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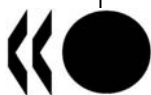
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**GUIDANCE DOCUMENT ON OVERVIEW OF RESIDUE CHEMISTRY STUDIES
(AS REVISED IN 2009)**

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**GUIDANCE DOCUMENT ON OVERVIEW OF
RESIDUE CHEMISTRY STUDIES**

(AS REVISED IN 2009)

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among UNEP, ILO, FAO, WHO, UNIDO, UNITAR and OECD

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 2009

Also published in the Series on Testing and Assessment:

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OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances-Monograph Guidance (1998, revised 2001, 2005)

OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances-Dossier Guidance (1998, revised 2001, 2005)

Report of the Pesticide Aquatic Risk Indicators Expert Group (2000)

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ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 30 industrialised countries in North America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

The Environment, Health and Safety Division publishes free-of-charge documents in ten different series: **Testing and Assessment; Good Laboratory Practice and Compliance Monitoring; Pesticides and Biocides; Risk Management; Harmonisation of Regulatory Oversight in Biotechnology; Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents; and the Safety of Manufactured Nanomaterials.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (<http://www.oecd.org/ehs/>).

This publication was produced within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The participating organisations are FAO, ILO, OECD, UNEP, UNIDO, UNITAR and WHO. The World Bank and UNDP are observers. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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FOREWORD

In 2003, the OECD initiated work to develop harmonised Test Guidelines and Guidance Documents on pesticide residue chemistry. Harmonised guidelines are essential to further work sharing goals of the Working Group on Pesticides for pesticide registration and re-registration. The harmonisation is based on guidelines currently used in Australia, Canada, Japan, the United States, the European Union and the Food and Agriculture Organisation (FAO) to provide for determination of pesticide exposure in food or animal feedstuffs. Data derived from such guidelines will not only be used by industry to fulfil pesticide registration requirements in countries/regions, but could also support FAO's development of recommendations on Maximum Residue Levels (MRLs). Several Guidance Documents and Test Guidelines (and templates for reporting test study summary data) have been developed within these activities:

Guidance Documents:

- *Definition of Residue (series on Testing and Assessment, No.63)*
- *Overview of Residue Chemistry Studies (series on Testing and Assessment, No. 64)*
- *Guidance Document on Pesticide Residue Analytical Methods (series on Testing and Assessment, No. 72)*
- *Guidance Document on Magnitude of Pesticide Residues in Processed Commodities (series on Testing and Assessment, No. 96)*

Test Guidelines:

- *TG 501: Metabolism in Crops,*
- *TG 502: Metabolism in Rotational Crops,*
- *TG 503: Metabolism in Livestock,*
- *TG 504: Residues in Rotational Crops (Limited Field Studies),*
- *TG 505: Residues in Livestock*
- *TG 506: Stability of Pesticide Residues in Stored Commodities*
- *TG 507: Nature of Pesticide Residues in Processed Commodities – High Temperature-Hydrolysis*
- *TG 508: Magnitude of Pesticide Residues in Processed Commodities*
- *TG 509: Crop Field Trial (to be published late 2009)*

The Test Guidelines and Guidance Documents were drafted by an OECD Expert Group on Pesticide Residue Chemistry, chaired by the United States and composed of experts from Australia, Canada, Germany, Italy, Japan, the Netherlands, New Zealand, the United Kingdom, the United States, the European Commission, the European Food Safety Authority (EFSA), FAO and CropLife International/BIAC. A small Steering Committee organised the work and identified issues for the Expert Group; it is composed of roughly one Expert Group member per different region (North America, Europe, Asia and Oceania) and organisation (EC, FAO and OECD). The work was carried out by drafting groups drawn from the Expert Group, one for each guideline and guidance document. The Expert Group reported to the Registration Steering Group/Working Group on Pesticides (RSG/WGP), which had management oversight of the initial phase of development up to production of draft proposals; the draft documents were submitted to the Working Group of National Co-ordinators of the Test Guidelines Program (WNT).

This document is an update of document ENV/JM/MONO(2006)32. It contains: (i) a Table of Raw Agricultural Commodities; (ii) national and regional tables of livestock feedstuffs; (iii) a Glossary of Terms; (iv) comprehensive submission criteria for supervised field trials in support of registration in all OECD countries; (v) instructions for calculating the 1x (lowest dose) pesticide oral administration level for livestock feeding studies, taking into account the various livestock diets around the world. It also provides a framework for a common international approach for use by OECD member countries in compiling livestock feedstuff information to prepare the ground so that national/ regional tables currently in use can be replaced by an internationally harmonised OECD Feedstuffs Derived from Field Crops Table. This Feed Table (Annex 4) has been updated from the previous version by changes from Australia and the USA and the addition of information for Japan.

This document is published on the responsibility of the Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals of the OECD.

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Introduction

1. Harmonization of guidelines for determination of pesticide residues provides a foundation for work sharing of residue chemistry reviews among OECD countries; harmonization will also lead to mutual acceptance of regulatory results, minimizing trade barriers. Harmonization is based on guidelines currently used in Australia, Canada, Japan, European Union (EU), Food and Agriculture Organization (FAO), and the United States (US) (1)(2)(3)(4)(5)(6).

2. This Overview Guidance Document summarizes the major guidance aspects provided in the OECD Harmonized Residue Guidelines for: 1) Metabolism in Crops; 2) Metabolism in Livestock; 3) Residues in Livestock; 4) Metabolism in Rotational Crops; 5) Residues in Rotational Crops (Limited Field Studies); 6) Storage Stability; 7) Processing Studies; 8) Crop Field Trials. This document also develops an approach for a Global Maximum Residue Limit (MRL) process to achieve use of harmonized studies for livestock food commodities, e.g., meat, milk and eggs, which can be used by all OECD member countries. The process to achieve use of a single globally acceptable feeding study for MRL setting and risk assessment for livestock food commodities involves four key components: 1) Harmonized guidance for a Guidance Document for Definition of the Residue; 2) Reasonable Worst Case Animal Diets/Maximum Reasonably Balanced Diet; 3) Harmonized Table of Livestock Feed Commodities; and 4) Definition of Reasonable Worst Case Livestock Feeding Levels. Each of these components is described. A Glossary of Residue Chemistry Terms is included as [Annex 1](#) and a list of commonly agreed residue terms used in the OECD Residue Chemistry guidelines and guidance documents is at [Annex 2](#). A table of Raw Agricultural Commodities (RACs) to be analyzed for crop metabolism and rotational crop studies is at [Annex 3](#). A Table of Feedstuffs Derived from Field Crops for use by OECD member countries is presented in [Annex 4](#). Annex 5 details the requirements of a comprehensive submission that is a submission to all OECD countries.

Residue Chemistry Test Guidelines and Guidance Documents

Metabolism in Crops

3. Studies of Metabolism in Crops are performed to elucidate the degradation pathway of the active ingredient, i.e., identify the degradation products when a pesticide is applied to a plant directly or indirectly, including the relative quantity of degradation products in extracts and non-extractable material. The composition of the terminal residue is determined before complete residue detection methodology and residue quantification data can be developed. To obtain this information, the pesticide is labeled with a radioactive atom to follow the compound to see if and where it breaks down within a plant.

4. Metabolism in Crops studies fulfill the following major purposes: to provide an estimate of total radioactive residue (TRR) in the various RACs; to identify the components of the terminal residue, which serves as part of the basis for setting the residue definition, thereby defining the components to be quantified by the residue analytical methodology; to elucidate the metabolic pathway of the active ingredient in treated crops; and to determine the distribution of residues within the plant into edible portions for human or livestock consumption.

5. Crop metabolism testing is performed for 3 crops drawn from 5 crop groups (root vegetables, leafy crops, fruits, pulses and oilseeds, and cereals). (A table of RACs to be analyzed for crop metabolism studies is at Annex 3.) If the resulting metabolic profiles in each crop are similar, no further testing is needed. If registration is sought for one crop group only, metabolism studies in one crop from that crop group will be sufficient as long as the crop is truly representative of the crop group and the metabolic pathway is elucidated. A sixth grouping consists of crops which each have distinct characteristics. Such miscellaneous crops are considered on a case-by-case basis. Paddy rice is an example of a special case.

(Extrapolation may be performed from other grains to upland rice but not to paddy rice). In addition, at least one study is called for in genetically modified crops that involve the insertion of a gene conveying resistance by means of metabolism.

6. Metabolism in Crops studies normally call for 1X application rates. When low residue levels in plants are expected from the maximum application rate, experiments at an exaggerated rate may be needed to provide sufficient material for analysis.

7. The identification of the components of the terminal residue and the definition of the residue of concern often present complex issues that must be resolved before finalizing the analytical methodology and gathering the quantitative residue data. Such issues concern determination that the residue has been sufficiently characterized and/or identified, identification of metabolites to be covered by the MRLs and decisions regarding components of the residue to be determined by the residue analytical methodology. The determination of whether the residue has been sufficiently characterized and/or identified will depend on the level of activity remaining unidentified, the importance of the crop commodity containing the unidentified residue as a food or feed, the chemical structure of the active ingredient and identified metabolites, and the toxicity of chemicals similar in structure to potential metabolites.

8. If a metabolite of a pesticide is identical to another registered pesticide or its metabolite or transformation product, authorities will take this into account in the course of risk assessment. In addition, attention should always be given to the possibility of new and unexpected metabolites of the pesticide which may affect future MRL proposals and/or risk assessments.

Metabolism in Livestock

9. Studies of Metabolism in Livestock are used to determine the qualitative and quantitative metabolism and/or degradation of the active ingredient resulting from pesticide use in feed stuffs, direct application to livestock, or premise treatment. The composition of the terminal residue in edible tissues, milk, and eggs must therefore be determined before complete residue detection methodology and residue quantification data can be developed.

10. Study designs for Metabolism in Livestock address two scenarios for pesticide use: 1) direct or premise application of the pesticide to livestock or, 2) application of the pesticide to plant commodities that can then be fed to animals. Livestock metabolism studies are generally carried out on ruminants (cows or goats) and poultry (chickens). The pesticide is radioactively labeled.

11. Metabolism in Livestock studies are applicable when pesticide use is expected to result in residues of the pesticide and/or its metabolites in edible livestock commodities. Such studies fulfil several purposes: to provide an estimate of total residues in the edible livestock commodities, as well as the excreta; to identify the major components of the terminal residue in the edible tissues, thus indicating the components to be looked for in residue quantification studies, i.e., definition of the residue; to indicate the metabolic pathway for the pesticide in ruminants and poultry; and to provide evidence whether a residue should be classified as fat-soluble. In some cases, a well-planned and conducted livestock metabolism study can also be used to address data requirements pertaining to livestock feeding.

12. Due to the global movement of feed items, and the resulting exposure of livestock, as well as the global movement of livestock commodities, Metabolism in Livestock studies are generally required whenever a pesticide is applied on crops used for feed even when the use pattern does not match the proposed domestic use within a country where registration is sought.

13. In order to elucidate metabolic pathways, animals should be sacrificed (and samples taken) at a time when residues in collected samples are high. The applicant will be asked to provide the scientific

basis which justifies the time of sacrifice chosen. This time should be preferentially 6 to 12 hours after the last dose. However, under no circumstances should the time of sacrifice be later than 24 hours after the last dose.

14. The following general principles apply when undertaking Metabolism in Livestock studies:

- Livestock are dosed at 1X, where 1X is the reasonable worst case worldwide dietary burden, or at 10 ppm in the diet as received, whichever is greater. For direct treatment 1X is the maximum dose applied to the animal. Five consecutive daily doses for ruminants and seven doses for poultry are recommended. In the case of direct treatment, repeat applications may be made if that is the intended use of the product.
- The results from one ruminant animal for oral treatment will generally be extrapolated to all ruminants. Similarly, the poultry metabolism study will be extended to all fowl. A swine metabolism study may be needed if the metabolic profile observed in the ruminant or poultry is significantly different from the profile observed in the rat. For dermal application, the target species, i.e., cattle, sheep, should be included in the study and extrapolation is not generally considered appropriate.
- Determinations as to whether sample integrity was maintained during collection, sample preparation, and storage should be made.
- Trigger values for identification/characterization of the components of the TRR are based on total ¹⁴C residues found in extracts and the extracted matrices and provide a regulatory minimum for characterization/identification of the residue. In cases where the pesticide is very toxic, identification of the TRR below the trigger values may be needed.

As in crop metabolism studies, the identification of new metabolites or transformation products, as well as metabolites or transformation products that are equivalent to those in already registered pesticides, is critical for MRL setting and risk assessment.

Analytical Methods

15. Analytical methods are used to generate the data for estimating dietary exposure assessments, to establish Maximum Residue Levels (MRLs), and to determine processing factors. Analytical methods are also used in enforcement of any statutory MRLs that may be established. Methods apply to all pesticides used on edible crops/livestock and subsequent produce and processed food products, and for products (e.g. meat, milk, eggs) from animals that may consume treated crops. Additionally, analytical methods are needed for conducting storage stability studies. Topics include: confirmatory techniques; derivatization; common moiety and non-specific methods, method validation criteria and the corresponding information to be reported.

16. During the conduct of the metabolism studies in crops, livestock, and rotational crop, applicants need to be aware that the ability of analytical methods (enforcement and data collection) to efficiently extract the residues defined for purposes of MRL or dietary risk assessment may need to be determined. Radiolabeled samples from these studies, therefore, may need to be retained for future analyses by the methods developed subsequently (sometimes referred to as "radiovalidation" of methods). Radiovalidation data would generally not be necessary, however, if the extraction procedures in the analytical methods substantially represent those used in the metabolism studies. If residue studies in rotational crops are required and the residue definition in rotational crops is the same as in primary crops, radiovalidation is not required, provided that extraction efficiency has been demonstrated in the primary crops. Radiovalidation

data can be reported as part of the metabolism study report, the analytical method report, or as a stand alone study report.

Residues in Livestock

17. Studies of Residues in Livestock are used to determine the quantity of pesticide residues in products of animal origin which will result from residues in feeding stuffs (including fodder crops) or from direct application to livestock and/or premise treatment. The objectives of the study are to establish maximum residue levels for food commodities of animal origin, and to ensure that residues transferred from animal feedstuffs do not pose unacceptable risks for consumers. A residue definition in plants based on the criteria in the OECD Guidance Document for Definition of the Residue is used to determine which component, parent (normal case) or a metabolite, should be fed to the animals. Similarly, a residue definition is used to decide what residues should be quantified in edible animal commodities

18. If pesticide residues are likely to be transferred to livestock in significant amounts from crops or parts of crops that are fed, the residue livestock studies are conducted as feeding studies. The data obtained provide quantitative information on the transfer of residues to meat, fat, milk, eggs and edible offal. Feeding studies are normally carried out in ruminants (cattle) and poultry (chicken). Results of studies in cattle may be extrapolated to other domestic animals (ruminants, horses, pigs, rabbits and others) and results in studies of laying hens may be used for other poultry species. Where the results of a pig metabolism study indicate routes of degradation with intermediates or end products that differ from those of the ruminant metabolism study and are considered to be of toxicological concern, then a pig feeding study needs to be conducted, unless the expected intake by pigs is not significant

19. Livestock are typically fed at 1X, 3X (or 5X), and 10X, where 1X is a level based on the lowest expected regional dietary burden, as estimated from the highest residue levels in individual feedstuffs (median residues in processed feedstuffs) and the percentage of each feedstuff in the regional livestock diets. Additional dose levels may be added by the applicant as necessary, for example, to refine dietary risk assessments. As the basic assumption is that all feedstuff that make up the total livestock diet will be pesticide treated, the dietary burden reflects the reasonable worst case that may occur in practice. (See Annex 4 – OECD Feedstuffs Derived from Field Crops.)

20. Production of high quality livestock in OECD countries generally is characterized by similarity in the quantitative content of feed components, e.g., protein or fibre content. However, it must be recognized that quality livestock, particularly beef and dairy cattle, sheep and goats, are managed under pasture and crop based grazing systems as well as more intensive lot feeding arrangements. Grazing livestock may also receive supplementary grain or conserved fodders (hay or silage) to enhance milk production, weight gain and/or body composition. The RAC used, e.g., soybean, barley, sorghum or canola, may differ from country to country and within a country depending on the season and local availability of feedstuffs. Price for feedstuff commodities is also a relevant factor contributing to changing levels of RACs in composite feed. Although it seems to be very ambitious to account for this variability at the international level, it can be done by grouping feed items according to their nutritional relevance. With this approach, comparable dietary burden calculations may be conducted.

21. For example, in the North American Free Trade Agreement (NAFTA) region, animal feeds are based on soybean, corn and cereals; in the European Union feeds are based on canola, corn and cereals; in Australia feeds are based on sorghum, wheat and oilseed meals; and in Japan feeds are based on forage and byproducts. Dietary burden would be calculated based on residue and intake data from North America, and compared with their equivalent data set from Europe, Japan, and Australia. Because of differences in the crops treated in different countries and regional differences in the livestock diets, the 10X dose may need to be adjusted upward to encompass a particular region, or a fourth feeding level might be necessary.

Harmonized feeding studies can be used by regulators in a consistent manner to set MRLs in their countries or regions.

22. When a pesticide is proposed for direct use on food animals, data are needed to determine the extent of residues in livestock commodities incurred by the use. Direct uses include pesticide application by back-line treatments, sprays, dips, pour-ons, dusts, dust-bags, back-rubbers, ear-tags or by jetting. The experimental treatment should reflect as closely as possible the conditions under which the pesticide will be used commercially, including formulation types and mode of treatment. All factors that might contribute to the variability of residue levels in animal commodities – such as animal husbandry conditions, gender and maturity according to Good Agricultural Practice (GAP) – should be considered and taken into account in the planning and conduct of trials. Separate studies should be carried out for each species of livestock to be treated.

23. In many cases it is not practical to remove animals from their housing while premise treatment takes place; an exception would be milking sheds. In the case of treatment to animal premises, the applicant may propose a scientific rationale to waive specific studies, based on data derived from direct animal treatments and animal husbandry practices. When the use of pesticides in agricultural buildings is such that label restrictions cannot preclude the possibility of residues in meat, milk or eggs, residue studies should be carried out reflecting the maximum conditions of exposure. The study should be conducted using the species and animal housing situation which gives the greatest potential for animal exposure and the studies should reflect all possible residue transfer routes.

24. In cases where quantifiable residues are present in the ruminant and laying hen foodstuff matrices sampled (milk, meat, fat or eggs), after the terminal dose at the nominal 1X dose level, some authorities call for depuration information to determine when residue levels in commodities will decline to the limit of quantitation (LOQ) of the enforcement method. Alternatively, the applicant may propose a scientific rationale for not providing depuration studies if the time course of depuration can be projected using the results of metabolism studies, the residue levels in meat, milk, fat or eggs resulting from consumption of feeds treated according to the proposed GAP, and any other relevant information. Information used for this purpose, and derived from metabolism studies, must take into account differences in dose levels, feeding duration or the livestock species used, which may affect the applicability of such data to the question of estimating appropriate depuration parameters. Applicants are encouraged to consult with a registration authority that does require depuration data before commencing a study.

Rotational Crops: Metabolism in Rotational Crops and Residues in Rotational Crops (limited field studies)

25. Field use of most pesticides eventually results in some soil contact of the pesticide, whether it is from intentional application to the soil, e.g., for pre-emergent weed or soil insect control, or inadvertent such by the overspray of foliage. The disposition of the pesticide in the soil is normally studied extensively as part of the environmental fate requirements for pesticide registration, with the exception of the potential for the pesticide and its soil metabolites or degradates to accumulate in rotational crops. Rotational crops, which are sometimes referred to as succeeding or following crops, for the purposes of this discussion are defined as any field or aquatic crops treated crop, which may be planted after the harvest of a pesticide treated primary crop (or may be replanted after failure of the pesticide treated primary crop).

26. Metabolism and residue studies conducted in rotational crops are typically required for uses of pesticides where it is reasonable that a food or livestock feed crop may be produced after the harvest of a pesticide treated crop (or in some cases replanting of crops after failure of the pesticide treated crop). Rotational crop studies are normally not required for pesticide uses in permanent crops (e.g., various tree

crops, vines) or semi-permanent crops (such as asparagus, pineapples) where rotations are not part of the normal agricultural practices. A more detailed list of permanent and semi-permanent crops is included in this guidance document at [Annex 3](#) – Raw Agricultural Commodities to be Analysed for Crop Metabolism and Rotational Crops Studies.

27. The purpose of studies of metabolism in rotational crops is to determine the nature and extent of potential residue accumulation in rotational crops from soil uptake. The metabolism study is considered a model or Tier 1 study and follows test guidance consistent with crop metabolism studies. Information on the nature of the residue is used by regulatory authorities to determine whether or not the residues are of toxicological concern and whether residues in rotational crops (limited field study) should be conducted.

28. Residues in Rotational Crops (Limited Field Studies) (Tier 2) are performed to determine if and at what levels residues detected in the Tier 1 study may be found under field conditions. The data generated are used to determine if MRLs in rotational crops will be required or to establish appropriate rotational restrictions, i.e., the time from application to a time when rotation crops can be planted where there will be no residues of toxicological significance in rotational crops.

29. Limited field rotational crop studies are conducted with a non-radiolabeled pesticide applied under the proposed agronomic use practices at the maximum seasonal application rates in at least two diverse agricultural regions representative of the proposed use. Justification should be provided as to the study design in terms of selection of trial sites, pesticide rates and timings and formulation type, primary crop (if planted), rotated crops and timings of replanting, bearing in mind typical agricultural practice. The study design should seek to address situations where the potential uptake of pesticide soil residues in rotational crops is the highest, either due to mode of application, soil type and soil temperatures, pesticide persistence or other environmental or cultural practices. A root/tuber crop, a small grain crop, and a leafy vegetable crop are used to represent all possible rotational crops. If there is no uptake of significant residues in one or two of the representative crops in the metabolism in rotational crop study, a limited field study is still required for three different representative crops. However, if there is a clear absence of residues indicated in the results of the Tier 1 study in any of the requested crop groups for Tier 2, then the applicant may propose an alternative representative crop/crop grouping to be tested. If the pesticide is to be applied primarily to paddy rice, an alternative study design, such as aging the pesticide under flood conditions prior to rotation to field crops, may be required. Applicants should consult with the appropriate national authority if pesticide registrations for paddy rice use are expected.

Tier Progression for Rotational Crops Studies

30. Metabolism and residue in rotational crops studies are usually conducted sequentially; a decision tree for when to conduct these studies, based on the nature and level of residues determined, is shown in Figure 1 of this guidance document. The metabolism in rotational crops study (Tier 1) uses radiolabeled active ingredient of the pesticide applied to the bare soil in a small plot or other confined test systems such as pots at the maximum seasonal application rate. Representative rotational crops (a root/tuber, a small grain, and a leafy vegetable) are planted after 3 rotational intervals, e.g., 7 to 30 days for assessing circumstances of crop failure or closely rotated crops, 60 to 270 days to reflect a typical rotation after harvest of the primary crop, and 270 to 365 days for crops rotated the following year. Rotational intervals should be based on the anticipated agricultural use of the pesticide. Soybeans may be substituted for a leafy vegetable due to the importance of this crop in certain rotational practices. The three rotated crops should be harvested and the appropriate RACs for human and livestock feed plant parts should be sampled and the TRR determined at all three rotational intervals. TRR analyses should be performed on selected crops at multiple intervals if both immature and mature crops are normally harvested in the course of usual agricultural practices. Samples harvested should include forage, hay, straw and grain for cereal crops; an immature and mature leafy vegetable sample and both the root or tuber and the aerial (leafy) portion of the

root crop, even if the leafy portion is not a RAC of the actual root crop planted. Data from the leafy portion of the root crop and the immature leafy vegetable are needed due to the three crops in the study being used as models to extrapolate to a wide range of food crops. In addition, there has been a significant increase in the culinary use of immature greens. For the purposes of this study, an immature leafy vegetable sample is defined as the crop stage representing approximately 50% of the normal time period for the plant to reach full maturity. At this point, if each of the three crops demonstrate a TRR of less than 0.01 mg/kg in edible portions (food or livestock feed) at all of the rotational intervals, then further characterisation work is usually not required, except in rare cases where regulatory authorities may have concerns regarding the presence of a pesticide or metabolite at levels less than 0.01 mg/kg. Determination of the presence (or absence) of specific pesticide or metabolites at levels less than 0.01 mg/kg may be required in these cases. Special attention should be paid to residues of toxicological concern in soil, which may be taken up by the rotated crop, but were not seen in the primary crop metabolism studies and/or livestock metabolism studies.

31. In cases where the TRRs exceed the trigger value (0.01 mg/kg) in a RAC from crops in the confined studies, then the nature of the residues in those test crops having a TRR greater than 0.01 mg/kg will normally need to be determined (see exceptions noted in paragraph 34 titled “How OECD countries approach rotational crops MRL decisions”). The applicant should characterize and, when feasible, identify significant residues in the crops tested. Criteria for characterization and identification of residues are discussed in the Metabolism in Rotational Crops test guideline. Significant residues include parent compound, closely related degradates, metabolites and/or their conjugates in the crop.

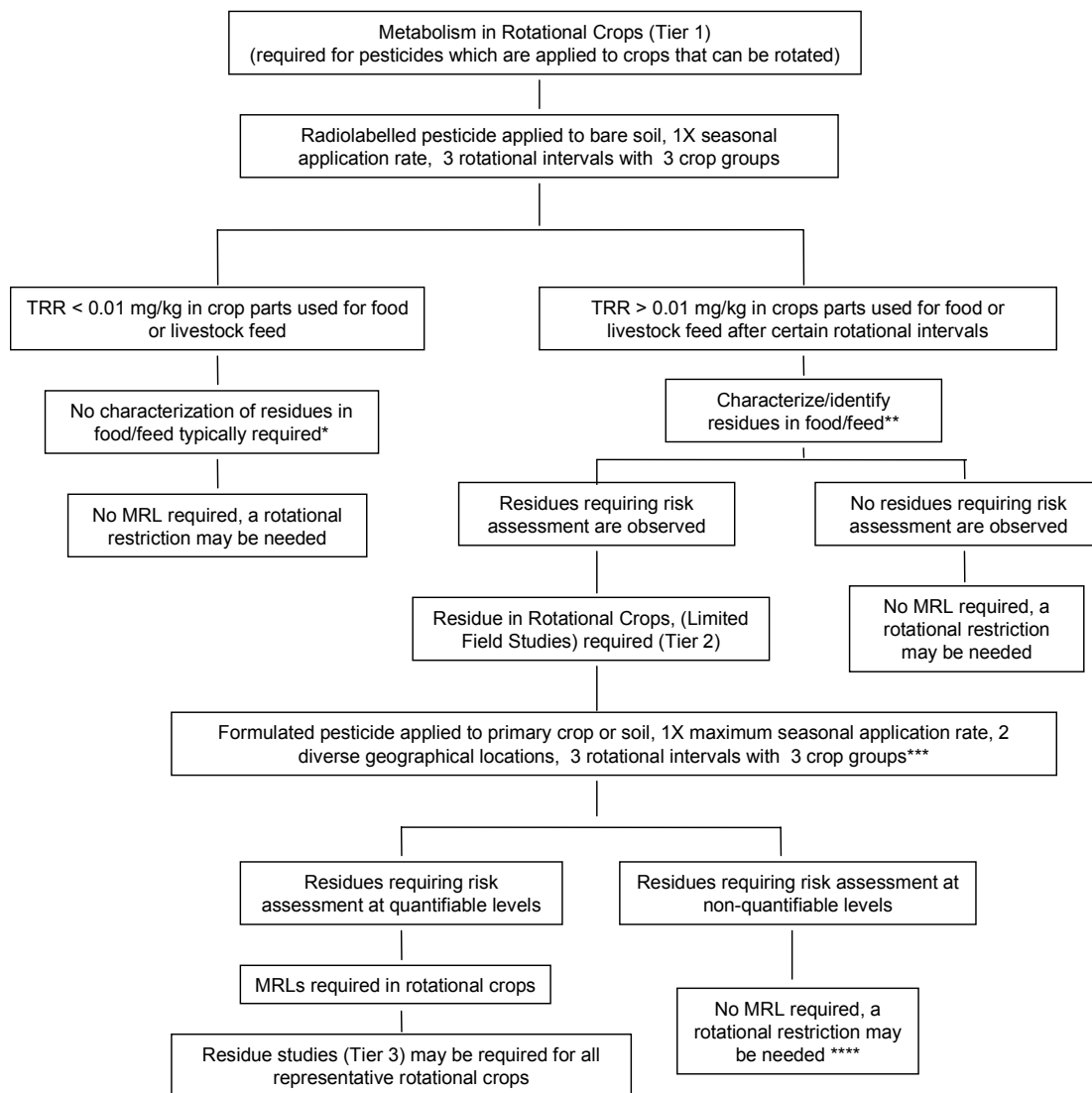
32. If the level of the TRR in the Metabolism in Rotational Crops (Tier 1 study) is equal to or exceeds 0.01 mg/kg (ppm) at the desired rotational interval and residues requiring risk assessment are observed, a Tier 2 study “Residues in Rotational Crops (Limited Field Study)” should be initiated. Alternatively, the applicant may propose a reasoned scientific justification for waiving the need for Tier 2 field trials on a case-by-case basis if a sound argument can be made that no significant residues of concern will be transferred to rotational crops. The proposal should take into consideration the nature and levels of residues from the Tier 1 study.

33. The following points will enter into the decision of whether or not to require the Tier 2 field trials:

1. If the residue definition that is being considered for rotational crops is either the same as for primary crops, or if the relative toxicology of the components being proposed for the residue definition for rotational crops is broadly similar to the residues for the primary crop residue definition, then it would normally be expected that Tier 2 limited field studies be conducted in rotational crops where residues above 0.01 mg/kg are indicated as possible from the Tier 1 study, taking account of relevant rotational intervals and pesticide label restrictions for plant-back intervals.
2. If the relative toxicology of the components found in the Metabolism in Rotational Crops study is considered to be less than that for the primary crops residue definition, then a scientific judgment taking account of the toxicology of the relevant residue can be made as to whether residue in rotational crop (Tier 2) studies are needed, even if residues above 0.01 mg/kg could be expected.
3. If residues requiring risk assessment in the metabolism study are greater than 0.01 mg/kg, but less than the LOQ of the analytical method to be used on field trial samples, the regulatory authority will consider waiving the need for field trials on a case-by-case basis.

4. If there are particular toxicological concerns, it may be necessary to require Tier 2 residues in rotational crops (limited field study) in circumstances where residues could be expected at low levels below 0.01 mg/kg.

Figure 1: Decision Guide for Tier 1 (Metabolism), Tier 2 (Residue Limited Field Trials) and Tier 3 (Residue Trials) in Rotational Crop Studies



* In some cases, determination of the presence or absence of specific pesticides below 0.01 mg/kg or metabolites may be necessary

** Characterization of TRR >0.01 mg/kg may not be necessary for countries which allow rotational restrictions on pesticide labels

***Fewer rotational intervals may be justified based on data from metabolism in rotational crop study or the ability to enforce rotational restrictions

**** Restrictions may be needed at certain rotational intervals.

34. If the limited field studies (Tier 2) are conducted and indicate that quantifiable residues of toxicological significance will occur in rotated crops, more extensive field studies (Tier 3) may be required to determine the magnitude of the residue in each crop group (or representative crop group) which could be planted in a typical crop rotation sequence. The design of extensive residue studies for the setting of MRLs is beyond the scope of this guidance document.

How OECD Countries Approach Rotational Crops MRL Decisions

35. Regulatory actions for MRL setting in rotational crops which vary in OECD countries may result in an exemption from an MRL decision (due to inadvertent residues of no toxicological or dietary risk), possible rotational restrictions based on residue accumulation (e.g., only certain crops or only the primary crops are permitted as a rotational crops), or requirements to set MRLs for rotational crops (e.g., NAFTA). In the European Union, currently there are no national provisions to set MRLs in rotational crops. If MRLs are needed they may be set at 0.01 mg/kg or at the LOQ. In this or similar cases when the applicant is not sure which regulatory actions may apply, regulatory authorities should be contacted for advice.

36. For the Metabolism in Rotational Crops study and for certain countries that allow rotational restrictions as part of the GAP, it may not be necessary to characterize radioactive residues in those test crops having a TRR greater than 0.01 mg/kg at early rotational intervals, if during the study, those residues decline to less than 0.01 mg/kg at later rotational intervals, since it is possible to enforce rotational restrictions on the label to when accumulation of residues in rotational crops is shown to be less than 0.01 mg/kg. Also, for certain countries that allow rotational restrictions on the label, more extensive residue studies in rotational crops (Tier 3) may not be required based on the result of accumulation at early rotational intervals in the Tier 2 study, if it can be demonstrated that at later rotational intervals no significant residues of toxicological concern would be found in the RACs. The maximum practical rotational restriction is one year.

37. Special provisions for the conduct of metabolism in crop rotational studies following application to paddy rice should be considered at the national level.

Processing Studies

38. Several processing operations have been identified as being representative of the most widely used industrial and domestic food processing technologies. These include:

- cooking vegetables, pulses and cereals in water
- preparation of fruit preserves
- preparation of fruit juices
- preparation of edible oil
- preparation of alcoholic beverages, *inter alia* beer and wine
- preparation of bread
- preparation of instant noodles
- frying of vegetables, meat and fish
- fermentation of milk and vegetables

39. When residues are present in raw agricultural commodities that are consumed after processing in either industrial or domestic situations, it may be necessary to investigate the Magnitude of the Residues in Processed Commodities. Depending upon the type of process involved and upon the chemical nature of the residue in the raw agricultural commodity, it should first be determined whether the Nature of the Residue in the Processed Commodities is likely to be different from that in the raw agricultural commodity.

Nature of the Residue in Processed Commodities

40. Studies on the Nature of the Residue in Processed Commodities are conducted as model studies to predict the degradation pathway of the active ingredient. These high temperature hydrolysis studies permit the identification of the degradation products that result from residues in a raw agricultural commodity when subjected to certain generic processing procedures, and include the determination of the relative amount of degradation products.

41. While recognising that nature of the residue studies are model studies, investigations into the nature of residues in processed commodities fulfill several major purposes:

- to provide an estimate of the relative composition of the total residues in the processed commodities.
- to identify the major components of the terminal residue in processed commodities, thus indicating the components to be included in the magnitude of residue studies (i.e. to determine the residue definition(s) for both risk assessment and enforcement).
- to elucidate the degradation pathway of the active ingredient in processed commodities under hydrolytic conditions.

Magnitude of the Residues in Processed Commodities

42. Studies on the Magnitude of Residues in Processed Commodities provide data on the transfer of residues to different processed commodities from the raw agricultural commodity. Studies on the magnitude of residues are conducted, typically using industrial or simulated industrial processes, in order to quantify levels of residues in processed commodities and to provide the distribution of residues (active ingredient, and/or metabolites, degradation products) in various processed products resulting from the processing of a commodity. This information about dilution and concentration of residues and the estimation of processing factors (the ratio of residue levels in processed commodities to those in the raw agricultural commodity (RAC)) is used to conduct refined dietary exposure assessments with primary processed products to assess consumer safety; provide results on residues in commodities that may be used as animal feedstuffs and thus to allow a more realistic calculation of the dietary burden of livestock; establish MRLs for processed commodities; and monitor compliance with the RAC MRL.

43. Processing guidance applies to raw agricultural commodities of plant origin. It also applies to RACs of animal origin in cases of direct animal treatment or veterinary use. Applicability of studies on the magnitude of residues in processed commodities depends upon the importance of a processed product in the human and/or animal diet; the possibility of residue levels in processed foods/feeds exceeding the level in a RAC; the level of residue in the plant or plant product to be processed (RAC); the physical-chemical properties of the active ingredient or relevant metabolites; and the possibility that degradation products of toxicological significance may be found after processing of the plant or plant product.

Processing factor

44. The processing factor (Pf), for residues of a compound in the processed commodity that originate only from residues of the same single compound in the RAC, is calculated as follows:

$$Pf = \frac{\text{residue level in processed commodity}}{\text{residue level in the RAC or commodity to be processed}}$$

Storage Stability

45. In most residue studies, samples are stored for a period of time prior to analysis. During this storage period residues of the pesticide and/or its metabolites included in the residue definitions may decline due to processes such as volatilization or enzymatic degradation. Therefore, in order to be certain that the level of residues that were present in MOR samples at the time of their collection are the same at the time of analysis, controlled studies are needed to assess the effect of storage on residue levels. Storage Stability studies allow applicants to demonstrate that pesticide residues are stable during frozen storage of the samples to be analysed or show the degree to which residues decline in that period of time.

46. In the case of studies involving crop commodities, the principles of extrapolation between commodities within specific commodity categories is recommended and the commodity categories are as follows: commodities with high water content; commodities with high acid content; commodities with high oil content; commodities with high protein content; and commodities with high starch content. If residues are shown to be stable in all commodities studied, a study on one commodity from each of the five commodity categories is acceptable. In such cases, residues in all other commodities would be assumed to be stable for the same duration of time under the same storage conditions.

47. If uses are sought in just one of the five commodity categories, guidance is provided on the number of representative commodities within each category for which stability data may need to be developed. Generally, if the stability of the test substance in 2-3 diverse commodities within the desired category is confirmed, further studies with other crops in that category are not required

If there is no observed decline of residues across the range of the five different commodity categories then specific freezer storage stability data for processed foods will not be needed. However, if instability is shown after a certain length of storage, the applicant should ensure that any commodities (RAC or processed commodity) are analysed within the demonstrated time period for stable storage.

Crop Field Trial Studies

48. Supervised field trials are conducted to determine the magnitude of the pesticide residue in or on raw agricultural commodities, including feed items, and to reflect pesticide use patterns that lead to the highest possible residues and/or commercial use patterns. Objectives of supervised field trials are to quantify/define the expected range of residue(s) in crops/commodities following treatment according to the proposed or established good agricultural practice (GAP); to determine, when appropriate, the rate of decline of the residue(s) of plant protection product(s) on commodities of interest; to determine Supervised Trial Median Residue and Highest Residue values for conducting dietary risk assessment; and to derive maximum residue limits (MRLs).

49. Harmonized supervised field trial guidelines provide a consistent method for generating residue data sets utilized for MRL setting among OECD countries by ensuring that these supervised field trials will be performed in similar fashion in all OECD countries/crop production regions. The Crop Field Trials Guideline provides information on the design and conduct of crop field trials, including guidance on plot and crop characteristics, the selection and application of the test substance and sample collection and preparation.

50. A complete data set in the context of the Crop Field Trials Test Guideline is the number of supervised field trials matching the *critical* GAP (cGAP) which are required for setting an appropriate MRL and/or obtaining a new registration or new use (i.e. plant protection product in/on a crop). A reduced data set on the other hand refers to a reduced number of supervised field trials matching the cGAP which may be adequate to obtain a new or amended registration and/or MRL for a plant protection product in/on

a specific crop. A reduced data set may be sufficient when conducting trials in cases where no residues are anticipated at or above the limit of quantitation. This may be the result of a very long pre-harvest interval or with seed treatment, pre-emergence or pre-plant uses of a plant protection product for example. This crop field trial guideline provides guidance for determining when complete data sets are necessary for determining MRLs and when it may be feasible to set an MRL using a reduced data set.

51. For the special case of comprehensive submissions for a crop/pesticide combination to all OECD countries/regions for supervised field trials performed at the same cGAP, a 40% reduction in total number of trials (i.e. the sum of all trials required per country/geographical region (Annex 5)) can be achieved given that the whole data package is submitted for evaluation and that residue levels are consistent within the whole data set.. This will provide a uniform basis for exposure assessment for registration and MRL setting in all OECD countries.

52. Representative commodities are used for extrapolation to one or more related commodities for data gathering, MRL setting, and risk assessment. Currently, the US and Codex crop grouping or classification systems are under revision. The new Codex Food and Feed Classification system, to be finished in 2012, will be adopted for use with the OECD Crop Field Trial test guideline

53. Bridging studies are an essential extrapolation tool to make the best use of existing data to support minor changes or variations to existing uses. A bridging study normally involves a comparison of different formulations or application methods for the purpose of data extrapolation, but may or may not involve side-by-side comparisons. If bridging trials are deemed necessary, data should be generated for at least 3 major crop groups (one crop per crop group), e.g. a leafy crop, a root crop, a tree fruit, a seed crop. The trials should be carried out on crops that would be expected to show high levels of residue (i.e. applications at or near harvest). If a bridging study is conducted and residues are significantly higher with a new formulation or different application method for example, generation of a complete data set may be necessary.

54. In the case of up to 25 % increases or decreases of the active substance application rate, number of applications or PHI under otherwise identical conditions, experience suggests that the residue results can be assumed to be comparable. This "25 % rule" may be applied to any one of the cGAP components (e.g., 25 % increase or decrease in application rate); however it is not acceptable to apply to more than one cGAP component at a time.

55. The supervised field trial guideline requires one sample from treated plots at each sampling interval for crops that have 8 or more supervised field trials for OECD multi-national submissions. For seven or fewer supervised field trials, some OECD countries/regions require analysis of two samples, e.g., NAFTA-only submissions.

Global Maximum Residue Limit Process for Livestock Food Commodities

56. Regulatory authorities use the results of livestock feeding studies to support MRLs in food of animal origin and to assess the dietary exposure of pesticides due to consumption of such foods. The resulting MRLs are legal standards in international trade. Animal feed stuffs and livestock food commodities (meat, milk, and eggs) are now widely transported regionally and globally. Global approaches to animal feeding levels and hence dosing levels for livestock feeding studies can be expected to lead to greater international acceptance of the results of these studies for MRL-setting purposes (e.g., national MRLs, FAO/Codex MRLs). The global MRL process to achieve use of a single Residues in Livestock study for MRL setting and risk assessment has four key components:

1. Harmonized Guidance for Definition of the Residue;

2. Reasonable Worst Case Animal Diets/Maximum Reasonably Balanced Diet;
3. Harmonized Table of Livestock Feed Commodities; and
4. Definition of Livestock Feeding Levels.

Guidance Document on the Definition of Residue

57. Harmonization of the definition of residue provides a common approach to residue identification of the pesticide and its metabolites. A pesticide residue is the combination of the pesticide and its metabolites, degradates, and other transformation products. The number of distinct chemical compounds in the residue may vary significantly from pesticide to pesticide. In some cases, only the parent pesticide may be found on treated commodities, while other pesticides produce dozens of metabolites. For each pesticide used on food or feed commodities, regulatory authorities need to choose which residue(s) will be used for 1) dietary risk assessment and 2) setting and enforcing tolerances/MRLs. The term "definition of residue" or "residue definition" is used to refer to those residues chosen for these two regulatory purposes. Residue analysis for risk assessment emphasizes analysis of the parent compound and its most toxic metabolites, taking into consideration both exposure and toxicity. Residue analysis for tolerance/MRL enforcement purposes focuses on those analytes which would indicate a possible misuse of the pesticide and which also can be detected and measured by a broad base of national laboratories (i.e., residues which are easy to measure (ideally by a multi-residue method), normally occur in large quantities, and are common to the commodities in which residues are expected). The Guidance Document on the Definition of Residue balances these concerns so that the appropriate chemical moieties can be analyzed.

58. The document draws on existing guidance from FAO and OECD member countries. It differentiates residue definitions for data generation and risk assessment purposes vs. MRL/tolerance-setting and enforcement purposes. Such guidance will be available to pesticide applicants so that they may propose definitions of the residue for each purpose and provide data for implementation.

59. The Guidance Document on the Definition of the Residue is based on the following considerations:

- The residue definition for MRL purposes should be based on a single compound whenever possible.
- The same residue definition should be used for all commodities if possible.
- Common moiety residues for MRL purposes should be avoided.
- The criteria for drinking water residues from US Environmental Protection Agency were retained for use by those authorities that consider residues in drinking water in their risk assessments.

Animal Diets

60. With dietary instructions, animal feeding levels of pesticides for purposes of assessing dietary residues in meat, milk and eggs can be realistic and neither significantly under- nor over-estimate dietary burdens. Nutritionally adequate animal diets are constructed based on GAP using information regarding: 1) diets for finishing animals (beef, pork, sheep, poultry)/methods of finishing before market/feeding practices and 2) diets for milk cows/feeding practices/milk production volumes per day per cow. Similar

considerations apply to broilers and laying hens. Such guidance can lay the groundwork for use of realistic animal intake levels of pesticides for purposes of assessing dietary residues in meat, milk and eggs.

Harmonized Table of Livestock Feed Commodities

61. Livestock feeding studies are based on detailed knowledge regarding the type of feedstuffs available for livestock, quantities being fed, and which feedstuff components might be used as alternatives and are interchangeable. Internationally harmonized feed tables can be used to ensure that feeding studies are conducted in such a way as to address the various feeding practices of all OECD countries. The objective of livestock residue studies is to provide data on the anticipated residue levels in foods of animal origin. Such data is needed for both MRL-setting and human risk assessment. Therefore, the livestock feeding studies focus on those animals that are in the egg or milk producing stage or are close to slaughter (e.g., last 100 days for cattle).

62. Livestock can be fed with a large variety of agricultural commodities and by-products if the diet is adjusted nutritionally using GAP. These feedstuffs must be combined in the proper proportions to allow adequate growth and maintenance in mature animals. In the early life stages, the diet is adjusted to cause a healthy, steady growth of the animal. Generally, many minor by-products, either from food or feed processing, are fed to immature animals prior to the finishing stage. As the animal grows, its nutrient requirements change. For example, diets are adjusted when the animal approaches the finished stage for beef or the maintenance stage for milk producing cows and the food commodities are ready to enter the consumer market.

63. Livestock rearing is linked to regional characteristics and seasonal availability of feedstuffs. Important drivers for the selection of feedstuffs are price, local availability, and, especially for more traditional farming, whether feedstuffs can be produced on the farm where the animals are located. In some countries, the trend in the production of livestock and livestock products is for production or finishing in specialised facilities, that either do not produce feed at all or produce only selected feedstuffs that are supplemented by commercially available compound feed. However, in other OECD countries, these intensive production systems co-exist with more extensive finishing systems, particularly for beef and dairy cattle, sheep and goats, that are based on grazing natural or improved pastures and fodder crops. Grazing livestock may be supplemented with grains, conserved fodders (hay or silage), by-products or compounded feeds to enhance growth rates, body composition or milk productions. Progress in animal nutritional sciences and the availability of low cost imported feedstuffs during the whole year can allow the production of highly standardized compound feed that supports animal production under controlled conditions. For example, for producers, milk or egg yields or body weight gains per day become predictable and fit well with their time-to-market demands. This may not apply in all countries or under particular production systems.

64. The OECD Table of Feedstuffs Derived from Field Crops (Annex 4) includes the types and percentages of livestock feed for all OECD countries/regions in a unified format to reflect national/regional livestock feeding information. This unified format assembles all data and information currently available. Tables of national/regional feeding practices allow pesticide levels for livestock feeding studies to be calculated for each region using a reasonable worst case diet or maximum reasonably balanced diet.

Harmonized Format

65. The harmonized format for the OECD Table of Feedstuffs Derived from Field Crops calls for individual feed commodities to be explicitly listed and grouped under feedstuff categories. The format provides separate columns for each country or region and includes data on cattle, swine, poultry and sheep. Selection of numerical values for entries is based on national agricultural practices, typical body weight of

the finished animal and daily feed consumption parameters. As a result, livestock feeding study levels can be based on a nutritionally balanced diet reflecting GAP and highest or median residues, depending on the feed (for raw or processed feedstuffs, respectively). Dosing determinations are based on the table of feed commodities (Annex 4).

66. The OECD Table of Feedstuffs Derived from Field Crops is based on a general understanding of feeding practices of mature animals and volumes of available feedstuffs in OECD member nations as well as the definitions for the mature marketable animal (life span, average weight, and rations at time of slaughter) in each area. The definitions of the livestock diets at this point are most germane to determining the potential for end levels of pesticide residues in meat, milk or eggs. Therefore, data are assembled and tabulated for the feedstuff associated with the production of finishing animals and milk/eggs. The focus is on livestock from larger production units, i.e., herd sizes of 50 or more cattle. However, consideration must also be given to diets of animals, particularly ruminants, that are managed under extensive grazing arrangements.

67. The following parameters were taken into consideration to tabulate regional/national livestock feedstuffs and diets:

- Estimates of crop acreage for RACs with feedstuffs commodities/production volumes/availabilities (local vs. national; all year vs. seasonal).
- Specific crops grown only as feedstuff including locations/production volumes/availabilities (local vs. national; all year vs. seasonal).
- Production volumes of livestock meat, milk, eggs for consumer markets. Information about exports.
- Locations of meat/milk/egg production areas. Random/centralized.
- Feedstuffs (RACs) imported.
- Livestock production trends including consideration of the relative importance of intensive (lot feeding) production systems and extensive (grazing) production systems. The likelihood of livestock consuming more defined and consistent rations. Production operations centralized/decentralized/intensive/extensive.
- Size of animals at slaughter or in milk or egg production.
- Type of feedstuff, based on local agricultural practice, e.g., growth stage or percent of dry matter in crops or pastures consumed.

NAFTA

68. In the NAFTA countries, as the size of the herd increases, the rations become more consistent. To meet consumer demands in terms of price and quality, specific beef and dairy breeds have been developed to produce more meat and more milk. In order to meet their financial targets, breeders or farmers rely on diets that are very specific with respect to the nutritional components, e.g., percentage of proteins, or carbohydrates. However, the source and nature of the RAC may change. Similarly, in the poultry and swine industry, special animals are bred for specific food items. For example, some poultry producers design a chicken for “chicken nuggets” which can involve a three year contract with a special fixed diet to produce this special fowl.

69. Data from commercial rearing are available (from the United States) that provide percentages for roughage, protein and carbohydrate content for nutritionally balanced diets for cattle, poultry and swine. The use of a *maximum reasonably balanced diet* (MRBD) represents a shift from using the maximum theoretical dietary burden. (See paragraph 78). The object of the MRBD is to propose a daily ration that allows animals to have steady weight gain, high milk volumes, and consistently high egg production. Additional considerations are required, however, for pesticides that show a high propensity to sequester in fatty tissue.

70. Reference animals include cattle (beef, dairy), swine (breeding, finishing), and poultry (broiler, layer, turkey). Beef and dairy cattle can be extended to goats, horses and sheep.

European Union

71. The European Union feedstuff tabulation lists maximum feed intake for livestock, which is relevant for cattle close to slaughter or high yielding dairy cows at their peak of milk production. This is only achievable on professionally managed farms. Based on data from European sources for EU-15, approximately an average of 80% of all cattle are housed on farms having herd sizes of 50 or more. The range of such herds for EU-15 range from a high of 95% to a low of 45%, depending on the specific nation /university dealing with production of livestock commodities.

Australia

72. Exported meat (sheep, beef) is a major commercial commodity in Australia. Body weight ranges of finished animals are very broad, depending on the target market. In Australia, beef cattle and sheep are raised on pastures. About one third of beef produced in Australia are "finished" on a grain based ration prior to live export or slaughter for export or domestic use. Some lot feeding is also undertaken with lambs intended for slaughter and young sheep produced for live export. Barley and sorghum are the most common feed grains used. Cattle are lot fed for periods varying from about 30 days to about 300 days depending on the level of marbling and weight required by the customer. However, to obtain a "grain fed" classification, cattle must be on that feed for at least 70 days for steers and 60 days for heifers. Most cattle in Australian feedlots, which supply about 30% of the cattle slaughtered, are destined for the Japanese market (49% of cattle on feed). In 2000-01 a total of 9 million cattle and calves were slaughtered. Australia exported 47% of this total, 40% went to the United States and 34% went to Japan. Other buyers include the Republic of Korea, Canada, Taiwan, the Philippines, and Indonesia. Australian customers traditionally prefer leaner meat, while the Japanese prefer highly marbled meat. The United States uses a significant amount of leaner "grass fed" Australian beef primarily in the production of hamburger patties.

73. There are around 2.02 million dairy cows in Australia and, they each produce 4,900 liters of milk per year. These cows are owned by approximately 9,600 dairy farms. Twenty-five years ago, there were 1.9 million cows producing 2,900 liters of milk per year and there were nearly 22,000 dairy farms. Thus the industry is characterized by fewer farms carrying much larger herds and achieving far greater productivity per cow and per farm. Dairy production in Victoria benefits from year-round pasture grazing. Victoria produces greater than 60% of Australia's milk. Only 30% of total milk is diverted to market. Victoria contributes less than 15% of this total. The majority is used in the manufacture of dairy products (cheese, butter, milk powder). The other regions (New South Wales, Queensland, and Western Australia; 25% of total milk) have less rainfall and are more subject to drought. New South Wales has larger cows and the highest producing cows, in some cases almost doubling the annual output per cow compared to Victoria's production. In these areas grain supplements are fed in addition to pasture grazing. A semi-mixed ration of forages, by-products, protein meals, and grains is fed. Such feedlot based dairying is expanding at a slow rate. There is a small and slowly expanding contribution from feedlot based dairying.

New Zealand

74. In New Zealand, livestock feeding systems (cattle, sheep and dairy cows) are based on all-year grazing on pasture (ryegrass/clover), with hay and silage used as supplementary feed in drought periods and to complement low winter pasture growth rates. Fodder brassicas (roots and tops) are used to finish stock in the summer and as an alternative complimentary feed in winter. The majority of this supplementary feed is grown 'on-farm', although there is some local or regional re-distribution.

75. Sheep numbers are in the order of 39 million, with an average flock size of 2,600. In 1998, about 27 million lambs and just under 6 million adult sheep were slaughtered, 96% of the lambs and 88% of the adult sheep being exported. The major export markets are Europe (37%), the United States (6%), Canada (2%) and Japan (2%). The average beef herd in New Zealand contains about 200 cattle, with the national herd being about 4.5 million animals. Annual slaughter figures for 1998 were 1.4 million calves and vealers (99% being exported) and 2.5 million cattle (83% exported). The major export markets for frozen or chilled beef are the United States (44%), the Republic of Korea (11%), Japan (12%), Taiwan (9%) and Canada (7%). There are about 5 million dairy cows in New Zealand, with a mean herd size of 220 cows, each producing on average 168 kg milk fat per year. The majority of milk produced (95%) is exported in the form of concentrated/sweetened milk and cream (27%), butter (9%), cheese (11%) and casein derivatives (7%). Exports are evenly distributed throughout most of Asia, the Pacific and the Middle East, with about 1-2% being exported to each country, although trade is slightly higher with the United States (3.5%) and Japan (2.5%).

Japan

76. In Japan, grains account for about 42% of the total amount (36 million metric tons), while forage and by-product feeds each account for around 32% and 26% respectively. Imported feeds, mostly grain, account for about 45% of total rations. Corn grain is used the most with all livestock species. Other grains used in lesser amounts are barley (beef), milo (poultry and swine), rye (beef and dairy), and wheat (beef, dairy, and swine). More forage and byproduct feeds are produced domestically than are imported.

77. About half of the byproduct feeds in Japan are consumed by cattle. The byproducts include grain brans, dried beet pulp, and oilseed meals. The ratio of byproduct feeds to grain in the diet is higher in the case of dairy cattle (0.98) or beef cattle (0.64) than with poultry (0.59) or swine (0.42). Most byproduct feeds used in poultry and swine production are mixed in advance with grain as formulated rations by feed companies. However, only half of the byproduct feeds consumed by cattle are used in this way. The remaining half is obtained by individual farmers in the areas where they live. This suggests that the byproducts produced locally are most effectively used in cattle diets. Dairy cattle have a higher ration of byproduct feeds in relation to grain (0.98 vs. 0.64) than beef cattle. Thus, the byproduct feedstuffs are most actively used by dairy farmers in Japan. These feedstuffs are distributed all over the country by large feed companies in the form of feed concentrates.

78. In response to recent shortage in feed supply and consequential price increase in the world and in order to improve the self-sufficiency of feeds in Japan, a number of efforts have been made, such as: promotion of feed use of domestically produced rice straw and whole crop rice silage (WCS); and encouragement to increase production of WCS and rice varieties for feed uses with higher yield than those for food uses. This new situation necessitated urgent establishment of MRLs for pesticides used for production of rice and WCS in feeds; and MRLs for foods from animals fed these feeds. To facilitate the process, Japan has developed tables of maximum proportion of agricultural commodities for cattle, swine and poultry on a basis of the answers from large feed companies and farmers to a questionnaire in Japan.

Reasonable Worst Case Feeding Levels

79. Currently, estimates of reasonable worst case feeding levels for livestock are used nationally and regionally, except in NAFTA, to calculate the daily dosage to be fed to animals in the Livestock Feeding study. A harmonized definition for and approach to reasonable worst case feeding levels/maximum reasonably balanced diet combined with consideration of the maximum reasonable balanced diet approach for NAFTA will enable one study to be performed as part of a global MRL approach for pesticides in all OECD countries.

80. Compound feed concentrates composed for a specific purpose will always provide similar nutritionally desirable properties, but individual components are subject to change, e.g., protein-rich raw materials, like meals of soybean or rapeseed, are interchangeable and will be chosen by the feed manufacturer based on the availability or cost of raw materials. In the OECD Feedstuffs Derived from Field Crops Table (Annex 4), the feed entries are structured in several feedstuff categories, which represent interchangeable types for feedstuffs.

81. Use of these categories can ensure that the highest residue levels are estimated and a realistic although **not** nutritionally optimal livestock diet is composed. Within each category, the feedstuff in each country for each animal (cattle, poultry, sheep, swine) with the highest pesticide residue calculated on a dry weight basis should be selected. Feedstuffs – one from each category – are allocated a percentage of that animal's diet until 100% of the diet is accounted for. Note that in some instances there may not be an adequate number of feedstuffs with residues to achieve 100%; non-treated items (no residue) are assumed to achieve the class percentage and 100% overall. Similar calculations are performed for each OECD country or region (except NAFTA, see paragraph 81). After comparison, the lowest national dietary burden of pesticide is selected for the livestock feeding study. An example calculation using the data in the OECD Table of Feedstuffs Derived from Field Crops (Annex 4) is presented below starting in paragraph 84.

Maximum Reasonably Balanced Diet

82. In the NAFTA region, feedstuffs are categorized as roughage, carbohydrate, and protein. Roughage [R] includes forage, silage, hay, hulls, leaves and vines. Carbohydrate Concentrate [CC] comprises cereal grains, grain milled by-products and waste. Protein Concentrate [PC] consists of oilseed meals, seeds, and alfalfa meal. Entries for the Canada/USA in the table in Annex 4 include consideration of the maximum percentages of the three classifications. Table 1 indicates the recommended percentages of the three classes for beef cattle, dairy cattle, laying hens, and swine.

Table 1. Feedstuff Classification and Target Daily Ration				
Classification	Beef	Dairy	Poultry (laying)	Swine
Roughage [R]	15%	45%	--	--
Carbohydrate Concentrate [CC]	80%	45%	75%	85%
Protein Concentrate [PC]	5%	10%	25%	15%

83. Within each classification (R, CC, PC), the feedstuff for each animal (cattle, poultry, sheep, swine) with the highest pesticide residue calculated on a dry weight basis should be selected. Feedstuffs are allocated a percentage of that animal's diet in each classification up to the maximum percentages indicated in Table 1. Contrary to the worst case feeding level approach, it is possible to select several feed commodities from a given class or category. If consideration of all treated commodities do not produce the

requisite percentages, non-treated items (no residue) are included to achieve the class percentage and 100% overall.

Dose Calculation for Residues in Livestock Studies: Example of dietary burden calculation using the Reasonable Worst Case Feeding Level approach and the Maximum Reasonably Balanced Diet approach

84. The calculation of the dietary burdens from the different regions is conducted in several steps as indicated in Figure 2. The dose calculation (1X) resulting from consideration of the various dietary burdens is outlined in Figure 3.

Figure 2: General Guidance for the Calculation of Dietary Burdens from Different Regions

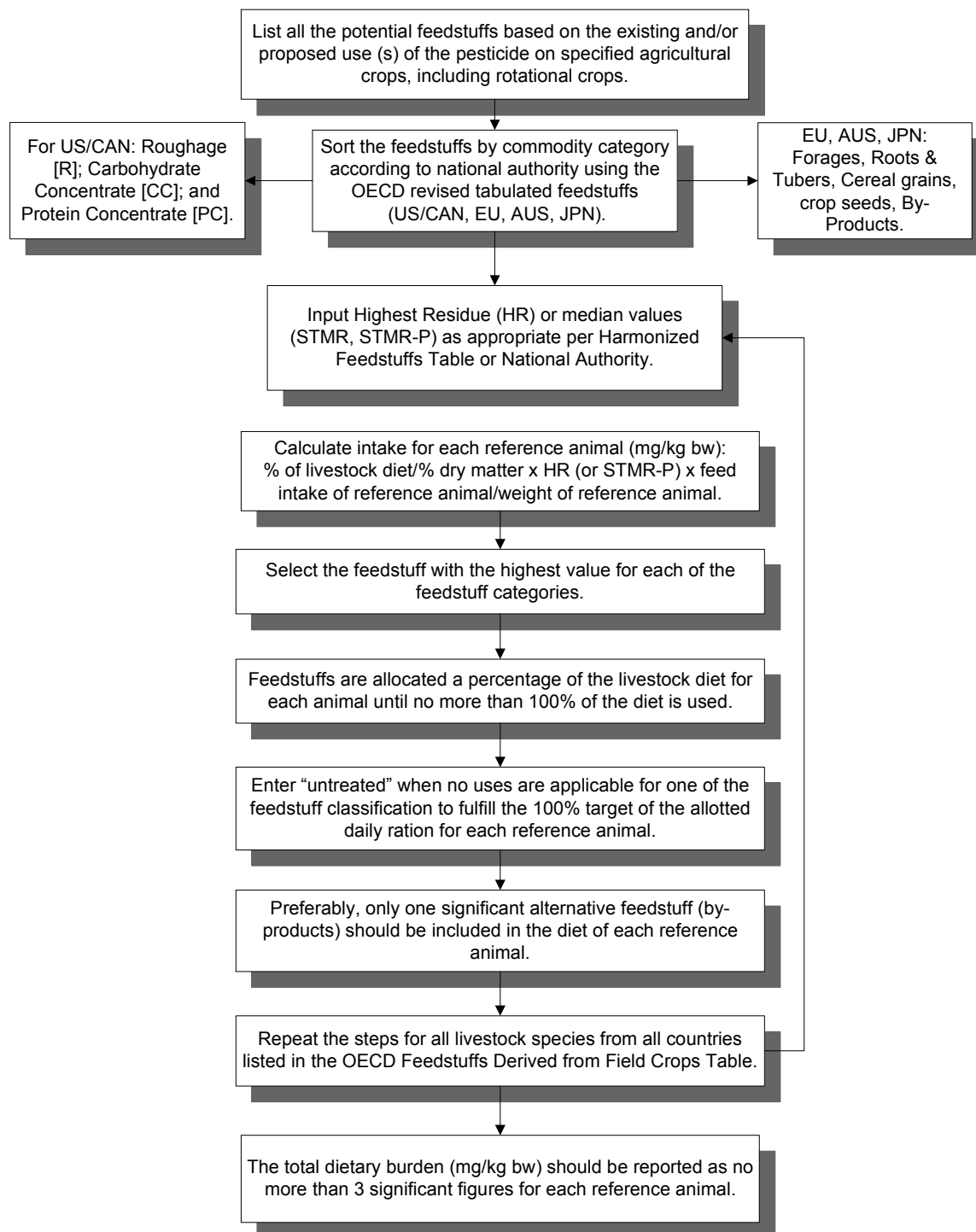
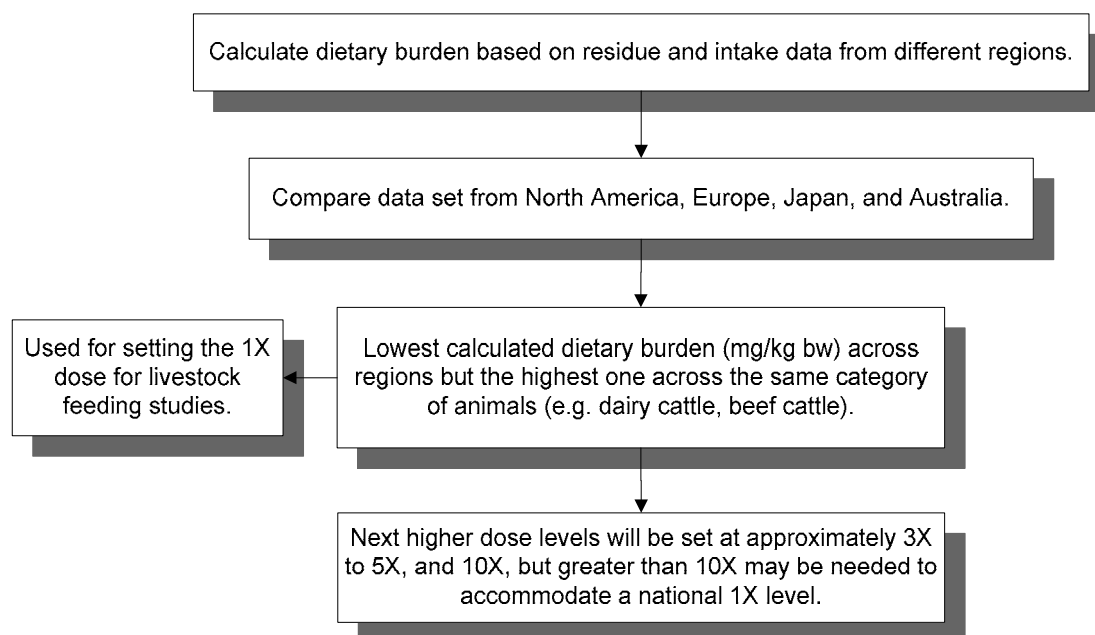


Figure 3: Dose Selection Based on International Dietary Contribution

85. The following example illustrates the overall process in limited detail: An active substance is intended to be registered in the United States, Canada, member states of the European Union, Australia, and Japan for a range of food crops and feedstuffs: Wheat, Corn, Barley, Soybean, Alfalfa, Potatoes, Carrots, Grapes, Apples, Almonds.

An example is given for beef cattle, but the same principle would apply to other livestock species such as sheep, swine, or poultry.

Category: Forages (wheat, soybean, corn, barley, alfalfa):

Forages	Commodity Category	Commodity Classification	Dry matter content [%]	Residues [mg/kg]
Alfalfa	forage	R	35	5
Alfalfa	hay	R	89	10
Alfalfa	meal	R	89	10
Barley	hay	R	88	2
Barley	straw	R	89	2
Barley	silage	R	40	-
Corn, field	silage	R	40	0.02
Wheat	forage	R	25	2
Wheat	hay	R	88	1
Wheat	straw	R	88	2
Wheat	silage	R	30	-
Soybean	forage	R	56	-
Soybean	hay	R	85	-
Soybean	silage	R	30	-

Category Roots & Tubers (Carrots, Potatoes):

Roots & Tubers	Commodity Category	Commodity Classification	Dry matter content [%]	Residues [mg/kg]
Carrot	culls	CC	12	0.02
Potato	Culls	CC	20	0.5

Category Cereal grains and Crop seeds (Barley, Corn, Soybean, Wheat):

Cereal Grains/Crops Seeds	Commodity Category	Commodity Classification	Dry matter content [%]	Residues [mg/kg]
Barley	Grain	CC	88	0.06
Corn, field	Grain	CC	88	0.02
Soybean	Seed	PC	89	0.04
Wheat	Grain	CC	89	0.01

Category By-Products (various by-products from food or feed processing)

Cereal Grains/Crops Seeds	Commodity Category	Commodity Classification	Dry matter content [%]	Residues [mg/kg]
Almond	hulls	R	90	1
Barley	bran fractions	-	90	0.1
Corn, field	aspirated grain fractions	CC	85	2
Corn, field	milled by-products	CC	85	1
Corn, field	hominy meal	CC	88	0.3
Corn gluten	feed	CC	40	0.2
Corn gluten	meal	CC	40	0.2
Soybean	aspirated grain fractions	CC	85	3
Soybean	hulls	R	90	1
Soybean	meal	PC	92	0.04
Soybean	okara	PC	20	0.05
Soybean	pollard	R	?	-
Wheat	aspirated grain fractions	CC	85	2
Wheat	milled byproducts	CC	88	0.3
Wheat gluten	meal	CC	40	0.2
Apples	pomace wet	CC	40	0.05
Grapes	pomace wet	CC	15	0.1

Calculation of beef cattle dietary burden based on NAFTA numbers:

Feedstuff	Commodity	DM	Diet	Animal	Animal	Highest	Residue
	Category			Daily intake	Body weight	Residue or STMR	Contribution
		%	%	kg	kg	mg/kg	mg/kg bw
Roughage							
Wheat	hay	88	15	9.1	500	1	0.003
Wheat	straw	88	10	9.1	500	2	0.004
Wheat	forage	25	0	9.1	500	2	0.000
Wheat	silage	30	0	9.1	500	-	0.000
Corn, field	silage	40	15	9.1	500	0.02	0.000
Barley	hay	88	15	9.1	500	2	0.006
Barley	straw	89	10	9.1	500	2	0.004
Soybean	hulls	90	15	9.1	500	1	0.003
Soybean	forage	56	0	9.1	500	-	0.000
Soybean	hay	85	0	9.1	500	-	0.000
Soybean	silage	30	0	9.1	500	-	0.000
Alfalfa	hay	89	15	9.1	500	10	0.031
Alfalfa	forage	35	0	9.1	500	5	0.000
Alfalfa	meal	89	0	9.1	500	10	0.000
Almond	hulls	90	0	9.1	500	1	0.000
Carbohydrate (CC)							
Wheat	grain	89	20	9.1	500	0.01	0.000
Wheat	milled byprod	88	40	9.1	500	0.3	0.002
Wheat	Aspirated grain fractions	85	5	9.1	500	2	0.002
Wheat	gluten meal	40	10	9.1	500	0.2	0.001
Soybean	aspirated grain fractions	85	5	9.1	500	3	0.003
Corn, field	grain	88	80	9.1	500	0.02	0.000
Corn, field	milled byprod	85	50	9.1	500	1	0.011
Corn, field	aspirated grain fractions	85	5	9.1	500	2	0.002
Corn	gluten feed	40	75	9.1	500	0.2	0.007
Corn	gluten meal	40	75	9.1	500	0.2	0.007
Corn	hominy meal	88	50	9.1	500	0.3	0.003
Barley	grain	88	50	9.1	500	0.06	0.001
Potato	culls	20	30	9.1	500	0.5	0.014
Apple	pomace, wet	40	0	9.1	500	0.05	0.000
Grapes	pomace, wet	15	0	9.1	500	0.1	0.000
Carrot	culls	12	0	9.1	500	0.02	0.000
Protein (PC)							
Soybean	seed	89	5	9.1	500	0.04	0.000
Soybean	okara	20	0	9.1	500	0.05	0.000
Soybean	meal	92	5	9.1	500	0.04	0.000

Category	%diet	Highest Dietary Contribution (mg/kg bw)
15% Roughage	15	0.031
80% Carbohydrate	30	0.014
	50	0.011
5% Protein	5	0.000
TOTAL	100	0.06

Calculation of beef cattle dietary burden based on EU numbers:

Forages	Commodity	DM	Diet	Animal Daily intake	Animal Body weight	Highest Residue or STMR	Residue Contribution
	Category	%	%	kg	kg	mg/kg	mg/kg bw
Alfalfa	forage	35	70	12	500	5	0.240
Alfalfa	hay	89	0	12	500	10	0.000
Alfalfa	meal	89	0	12	500	10	0.000
Barley	straw	89	30	12	500	2	0.016
Barley	hay	88	0	12	500	2	0.000
Barley	silage	40	30	12	500	-	0.000
Corn, field	silage	40	15	12	500	0.02	0.000
Wheat	forage	25	20	12	500	2	0.038
Wheat	hay	88	100	12	500	1	0.027
Wheat	straw	88	20	12	500	2	0.011
Wheat	silage	30	0	12	500	-	0.000
Soybean	forage	56	0	12	500	-	0.000
Soybean	hay	85	0	12	500	-	0.000
Soybean	silage	30	0	12	500	-	0.000
Roots/tubers							
Carrot	culls	12	15	12	500	0.02	0.001
Potato	culls	20	30	12	500	0.5	0.018
Cereal grains							
Barley	grain	88	70	12	500	0.06	0.001
Corn, field	grain	88	80	12	500	0.02	0.000
Soybean	seed	89	10	12	500	0.04	0.000
Wheat	grain	89	40	12	500	0.01	0.000
By-products							
Almond	hulls	90	0	12	500	1	0.000
Apple	wet pomace	40	20	12	500	0.05	0.001
Barley	bran fractions	90	0	12	500	0.1	0.000
Corn, field	milled by-products	85	30	12	500	1	0.008
Corn, field	gluten feed	40	30	12	500	0.2	0.004
Corn, field	gluten meal	40	15	12	500	0.2	0.002

Corn, field	aspirated grain fractions	85	0	12	500	2	0.000
Corn, field	hominy meal	88	0	12	500	0.3	0.000
Grapes	pomace, wet	15	0	12	500	0.1	0.000
Soybean	aspirated grain fractions	85	0	12	500	3	0.000
Soybean	meal	92	20	12	500	0.04	0.000
Soybean	hulls	90	10	12	500	1	0.000
Soybean	okara	20	0	12	500	0.05	0.000
Soybean	pollard	?	0	12	500	-	0.000
Wheat	milled by-products	88	30	12	500	0.3	0.002
Wheat	gluten meal	40	15	12	500	0.2	0.002
Wheat	aspirated grain fractions	85	0	12	500	2.	0.000

Category	%diet	Dietary	Adjusted % diet	Adjusted Dietary (mg/kg bw)
Forages	70	0.240	70	0.240
Roots/tubers	30	0.018	30	0.018
Cereal grains	70	0.001	0	0
By-products	30	0.008	0	0
TOTAL	200	0.267	100	0.26

Calculation of beef cattle dietary burden based on Australia numbers:

Forages	Commodity	DM	Diet	Animal	Animal	Highest	Residue
	Category			Daily intake	Body weight	Residue or STMR	Contribution
		%	%	kg	kg	mg/kg	mg/kg bw
Alfalfa	forage	35	100	20	500	5	0.571
Alfalfa	hay	89	80	20	500	10	0.360
Alfalfa	meal	89	40	20	500	10	0.180
Barley	hay	88	100	20	500	2	0.091
Barley	straw	89	100	20	500	2	0.090
Barley	silage	40	100	20	500	-	0.000
Corn, field	silage	40	80	20	500	0.02	0.002
Wheat	forage	25	100	20	500	2	0.320
Wheat	hay	88	100	20	500	1	0.045
Wheat	straw	88	80	20	500	2	0.073
Wheat	silage	30	90	20	500	-	0.000
Soybean	forage	56	100	20	500	-	0.000
Soybean	hay	85	80	20	500	-	0.000
Soybean	silage	30	80	20	500	-	0.000
Roots/tubers							
Carrot	culls	12	5	20	500	0.02	0.000
Potato	culls	20	10	20	500	0.5	0.010

Cereal grains							
Barley	grain	88	80	20	500	0.06	0.002
Corn, field	grain	88	80	20	500	0.02	0.001
Soybean	seed	89	20	20	500	0.04	0.000
Wheat	grain	89	80	20	500	0.01	0.000
By-products							
Almond	hulls	90	10	20	500	1	0.004
Apple	wet pomace	40	20	20	500	0.05	0.001
	milled						
Corn, field	byproducts	85	15	20	500	1	0.007
Corn, field	gluten feed	40	20	20	500	0.2	0.004
Corn, field	gluten meal	40	20	20	500	0.2	0.004
	aspirated grain						
Corn, field	fractions	85	0	20	500	2	0.000
Corn, field	hominy meal	88	40	20	500	0.3	0.005
Grapes	wet pomace	15	20	20	500	0.1	0.005
	aspirated grain						
Soybean	fractions	85	0	20	500	3	0.000
Soybean	meal	92	10	20	500	0.04	0.000
Soybean	hulls	90	0	20	500	1	0.000
Soybean	okara	20	0	20	500	0.05	
Soybean	pollard	?	15	20	500	-	0.000
	milled						
Wheat	byproducts	88	40	20	500	0.3	0.005
Wheat	gluten meal	40	0	20	500	0.2	0.000
	aspirated grain						
Wheat	fractions	85	0	20	500	2	0.000

Category	%diet	Dietary	Adjusted % diet	Adjusted Dietary (mg/kg bw)
Forages	100	0.571	100	0.571
Roots/tubers	10	0.010	0	0
Cereal grains	80	0.002	0	0
By-products	15	0.007	0	0
TOTAL	205	0.59	100	0.57

Calculation of beef cattle dietary burden based on Japan numbers:

Forages	Commodity	DM	Diet	Animal	Animal	Highest	Residue
	Category			Daily intake	Body weight	Residue or STMR	Contribution
		%	%	kg	kg	mg/kg	mg/kg bw
Forages							
Alfalfa	hay	89	10	14	730	10	0.022
Alfalfa	meal	89	10	14	730	10	0.022
Alfalfa	forage	35	0	14	730	5	0.000
Barley	straw	89	0	14	730	2	0.000
Barley	hay	88	0	14	730	2	0.000
Barley	silage	40	0	14	730	-	0.000
Corn, field	Silage	40	0	14	730	0.02	0.000
Wheat	forage	25	0	14	730	2	0.000
Wheat	hay	88	0	14	730	1	0.000
Wheat	straw	88	0	14	730	2	0.000
Wheat	silage	30	0	14	730	-	0.000
Soybean	forage	56	0	14	730	-	0.000
Soybean	hay	85	0	14	730	-	0.000
Soybean	silage	30	0	14	730	-	0.000
Roots/tubers							
Carrot	culls	12	0	14	730	0.02	0.000
Potato	culls	22	0	14	730	0.5	0.000
Cereal grains							
Barley	grain	88	70	14	730	0.06	0.001
Corn, field	grain	88	75	14	730	0.02	0.000
Soybean	seed	89	15	14	730	0.04	0.000
Wheat	grain	89	25	14	730	0.01	0.000
By-products							
Almond	hulls	90	0	14	730	1	0.000
Apple	pomace, wet	40	0	14	730	0.05	0.000
Barley	bran fractions	90	10	14	730	0.1	0.000
Corn, field	milled by-products	85	5	14	730	1	0.000
Corn, field	gluten feed	40	25	14	730	0.2	0.002
Corn, field	gluten meal	40	0	14	730	0.2	0.000
Corn, field	aspirated grain fractions	85	0	14	730	0.2	0.000
Corn, field	hominy meal	88	35	14	730	0.3	0.002
Grapes	pomace, wet	15	0	14	730	0.1	0.000
Soybean	aspirated grain fractions	85	0	14	730	3	0.000
Soybean	meal	92	65	14	730	0.04	0.000
Soybean	hulls	90	0	14	730	1	0.000
Soybean	okara	20	40	14	730	0.05	0.002
Soybean	pollard	?	0	14	730	-	0.000
Wheat	milled by-products	88	55	14	730	0.3	0.004
Wheat	gluten meal	40	0	14	730	0.2	0.000
Wheat	Aspirated grain fractions	85	0	14	730	0.2	0.000

	%diet	Dietary	Adjusted % diet	Adjusted Dietary (mg/kg bw)
Forages	10	0.022	10	0.022
Roots/tubers	0	0.000	0	0.000
Cereal grains	70	0.001	25	0.000
By-products	65	0.004	65	0.004
TOTAL	145	0.027	100	0.026

In summary, dose levels per livestock species and region:

Livestock	Region	Dose level [mg/kg bw]
Beef Cattle	NAFTA	0.06
Beef Cattle	EU	0.26
Beef Cattle	Australia	0.57
Beef Cattle	Japan	0.03

85. In this example, the lowest dose received by beef cattle was **0.03 mg/kg bw** according to Japan dietary contributions. Therefore, the dose level of 0.03 mg/kg body weight is selected as the international 1X dose level for the livestock feeding study. The 10X dose would be calculated at about 0.3 mg/kg body weight. However, a higher dose level (**0.6 mg/kg bw**, or 20X) is needed to encompass the 1X level for Australia. The mid-range dose might be selected at **0.3 mg/kg bw** (10X) to accommodate the 1X dose in Europe. Note that in practice it would be necessary to calculate also the anticipated dietary exposure of dairy cattle. The higher exposure of dairy and beef cattle would be selected (from within the lowest dietary exposure across the regions). For example, if the dose level for dairy cattle in Japan was 0.05 mg/kg bw, then the dairy cattle dose level (and not the beef cattle level of 0.03 mg/kg) would be selected as the 1X dose.

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ANNEX 1

GLOSSARY OF RESIDUE CHEMISTRY TERMS

This glossary of residue chemistry terms was compiled from the various documents (test guidelines, directives, reports, etc.) reviewed during the preparation of the OECD draft Residue Test Guidelines.

Acceptable daily intake (ADI) of a chemical is the daily intake which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time of the evaluation of the chemical by the Joint FAO/WHO Meeting on Pesticide Residues. It is expressed in milligrams of the chemical per kilogram of body weight. (FAO Manual)

Active ingredient(s) is the component(s) of a formulation responsible for the direct or indirect biological activity against pests or diseases, or in regulating metabolism/growth, etc. A single active ingredient may be comprised of one or more chemicals or biological entities which may differ in relative activity. A formulation may contain one or more active ingredients. (FAO Specifications)

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

Active ingredient(s) is the component(s) of a formulation responsible for the direct or indirect biological activity against pests or diseases, or in regulating metabolism/growth, etc. A single active ingredient may be comprised of one or more chemicals or biological entities which may differ in relative activity. A formulation may contain one or more active ingredients. (FAO Specifications)

Adjuvant refers to any product added to the spray tank for the purpose of improving the performance of the test substance/active ingredient. Adjuvants may be characterized for example as wetting agents, spreader-stickers, compatibility agents, buffering agents, de-foamers, non-ionic surfactants, crop oil concentrates, etc.

Aggregate sample is a sample made up of set proportions of other samples, typically an average by weight. See also composite sample.

Analytical Method Validation Parameters. To be fit for the intended purpose, the analytical method should meet standards for certain validation parameters. Typical validation characteristics for residue analytical methods that should be considered are: recovery, selectivity (specificity), calibration, precision (repeatability, reproducibility), limit of detection(LOD), and limit of quantitation (LOQ). These parameters are defined below.

Recovery is the amount measured as a percentage of the amount of analyte(s) (active substance and relevant metabolites) originally added to a sample of the appropriate matrix, which contains either no detectable level of the analyte or a known detectable level. Recovery experiments provide information on both precision and trueness (bias), and thereby the accuracy of the method.

Selectivity (Specificity) refers to the extent to which the method can be used to determine particular analytes in mixtures or matrices without interferences from other components of similar behaviour. Some regulatory authorities use the term specificity to refer to selectivity.

Calibration refers to the ability of a detection system to produce an acceptable, well defined, correlation between the instrumental response and the concentration of the analyte in the sample. The analyte concentration to be measured should be within the defined dynamic range of the instrument.

Repeatability refers to the closeness of agreement between mutually independent test results obtained with the same method on identical test material in the same laboratory by the same operator using the same equipment within short intervals of time. The repeatability (within-run effect) includes contributions from any part of the procedure that varies within a run, including contributions from normal gravimetric and volumetric errors, heterogeneity of the test material, and other procedural errors during the analysis.

Reproducibility refers to the closeness of agreement between independent results obtained with the same method on identical test material obtained but under different conditions. Within-laboratory or intra-laboratory reproducibility or single-laboratory reproducibility (run effect) contributes to day-to-day variations in the analytical system due to changes of analyst, batches of reagents, recalibration of instruments and laboratory environment (e.g. temperature changes). Between-laboratory or inter-laboratory or multiple-laboratory reproducibility (laboratory effect) contributes to additional variations such as variations in calibration standards, differences between local interpretations of a protocol, differences in equipment or reagent source, or environmental factors, such as differences in average climatic conditions.

Limit of Detection (LOD) of an analytical procedure is the lowest amount of an analyte in a sample that can be detected but not necessarily quantitated as an exact value. At the limit of detection, a positive identification can be achieved with reasonable and/or previously determined confidence in a defined matrix using a specific analytical method. The LOD is typically not required. However, if needed for a refined assessment (or some other purpose), an explanation of how the LOD was derived should be provided.

Limit of quantitation (LOQ) is defined from a regulatory perspective as the lowest concentration tested at which an unambiguous identification of the analyte can be proven and at which an acceptable mean recovery with an acceptable relative standard deviation (RSD) is obtained, also referred to as the limit of determination (LOD) or Lowest Limit of Method Validation (LLMV). The LOQ should be low enough to achieve the intended purpose of the method. From an analytical perspective, 6-10 times the standard deviation of the noise provides an estimate of the LOQ, which is then verified by the fortification experiments. If not stated otherwise, this document refers to the LOQ from the regulatory perspective.

Applicant means a person who applies for a registration, amended registration, or re-registration.

Bioaccumulation is the process by which the amount of a substance in a living organism (or its parts) increases with time. (Australia Sec. 4 Data Requirements)

Bioaccumulation is the progressive increase in the amount of a substance in an organism or part of an organism which occurs because the rate of intake exceeds the organisms' ability to remove the pesticide from the body. (Draft IUPAC Glossary of Pesticide Terms]

Biotransformation is the process by which xenobiotics are converted into metabolites by an animal or plant, including the enzymatic conversion of chemicals into compounds that can be more easily excreted. This term is often used synonymously with the term "metabolism". (Australia Sec. 4 Data Requirements)

Commodity group: Commodities within a commodity group are intended to have similar residue characteristics and to be suitable for setting group MRLs. Commodity groups (e.g., pome fruits, cereal grains) within the Codex Classification for Foods and Feeds are suitable for establishing group MRLs. Note that a given crop may be included in more than one commodity group. For example, wheat is a crop, and the commodities are grain (cereal grain commodity group) and straw (straw, fodder and forage of cereal grains and grasses commodity group).

Common moiety is a molecular sub-unit which is common to the structure of several pesticides or metabolites. (Draft IUPAC Glossary of Pesticide Terms)

Common moiety method is an analytical method in which the parent and metabolites cannot be determined individually.

Compliance means meeting of official maximum residue limit (MRL) standards by residue levels in food consignments sampled and tested by approved methods. (Draft IUPAC Glossary of Pesticide Terms)

Composite sample means combined increment samples, or combined replicate samples, or combined samples from replicate trials. This term is preferred to 'bulk sample' which is ambiguous. (Draft IUPAC Glossary of Pesticide Terms)

Control sample (field) is the sample from a field test plot to which no pesticide was applied (a zero rate sample) or which received chemical treatments identical to the test plots except for the test chemical. (Draft IUPAC Glossary of Pesticide Terms)

Crop Field Trial – see "Supervised Field Trial"; these terms are considered synonymous for purposes of the Crop Field Trial Guideline.

Crop field trial site is a geographically defined address/location within a country/region/state of a field, space, greenhouse or other area in/on which a pesticide field trial is conducted. A site may consist of several *plots* (areas with defined boundaries on which a crop is grown), including control and one or more treated plots, each of which receives a specific pesticide application regimen. The trial location for a post-harvest application is defined as the location where the post-harvest treatment takes place (for example treatment room or storage location). Additionally, the trial location for a seed treatment crop field trial is defined as the location where the seed is planted or sown.

Crop Group refers to a group of crops in which the expected residues on the commodities are likely to be similar (from treatment under similar GAP) and where group or subgroup MRLs can be considered. Crop grouping is based on similarities in appearance, harvestable commodity, edible portions and/or growth habits etc.

Definition of residues (for compliance with MRLs) is that combination of the pesticide and its metabolites, derivatives and related compounds to which the MRL applies. The residue definition for compliance with MRLs depends on the results of metabolism and toxicology studies, supervised residue trials, analytical methods and its general suitability for monitoring compliance with Good Agriculture Practice. (FAO Manual)

Degradate is any environmental degradation product that may be present as a residue due to photodegradation, microbial degradation, hydrolysis, or other environmental processes.

Diastereomers are stereoisomers not related as mirror images. (NAFTA)

Dislodgeable residue is the portion of a pesticide residue on treated vegetation that is readily removable and may be used as an index for risk to farm workers. It is generally measured by the residue removed when leaf discs are shaken briefly in water. (Draft IUPAC Glossary of Terms Related to Pesticides).

Dry weight basis is the pesticide residue concentration reported as if the residue were wholly contained in the dry matter of the sample, i.e. analytical results are corrected for the water content of the test sample. Residues in soils and feeds, and maximum residue limits (MRLs) for feedstuffs are expressed on a dry weight basis. (Draft IUPAC Glossary of Terms Related to Pesticides).

Enantiomer is one of a pair of molecular species that are non-superimposable mirror images of each other. (NAFTA)

End-use product is a product containing active ingredient(s), and usually formulant(s), that is labeled with instructions for direct pest control use or application (See also 'Product')

Estimated daily intake (EDI) is the predicted daily intake of a pesticide residue, based on the most realistic estimation of residues in food items and the best available food consumption data for a specific population. Residue levels are estimated taking into account known uses of the pesticide, the proportion of commodity treated and the quantity of contaminated commodities. The EDI is expressed in milligrams of residues per person. (WHO, 1989) (Draft IUPAC Glossary of Terms Related to Pesticides)

Estimated maximum daily intake (EMDI) is the predicted maximum daily intake of a pesticide residue, based on the assumptions of average daily food consumption per person and maximum residues in the edible portion of a commodity, corrected for the reduction or increase in residues resulting from preparation, cooking, or commercial processing. The EMDI is expressed in milligrams of residues per person. (WHO, 1989) (Draft IUPAC Glossary of Terms Related to Pesticides).

Extrapolation refers to a system projection of data from one system to another system. In this sense, data received from one formulation can be extrapolated to another formulation under certain circumstances. In some instances, extrapolation of field trial data obtained from one commodity are used to predict the residue behaviour of another similar commodity under described circumstances and thus proposing the same MRLs for both commodities.

Fat basis. Residues and maximum residue limits (MRLs) of fat-soluble pesticides in animal commodities may be expressed in terms of their concentration in the fat rather than the whole product. (Draft IUPAC Glossary of Terms Related to Pesticides)

Fat solubility. In determining "fat solubility" for a residue, the following factors should be considered:

- When available, it is the partitioning of the residue (as defined) in muscle versus fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being "fat soluble".
- In the absence of useful information on the distribution of residues in muscle and fat, residues with $\log P_{ow} > 3$ are likely to be "fat soluble".

Note: In the design of animal feeding studies, account should be taken of the likely fat solubility of residues with $\log P_{ow} > 3$. When no evidence is available to the contrary and $\log P_{ow}$ exceeds three, the compound would be designated fat-soluble and when $\log P_{ow}$ is less than 3 it would not be so designated. (Report of the JMPR meeting 2005)

Formulant is any substance or group of substances other than an *active ingredient* that is intentionally added to a pest control product to improve its physical characteristics, e.g., sprayability, solubility, spreadability and/or stability.

Fortified sample. See spiked sample.

Fresh weight basis. Pesticide residues are reported on the laboratory sample as it is received, with no allowance for the moisture content. Maximum residue limits (MRLs) and pesticide residues in food commodities are expressed in this way. (Draft IUPAC Glossary of Terms Related to Pesticides)

Good Agricultural Practice in the use of Pesticides (GAP) includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable.

Authorized safe uses are determined at the national level and include nationally registered or recommended uses, which take into account public and occupational health and environmental safety considerations.

Actual conditions include any stage in the production, storage, transport, distribution of food commodities and animal feed. (CAC, 1995) (FAO Manual)

Critical Good Agricultural Practice (cGAP) is the GAP selected to represent the worst-case use scenario within the context of national, regional, or global uses that will be producing the highest possible field residues on crop commodities. It usually includes the maximum use-rate and number of applications and the minimum re-treatment and pre-harvest intervals.

Extrapolation group/Crop Group refers to a group of crops in which the expected residues at harvest could be similar, based on similarities in appearance, harvestable commodity, edible portions and/or growth habits etc. Crops within a crop group should have similar growth pattern and production characteristics, similar cultural practices, and similar pests that require the same pesticide treatment. Such crop groups are suitable for inclusion on product labels in the directions for use tables for use of a pesticide (see commodity group)..

Good experimental field practice is the formalised process for designing and recording the practices used in the performance of field investigations with pesticides, and which assure the reliability and integrity of the data. See Good laboratory practice. (Draft IUPAC Glossary of Terms Related to Pesticides)

Good laboratory practice (GLP) is the formalised process and conditions under which laboratory studies on pesticides are planned, performed, monitored, recorded, reported and audited. Studies performed under GLP are based on the national regulations of a country and are designed to assure the reliability and integrity of the studies and associated data. The U.S. Environmental Protection Agency GLP definition also covers field experiments (see Good experimental field practice). (after OECD, 1992) (Draft IUPAC Glossary of Terms Related to Pesticides)

Highest residue – The Highest residue (HR) level (expressed as mg/kg) in a composite sample of the edible portion of a food commodity when a pesticide has been used according to the maximum GAP conditions. The HR is estimated as the highest of the residue values (typically, one from each trial) from supervised trials conducted according to maximum GAP conditions, and includes residue components defined by the JMPR for estimation of dietary intake. (new definition) (FAO Manual)

Impurity is any substance in a control product other than an active ingredient or a formulant, e.g. contaminants, residual starting materials, reaction products, degradation products or products added for purposes of extraction or purification. (NAFTA)

Inert ingredient is any substance (or group of structurally similar substances if designated by the Agency), other than an active ingredient, which is intentionally included in a pesticide product.

Isomer is one of several species (or molecular entities) that have the same atomic composition (molecular formula) but different line formulae or different stereochemical formulae and hence different physical and/or chemical properties. (IUPAC 'Gold Book Online, 1997'). (Draft IUPAC Glossary of Terms Related to Pesticides)

Limit of detection (LOD) is the lowest concentration of a pesticide residue in a defined matrix where positive identification can be achieved using a specified method. (Draft IUPAC Glossary of Terms Related to Pesticides). See **Analytical Method Validation Parameters**.

Limit of quantitation (LOQ) is the lowest concentration of a pesticide residue in a defined matrix where positive identification and quantitative measurement can be achieved using a specified method. (Draft IUPAC Glossary of Terms Related to Pesticides). See **Analytical Method Validation Parameters**.

Major metabolites are considered to be those which contribute to 10% or more of the total radioactive residue (TRR) in the nature of the residue (metabolism) studies in plants and livestock or in confined rotational crop studies. The percentage of a metabolite will vary with time.

Maximum Residue Limit (MRL) is the maximum concentration of a residue that is legally permitted or recognized as acceptable in, or on, a food, agricultural commodity or animal feedstuff as set by Codex or a national regulatory authority. The term tolerance used in some countries is, in most instances, synonymous with MRL. It is normally expressed as mg/kg fresh weight.(after FAO, 1986) (Draft IUPAC Glossary of Terms Related to Pesticides)

The **maximum residue level** is estimated as the maximum concentration of residues (expressed as mg/kg) which may occur in a food or feed commodity following Good Agricultural Practices. The estimated maximum residue level is considered by regulatory agencies to be suitable for establishing MRLs. (FAO Manual, 2002).

Metabolism is the sum total of all physical and chemical processes that take place within an organism; in a narrower sense, the physical and chemical changes that occur for a pesticide within an organism. It includes uptake and distribution within the body, changes (biodegradation), and elimination of pesticides and their metabolites. In plant studies, the term "metabolism" is used in a wider context than in animals studies, to include the formation of all products (degradates) of the pesticide in or on the plant, regardless of whether they result from internal plant metabolic processes, from chemical reactions (hydrolysis and photolysis) or biological processes outside the plant (e.g. microbial degradation in the soil). (Draft IUPAC Glossary of Terms Related to Pesticides) (Australia Sec. 4 Data Requirements)

Metabolite denotes any plant or livestock biotransformation product.

Minor Metabolites are metabolites or degradates that comprise less than 10% of the total radioactive residue (TRR) (or applied dose in environmental studies).

Multiresidue method is an analytical method which measures a number of pesticide residues simultaneously. (Draft IUPAC Glossary of Terms Related to Pesticides)

Nominal concentration is the typical amount, or guarantee, of an ingredient that is expected to be present in a representative sample of a pest control product at the time of its production. (NAFTA)

Pharmacokinetics is the study of the movement of drugs within the body (i.e. the absorption, distribution via the blood, metabolism and excretion). The term is usually applied to medicines or therapeutic agents tested at doses related to their therapeutic action but can be applied to any xenobiotic chemicals. See also Toxicokinetics. (Australia Sec. 4 Data Requirements)

Pre-harvest interval (PHI) is the time interval between the last application of a pesticide to the next normal harvest. See withholding period. (Draft IUPAC Glossary of Terms Related to Pesticides)

Post-harvest treatment refers to a pesticide application to the harvested crop, which may occur before or during storage.

Pre-slaughter interval is the minimum permissible time between the final application of a pesticide to an animal and the collection of eggs or milk, or slaughter, for human consumption.

Primary feed commodity means the product in or nearly in its natural state intended for sale to: a) the stock farmer as feed which is used without further processing for livestock animals or after silaging or similar farm processes; and b) the animal feed industry as a raw material for preparing compounded feeds. It includes irradiated primary food commodities and products after removal of certain parts of the plant or parts of animal tissue. The term "raw agricultural commodity (RAC)" means the same as "primary food commodity" (FAO Manual).

Primary processed commodities means the products - resulting from the application of physical, chemical or biological processes or combinations of these to a "primary food commodity" - intended for direct sale to the consumer, for direct use as an ingredient in the manufacture of food or for further processing. A primary processed commodity is derived from mechanical or chemical processing of the RAC and is not a multi-component product (Codex).

Product is a formulation containing one or more active constituent(s), and possibly non-active constituent(s), which is intended for application and administration, with or without dilution before use, and which is labeled with directions for use. (Australia Sec. 4 Data Requirements)

Raw agricultural commodity (RAC) means the product in or nearly in its natural state intended for sale or consumption without further processing, or for processing into food for sale to the consumer. It includes irradiated primary food commodities and products after removal of certain parts of the plant or parts of animal tissue. The term "raw agricultural commodity (RAC)" means the same as "primary food commodity". (FAO Manual)

Reasonable diet is a nutritionally balanced diet as used by farmers to produce high quality livestock products (meat, milk, eggs, etc.).

Reasonable worst case dietary exposure refers to the livestock diet being constructed with a realistic mixture of feeds as used in commercial practice and that all livestock feeds should be considered as having maximum or median residues depending on the feed (i.e., raw or processed).

Regulatory method is a validated analytical method which can be applied using commonly available laboratory equipment and instrumentation. A regulatory method has the precision, specificity, limit of

determination, etc., needed to test compliance with the regulations. (Draft IUPAC Glossary of Terms Related to Pesticides)

Repeatability. For an analytical method, the closeness of agreement between results of measurements on identical test material subject to the following conditions: same analyst, same instrumentation, same location, same conditions of use, repetition over a short period of time. (after Metrology, 1984) (Draft IUPAC Glossary of Terms Related to Pesticides)

Representative commodities are those designated commodities from which extrapolations of residue levels and resulting MRLs can be made to one or more related commodities or to an entire group of commodities ('crops').

Reproducibility. For an analytical method, it is the closeness of agreement between results of measurements on identical test material where individual measurements are carried under changing conditions such as: analyst, instrumentation, location, conditions of use, time. (after Metrology, 1984) (Draft IUPAC Glossary of Terms Related to Pesticides)

[A pesticide] **residue** is defined as the combination of the pesticide and its metabolites, degradates (metabolites/degradates) and other transformation products which remain in, or on, a feed or food commodity, soil, air or water following use of a pesticide.

Residue definition comprises the pesticide, its metabolites, derivatives and related compounds to which the maximum residue limit (MRL) applies, as specified by Codex or a national regulatory authority. (Draft IUPAC Glossary of Terms Related to Pesticides)

Rotational crop is a crop grown in sequence of two or more different crop. (Draft IUPAC Glossary of Terms Related to Pesticides)

Sample is a defined representative amount of individual raw agricultural commodity unit(s) (e.g. specific number of fruits or tubers, a set weight of grain, etc.) randomly selected from a plot which may be composited for pesticide analysis.

Seed means any generative part of a plant used for propagation purposes including true seeds, seed-like fruits, bulbs, tubers and corms but does not include whole plants or cuttings. (Canada Pest Products Control Act)

Seed treatment application is made to the seeds of crops prior to planting or sowing, which may occur at a seed treatment facility or in the field immediately prior to planting or sowing.

Spiked sample (fortified sample) is a control sample with a known amount of pesticide added. It is used to test the accuracy (especially the efficiency of recovery) of an analytical method. (Draft IUPAC Glossary of Terms Related to Pesticides)

Stereoisomers are isomers having identical atomic connectivities and differing only by the spatial arrangements of their atoms or groups. Subclasses are enantiomers and diastereomers. (NAFTA)

Storage stability test measures the chemical and physical stability of the product stored under defined, often worst case, conditions. For pesticide residues, it is a test which measures stability of residues in stored analytical samples, usually held under frozen conditions at a specified temperature. (Draft IUPAC Glossary of Terms Related to Pesticides)

Supervised Field Trials are residue field trials conducted on crops typically according to the principles of Good Laboratory Practice (GLP) in order to assess the magnitude of the residues under the conditions of the critical Good Agricultural Practice (cGAP).

Supervised trials median residue (STMR) is the expected residue level (expressed as mg/kg) in the edible portion of a food commodity when a pesticide has been used according to maximum Good Agriculture Practice conditions. The STMR is estimated as the median of the residue values (one from each trial) from supervised trials conducted according to maximum Good Agriculture Practice conditions. (FAO Manual)

Target animals are those animals that will be exposed to an agricultural or veterinary product, either by direct administration (as for veterinary products) or in contaminated feedstuff. (Australia Sec. 4 Data Requirements)

Target plants are those crops that will be exposed to an agricultural product. (Australia Sec. 4 Data Requirements)

Technical Grade Active Ingredient (TGAI) is the pesticide chemical (typically 95-100% active ingredient and up to 5% impurities) as it is manufactured by a chemical company prior to being formulated into an end-use product (e.g., wettable powders, granules, emulsifiable concentrates).

Theoretical maximum daily intake (TMDI) is a prediction of the maximum daily intake of a pesticide residue, based on the assumption of levels of residues in food at maximum residue limits and average daily consumption of food per person. The TMDI is expressed in milligrams of residue per person. (WHO, 1989). (Draft IUPAC Glossary of Terms Related to Pesticides)

Tolerance is the maximum amount of a pesticide chemical residue that may lawfully be present in, or on, a raw agricultural commodity, or processed food, or animal feed.

Total radioactive residue (TRR) is used to describe the sum of the parent pesticide and its degradation products, metabolites (free or bound) and impurities in a sample.

Total terminal residue (TTR) is the summation of levels of all the compounds comprising residues of a pesticide in a food. (Draft IUPAC Glossary of Terms Related to Pesticides)

Toxicokinetics is the study of the movement of xenobiotic chemical agents within the body (i.e. the absorption, distribution via the blood, metabolism and excretion), to provide key information for the assessment of possible toxicity at elevated doses. The term is sometimes used interchangeably with 'pharmacokinetics' but the latter term applies more specifically to medicines or therapeutic agents. (Australia Sec. 4 Data Requirements)

Transformation product is a chemical species resulting from environmental or metabolic processes on a pesticide. (Draft IUPAC Glossary of Terms Related to Pesticides)

Trigger value is the numerical value for a property of a pesticide, set by regulatory authorities, which determines the sequence and type of tests in a tiered assessment scheme. (Draft IUPAC Glossary of Terms Related to Pesticides)

Unextracted radiolabel. The term 'unextracted' radiolabel describes the [radiolabeled] components which are not extracted and identified. (JMPR)

Withholding period is the minimum permissible time between the last application of a pesticide to a crop (including pasture) and harvesting for human consumption or grazing with livestock. It is the minimum permissible time between the final application of a pesticide to an animal and the collection of eggs or milk, or slaughter, for human consumption. See also pre-harvest interval. (Draft IUPAC Glossary of Terms Related to Pesticides)

Xenobiotic chemicals are compounds "foreign" to an organism, e.g., environmental contaminants, agricultural and veterinary chemicals, drugs (FAO Manual).

Zero tolerance is the limit for a pesticide residue in food or feed which is assumed to be zero and therefore any detectable residue is deemed illegal. Zero tolerances are used by some regulatory systems, e.g., United States, where no maximum residue limits have been established for particular pesticide/crop combinations. (Draft IUPAC Glossary of Terms Related to Pesticides)

ANNEX 2

COMMON TERMS AGREED AS PART OF THE OECD TEST GUIDELINES
FOR RESIDUE CHEMISTRY

In order to obtain consistency in the use of common terms in the preparation of the Test Guidelines, the following list indicates the preferred word (**in bold**) to use when multiple alternate terms are available.

Terms where one form is desired

1. **Applicant**/Registrant/Notifier/Petitioner/Contractor/Data generators/Studygenerators/Sponsor, etc.
2. **Pesticide**/Crop protection agent/Crop protection product/Plant protection product
3. **Metabolic pathway**/Metabolic route/Metabolic degradation
4. **Radioactivity**/Activity/¹⁴C
5. **Exaggerated rate**/Overdose
6. **Active ingredient**/Active substance
7. **Plant part**/Crop part
8. **Regulatory Authority**/Agency/Authority/Competent authority/Designated national authority
9. **Foliar application or Soil application**/Surface application
10. **Total radioactive residue (TRR)**/Total radioactivity/Total activity
11. **Residue of concern (ROC)**/Total toxic residue (TTR)
12. **Rotational crop**/Following crop/Succeeding crop
13. **Livestock**/Farm animal/Domestic animal
14. **Maximum Residue Limit (MRL)**/Tolerance
15. **Edible offal**/Meat by-products
16. **Feedstuffs**/Feeding stuffs
17. **Unextracted radiolabel**/bound residues

18. Raw agricultural commodity (RAC)/primary food commodity

19. Field trial/supervised field trial

Terms where alternate forms, depending on context, may be used

1. **a) Metabolite** – biological
 b) Degradation product – exogenous
2. **a) Dosing** – to an animal
 b) Application – to a plant or non-oral treatment of animals
3. **a) Trigger** – use as a verb
 b) Trigger value/Trigger level
4. **a) Food commodities**
 b) Feed commodities
5. **a) Plant**
 b) Crop
6. **a) Limit of Detection (LOD)**
 b) Limit of Quantitation (LOQ)

ANNEX 3

**RAW AGRICULTURAL COMMODITIES TO BE ANALYZED FOR
CROP METABOLISM AND ROTATIONAL CROPS STUDIES**

RACs To Be Analyzed For Crop Metabolism And Rotational Crops Studies*	
Crop	Raw Agricultural Commodity
Alfalfa	forage hay seed
Almond*	nutmeat hulls
Apple*	fruit
Apricot*	fruit
Artichoke, Globe*	flower head
Asparagus*	spears (stems)
Avocado*	fruit
Banana *	whole fruit
Barley	grain hay straw
Bean	bean, succulent seed
Beet, garden	root tops (leaves)
Beet, sugar	root tops (leaves)
Blackberry *	berry
Blueberry*	berry
Broccoli	flower head and stem
Brussels sprouts	leaf sprouts
Buckwheat	grain
Cabbage	fresh, w/wrapper leaves
Cacao bean *	bean
Canola	seed
Carrot	root
Cauliflower	flower head and stem
Celery	untrimmed leaf stalk (petiole)
Cherry, sweet*	fruit
Cherry, tart (sour)*	fruit
Chicory	root tops (leaves)
Citrus*	fruit, whole
Clover	forage hay
Coconut*	coconut (meat and liquid combined)
Coffee*	bean, green
Collards	greens

RACs To Be Analyzed For Crop Metabolism And Rotational Crops Studies*	
Crop	Raw Agricultural Commodity
Corn, field	grain forage stover
Corn, pop	grain stover
Corn, sweet	sweet corn, (K+CWHR) forage stover
Cotton	undelinted seed cotton gin by-products
Cowpea	seed hay forage
Crabapple*	fruit
Cranberry*	berry
Crownvetch	forage hay
Cucumber	fruit
Dewberry*	berry
Eggplant	fruit
Elderberry*	berry
Endive/Escarole	leaves
Fig*	fruit
Flax	seed
Garlic	bulb
Ginseng*	root, dried
Gooseberry*	berry
Grape*	fruit
Grass (pasture & rangeland)	forage hay
Herbs	fresh
Hops	hops cones, dried
Horseradish	root
Huckleberry*	berry
Jerusalem artichoke	tuber
Kale	leaves
Kiwifruit*	fruit
Kohlrabi	bulbous stem and leaves
Kumquat*	fruit
Leek	whole plant
Lentil	seed
Lespedeza	forage hay
Lettuce, head	fresh, w/wrapper leaves
Lettuce, leaf	leaves
Loganberry*	berry
Lupin	seed
Mango*	fruit
Millet	grain forage

RACs To Be Analyzed For Crop Metabolism And Rotational Crops Studies*	
Crop	Raw Agricultural Commodity
	hay straw
Mung bean	bean bean sprouts
Mushroom*	cap and stem
Muskmelon	fruit
Mustard greens	greens (leaves)
Nectarine*	fruit
Nuts *	nutmeat
Oats	grain forage hay straw
Okra	fruit (pods)
Olives*	fruit
Onion, bulb	bulb
Onion, green	whole plant, w/o roots
Papaya*	fruit
Parsley	leaves, fresh
Parsnip	root
Passion fruit*	fruit
Pawpaw*	fruit
Pea	pea, succulent seed
Pea, field	seed vines hay
Peach*	fruit
Peanut	nutmeat hay
Pear*	fruit
Pepper, bell and non-bell	fruit
Peppermint	tops (leaves and stems)
Pimento	fruit
Pineapple*	fruit
Plantain *	whole fruit
Plum*	fruit
Potato	tuber
Pumpkin	fruit
Quince*	fruit
Radicchio (red chicory)	leaves, fresh
Radish	root tops (leaves)
Rape	seed forage
Rape greens	greens (leaves)
Raspberry, black and red*	berry
Rhubarb*	petioles
Rice	grain straw

RACs To Be Analyzed For Crop Metabolism And Rotational Crops Studies*	
Crop	Raw Agricultural Commodity
Rutabaga	root
Rye	grain forage straw
Safflower	seed
Salsify	root tops (leaves)
Sesame	seed
Shallot	bulb
Sorghum, grain	grain forage stover
Sorghum, sweet	stalk
Sorghum forages, sudangrass	(See Grass)
Soybean	seed forage hay
Spearmint	tops (leaves and stems)
Spices	fresh
Spinach	leaves
Squash	fruit
Strawberry	berry
Sugarcane	cane
Sunflower	seed
Sweet potato	root
Swiss chard	petioles
Taro	corm foliage
Tea *	plucked leaves
Tomato	fruit
Trefoil	forage hay
Turnip	root tops (leaves)
Vetch	forage hay
Watercress	leaves and stems
Watermelon	fruit
Wheat	grain forage hay straw
Yam	tuber

* Permanent or semi-permanent crops, rotational crop studies are not required

ANNEX 4

HARMONIZED FEEDSTUFFS TABLE

OECD FEEDSTUFFS DERIVED FROM FIELD CROPS																																							
Feb-09										PERCENT OF LIVESTOCK DIET																													
* <																																							

						CATTLE								SHEEP						SWINE								POULTRY								
						BEEF				DAIRY				RAM/EWE					LAMB			BREEDING				FINISHING						BROILER				LAYER
						US	EU	AU	JP	US	EU	AU	JP	US	EU	AU	US	EU	AU	US	EU	AU	US	EU	AU	US	EU	AU	JP	US	EU	AU	JP	US		
CROP	FEEDSTUFF	IFN Code	Class.	Residue Level	DM	CAN				CAN				CAN			CAN			CAN			CAN					CAN				CAN				
Corn, field	stover	3-28-251	R	HR	83	15	25	40	*	15	20	40	*	50	*	*	25	*	*	*	20	*	*	*	*	*	*	*	*	*	*	*				
Corn, pop	stover	2-02-963	R	HR	85	15	25	20	*	*	20	20	*	25	*	*	25	*	*	*	20	*	*	*	*	*	*	*	*	*	*	*				
Corn, sweet	forage	1-08-407	R	HR	48	*	*	80	*	45	*	40	*	75	*	25	25	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*				
Corn, sweet	stover	NA	R	HR	83	*	*	40	*	15	*	20	*	70	*	30	30	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*				
Cowpea	forage	2-01-655	R	HR	30	*	35	100	*	20	35	60	*	75	35	100	30	35	100	*	20	*	*	*	*	*	*	*	*	*	*	*				
Cowpea	hay	1-01-645	R	HR	86	*	35	100	*	20	35	60	*	50	35	65	20	35	35	*	20	10	*	*	10	*	*	*	*	*	*	*				
Crown vetch	forage	2-19-834	R	HR	30	*	*	100	*	10	*	100	*	80	*	95	30	*	95	*	*	*	*	*	*	*	*	*	*	*	*	*				
Crown vetch	hay	1-20-803	R	HR	90	*	*	100	*	*	*	100	*	65	*	70	20	*	35	*	*	*	*	*	*	*	*	*	*	*	*	*				
Grass	forage (fresh)	2-02-260	R	HR	25	*	50	100	5	45	60	100	10	95	95	100	25	50	100	*	20	*	*	*	*	*	*	*	*	*	*	*				
Grass	hay	1-02-250	R	HR	88	15	50	100	40	45	60	60	70	90	90	70	15	30	25	*	20	10	*	*	10	*	*	*	*	*	*	*				
Grass	silage	3-02-222	R	HR	40	*	50	100	5	45	60	60	80	90	90	75	20	50	50	*	20	*	*	*	*	*	*	*	*	*	*	*				
Kale	leaves	2-02-446	R	HR	15	*	20	*	*	*	20	40	*	*	10	*	*	10	*	*	10	*	*	*	*	*	*	*	*	*	*	*				
Lespedeza	forage	2-07-058	R	HR	22	*	*	20	*	40	*	60	*	80	*	*	30	*	*	*	*	*	10	*	*	*	*	*	*	*	*	*				
Lespedeza	hay	1-02-522	R	HR	88	15	*	20	*	40	*	60	*	70	*	20	20	*	*	*	*	*	10	*	*	*	*	*	*	*	*	*				
Millet	forage	2-03-801	R	HR	30	*	*	100	*	20	30	50	*	80	*	100	35	*	60	*	*	*	*	*	*	*	*	*	*	*	*	*				
Millet	hay	1-03-119	R	HR	85	10	*	100	*	20	*	50	*	75	*	65	20	*	20	*	*	10	*	*	10	*	*	*	*	*	*	*				
Millet	straw	1-23-802	R	HR	90	10	10	80	*	10	*	50	*	50	*	35	15	*	15	*	*	10	*	*	10	*	*	*	*	*	*	*				
Oat	forage	2-03-292	R	HR	30	*	20	100	*	30	20	90	5	25	40	100	35	40	100	*	20	*	*	*	*	*	*	*	*	*	*	*				
Oat	hay	1-03-280	R	HR	90	15	20	100	*	30	20	90	5	80	40	65	20	40	20	*	20	10	*	*	10	*	*	*	*	*	*	*				
Oat	straw	1-03-283	R	HR	90	10	20	80	*	10	20	60	5	10	40	35	20	40	15	*	*	10	*	*	10	*	*	*	*	*	*	*				

						CATTLE								SHEEP						SWINE									POULTRY																		
						BEEF						DAIRY				RAM/EWE				LAMB				BREEDING				FINISHING				BROILER				LAYER						TURKEY					
						US	EU	AU	JP		US	EU	AU	JP		US	EU	AU	US	EU	AU	US	EU	AU	US	EU	AU	JP		US	EU	AU	JP		US	EU	AU	JP		US	EU	AU					
CROP	FEEDSTUFF	IFN Code	Class.	Residue Level	DM	CAN					CAN				CAN			CAN			CAN			CAN			CAN				CAN				CAN				CAN								
Oat	silage	3-03-298	R	HR	35	*	*	100	*	*	*	40	5	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Pea	vines	3-03-596	R	HR	25	*	20	60	*	10	20	40	*	75	20	90	35	20	90	*	20	*	*	*	*	*	*	*	*	*	*	*	10	*	*	*	*	*	*	*	*	*	*	*	*		
Pea	hay	1-03-572	R	HR	88	*	25	100	*	10	30	70	*	75	20	70	25	20	30	*	20	15	*	*	10	*	*	*	*	*	*	10	*	*	*	*	*	10	*	*	*	*	*	*	*	*	
Pea	silage	3-03-590	R	HR	40	*	25	100	*	10	30	40	*	73	20	75	35	20	70	*	20	*	*	*	*	*	*	*	*	*	*	10	*	*	*	*	*	10	*	*	*	*	*	*	*		
Peanut	hay	1-03-619	R	HR	85	*	*	60	*	15	*	60	*	79	*	25	25	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
Rape	forage	2-03-867	R	HR	30	*	10	100	*	10	10	40	*	50	40	90	30	40	90	*	20	*	*	*	*	*	*	*	*	*	*	10	*	*	*	*	*	10	*	*	*	*	*	*	*		
Rice	straw	1-03-925	R	HR	90	*	10	60	55	*	5	20	25	10	10	20	10	10	15	*	*	10	*	*	10	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		
Rice	whole crop silage			HR	40				5				55																																		
Rye	forage	2-04-018	R	HR	30	*	20	100	*	20	20	20	*	75	40	100	30	40	100	*	20	*	*	*	*	*	*	*	*	*	10	*	*	*	*	*	10	*	*	*	*	*	*	*			
Rye	straw	1-04-007	R	HR	88	10	20	20	*	10	20	20	5	25	40	20	10	40	20	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		
Rye	silage			HR	28				*				5																																		
Sorghum,forage	see Grasses																																														
Sorghum, grain	forage	2-04-317	R	HR	35	15	20	70	*	40	20	70	40	30	20	100	30	20	65	*	20	10	*	*	*	*	*	*	*	*	10	*	*	*	*	*	10	*	*	*	*	*	*	*			
Sorghum, grain	stover	1-07-960	R	HR	88	15	15	70	*	15	15	70	5	30	20	*	20	20	*	*	20	*	*	*	*	*	*	*	*	10	*	*	*	*	*	10	*	*	*	*	*	*	*	*			
Sorghum, grain	silage			HR	21				*				10																																		
Soybean	forage	2-04-574	R	HR	56	*	*	100	*	20	*	40	*	80	*	90	35	*	80	*	*	*	*	*	*	*	*	*	*	10	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		
Soybean	hay	1-04-558	R	HR	85	*	*	80	*	20	*	40	*	65	*	70	20	*	25	*	*	*	*	*	*	*	*	*	*	10	*	*	*	*	*	*	10	*	*	*	*	*	*	*	*		
Soybean	silage	3-04-581	R	HR	30	*	*	80	*	20	*	40	*	70	*	75	40	*	65	*	*	*	*	*	*	*	*	*	*	10	*	*	*	*	*	*	10	*	*	*	*	*	*	*	*		
Sugarcane	tops	2-04-692	R	HR	25	*	*	50	*	*	*	25	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		
Trefoil	forage	2-20-786	R	HR	30	*	20	100	*	40	40	40	*	75	40	90	35	20	90	*	20	*	*	*	*	*	*	*	10	*	*	*	*	*	*	10	*	*	*	*	*	*	*	*			
Trefoil	hay	1-05-044	R	HR	85	15	20	90	*	40	40	40	*	60	40	70	25	20	70	*	20	15	*	*	10	*	*	*	*	10	*	*	*	*	*	10	*	*	*	*	*	*	*	*			
Triticale	forage	2-02-647	R	HR	30	*	20	100	*	20	20	70	*	60	40	100	30	30	100	*	20	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*		

						CATTLE								SHEEP								SWINE		POULTRY																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																						
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CROP	FEEDSTUFF	IFN Code	Class.	Residue Level	DM	CAN				CAN				CAN			CAN			CAN			CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN			

Roots & Tubers																																						
Carrot	culls	2-01-146	CC	HR	12	*	15	5	*	10	15	5	*	20	20	*	40	20	*	*	25	10	*	25	5	*	*	10	*	*	*	10	*	*	*	10	*	
Cassava/lapioca	roots	2-01-156	CC	HR	37	*	20	*	*	*	15	*	*	*	20	*	*	20	*	*	40	*	*	40	*	*	*	*	20	*	*	*	15	*	*	*	5	*
Potato	culls	4-03-787	CC	HR	20	30	30	10	*	10	30	10	*	50	30	*	40	20	*	*	50	10	*	50	*	*	*	10	*	*	*	10	*	*	*	20	*	
Swede	roots	4-04-001	CC	HR	10	*	40	10	*	*	20	10	*	*	30	80	*	30	80	*	40	5	*	40	*	*	*	10	*	*	*	10	*	*	*	10	*	
Turnip	roots	4-05-067	CC	HR	15	*	20	10	*	10	20	10	*	75	30	80	75	30	80	*	40	5	*	40	5	*	*	10	*	*	*	10	*	*	*	10	*	
Cereal Grains/Crops Seeds																																						
Barley	grain	4-00-549	CC	STMR	88	50	70	80	70	45	40	40	40	40	40	85	40	60	85	20	80	85	20	80	80	30	75	70	15	10	75	100	15	*	75	50	15	
Bean	seed	4-00-515	PC	STMR	88	*	20	50	*	*	20	15	*	20	20	85	20	20	85	*	20	20	*	20	20	*	*	20	70	*	*	20	70	*	*	20	70	
Corn, field	grain	4-20-698	CC	STMR	88	80	80	80	75	45	30	20	80	50	30	85	50	30	85	85	70	80	85	70	80	85	75	70	*	70	75	70	*	80	75	50	*	
Corn, pop	grain	4-02-964	CC	STMR	88	80	*	80	75	45	30	20	80	50	30	85	50	30	85	*	*	*	*	*	*	*	75	*	*	70	75	*	*	80	*	*	*	
Cowpea	seed	5-01-661	PC	STMR	88	*	20	20	*	*	20	20	*	*	20	75	*	20	75	10	10	10	10	20	10	*	10	5	5	*	10	10	5	*	10	5	10	
Lupin	seed	5-02-707	PC	STMR	88	*	20	40	*	*	20	20	*	*	10	100	*	10	100	*	15	25	*	20	25	*	10	15	15	*	10	10	10	*	10	10	50	
Millet	grain	4-03-120	CC	STMR	88	50	40	50	*	20	40	50	*	40	30	*	40	30	*	20	70	70	20	70	70	*	60	70	70	*	60	70	60	*	60	50	15	
Oat	grain	4-03-309	CC	STMR	89	*	40	80	55	20	40	10	5	*	40	90	*	60	90	*	70	80	*	70	80	*	75	70	15	*	75	70	15	*	75	50	5	
Pea	seed	5-03-600	PC	STMR	90	*	20	40	*	*	20	20	*	20	20	*	20	20	*	15	20	40	15	20	40	*	20	20	5	*	20	20	5	*	20	20	40	
Rice	grain	4-03-939	CC	STMR	88	20	*	40	*	20	*	20	*	20	*	*	20	*	*	20	*	60	20	*	65	*	20	*	50	*	20	*	50	*	20	*	60	
Rye	grain	4-04-047	CC	STMR	88	20	40	80	35	20	40	*	15	20	40	*	20	45	*	*	70	80	*	70	70	35	35	70	50	*	35	35	35	*	35	60	60	
Sorghum, grain	grain	4-04-383	CC	STMR	86	40	40	80	35	45	40	50	30	40	40	80	50	40	80	80	70	80	80	70	80	55	75	70	70	65	75	70	70	55	75	50	15	
Soybean	seed	5-64-610	PC	STMR	89	5	10	20	15	10	10	20	10	25	10	40	15	20	40	15	10	10	15	20	10	*	20	20	15	*	20	15	15	*	20	15	15	
Triticale	grain	4-20-362	CC	STMR	89	20	40	80	*	20	40	30	*	20	30	85	20	40	85	*	60	80	*	60	80	*	75	15	*	*	75	15	*	*	75	15	60	

By-products																																																			
								CATTLE												SHEEP								SWINE				POULTRY																			
								BEEF						DAIRY								RAM/EWE				LAMB				BREEDING				FINISHING				BROILER				LAYER						TURKEY			
								US	EU	AU	JP	US	EU	AU	JP	US	EU	AU	US	EU	AU	US	EU	AU	US	EU	AU	JP	US	EU	AU	JP	US	EU	AU	JP	US	EU	AU	JP	US	EU	AU	JP							
CROP	FEEDSTUFF	IFN Code	Class.	Residue Level	DM	CAN					CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				CAN				
Almond	hulls	4-00-359	R	STMR	90	*	*	10	*	10	*	10	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
Apple	pomace, wet	4-00-419	CC	STMR	40	*	20	20	*	10	10	10	*	10	10	*	10	10	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
Barley	bran fractions			STMR	90				10				*																	*				5																	
Beet, sugar	dried pulp	4-29-307	R	STMR	88	15	20	*	5	15	20	*	40	15	40	*	20	40	*	*	20	*	*	20	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*			
Beet, sugar	ensiled pulp	4-00-662	R	STMR	15	*	25	*	*	*	40	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*			
Beet, sugar	molasses	4-30-289	CC	STMR	75	10	10	*	*	10	10	*	*	15	5	*	10	5	*	*	5	*	*	5	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*			
Brewer's grain	dried	5-00-516	CC	STMR	92	50	10	50	45	30	15	20	40	70	30	*	40	10	*	*	10	10	*	10	10	*	*	10	*	*	10	*	*	10	*	*	*	*	10	*	*	*	10	*	*	10	5				
Canola	meal	5-08-136	PC	STMR	88	5	*	20	*	10	10	15	*	15	*	35	15	*	35	15	20	20	15	20	20	*	15	18	5	*	15	10	5	*	15	20	*														
Citrus	dried pulp	4-01-237	R	STMR	91	10	5	30	*	10	20	30	*	20	*	*	15	*	*	*	15	10	*	*	10	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*			
Coconut	meal	5-01-572	PC	STMR	91	*	20	30	*	*	10	*	*	*	20	35	*	20	35	*	*	10	*	*	10	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*			
Corn, field	asp gr fn	4-02-880	CC	STMR	85	5	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*				
Corn, field	milled bypds	5-28-235	CC	STMR	85	50	30	15	5	25	30	15	*	35	30	*	50	30	*	60	75	70	60	75	70	*	50	60	*	*	50	50	*	*	50	50	*	*	50	50	20										
Corn, field	hominy meal	4-03-010	CC	STMR	88	50	*	40	35	25	*	40	*	50	*	*	50	*	*	20	*	40	20	*	40	*	20	*	20	*	20	20	20	*	20	20	20	*	20	20	*										
Corn, sweet	cannery waste	2-02-875	CC	STMR	30	*	*	30	*	10	*	10	*	30	*	*	20	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*			
Corn gluten	feed	5-28-243	CC	STMR	40	75	30	20	25	25	30	*	20	35	30	80	50	30	80	20	20	20	20	20	20	10	*	10	*	*	*	*	*	*	*	10	*	*	*												
Corn gluten	meal	5-28-242	CC	STMR	40	75	15	20	*	25	20	*	15	35	30	*	50	30	*	20	10	25	20	10	25	5	*	10	*	*	*	10	*	*	*	10	*	*	*	10	10										
Cotton	meal	5-01-617	PC	STMR	89	5	5	30	*	10	5	15	*	15	15	45	10	10	45	15	10	10	15	5	10	*	20	5	10	*	20	5	10	*	20	10	*	20	10	*											
Cotton	undelinted seed	5-01-614	PC	STMR	88	*	*	30	*	10	10	20	*	25	*	25	25	*	25	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*				
Cotton	hulls	1-01-599	R	STMR	90	10	*	20	*	*	*	10	*	15	*	20	20	*	20	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*				
Cotton	gin byproducts	1-08-413	R	STMR	90	5	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*					
Distiller's grain	dried	5-00-518	CC	STMR	92	50	10	50	10	25	10	*	15	35	10	*	25	10	*	*	20	20	*	20	20	*	*	10	*	5	*	10	*	5	*	10	*	5	*	10	*										

						BEEF				DAIRY				RAM/EWE			LAMB			BREEDING			FINISHING			BROILER				LAYER		TURKEY					
						US	EU	AU	JP	US	EU	AU	JP	US	EU	AU	US	EU	AU	US	EU	AU	US	EU	AU	JP	US	EU	AU	JP	US	EU	AU	JP	US	EU	AU
CROP	FEEDSTUFF	IFN Code	Class.	Residue Level	DM	CAN				CAN				CAN			CAN			CAN			CAN			CAN				CAN				CAN			
Flaxseed/linseed	meal	5-02-043	PC	STMR	88	5	10	10	*	10	15	10	*	15	20	*	20	10	*	10	20	10	10	20	10	*	20	10	*	*	20	10	*	*	20	10	*
Grape	pomace, wet	2-02-206	CC	STMR	15	*	*	20	*	*	*	20	*	*	*	*	*	*	*	*	*	10	*	*	10	*	*	*	*	*	*	*	*	*	*	*	20
Lupin seed	meal	NA	PC	STMR	85	*	20	15	*	*	20	15	*	*	25	*	*	20	*	*	10	25	*	10	25	*	*	10	20	*	*	10	20	*	*	10	*
Palm	kernel meal	5-03-486	PC	STMR	90	*	*	20	5	*	25	10	5	*	*	*	*	*	*	*	10	10	*	10	10	15	*	*	*	*	*	*	*	*	*	5	10
Peanut	meal	5-03-649	PC	STMR	85	*	20	10	*	10	10	15	*	20	20	*	15	20	*	15	20	10	15	20	10	*	25	10	10	*	25	10	10	*	25	10	*
Pineapple	process waste	NA	R	STMR	25	10	*	60	*	10	*	30	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Potato	process waste	4-03-777	CC	STMR	12	30	40	5	*	10	30	*	*	50	40	*	25	20	*	*	20	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	
Potato	dried pulp	4-03-775	CC	STMR	88	*	10	5	*	*	10	5	*	*	40	*	*	20	*	*	10	*	*	20	*	*	*	20	*	*	*	15	*	*	*	*	5
Rape	meal	5-26-093	PC	STMR	88	*	20	15	15	*	10	15	25	15	15	*	15	15	*	*	10	15	*	20	15	20	*	*	5	5	*	10	5	15	*	20	*

[illegible]

OECD Feedstuffs Table Endnotes

General Comments

Percent of Livestock Diet. Percentages of feedstuffs in livestock daily rations for mature and marketable animals are best estimates based upon production data of livestock meat, milk, and eggs for human consumption. Percent of diet is based on a dry weight basis for beef and dairy cattle, sheep, and on an as-fed basis for poultry and swine. The reference animals used for the table values are based on the listed body weights and daily dry matter intake. For data for feedstuffs other than those listed here, contact your OECD delegate, or the Health Effects Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue N.W., Washington, D.C., 20460.

IFN Codes. International Feed Nomenclature. IFN codes are listed for most commonly used feedstuffs from crops.

Classification of Feedstuff. R: roughage; CC: carbohydrate concentrate; PC: protein concentrate.

Residue Level. HR: Highest Residue (or HAFT); **STMR:** Supervised Trial Median Residue.

Percent DM. Percent dry matter. For beef, dairy, and sheep feedstuffs, the percent moisture should be reported for representative samples of raw agricultural and processed commodities.

* Indicates that item is not used or is a minor feedstuff (less than 5 percent of livestock diet).

Label restrictions. Label restrictions against feeding may be allowed; e.g., “Do not feed green immature growing plants to livestock”, or, “Do not harvest for livestock feed.” Registrant should contact appropriate regulatory agency for allowable restrictions.

Maximum Reasonably Balance Diet

The NAFTA approach does not select commodities from each of the categories forages, grain, byproducts, and roots and tubers. Rather it selects Roughage (R), Carbohydrate Concentrate (CC), and Protein Concentrate (PC) until the following percentages of diet are achieved:

Classification	Beef	Dairy	Poultry (laying)	Swine
Roughage [R]	15%	45%	--	--
Carbohydrate Concentrate [CC]	80%	45%	75%	85%
Protein Concentrate [PC]	5%	10%	25%	15%

Reasonable Worst Case Feeding Levels approach selects one feed item from each of the categories forages, grains, byproducts, and roots and tubers. In each category, the commodity producing the highest pesticide residue is selected.

Forages

Alfalfa. Residue data are needed from a minimum of three cuttings, unless climatic conditions restrict the number of cuttings. Cut sample at late bud to early bloom stage (first cut), and/or at early (one-tenth) bloom stage (later cuts). **Alfalfa meal (17% protein).** Residue data are not needed for meal; however, the meal should be included in the livestock diet, using the hay MRL. **Alfalfa hay** should be field-dried to a

moisture content of 10 to 20 percent. **Alfalfa silage.** Residue data on silage are optional, but are desirable for assessment of dietary exposure. Cut at late bud to one-tenth bloom stage for alfalfa, allow to wilt to approximately 60 percent moisture, then chop fine, pack tight, and allow to ferment for three weeks maximum in an air-tight environment until it reaches pH 4. This applies to both silage and haylage. In the absence of silage data, residues in forage will be used for silage, with correction for dry matter.

Barley hay. Cut when the grain is in the milk to soft dough stage. Hay should be field-dried to a moisture content of 10 to 20 percent. **Barley straw.** Plant residue (dried stalks or stems with leaves) left after the grain has been harvested (threshed). **Barley silage.** Residue data on silage are optional, but are desirable for assessment of dietary exposure. Cut sample at boot to early head stage, allow to wilt to 55 to 65 percent moisture, then chop fine, pack tight, and allow to ferment for three weeks maximum in an air-tight environment until it reaches pH 4. In the absence of silage data, residues in forage will be used for silage, with correction for dry matter.

Beet, sugar, tops. Based on current US agricultural practices, tops are fed only to grazing beef cattle and sheep. Other countries may feed differently.

Clover forage. Cut sample at the 4-8 inch to prebloom stage, at approximately 30 percent DM. **Clover hay.** Cut at early to full bloom stage. Hay should be field-dried to a moisture content of 10 to 20 percent. Residue data for clover seeds are not needed. **Clover silage.** Residue data on silage are optional, but are desirable for assessment of dietary exposure. Cut sample at early to one-fourth bloom stage for clover, allow to wilt to approximately 60 percent moisture, then chop fine, pack tight, and allow to ferment for three weeks maximum in an air-tight environment until it reaches pH 4. This applies to both silage and haylage. In the absence of silage data, residues in forage will be used for silage, with correction for dry matter. IFN codes are given for most commonly used red clover.

Corn forage (field and pop). Cut sample (whole aerial portion of the plant) at late dough/early dent stage (black ring/layer stage for corn only). **Corn stover (field and pop).** Mature dried stalks from which the grain or whole ear (cob + grain) have been removed; contains 80 to 85 percent DM. **Corn silage (field and pop).** Freshly cut samples may be analyzed, or ensiled samples after ensiling for three weeks maximum, and reaching pH 5 or less, with correction for percent dry matter.

Corn forage (sweet). Samples should be taken when sweet corn is normally harvested for fresh market, and may or may not include the ears. Freshly cut samples may be analyzed, or ensiled samples after ensiling for three weeks maximum, and reaching pH 5 or less, with correction for percent dry matter.

Cowpea forage. Cut sample at 6 inch to prebloom stage, at approximately 30 percent DM. **Cowpea hay.** Cut when pods are one-half to fully mature. Hay should be field-dried to a moisture content of 10 to 20 percent.

Crownvetch forage. Cut sample at 6 inch to prebloom stage, at approximately 30 percent DM.

Crownvetch hay. Cut at full bloom stage. Hay should be field-dried to a moisture content of 10 to 20 percent.

Grass. Zero day crop field residue data for grasses cut for forage should be provided unless it is not feasible, e.g., preplant/preemergent pesticide uses. A reasonable interval before cutting for hay is allowed. **Grass forage.** Cut sample at 6-8 inch to boot stage, at approximately 25 percent DM. **Grass hay.** Cut in boot to early head stage. Hay should be field-dried to a moisture content of 10 to 20 percent. Included are sudangrass and sorghum forages and their hybrids. For grass grown for seed only, PGIs (pregrazing interval) and PHIs (preharvest interval) are acceptable. Residue data may be based on the re-growth after

harvesting the seed. **Grass silage.** Residue data on silage are optional, but are desirable for assessment of dietary exposure. Cut sample at boot to early head stage, allow to wilt to 55 to 65 percent moisture, then chop fine, pack tight, and allow to ferment for three weeks maximum in an air-tight environment until it reaches pH 4. In the absence of silage data, residues in forage will be used for silage, with correction for dry matter.

For the three grass feed types in Japan, the listed values are the highest of percentages of Italian rye grass, orchard grass and timothy in diet for beef cattle and dairy cattle..

Lespedeza forage. Cut sample at 4-6 inch to prebloom stage, at 20 to 25 percent DM. **Lespedeza hay.** Annual/Korean. Cut at early blossom to full bloom stage. **Sericea.** Cut when 12-15 inches tall. Hay should be field-dried to a moisture content of 10 to 20 percent.

Millet forage. Cut sample at 10 inch to early boot stage, at approximately 30 percent DM. **Millet hay.** Cut at early boot stage or approximately 40 inches tall, whichever is reached first. Hay should be field-dried to a moisture content of 10 to 20 percent. Millet includes pearl millet. **Millet straw.** Data are required for proso millet only: **Proso millet straw.** Plant residue (dried stalks or stems with leaves) left after the grain has been harvested.

Oats forage. Cut sample between tillering to stem elongation (jointing) stage. **Oats hay.** Cut sample from early lower to soft dough stage. Hay should be field-dried to a moisture content of 10 to 20 percent. **Oats straw.** Cut plant residue (dried stalks or stems with leaves) left after the grain has been harvested (threshed).

Pea, field. Does not include the canning field pea cultivars used for human food. It includes cultivars grown for livestock feeding only such as 'Austrian winter pea'. **Field pea vines.** Cut sample anytime after pods begin to form, at approximately 25 percent DM. **Field pea hay.** Succulent plant cut from full bloom thru pod formation. Hay should be field-dried to a moisture content of 10 to 20 percent. **Pea, field, silage.** Use field pea vine residue data for field pea silage, with correction for dry matter.

Peanut hay. Peanut hay consists of the dried vines and leaves left after the mechanical harvesting of peanuts from vines that have been sun-dried to a moisture content of 10 to 20 percent.

Rice straw. Stubble (basal portion of the stems) left standing after harvesting the grain. In Japan, the maximum fed to cattle destined for human consumption is limited to 20% on a wet weight basis by a regulation, and the maximum fed to lactating cows is limited to 20% on a wet basis by a regulation.

Rye forage. Cut sample at 6-8 inch stage to stem elongation (jointing) stage, at approximately 30 percent DM.

Rye straw. Cut plant residue (dried stalks or stems with leaves) left after the grain has been harvested (threshed).

Sorghum forage. Cut sample (whole aerial portion of the plant) at soft dough to hard dough stage. Forage samples should be analyzed as is, or may be analyzed after ensiling for three weeks maximum, and reaching pH 5 or less, with correction for dry matter. **Sorghum stover.** Mature dried stalks from which the grain have been removed; contains approximately 85 percent DM.

Soybean forage. Cut samples at 6-8 inches tall (sixth node) to beginning pod formation, at approximately 35 percent DM. **Soybean hay.** Cut samples at mid-to-full bloom and before bottom leaves begin to fall or when pods are approximately 50 percent developed. Hay should be field-dried to a moisture content of 10

to 20 percent. **Soybean silage.** Residue data on silage are optional. Harvest sample when pods are one-half to fully mature (full pod stage). In the absence of silage data, residues in forage will be used for silage, with correction for dry matter.

Trefoil forage. Cut sample at 5-10 inch or early bloom stage, at approximately 30 percent DM. **Trefoil hay.** Cut at first flower to full bloom. Hay should be field-dried to a moisture content of 10 to 20 percent.

Triticale. See wheat.

Vetch forage. Cut sample at 6 inch to prebloom stage, at approximately 30 percent DM. **Vetch hay.** Cut at early bloom stage to when seeds in the lower half of the plant are approximately 50 percent developed. Hay should be field-dried to a moisture content of 10 to 20 percent. Vetch does not include crownvetch.

Wheat. Includes emmer wheat and triticale. No processing study is needed for a specific MRL on emmer wheat. **Wheat forage.** Cut sample at 6-8 inch stage to stem elongation (jointing) stage, at approximately 25 percent DM. **Wheat hay.** Cut samples at early flower (boot) to soft dough stage. Hay should be field-dried to a moisture content of 10 to 20 percent. **Wheat straw.** Cut plant residue (dried stalks or stems with leaves) left after the grain has been harvested (threshed).

Roots & Tubers

Carrot culls. Residue data for the raw agricultural commodity will cover residues on culls.

Cassava/tapioca roots. The whole root chipped mechanically into small pieces, then dried, and the dried chips pelted.

Potato culls. Whole unpeeled potato not suited for fresh market or processing.

Cereal Grains/Crop Seeds

Barley or oat grain. Residue data are needed for kernel (caryopsis) with hull (lemma and palea).

Bean, cowpea, lupin, pea, soybean, vetch seed. Residue data are needed for mature, dried seed.

Corn grain (field and pop). Residue data are needed for mature kernel (caryopsis) with cob removed.

Millet grain. Residue data are needed for kernel plus hull (lemma and palea). **Pearl millet grain.** Residue data are needed for kernel with hull (lemma and palea) removed

Rice grain. Residue data are needed for kernel (caryopsis) either with hull or without hull. Registrant should contact appropriate regulatory agency for their specific data needs for rice grain.

Rye, triticale, sorghum (grain), or wheat grain. Residue data are needed for kernel (caryopsis) with hull (lemma and palea) removed.

By-products

General. In the US, no more than one by-product (almond hulls, apple pomace, aspirated grain fractions, carrot culls, citrus pulp, sweet corn cannery waste, cotton gin byproducts, pineapple process waste, potato culls, potato processing waste) would be included in a diet.

Almond hulls. Dried pericarp which surrounds the nut.

Apple pomace, wet. By-product of the apple processing industry which remains after cider has been expressed from small whole apples, and the stems, cores, and peelings remaining after preparation of apple juice and sauce for human consumption.

Aspirated grain fractions ("grain dust"). Dust collected at grain elevators during the moving/handling of grains/oilseeds for environmental and safety reasons. **Residue data should be provided for any post-harvest use on corn, sorghum, soybeans or wheat.** For a pre-harvest use after the reproduction stage begins and seed heads are formed, data are needed unless residues in the grain are less than the limit of quantitation of the analytical method. For a pre-harvest use during the vegetative stage (before the reproduction stage begins), data will not normally be needed unless the plant metabolism or processing study shows a concentration of residues of regulatory concern in an outer seed coat (e.g., wheat bran, soybean hulls). If a MRL is needed, then it should be set at the higher of the residues found in the aspirated grain fraction of corn, sorghum, soybean, or wheat.

Beet, sugar, dried pulp. Dried material remaining from sugar beets which have been cleaned and freed from crowns, leaves, and sand and to which has been extracted in the process of manufacturing sugar. Moisture content should be defined.

Beet, sugar, molasses. The by-product of the manufacture of sucrose from sugar beets, and contains not less than 48% total sugars expresses as invert and its density determined by double dilution must not be less than 79,5 Brix.

Brewer's grains. Dried extracted residue of barley malt alone or in a mixture with other cereal grain or cereal products resulting from the manufacture of wort or beer and may contain pulverized dried spent hops in an amount not to exceed 3%, evenly distributed. Moisture content should be defined.

Canola meal. Meal obtained after the removal of most of the oil by direct solvent or prepress solvent extraction process.

Citrus, dried pulp. It is the ground peel, residue of the inside portions, and occasional fruits of the citrus family which have been dried, producing a coarse, flaky product. It may contain dried citrus meal or pellets and whole citrus seeds.

Coconut meal. It is the ground residue which remains after removal of most of the oil from dried meat of coconut by a mechanical or solvent extraction process.

Corn (field) milled byproducts. (Dry milled: grits, meal, flour and refined oil). If a MRL is needed for dry-milled processed commodities, then it should be set at the highest concentration for grits, meal, and flour.

Corn (field). Hominy meal. A mixture of corn bran, germ, and part of starchy portion of corn kernels as produced in making of pearl hominy, hominy grits, or table meal (< 4% fat).

Corn gluten feed. Part of the commercial shelled corn that remains after the extraction of the larger portion of the starch, gluten, and germ by the processes employed in wet milling of field corn.

Corn gluten meal. It is the dried residue from corn after the removal of the larger portion of the starch and germ, and the separation of the bran by the process employed in wet milling of field corn.

Corn, sweet. Residue data on early sampled field corn should suffice to provide residue data on sweet corn, provided the residue data are generated at the milk stage on kernel plus cob with husk removed and there are adequate numbers of trials and geographical representation from the sweet corn growing regions.

Corn (sweet) cannery waste. It includes husks, leaves, cobs, and kernels. Residue data for forage will be used for sweet corn cannery waste.

Cotton meal. Material obtained by finely grinding the cake which remains after removal of most of the oil from the cottonseed either by a mechanical or solvent extraction process.

Cotton undelinted seed. Whole seed removed in the ginning process and still has fine cotton fibers attached.

Cotton hulls. It consists primarily of the outer covering of the harvested cottonseed.

Cotton gin byproducts (commonly called gin trash). Include the plant residues from ginning cotton, and consist of burrs, leaves, stems, lint, immature seeds, and sand and/or dirt. Cotton must be harvested by commercial equipment to provide an adequate representation of plant residue for the ginning process. Two field trials for harvesting of stripper cotton are needed. No data are needed for picker cotton.

Distiller's grains. The material obtained after distillation of ethyl alcohol from grain or grain mixture which has undergone yeast fermentation. Moisture content should be defined.

Flaxseed/linseed meal. The ground residue which remains after removal of most of the oil from the whole flaxseed by a mechanical or solvent extraction process.

Grape pomace, wet. Wet debris left behind after fruit have been pressed for juice, also called "marc". Moisture content should be defined.

Lupin seed meal The ground residue which remains after removal of most of the oil from the whole lupin seed by a mechanical or solvent extraction process.

Palm kernel meal. It is the ground residue which remains after removal of most of the oil from the whole palm kernel by a mechanical or solvent extraction process.

Peanut meal, It is the ground residue which remains after removal of most of the oil from the shelled nut by a mechanical or solvent extraction process.

Pineapple process residue (also known as wet bran). A wet waste by-product from the fresh-cut product line that includes pineapple tops (minus crown), bottoms, peels, any trimmings with peel cut up, and the pulp (left after squeezing for juice); it can include culls.

Potato dried pulp. Dried processed potato waste. See processed potato waste.

Processed potato waste. (including wet and dry peel, raw chip, French fries, and cooked potatoes). MRLs for wet peel should be used for dietary burden calculations. Residue data may be provided from

actual processed potato waste generated using a pilot or commercial scale process that gives the highest percentage of wet peel in the waste.

Rapeseed meal. Residue data are not needed for rapeseed oil since it is produced for industrial uses and is not an edible oil. The edible oil is only produced from canola. (See canola).

Rice hulls. Consist primarily of the outer covering of the rice grain (with bran).

Safflower meal. It is the ground residue which remains after removal of most of the oil from the whole safflower seed by a mechanical or solvent extraction process.

Soybean okara. Okara or soy pulp is a white or yellowish pulp consisting of insoluble parts of the soybean which remain in the filter sack when pureed soybeans are filtered in the production of soy milk. As a significant byproduct of soy milk and tofu manufacturing, okara is used as animal feed.

Soybean meal. Material obtained by grinding the cake or chips which remain after the removal of most of the oil by solvent extraction process.

Sugarcane molasses. Residue data are needed for blackstrap molasses.

Sugarcane bagasse. US data indicates that sugarcane bagasse is mainly used for fuel. Other countries may use differently.

Sunflower meal. The ground residue which remains after removal of most of the oil from the whole sunflower seed by a mechanical or solvent extraction process.

Tomato pomace, wet. By-product of tomato paste production consisting mainly of skins and seeds.

Wheat milled byproducts. If a MRL is needed, then it should be set at the highest value for wheat middlings, bran and shorts.

ANNEX 5

COMPREHENSIVE SUBMISSION

In the case of a comprehensive submission to *all* OECD countries, 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 assumption is that the number of trials specified in each crop production region reflects the economic (acreage) importance and/or dietary significance of the crop/commodity within that crop production region.

Therefore there is no need to further consider acreage or dietary intake for a crop/commodity or to determine whether a crop is major or minor in terms of acreage, diet and/or trade on a global basis for the purpose of determining a minimum number of supervised field trials where regulators may accept data sets from other countries where comparability of cGAP can be demonstrated..

The reduction in the total number of trials within any OECD country of crop production region is compensated for by the total number of supervised 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 supervised field trials in their specific country/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.

To qualify for this comprehensive submission approach, all Supervised Field Trials must meet the following criteria:

- (1) Field trials are conducted according to the cGAP (within +/- 25% of the application rate, number of applications or PHI). At least 50% of the trials must be conducted at or above (within 25%) the cGAP. In addition, for some authorities at least 50% of the trials need to be decline studies.
- (2) The trials span a range of representative crop production practices for each crop including those likely to lead to the highest residues (e.g. irrigated/non-irrigated, trellis/non-trellis production, fall-planted/spring-planted, etc).

Any reduction in the number of supervised field trials should be distributed proportionally among the crop production regions as shown in the example for a 40% reduction for barley below.

Country/Region ¹	US/CAN	EU	JP	AUS	NZ	Total
Number w/out reduction	24	16	2	8	4	54
Number w/ 40% reduction	14	10	2	5	2	33

¹ US/CAN – United States/Canada; EU = European Union; JP = Japan; AUS = Australia; NZ = New Zealand.

The minimum total number of trials for any crop in a comprehensive submission is eight (with the exception of four trials for postharvest use as noted below). The total number of trials to be conducted

may not be less than the requirement for any given individual region. For example, some crops such as dried lima beans have fewer total trials (14) than required in the EU alone (16) if the 40% reduction were to be strictly applied.

In no case may the number of trials in a given crop production region be reduced below 2. Thus, in the above example the 40% reduction does not apply in Japan and therefore the total number of trials is 33 rather than 32, which is the actual 40% reduction from 54

The trials specified in each crop production region reflect the legal or guideline requirements in those regions as of June 2008. In the event that the number of required trials changes in any given region, the total number and reduced number should be adjusted accordingly.

It is important to keep in mind that this comprehensive strategy would only be applicable for an OECD-wide submission. If for example the MRL submission is only for US/CAN, crop field trial guidelines, with respect to the number of trials, for US/CAN should be followed. Furthermore if MRLs/authorisations in additional countries/regions are pursued following the previous establishment of an MRL in another OECD country/region, the regulatory authority in the additional countries/regions should be consulted to determine what residue data are required. For example, following establishment of an MRL/authorisation in US/CAN, if an MRL/authorisation for the same product is pursued in EU, the applicant should consult with EU regulatory authorities about the possibility of using residue data from the US/CAN MRL/authorisation submission and performing fewer supervised field trials in EU.

The table addresses only supervised field trials and not greenhouse (glasshouse) or post harvest treatments. For similar critical GAPs, it is suggested that a minimum of eight greenhouse trials are needed for the OECD countries and that four post harvest trials are needed. For such trials, geographic distribution typically is not an issue. However for active ingredients which are susceptible to photo-degradation, consideration should be given to locations at different latitudes and to winter/summer periods for greenhouse trials.

Minimum number of Supervised Field Trials Required at cGAP for Field (or Outdoor) Uses												
Number of trials currently required by region ¹							Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU ²	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Acerola (Barbados cherry)	1	4	2			7	1	2	2			5
Alfalfa	18	12	2		4	36	11	7	2		2	22
Almond	5	4	2	6	2	19	3	2	2	4	2	13
Apple	20	16	2	8	6	52	12	10	2	5	4	33
Apple, Sugar	2	4	2			8	2	2	2			6
Apricot	7	12	2	6	2	29	4	7	2	4	2	19
Arracacha	2	4	2			8	2	2	2			6
Artichoke, Globe	3	4	2		2	11	2	2	2		2	8
Artichoke, Jerusalem	3	4	2		2	11	2	2	2		2	8
Asparagus	10	8	2	4	4	28	6	5	2	2	2	17
Atemoya	1	4	2		2	9	1	2	2		2	7
Avocado	5	4	2	8	2	21	3	2	2	5	2	14
Banana	5	4	2	8		19	3	2	2	5		12
Barley	24	16	2	8	4	54	14	10	2	5	2	33
Bean, Dried	12	16	2		2	32	7	10	2		2	21
Bean, Edible Podded	9	16	2		4	31	5	10	2		2	19
Bean, Lima, Dried	3	16	2		2	23	2	10	2		2	16
Bean, Lima, Green	8	8	2	8	2	28	5	5	2	5	2	19
Bean, Mung	3	16	2		2	23	2	10	2		2	16
Bean, Snap	8	16	2		2	28	5	10	2		2	19
Bean, Succulent Shelled	8	16	2		2	28	5	10	2		2	19
Beet, Garden	8	4	2		2	16	5	2	2		2	11
Blackberry	5	4	2		2	13	3	2	2		2	9
Blueberry	11	4	2	4	2	23	7	2	2	2	2	15
Bok choy	2	4	2		2	10	2	2	2		2	8
Boysenberry	2	8	2		2	14	2	5	2		2	11
Broccoli	12	8	2	8	4	34	7	5	2	5	2	21

Minimum number of Supervised Field Trials Required at cGAP for Field (or Outdoor) Uses												
Number of trials currently required by region ¹							Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU ²	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Broccoli, Chinese (gai lon)	2	8	2		2	14	2	5	2		2	11
Brussels Sprouts	5	12	2	4	2	25	3	7	2	2	2	16
Buckwheat	9	8	2		2	21	5	5	2		2	14
Cabbage	12	12	2	8	4	38	7	7	2	5	2	23
Cabbage, Chinese	5	8	2		2	17	3	5	2		2	12
Cacao Bean (cocoa)	3	8	2			13	2	5	2			9
Calabaza	2	4	2			8	2	2	2			6
Calamondin	1	4	2			7	1	2	2			5
Canary seed	5	4				9	3	2	2			7
Canola	22	12	2	8	2	46	13	7	2	5	2	29
Cantaloupe	8	12	2	8	2	32	5	7	2	5	2	21
Carambola	2	4	2		2	10	2	2	2		2	8
Caraway seed	2	4				6	2	2	2			6
Carob	3	4	2			9	2	2	2			6
Carrot	12	16	2	8	4	42	7	10	2	5	2	26
Cassava, bitter or sweet	2	4	2		2	10	2	2	2		2	8
Cauliflower	11	12	2	8	2	35	7	7	2	5	2	23
Celery	12	8	2	4	4	30	7	5	2	2	2	18
Cherry, Sweet	9	4	2	3	4	22	5	2	2	2	2	13
Cherry, Tart (Sour)	8	4	2	3	2	19	5	2	2	2	2	13
Chestnut	3	4	2	4	2	15	2	2	2	2	2	8
Chickpea (garbanzo bean)	3	16	2	4	2	27	2	10	2	2	2	18
Chicory	2	8	2		2	14	2	5	2		2	11
Clover	12	12	2		4	30	7	7	2		2	18
Coconut	5	4	2			11	3	2	2			7
Coffee	5	4	2	4		15	3	2	2	2		9
Collards	5	8	2		2	17	3	5	2		2	12
Corn, Field	20	16	2	2	4	44	12	10	2	2	2	28
Corn, Pop	3		2			5	2	0	2			4

Minimum number of Supervised Field Trials Required at cGAP for Field (or Outdoor) Uses												
Number of trials currently required by region ¹							Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU ²	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Corn, Sweet	14	8	2	6	2	32	8	5	2	4	2	21
Cotton	12	8	2	8		30	7	5	2	5		19
Cowpea (dried shelled bean)	5	16	2		2	25	3	10	2		2	17
Cowpea (forage/hay)	3	12	2		2	19	2	7	2		2	13
Cowpea (succulent shelled bean)	3	8	2		2	15	2	5	2		2	11
Crabapple	3	8	2		2	15	2	5	2		2	11
Cranberry	6	4	2		2	14	4	2	2		2	10
Cress, Upland	1	4	2			7	1	2	2			5
Cucumber	11	16	2	4	4	37	7	10	2	2	2	23
Currant	2	8	2		2	14	2	5	2		2	11
Dandelion	1	8	2		2	13	1	5	2		2	10
Dasheen (taro)	2	4	2		2	10	2	2	2		2	8
Date	3	4	2			9	2	2	2			6
Dill (dill seed, dillweed)	2	8	2		2	14	2	5	2		2	11
Eggplant	3	8	2		2	15	2	5	2		2	11
Elderberry	3	4	2		2	11	2	2	2		2	8
Endive (escarole)	3	4	2		2	11	2	2	2		2	8
Fennel		8	2			10		5	2			7
Fig	3	4	2		2	11	2	2	2		2	8
Filbert (hazelnut)	5	4	2		2	13	3	2	2		2	9
Flax (= linseed)	10	8	2		2	22	6	5	2		2	15
Fodder beet	0	8	2		4	14	0	5	2		2	9
Garlic	3	8	2		2	15	2	5	2		2	11
Genip	1	4	2			7	1	2	2			5
Ginger	2	4	2			8	2	2	2			6
Ginseng	5	4	2			11	3	2	2			7
Gooseberry	3	4	2		2	11	2	2	2		2	8
Grape	16	16	2		6	40	10	10	2		4	26

Minimum number of Supervised Field Trials Required at cGAP for Field (or Outdoor) Uses												
Number of trials currently required by region ¹							Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU ²	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Grape, table		12	2	8	4	26		7	2	5	2	16
Grapefruit	8	4	2	2	2	18	5	2	2	2	2	13
Grasses	12	16	2		4	34	7	10	2		2	21
Guar	3	4	2			9	2	2	2			6
Guava	2	4	2		2	10	2	2	2		2	8
Herbs		4	2			6		2	2			4
Hops	3	12	2		2	19	2	7	2		2	13
Horseradish	3	4	2		2	11	2	2	2		2	8
Huckleberry	3	4	2		2	11	2	2	2		2	8
Kale	3	12	2		2	19	2	7	2		2	13
Kiwi fruit	3	4	2		6	15	2	2	2		4	10
Kohlrabi	3	8	2		2	15	2	5	2		2	11
Kumquat	1	4	2		2	9	1	2	2		2	7
Leek	5	12	2	4	2	25	3	7	2	2	2	16
Lemon	5	8	2	6	2	23	3	5	2	4	2	16
Lentil	8	4	2		2	16	5	2	2		2	11
Lettuce, Head	13	8	2	8	3	34	8	5	2	5	2	22
Lettuce, Leaf	13	8	2	8	3	34	8	5	2	5	2	22
Lime	3	4	2		2	11	2	2	2		2	8
Loganberry	2	8	2		2	14	2	5	2		2	11
Longan	1	4	2			7	1	2	2			5
Lotus Root	1	4	2			7	1	2	2			5
Lychee	1	4	2	2		9	1	2	2	2		7
Macadamia Nut	3	4	2	6	2	17	2	2	2	4	2	12
Mamey Sapote	2	4	2			8	2	2	2			6
Mandarin (tangerine)	5	8	2	8	4	27	3	5	2	5	2	17
Mango	3	4	2	8		17	2	2	2	5		11
Melon	3	12	2		2	19	2	7	2		2	13
Melon, Casaba	3	12	2		2	19	2	7	2		2	13

Minimum number of Supervised Field Trials Required at cGAP for Field (or Outdoor) Uses												
Number of trials currently required by region ¹							Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU ²	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Melon, Crenshaw	3	12	2		2	19	2	7	2		2	13
Melon, Honeydew	5	12	2		2	21	3	7	2		2	14
Millet, Proso	8	8	2		2	20	5	5	2		2	14
Mint	5	8	2		2	17	3	5	2		2	12
Mulberry	3	8	2			13	2	5	2			9
Mushrooms	3	8	2	6	2	21	2	5	2	4		13
Muskmelons	8	12	2		2	24	5	7	2		2	16
Mustard Greens	8	8	2		2	20	5	5	2		2	14
Mustard, Chinese	2	8	2		2	14	2	5	2		2	11
Mustard seed	5	8				13	3	5	2			10
Nectarine	10	12	2	8	2	34	6	7	2	5	2	22
Oat	26	16	2	6	2	52	16	10	2	4	2	34
Okra	5	4	2		2	13	3	2	2		2	9
Olive	3	8	2		2	15	2	5	2		2	11
Onion, Dry Bulb	12	16	2	8	4	42	7	10	2	5	2	26
Onion, Green	5	8	2	4	2	21	3	5	2	2	2	14
Orange, Sour and Sweet	16	8	2	8	4	38	10	5	2	5	2	24
Papaya	3	4	2			9	2	2	2			6
Parsley	3	4	2	2	2	13	2	2	2	1	2	9
Parsnip	6	8	2		2	18	4	5	2		2	13
Passion Fruit	2	4	2		2	10	1	2	2		2	7
Pawpaw	3	4	2			9	2	2	2			6
Pea, Chinese	1	8	2		2	13	1	5	2		2	10
Pea, Dried Shelled	13	16	2	8	2	41	8	10	2	5	2	27
Pea, Edible podded	8	12	2	6	2	30	5	7	2	4	2	20
Pea, Edible Podded	3	8	2		2	15	2	5	2		2	11
Pea, Field (Austrian Winter) (forage/hay)	3	12	2	8	2	27	2	7	2	5	2	18

Minimum number of Supervised Field Trials Required at cGAP for Field (or Outdoor) Uses												
Number of trials currently required by region ¹							Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU ²	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Pea, Succulent Shelled (Pea, Garden, Succulent)	14	12	2		2	30	8	7	2		2	19
Peach	16	12	2	8	4	42	10	7	2	5	2	26
Peanut	12	4	2	8		26	7	2	2	5		16
Peanut, Perennial	3	4	2			9	2	2	2			6
Pear	11	16	2	8	4	41	7	10	2	5	2	26
Pecan	5	4	2	4	2	17	3	2	2	2	2	11
Pepper, (other than bell)	3	4	2		2	11	2	2	2		2	8
Pepper, Bell	12	12	2		2	28	7	7	2		2	18
Persimmon	3	4	2		4	13	2	2	2		2	8
Pimento	2	4	2		2	10	2	2	2		2	8
Pineapple	8	4	2			14	5	2	2			9
Pistachio	3	4	2			9	2	2	2			6
Plantain	3	4	2			9	2	2	2			6
Plum	11	12	2	8	2	35	7	7	2	5	2	23
Pomegranate	3	4	2			9	2	2	2			6
Potato	26	16	2	8	4	56	16	10	2	5	2	35
Pumpkin	8	8	2	4	2	24	5	5	2	2	2	16
Quince	3	4	2		2	11	2	2	2		2	8
Radish	7	8	2		2	19	4	5	2		2	13
Radish, Oriental (daikon)	2	4	2		2	10	2	2	2		2	8
Rapeseed	3	12	2		2	19	2	7	2		2	13
Raspberry, Black and Red	6	4	2		2	14	4	2	2		2	10
Rhubarb	5	4	2		2	13	3	2	2		2	9
Rice	16	8	2	6		32	10	5	2	4		21
Rice, Wild	5	8	2			15	3	5	2			10
Rutabaga	8	8	2		2	20	5	5	2		2	14
Rye	10	16	2		2	30	6	10	2		2	20

Minimum number of Supervised Field Trials Required at cGAP for Field (or Outdoor) Uses												
Number of trials currently required by region ¹							Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU ²	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Safflower	6	8	2		2	18	4	5	2		2	13
Sainfoin	3	12	2		2	19	2	7	2		2	13
Salsify	3	8	2		2	15	2	5	2		2	11
Saskatoons	2	4				6	2	2	2			6
Sesame	3	4	2			9	2	2	2			6
Shallot	3	8	2		2	15	2	5	2		2	9
Sorghum, Grain	12	8	2	6	2	30	7	5	2	4	2	20
Soybean (dried)	20	12	2	8	4	46	12	7	2	5	2	28
Spices		4	2			6		2	2			4
Spinach	11	8	2		2	23	7	5	2		2	16
Squash, Summer	11	8	2		4	25	7	5	2		2	16
Squash, Winter	5	8	2		2	17	3	5	2		2	12
Strawberry	10	16	2	8	4	40	6	10	2	5	2	25
Sugar Beet	14	16	2	2		34	8	10	2	2		22
Sugarcane	8	4	2	8		22	5	2	2	5		14
Sunflower	10	12	2	8	2	34	6	7	2	5	2	22
Sweet Potato	8	4	2		2	16	5	2	2		2	11
Swiss Chard	3	4	2		2	11	2	2	2		2	8
Tangelo	3	4	2		2	11	2	2	2		2	8
Tanier (cocoyam)	2	4	2			8	2	2	2			6
Tea		4	2			6		2	2			4
Tobacco	8	4	2		2	16	5	2	2		2	11
Tomato	27	16	2	8	4	57	16	10	2	5	2	35
Triticale	5	16	2	4	2	29	3	10	2	2	2	19
Turnip, root	5	4	2		4	15	3	2	2		2	9
Turnip, tops (leaves)	5	4	2		2	13	3	2	2		2	9
Walnut, Black and English	3	8	2		2	15	2	5	2		2	11
Watercress	2	4	2		2	10	2	2	2		2	8
Watermelon	8	4	2	4	2	20	5	2	2	2	2	13

Minimum number of Supervised Field Trials Required at cGAP for Field (or Outdoor) Uses												
Number of trials currently required by region ¹							Number of Trials Required by Region with 40% Reduction					
	NAFTA	EU ²	JP	AUS	NZ	Total	NAFTA	EU	JP	AUS	NZ	Total
Wheat	33	16	2	12	4	67	20	10	2	7	2	41
Yam, True	3	4	2		2	11	2	2	2		2	8

¹ NAFTA – United States/Canada; EU = European Union;; JP = Japan;; AUS = Australia; NZ = New Zealand.

²EU – based on major/minor crop distinction for EU-N and EU-S