		
004 Berries and other small fruits	004A, Cane berries		
	004B. Bush berries		
	004C, Large		
	shrub/tree berries		
	004D, Small fruit vine		
	climbing		
	004E, Low growing		
	berries		
	0004 Dulh aniana	Onion hulh	to submerve 000A
009 Buib vegetables	009A, BUID ONIONS		to subgroup 009A
	UU9B, Spring Unions		
		green	to group 009
012 Eruiting	0124 Tomotooo	tomata	to subgroup 012A
vegetables, other than Cucurbits	UTZA, Tomaloes	lonalo	
	012B, Peppers	Sweet pepper; and	to subgroup 012B
		one cultivar of chili	
		pepper	
	012C, Eggplants	One cultivar of large	to subgroup 012C
		variety of eggplant and	
		one cultivar of small	
			to group 12
		romato; sweet pepper;	to group 12
		cultivar of small variety	
		equilibriant	
018 Edible Funai			

Codex Crop Group ¹	Codex Subgroups ¹	Codex Representative Crop (for group or subgroup) ²	Extrapolation ²
022 Tree nuts			
000 Oileand	0224 Dana acada		
	023A, Rape seeds		
	seeds		
	023C, Cottonseed		
	023D, Other oilseeds		
	023E, Oilfruits (fruits of palm trees)		
027 Herbs	027A, Herbs (herbaceous plants)		
	027B, Leaves of woody plants (leaves of shrubs and trees)		
	· · · · ·		
028 Spices	028A, Seeds		
	028B, Fruit or berry		
	028C, Bark		
	028D, Root or rhizome		
	028E, Buds		
	028F, Flower or stigma		
	028G, Aril		
<u> </u>			
		L	

¹ Currently elaborated crop groups and subgroups. Additional group will be added later.

² For the moment only proposals for Group 009 Bulb vegetables and group 012 Fruiting vegetables, other than Cucurbits are elaborated. Missing entries will be added later.

Appendix 2: Criteria for Crop Groups in National Governments

Japan Criteria

Basis for Crop/Commodity Categorization in Japan

The work is currently ongoing as a part of the review of pesticide registration scheme in Japan on the classification of all food commodities/crops for which there are registered uses of pesticides and/or MRLs. The work uses the Codex Classification as a basis although some Japanese specific situations may be taken into consideration.

NAFTA Criteria

The following 15 points are addressed in constructing rationale for a crop definition and/or group /subgroup proposal:

- 1. Botany and Nomenclature of Commodity:
 - Botanical Family and Family Characteristics of proposed commodities;
 - Genus and Species;
 - Common names and/or synonyms; and
 - Cultivars/hybrids where appropriate.
- 2. Commodity Geographical Distribution and Production in the U.S.
- 3. Global Commodity Geographical Distribution and Production.
- 4. Commodity Imports/Exports.
- 5. Cultural Practices:
 - Planting Rate(s);
 - Planting Date(s);
 - Row or Broadcast Crop;
 - Growing Season;
 - Growth and development of crop and growth stages;
 - Irrigation;

- Worker practices;
- Harvesting practices;
- Post-harvest activities;
- Crop rotations; and
- Processing of commodity.
- 6. Commercial Importance of Commodity (Current and Projected).
- 7. Possibilities for Genetic Improvement (Cultivars, Hybrids).
- 8. Comparison of Edible Part(s):
 - Description of fruit/vegetable;
 - What is consumed;
 - When harvested;
 - How harvested;
 - How often harvested;
 - Uses of commodity such as livestock feed, syrup, jelly, production, foods, shampoos, biodiesels, medicines, adhesives);
 - Surface area to weight ratio of commodity;
 - Leaf shape and area;
 - Type of fruit/vegetable surface (smooth, hairy);
 - Weight of fruit/vegetable; and
 - Similarities to other commodities.
- 9. Livestock Feed Item(s) for Beef and Dairy Cattle, Poultry, and Swine (include Importance of Feedstuffs (>250,000 tons) and Percent of Livestock Diet).
- 10. Processed Products (such as oil or flour) and/or Fresh Market as Whole Fruit/Vegetable.
- 11. Comparison of Pest Problems:
 - Insects;
 - Diseases;
 - Nematodes;

- Weeds;
- Vertebrates (such as moles, rodents); and
- Other pests.
- 12. Comparison of Potential Residue Levels (Tolerance/MRL).
- 13. Compare Codex Classification of Food and Feed Crops (Harmonization for International Considerations) with U.S.
- 14. Justification(s) for a Crop Group/Subgroup Definition:
 - Selection of Representative Crops Utilized for Residue Field Trials to Cover Entire Crop Group; and
 - Selection of Representative Crops Utilized for Residue Field Trials to Cover Crop Subgroup.
- 15. References Including:
 - Scientific Literature, world complete literature search [USDA National Agricultural Library Agricola];
 - Current Research Projects [USDA Current Research Information System (CRIS)];
 - Scientific names [USDA GRIN (http://www.ars-grin.gov/cgi-bin/npgs/htm/taxecon/pl)];
 - Specific Codex Classification of Foods and Animal Feeds;
 - Previous IR-4 Petitions for Commodity or Crop Group;
 - Copies of Pertinent Reference Pages; and
 - Classic Monograph Reference Adapted from Foods and Feed Crops of the United States. 1998. George Markle, Jerry Baron, and Bernard Schneider. Second Edition. Meisterpro Publication.

Australian Criteria

For crop groups no own criteria:

• Crop groups used as defined by CODEX.

Crop group are further divided into subgroups:

• These are primarily indicative of form and growth habit;

- The subgroups are based on differences in the size of the commodity, whether there are any covering leaves to protect the edible part of the crop and the nature of the commodity;
- The subgroups are intended to reflect factors which may contribute to varying residue levels across the whole crop group; and
- Other criteria which may contribute to the subgroups include the surface of the crop, i.e. curly leaf vs straight leaf or hairy surface vs wrinkled surface vs smooth surface.

European Criteria

European criteria are not described. Some of the criteria taken into consideration are given below:

- Botanical characteristics;
- Morphological aspects;
- Surface area to weight ratio of commodity; and
- Codex Classification of Food and Feed Crops.

Appendix 3: Proposed Number of Residue Trials for Comprehensive Submissions

(Preliminary proposal to be redrafted in the light of new Codex Classification)

Minimum number of Supervised Field Trials Conducted at cGAP									
		Additional Canadian (where US trials do not							After 40%
Crop ¹	US	overlap)	EU ²	JP ³	AUS	NZ	Other	Total	reduction ⁴
Acerola (Barbados cherry)	1		4	2				7	8
Alfalfa	12	6		2		4		24	15
Almond	5		4	2	6	2		19	13
Apple	16	4	16	6	8	6		52	32
Apple, Sugar	2		4	2				8	8
Apricot	5	2	12	2	6	2		29	20
Arracacha	2		4	2				8	8
Artichoke, Globe	3		4	2		2		11	8
Artichoke, Jerusalem	3		4	2		2		11	8
Asparagus	8	2	8	2	4	4		28	18
Atemoya	1		4	2		2		9	8
Avocado	5		4	2	8	2		21	14
Banana	5		4	2	8			19	12
Barley	12	12	16	3	8	4		54	33
Bean, Dried	12	1	16	2		2		33	22
Bean, Edible Podded	8		16	2		4		30	19
Bean, Lima, Dried	3			2		2		7	8
Bean, Lima, Green	8			2	8	2		20	14
Bean, Mung	3			2		2		7	8
Bean, Snap	8	1		2		2		13	10
Bean, Succulent Shelled	8		16	3		2		28	18
			4					16	
Beet, Garden	5	3	(12)	2		2		(24)	11 (16)
Blackberry	5		4	2		2		13	9
Blueberry	8	3	4	2	4	2		23	15
Bok choi	2			2		2		6	8
Boysenberry	2		4	2		2		10	9
Broccoli	8	4	8	3	8	4		34	21
Broccoli, Chinese (gai lon)	2			2		2		6	8
Brussels Sprouts	3		8	2	4	2		19	14
Buckwheat	5			2		2		9	8
Cabbage	8	4	12	6	8	4		38	24
Cabbage, Chinese	3		4	6		2		11	8
Cacao Bean (cocoa)	3		8	2				13	10
Calabaza	2			2				4	8
Calamondin	1			2				3	8
			12					46	
Canola	8	14	(16)	2	8	2		(50)	29 (32)
Cantaloupe	8		12	2	8	2		32	21
Capsicum (pepper)					8				8
Carambola	2		4	2		2		10	9
Carob	3		4	2				9	8

Minimum number of Supervised Field Trials Conducted at cGAP									
		Additional Canadian							
		(where US							
1		trials do not	2	2					After 40%
Crop	US	overlap)	EU ²	JP°	AUS	NZ	Other	Total	reduction [*]
Carrot	8	4	16	6	8	4		42	26
Cassava, bitter or sweet	2		4	2		2		10	9
			12					35	
Cauliflower	8	3	(16)	2	8	2		(39)	23 (25)
Celery	8	4	8	3	4	4		30	19
			8					25	
Cherry, Sweet	8		(12)	2	3	4		(29)	16 (18)
			8					23	
Cherry, Tart (Sour)	8		(12)	2	3	2		(27)	15 (18)
Chestnut	3		4	2	4	2		15	11
Chickpea (garbanzo bean)	3			2	4	2		11	9
Chicory	2		4	2		2		10	9
Clover	12			2		4		18	12
Coconut	5		4	2				11	8
Coffee	5		8	2	4			19	12
Collards	5		8	2		2		17	12
Corn, Field	20		16	2	2	4		44	28
Corn, Pop	3			2				5	8
Corn, Sweet	12	2	8	3	6	2		32	22
Cotton	12		8	2	8			30	19
Cowpea (dried shelled bean)	5			2		2		9	8
Cowpea (forage/hay)	3			2		2		7	8
Cowpea (succulent shelled									
bean)	3			2		2		7	8
Crabapple	3		8	2		2		15	11
Cranberry	5	1	4	2		2		14	10
Cress, Upland	1		4	2				7	8
Cucumber	8	3	12	6	4	4		33	21
Currant	2		8	2		2		14	11
Dandelion	1		8	2		2		13	11
Dasheen (taro)	2		4	2		2		10	9
Date	3		4	2				9	8
Dill (dill seed, dillweed)	2		8	2		2		14	11
Eggplant	3		8	6		2		15	11
Elderberry	3		4	2		2		11	8
Endive (escarole)	3		8	2		2		15	11
Fennel			8	2				10	8
Fig	3		4	2		2		11	8
Filbert (hazelnut)	3		4	2		2		11	8
Flax	5	5		2		2		14	10
Fodder beet			16	2		4		22	16
Garlic	3		8	2		2		15	11
Genip	1			2				3	8
Ginger	2		4	3				8	8
Ginseng	3		4	2				9	8
Gooseberrv	3		8	2		2		15	11
Grape	12	4	16	3		6	1	40	25
Grape, table		<u>·</u>	16	3	8	4		30	19
Grapefruit	8		4	2	2	2		18	13

Minimum number of Supervised Field Trials Conducted at cGAP									
		Additional							
		Canadian							
		(where US							
_ 1		trials do not	2	3				_	After 40%
Crop	US	overlap)	EU	JP°	AUS	NZ	Other	Total	reduction
Grasses	12			2		4		18	12
Guar	3			2				5	8
Guava	2		4	2		2		10	9
Herbs			8	2				10	8
Hops	3		8	2		2		15	11
Horseradish	3		8	2		2		15	11
Huckleberry	3		4	2		2		11	8
Kale	3		12	2		2		19	13
								15	
Kiwi fruit	3		4 (8)	3		6		(19)	10 (12)
Kohlrabi	3		8	2		2		15	11
Kumquat	1		4	2		2		9	8
Leek	3		12	6	4	2		23	15
Lemon	5		8	2	6	2		23	15
Lentil	3	2	4	2		2		13	10
Lettuce, Head	8	5	16	6	8	3		42	26
Lettuce, Leaf	8		16	2	8	3		37	23
Lime	3		4	2		2		11	8
Loganberry	2		8	2		2		14	11
Longan	1		4	2				7	8
Lotus Root	1		4	3				7	8
Lychee	1		4	2	2			9	8
Macadamia Nut	3		4	2	6	2		17	12
Mamey Sapote	2		4	2				8	8
Mandarin (tangerine)	5		8	6	8	4		27	17
Mango	3		4	2	8			17	11
Melon	-		12	3	-	2		16	12
Melon, Casaba	3			3		2		7	8
Melon Crenshaw	3			3		2		7	8
Melon Honeydew	5	3		3		2		12	9
Millet Proso	5	3	8	2		2		20	14
Mint	5	ŭ	8	2		2		17	12
Mulberry	3		8	2		-		13	9
Mushrooms	3		4	2	6	2		17	12
Muskmelons	8		•	3	Ŭ	2		12	9
Mustard Greens	8			2		2		12	9
Mustard Chinese	2			2		2		6	8
Nectarine	8	2	12	2	8	2		34	23
Oat	16	10	16	2	6	2		52	33
Okra	5	10	10	2	0	2		13	33
	3		 8	2		2		15	11
	2 2	1	16	6	Q	<u> </u>		13	26
Onion, Groon	2		10	6	0			- +2	20
Orion, Green	16	2	0	0	4	Z		21	10
Papaya	01		0	2	0	4		30	24
Fapaya Daralay	<u> </u>		4	2	0	0		9	8
Derenin	3		4	2	2	2		13	10
	3		ŏ ₄	2		2		15	11
	2		4	2		2		10	8
Pawpaw	3	1	4	2	1	1		9	8

Minimum number of Supervised Field Trials Conducted at cGAP									
		Additional Canadian							
		trials do not							After 40%
Crop ¹	US	overlap)	EU ²	JP ³	AUS	NZ	Other	Total	reduction ⁴
Pea, Chinese	1	• • •		2		2		5	8
Pea, Dried Shelled	5	6	16	2	8	2		39	25
Pea, Edible podded	8		8	2	6	2		26	17
Pea, Edible Podded	3			2		2		7	8
Pea, Field (Austrian Winter)									
(forage/hay)	3			2	8	2		15	11
Pea, Succulent Shelled (Pea,			12					26	
Garden, Succulent)	8	2	(16)	2		2		(30)	18 (20)
Peach	12	4	12	3	8	4		42	26
Peanut	12		4	2	8			26	16
Peanut, Perennial	3			2				5	8
Pear	8	3	16	6	8	4		41	25
Pecan	5		4	2	4	2		17	12
Pepper, (other than bell)	3			2		2		7	8
			12					28	
Pepper, Bell	8	4	(16)	3		2		(32)	18 (21)
Persimmon	3		4	6		4		13	9
Pimento	2		4	2		2		10	9
Pineapple	8		4	2				14	9
Pistachio	3		4	2				9	8
Plantain	3		4	2				9	8
	Ť		. 12	_				35	
Plum	8	3	(16)	2	8	2		(39)	23 (25)
Pomegranate	3		4	2				9	8
Potato	16	10	16	6	8	4		56	34
Pumpkin	5		8	3	4	2		21	14
Quince	3		8	2	-	2		15	11
Radish	5	2	8	2		2		19	14
Radish Oriental (daikon)	2			6		2		6	8
	-		12	Ŭ				19	
Rapeseed	3		(16)	2		2		(23)	13 (25)
Raspberry Black and Red	5	1	8	2		2		18	13
Rhubarb	2	1	8	2		2		15	12
Rice	16		8	6	6			32	20
Rice, Wild	5		-	2	-			7	8
Rutabaga	3	2		2		2		9	8
Rve	5	5	16	2		2		30	20
Safflower	5	2	4	2		2		15	11
Sainfoin	3			2		2		7	4
Salsify	3		8	2		2		15	8
Sesame	3		4	2				.0	8
Shallot	1		. 8	2		2		13	10
Sorghum Grain	12		8	2	6	2		30	20
	- 12		12			~		46	20
Sovbean (dried)	20		(16)	6	R	۵		(50)	28 (31)
Spices		<u> </u>	8	2	5	7		10	20 (01)
Spinach	8	3	8	6		2		23	15
		5	2 8	0				20	
Squash, Summer	8	2	(12)	2		4		(28)	16 (20)

Minimum number of Supervised Field Trials Conducted at cGAP									
Gron ¹	116	Additional Canadian (where US trials do not ovortan)	EU ²	ID ³		N7	Othor	Total	After 40%
Squash Winter	5	overlap)	8	Ј Г 3	A03	2	Other	17	12
Strawberry	8	2	16	3	8	<u> </u>		40	26
Sugar Beet	12	3	16	3	2	-		35	20
Sugarcane	8	5	10	3	8			18	12
	0		12	5	0			34	12
Sunflower	8	2	(16)	2	8	2		(38)	23 (25)
Sweet Potato	8		4	6		2		16	11
Swiss Chard	3		8	2		2		15	11
Tangelo	3		4	2		2		11	8
Tanier (cocoyam)	2			2				4	8
Теа			8	6				10	8
Tobacco	3	5	4	2		2		16	11
Tomato	16	11	16	6	8	4		57	35
Triticale			16	2	4	2			16
Turnip, root	5		8	3		4		19	12
Turnip, tops (leaves)	5		8	3		2		17	12
Walnut, Black and English	3		8	2		2		15	11
Watercress	2		8	2		2		14	11
			4					20	
Watermelon	8		(16)	6	4	2		(32)	14 (21)
Wheat	20	13	16	6	12	4		67	41
Yam, True	3		4	3		2		11	8

¹ Crops to be reconsidered after Codex classification is finalised.

² Number of trials for fodder crops in Europe not yet harmonised, although criteria are available that allow specifying number of trials i.e. cultivation area (ha) and production (t). Number in brackets indicate changes that will apply from 1st January 2013

³ Japanese government revised the requirements for residue data, depending on the production volume and consumption of each crop/commodity, within the review of pesticide registration scheme. These requirements will become effective in 2014.

⁴ To take into account that no reduction on two trials in an OECD country is possible and that a minimum of eight trials for a comprehensive submission is required.