Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

10-Oct-2006

English - Or. English

ENV/JM/MONO(2006)32
Unclassified

ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

SERIES ON TESTING AND ASSESSMENT
Number 64

SERIES ON PESTICIDES
Number 32

GUIDANCE DOCUMENT ON OVERVIEW OF RESIDUE CHEMISTRY STUDIES

JT03215494

English - Or. English

OECD Environment, Health and Safety Publications

Series on Testing and Assessment

No. 64

and

Series on Pesticides

No. 32

GUIDANCE DOCUMENT ON OVERVIEW OF RESIDUE CHEMISTRY STUDIES

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris, 2006

Also published in the Series on Testing and Assessment:

No. 1, *Guidance Document for the Development of OECD Guidelines for Testing of Chemicals (1993; reformatted 1995, revised 2006)*

No. 2, *Detailed Review Paper on Biodegradability Testing (1995)*

No. 3, *Guidance Document for Aquatic Effects Assessment (1995)*

No. 4, *Report of the OECD Workshop on Environmental Hazard/Risk Assessment (1995)*

No. 5, *Report of the SETAC/OECD Workshop on Avian Toxicity Testing (1996)*

No. 6, *Report of the Final Ring-test of the Daphnia magna Reproduction Test (1997)*

No. 7, *Guidance Document on Direct Phototransformation of Chemicals in Water (1997)*

No. 8, *Report of the OECD Workshop on Sharing Information about New Industrial Chemicals Assessment (1997)*

No. 9, *Guidance Document for the Conduct of Studies of Occupational Exposure to Pesticides during Agricultural Application (1997)*

No. 10, *Report of the OECD Workshop on Statistical Analysis of Aquatic Toxicity Data (1998)*

No. 11, *Detailed Review Paper on Aquatic Testing Methods for Pesticides and industrial Chemicals (1998)*

No. 12, *Detailed Review Document on Classification Systems for Germ Cell Mutagenicity in OECD Member Countries (1998)*

No. 13, *Detailed Review Document on Classification Systems for Sensitising Substances in OECD Member Countries 1998)*

No. 14, *Detailed Review Document on Classification Systems for Eye Irritation/Corrosion in OECD Member Countries (1998)*

No. 15, *Detailed Review Document on Classification Systems for Reproductive Toxicity in OECD Member Countries (1998)*

No. 16, *Detailed Review Document on Classification Systems for Skin Irritation/Corrosion in OECD Member Countries (1998)*

No. 17, *Environmental Exposure Assessment Strategies for Existing Industrial Chemicals in OECD Member Countries (1999)*

No. 18, *Report of the OECD Workshop on Improving the Use of Monitoring Data in the Exposure Assessment of Industrial Chemicals (2000)*

No. 19, *Guidance Document on the Recognition, Assessment and Use of Clinical Signs as Humane Endpoints for Experimental Animals used in Safety Evaluation (1999)*

No. 20, *Revised Draft Guidance Document for Neurotoxicity Testing (2004)*

No. 21, *Detailed Review Paper: Appraisal of Test Methods for Sex Hormone Disrupting Chemicals (2000)*

No. 22, *Guidance Document for the Performance of Out-door Monolith Lysimeter Studies (2000)*

No. 23, *Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures (2000)*

No. 24, *Guidance Document on Acute Oral Toxicity Testing (2001)*

No. 25, *Detailed Review Document on Hazard Classification Systems for Specifics Target Organ Systemic Toxicity Repeated Exposure in OECD Member Countries (2001)*

No. 26, *Revised Analysis of Responses Received from Member Countries to the Questionnaire on Regulatory Acute Toxicity Data Needs (2001)*

No 27, *Guidance Document on the Use of the Harmonised System for the Classification of Chemicals Which are Hazardous for the Aquatic Environment (2001)*

No 28, *Guidance Document for the Conduct of Skin Absorption Studies (2004)*

No 29, *Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media (2001)*

No 30, *Detailed Review Document on Hazard Classification Systems for Mixtures (2001)*

No 31, *Detailed Review Paper on Non-Genotoxic Carcinogens Detection: The Performance of In-Vitro Cell Transformation Assays (draft)*

No. 32, *Guidance Notes for Analysis and Evaluation of Repeat-Dose Toxicity Studies (2000)*

No. 33, *Harmonised Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures (2001)*

No. 34, *Guidance Document on the Development, Validation and Regulatory Acceptance of New and Updated Internationally Acceptable Test Methods in Hazard Assessment (2005)*

No. 35, *Guidance notes for analysis and evaluation of chronic toxicity and carcinogenicity studies (2002)*

No. 36, *Report of the OECD/UNEP Workshop on the use of Multimedia Models for estimating overall Environmental Persistence and long range Transport in the context of PBTS/POPS Assessment (2002)*

No. 37, *Detailed Review Document on Classification Systems for Substances Which Pose an Aspiration Hazard (2002)*

No. 38, *Detailed Background Review of the Uterotrophic Assay Summary of the Available Literature in Support of the Project of the OECD Task Force on Endocrine Disrupters Testing and Assessment (EDTA) to Standardise and Validate the Uterotrophic Assay (2003)*

No. 39, *Guidance Document on Acute Inhalation Toxicity Testing (in preparation)*

No. 40, *Detailed Review Document on Classification in OECD Member Countries of Substances and Mixtures Which Cause Respiratory Tract Irritation and Corrosion (2003)*

No. 41, *Detailed Review Document on Classification in OECD Member Countries of Substances and Mixtures which in Contact with Water Release Toxic Gases (2003)*

No. 42, *Guidance Document on Reporting Summary Information on Environmental, Occupational and Consumer Exposure (2003)*

No. 43, *Draft Guidance Document on Reproductive Toxicity Testing and Assessment (in preparation)*

No. 44, *Description of Selected Key Generic Terms Used in Chemical Hazard/Risk Assessment (2003)*

No. 45, *Guidance Document on the Use of Multimedia Models for Estimating Overall Environmental Persistence and Long-range Transport (2004)*

No. 46, *Detailed Review Paper on Amphibian Metamorphosis Assay for the Detection of Thyroid Active Substances (2004)*

No. 47, *Detailed Review Paper on Fish Screening Assays for the Detection of Endocrine Active Substances (2004)*

No. 48, *New Chemical Assessment Comparisons and Implications for Work sharing (2004)*

No. 49, *Report from the Expert Group on(Quantitative) Structure-Activity Relationships [(Q)SARs] on the Principles for the Validation of (Q)SARs (2004)*

No. 50, *Report of the OECD/IPCS Workshop on Toxicogenomics (2005)*

No. 51, *Approaches to Exposure Assessment in OECD Member Countries: Report from the Policy Dialogue on Exposure Assessment in June 2005 (2006)*

No. 52, *Comparison of emission estimation methods used in Pollutant Release and Transfer Registers (PRTRs) and Emission Scenario Documents (ESDs): Case study of pulp and paper and textile sectors (2006)*

No. 53, *Guidance Document on Simulated Freshwater Lentic Field Tests (Outdoor Microcosms and Mesocosms) (2006)*

No. 54, *Current Approaches in the Statistical Analysis of Ecotoxicity Data: A Guidance to Application (2006)*

No. 55, *Detailed Review Paper on Aquatic Arthropods in Life Cycle Toxicity Tests with an Emphasis on Developmental, Reproductive and Endocrine Disruptive Effects (2006)*

No. 56, *Guidance Document on the Breakdown of Organic Matter in Litter Bags (2006)*

No. 57, *Detailed Review Paper on Thyroid Hormone Disruption Assays (2006)*

No. 58, *Report on the Regulatory Uses and Applications in OECD Member Countries of (Quantitative) Structure-Activity Relationship [(Q)SAR] Models in the Assessment of New and Existing Chemicals (2006)*

No. 59, *Report of the Validation of the Updated Test Guideline 407: Repeat Dose 28-Day Oral Toxicity Study in Laboratory Rats (2006)*

No. 60, *Report of the Initial Work Towards the Validation of the 21-Day Fish Screening Assay for the Detection of Endocrine Active Substances (Phase 1A) (2006)*

No. 61, *Report of the Validation of the 21-Day Fish Screening Assay fort he Detection of Endocrine Active Substances (Phase 1B) (2006)*

No. 62*, Final OECD Report of the Initial Work Towards the Validation of the Rat Hershberger Assay : Phase-1, Androgenic Response to Testosterone Propionate, and Anti-Androgenic Effects of Flutamide (2006)*

No. 63, *Guidance Document on the Definition of Residue (2006)*

No. 64, *Guidance Document on Overview of Residue Chemistry Studies (2006)*

Also published in the Series on Pesticides:

No.1 *Data Requirements for Pesticide Registration in OECD Member Countries: Survey Results* (1993)

No.2 *Final Report on the OECD Pilot Project to Compare Pesticide Data Reviews* (1995)

No.3 *Data Requirements for Biological Pesticides* (1996)

No.4 *Activities to Reduce Pesticide Risks in OECD and Selected FAO Countries. Part I: Summary Report* (1996)

No.5 *Activities to Reduce Pesticide Risks in OECD and Selected FAO Countries. Part II: Survey Responses* (1996)

No.6 *OECD Governments' Approaches to the Protection of Proprietary Rights and Confidential Business Information in Pesticide Registration* (1998)

No.7 *OECD Survey on the Collection and Use of Agricultural Pesticide Sales Data: Survey Results* (1999)

No.8 *Report of the OECD/FAO Workshop on Integrated Pest Management and Pesticide Risk Reduction* (1999)

No.9 *Report of the Survey of OECD Member Countries' Approaches to the Regulation of Biocides* (1999)

No.10 *Guidance Notes for Analysis and Evaluation of Repeat-Dose Toxicity Studies* (2000)

No.11 *Survey of Best Practices in the Regulation of Pesticides in Twelve OECD Countries* (2001*)*

No.12 *Guidance for Registration Requirements for Pheromones and Other Semiochemicals Used for Arthropod Pest Control* (2001)

No.13 *Report of the OECD Workshop on Sharing the Work of Agricultural Pesticide Reviews*

No.14 *Guidance Notes for Analysis and Evaluation of Chronic Toxicity and Carcinogenicity Studies.*

No. 15 *Persistent, Bioaccumulative and Toxic Pesticides in OECD Member Countries, (2002)*

No. 16 *OECD Guidance for Industry Data Submissions for Pheromones and Other Semiochemicals and their Active Substances (Dossier Guidance for Pheremones and Other Semiochemicals) (2003)*

No. 17 *OECD Guidance for Country Data Review Reports for Pheremones and Other Semiochemicals and their Active Substances (Monograph Guidance for Pheremones and other Semiochemicals), (2003)*

No. 18 *Guidance for Registration Requirements for Microbial Pesticides (2003)*

No. 19 *Registration and Work sharing, Report of the OECD/FAO Zoning Project (2003)*

No. 20 *OECD Workshop on Electronic Tools for data submission, evaluation and exchange for the Regulation of new and existing industrial chemicals, agricultural pesticides and biocides (2003)*

No. 21 *Guidance for Regulation of Invertebrates as Biological Control Agents (IBCAs) (2004)*

No. 22 *OECD Guidance for Country Data Review Reports on Microbial Pest Control Products and their Microbial Pest Control Agents (Monograph Guidance for Microbials) (2004)*

No. 23 *OECD Guidance for Industry Data Submissions for Microbial Pest Control Product and their Microbial Pest Control Agents (Dossier Guidance for Microbials) (2004)*

No. 24 *Report of the OECD Pesticide Risk Reduction Steering Group Seminar on Compliance (2004)*

No. 25 *The Assessment of Persistency and Bioaccumulation in the Pesticide Registration Frameworks within the OECD Region*

No. 26 *Report of the OECD Pesticide Risk Reduction Group Seminar on Minor Uses and Pesticide Risk Reduction*

No. 27 *Summary Report of the OECD Project on Pesticide Terrestrial Risk Indicators (TERI) (2005)*

No. 28 *Report of the OECD Pesticide Risk Reduction Steering Group: Seminar on Pesticide Risk Reduction through Good Container Management (2005)*

No. 29 *Report of the OECD Pesticide Risk Reduction Steering Group Seminar on Risk Reduction through Good Pesticide Labelling (2006)*

No. 30 *Report of the OECD Pesticide Risk Reduction Steering Group: The Second Risk Reduction Survey (2006)*

No. 31 *Guidance Document on the Definition of the Residue (2006)*

No. 32 *Guidance Document on Overview of Residue Chemistry Studies(2006)*

Published separately:

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)

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.

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). Two guidance documents and five Test Guidelines (and templates for reporting test study summary data) have been developed within the first phase of these activities:

Guidance Documents:

- *Definition of Residue,* and
- *Overview of Residue Chemistry Studies*

Test Guidelines:

- *Metabolism in Crops* (including selection of representative crop groups for metabolism studies),
- *Metabolism in Rotational Crops,*
- *Metabolism in Livestock* (including triggers for livestock feeding studies),
- *Residues in Rotational Crops (Limited Field Studies), and*
- *Residues in Livestock*

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).

The five draft Test Guidelines were approved by the WNT at their 18th Meeting in May 2006. They were then submitted to the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, the Environment Policy Committee (EPOC) and the Council for endorsement. They will be published as the 18th Addendum to the *OECD Guidelines for the Testing of Chemicals* under a new section: Section 5: Other Test Guidelines – Part A: Pesticide Residue Chemistry. The Test Guidelines numbers will be: 501 (Metabolism in Crops); 502 (Metabolism in Rotational Crops); 503 (Metabolism in Livestock); 504 (Residues in Rotational Crops – Limited Field Studies); and 505 (Residues in Livestock).

The draft *Guidance Document on the Definition of Residue* and the draft *Guidance Document on Overview of Residue Chemistry Studies* were approved by the WNT at their 18th Meeting in May 2006.

The Overview of Residue Chemistry Studies Guidance Document contains: (i) a Table of Raw Agricultural Commodities; (ii) national and regional tables of livestock feedstuffs; and (iii) a Glossary of Terms. This document 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 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.

TABLE OF CONTENTS

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 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; and 5) Residues in Rotational Crops (Limited Field Studies). 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; 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, along with an example of how the table is to be used, is presented in Annexes 4-5.

Residue Chemistry Test Guidelines

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 ^{14}C 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.

Radiovalidation of Residue Analytical Method Extraction Efficiency

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

Residues in Livestock

16. 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 (7) 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

17. 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

18. Livestock are typically fed at 1X, 3X (or 5X), and 10X, where 1X is a level based on consideration of the highest residue levels (median values for processed commodities) determined in the individual feedstuffs and with consideration of their percentage in the livestock diet. 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.)

19. 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.

20. 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; while in Australia feeds are based on sorghum, wheat and oilseed meals.. Dietary burden would be calculated based on residue and intake data from North America, and compared with their equivalent data set from Europe and Australia.. The highest dietary burden obtained from these regions would then be used to set the 1X dose for the livestock feeding study. Harmonized feeding studies can be used by regulators in a consistent manner to set MRLs in their countries or regions. Annex 4 provides examples of calculations of dietary burden.

21. 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.

22. 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.

23. 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)

24. 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).

25. 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.

26. 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.

27. 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.

28. 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

29. 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.

30. 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.

31. 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.

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

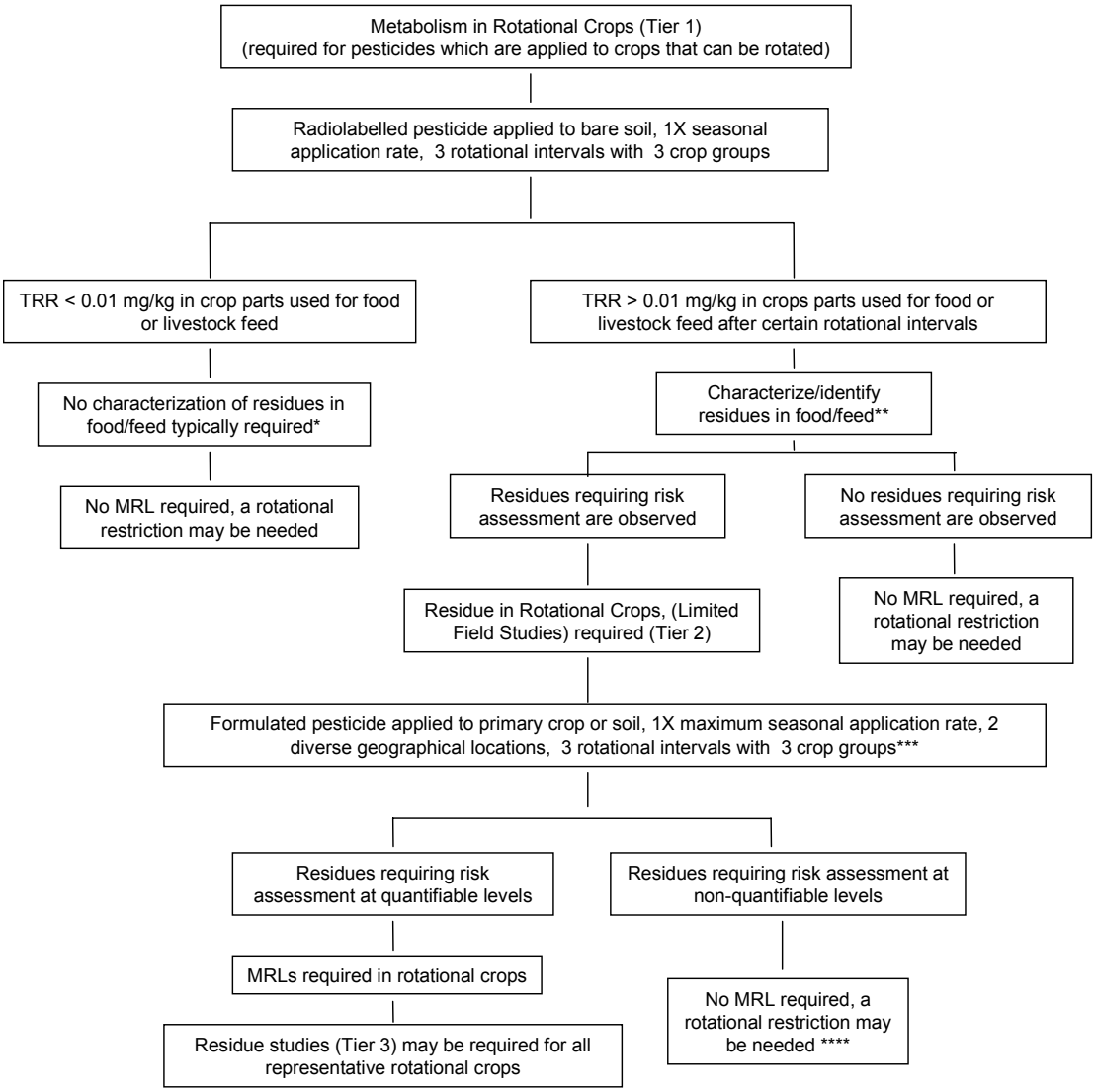
(i) If the residue definition that is being considered for rotational crops is either the same as for primary crops, or if the relative toxicology of the components being proposed for the residue definition for rotational crops is broadly similar to the residues for the primary crop residue definition, 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.

(ii) 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.

(iii) 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.

(iv) 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 rotationall crop study or the ability to enforce rotational restrictions

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

33. 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?

34. 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.

35. 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.

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

Global Maximum Residue Limit Process for Livestock Food Commodities

37. 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). The global MRL process to achieve use of a single Residues in Livestock study for MRL setting and risk assessment has four key components:

(i) Harmonized Guidance for Definition of the Residue;

(ii) Reasonable Worst Case Animal Diets;

(iii) Harmonized Table of Livestock Feed Commodities; and

(iv) Definition of Reasonable Worst Case Livestock Feeding Levels.

Guidance Document on the Definition of Residue

38. 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.

39. 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.

40. The Guidance Document on the Definition of 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

41. 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. Such guidance can lay the groundwork for use of realistic animal feeding levels of pesticides for purposes of assessing dietary residues in meat, milk and eggs.

Harmonized Table of Livestock Feed Commodities

42. 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. Because

the objective of livestock residue studies is to provide data for MRL setting, 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).

43. 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.

44. 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 dair 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. This may not apply in all countries or under particular production systems. 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.

45. 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.

Harmonized Format

46. 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 maximum or median residues, depending on the feed (for raw or processed feedstuffs, respectively). Dosing determinations are based on the table of feed commodities.

47. 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.

48. 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.

49. In the United States, 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. In the American swine industry, the finished animal providing fresh pork to the consumer market weights 250 lb and is produced in 6 months, mainly on a constant diet of corn grain (sometimes replaced with other cereal grains such as sorghum) at 80-85% and usually soybean meal at 10-15% (or canola, cottonseed, sunflower or other oilseed meal).

50. 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 80% (average) of all cattle are housed on farms having herd sizes of 50 or more. The range of such herds for EU-15 has a high of 95% and a low of 45% depending on the specific nation /university dealing with production of livestock commodities would be beneficial.

51. 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 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.

52. 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.

53. 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.

54. 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%).

55. In Japan, grains account for about 40% of the total amount (37 million metric tons on a dry matter basis), while forage and by-product feeds each account for around 30%. Imported feeds, mostly

grain, account for about 60% 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 by-product feeds are produced domestically than are imported, but about 20% of forage and 40% of by-product feeds are imported.

56. 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 cattle (1.54) than with poultry (0.50) or swine (0.38). 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. Lactating cows have a higher ration of byproduct feeds in relation to grain (1.73 vs. 0.68) than finishing beef cattle. Thus, the byproduct feedstuffs are most actively used by dairy farmers in Japan. Other byproducts are fishmeal and fish cake, corn starch byproducts (gluten meal and gluten feed), and soy sauce cake. Oil meals, wheat bran, defatted rice bran, and corn starch byproducts, which collectively accounted for 79% of the total by-product feeds, are the most used materials in formulated rations with a high rate of use as feedstuffs (84%). These feedstuffs are distributed all over the country by large feed companies in the form of feed concentrates. Additional data for the domestic forages that are currently being used in livestock feeding in Japan's beef and milk operations are needed to have a better understanding of the cattle rations.

Reasonable Worst Case Feeding Levels

57. Currently, estimates of reasonable worst case feeding levels for livestock are used nationally and regionally 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 will enable one study to be performed as part of a global MRL approach for pesticides in all OECD countries.

58. 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.

59. 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 are allocated a percentage of that animal's diet until 100% of the diet is accounted for. Similar calculations are performed for each OECD country or region. After comparison, the highest 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 is presented in Annex 5.

LITERATURE

(1) Australian Pesticides and Veterinary Medicines Authority. Residue Guidelines for Agricultural and Veterinary Products. http://www.apvma.gov.au/guidelines/residueguidelines.shtml

(2) Canadian Pest Management Regulatory Agency. (1998). Regulatory Directive 98-02. Residue Chemistry Guidelines.

http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802a-e.pdf
http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802b-e.pdf
http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802c-e.pdf

(3) European Commission. http://europa.eu.int/comm/food/fs/ph_ps/pro/wrkdoc/index_en.htm.

(4) Food and Agriculture Organization of the United Nations. (2002). FAO Manual on the submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed. Rome.

(5) Japanese Agricultural Chemicals Inspection Station. Data Requirements and Test Guideline. http://www.acis.go.jp/eng/indexeng.htm.

(6) U.S. Environmental Protection Agency. (1996). OPPTS Harmonized Test Guidelines. Series 860: Residue Chemistry.
http://www.epa.gov/opptsfrs/OPPTS_Harmonized/860_Residue_Chemistry_Test_Guidelines/index.html

(7) OECD Guidance Document on the Definition of Residue. (2006). Environment, Health and Safety Publication, Series on Testing and Assessment, No. XX – Series on Pesticides, No. XX, Paris 2006

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)

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)

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

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)

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)

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. (NAFTA)

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).

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 3, 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 stability. (NAFTA)

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 (GAP) in the use of pesticides 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. (FAO Manual).

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 **t**he 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)

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).

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).

Major metabolites are considered to be those which at any point in time 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.

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).

Metabolism is the **s**um 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 **a**nalytical 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)

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).

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 processing into food for sale to the consumer or as a food without further processing. 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)

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)

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)

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 (GAP).

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 **a**nimals 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 (typicaly 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

(i) **Applicant**/Registrant/Notifier/Petitioner/Contractor/Data generators/Studygenerators/Sponsor, etc.

(ii) **Pesticide/**Crop protection agent/Crop protection product/Plant protection product

(iii) **Metabolic pathway**/Metabolic route/Metabolic degradation

(iv) **Radioactivity**/Activity/^{14}C

(v) **Exaggerated rate**/Overdose

(vi) **Active ingredient**/Active substance

(vii) **Plant part**/Crop part

(viii) **Regulatory Authority**/Agency/Authority/Competent authority/Designated national authority

(ix) **Foliar application or Soil application**/Surface application

(x) **Total radioactive residue (TRR)**/Total radioactivity/Total activity

(xi) **Residue of concern (ROC)**/Total toxic residue (TTR)

(xii) **Rotational crop**/Following crop/Succeeding crop

(xiii) **Livestock/**Farm animal/Domestic animal

(xiv) **Maximum Residue Limit (MRL)/**Tolerance

(xv) **Edible offal/**Meat byproducts

(xvi) **Feedstuffs/**Feeding stuffs

(xvii) **Unextracted radiolabel/**bound residues

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

(i) **a) Metabolite** – biological
b) Degradation product – exogenous

(ii) **a) Dosing** – to an animal
b) Application – to a plant or non-oral treatment of animals

(iii) **a) Trigger** – use as a verb
b) Trigger value/Trigger level

(iv) **a) Food commodities**
b) Feed commodities

(v) **a) Plant**
b) Crop

(vi) **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

RACs To Be Analyzed For Crop Metabolism And Rotational Crops Studies*	
Crop	**Raw Agricultural Commodity**
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
Corn, field	grain forage stover
Corn, pop	grain stover
Corn, sweet	sweet corn, (K+CWHR) forage stover
Cotton	undelinted seed cotton gin byproducts
Cowpea	seed hay forage
Crabapple*	fruit
Cranberry*	berry
Crownvetch	forage hay
Cucumber	fruit

RACs To Be Analyzed For Crop Metabolism And Rotational Crops Studies*	
Crop	**Raw Agricultural Commodity**
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

RACs To Be Analyzed For Crop Metabolism And Rotational Crops Studies*	
Crop	**Raw Agricultural Commodity**
Mango*	fruit
Millet	grain forage 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

RACs To Be Analyzed For Crop Metabolism And Rotational Crops Studies*	
Crop	**Raw Agricultural Commodity**
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
Rutabaga	root
Rye	grain forage straw
Safflower	seed
Salsify	root tops (leaves)
Sesame	seed
Shallot	bulb
Sorghum, grain	grain forage stover

RACs To Be Analyzed For Crop Metabolism And Rotational Crops Studies*	
Crop	**Raw Agricultural Commodity**
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

TABLE OF OECD FEEDSTUFFS DERIVED FROM FIELD CROPS

OECD FEEDSTUFFS DERIVED FROM FIELD CROPS

Draft Feb 23 2006

Discard all previous drafts

PERCENT OF LIVESTOCK DIET

Draft March 23 2006						CATTLE						SHEEP						SWINE						POULTRY								
						BEEF			DAIRY			RAM/EWE			LAMB			BREEDING			FINISHING			BROILER			LAYER			TURKEY		
						US	EU	AU	US	EU	AU	US	EU	AU	US	EU	AU	US	EU	AU	US	EU	AU	US	EU	AU	US	EU	AU	US	EU	AU
CROP	FEEDSTUFF	IFN Code	Class.	Residue Level	DM	CAN			CAN			CAN			CAN			CAN			CAN			CAN			CAN			CAN		
Body weight (kg)						500	500	400	600	650	600	85	75	85	40	40	40	270	260	270	100	100	100	2	1.7	2	1.9	1.9	1.9	8	7	8
Daily intake (DM in kg)						9.1	12	9.1	24	25	18	2	2.5	2	1.5	1.7	1.5	2	6	2	3.1	3	3.1	0.16	0.12	0.16	0.12	0.13	0.12	0.5	0.5	0.5
Forages																																
Alfalfa	forage	2-00-196	R	HR	35	60	70	100	40	40	60	90	40	100	90	40	90	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Alfalfa	hay	1-00-054	R	HR	89	60	*	80	40	40	60	70	40	70	70	40	35	*	*	10	*	*	10	*	*	*	*	*	*	*	*	*
Alfalfa	meal	1-00-023	R	HR	89	25	25	40	40	40	40	20	20	*	20	20	*	20	10	10	10	10	10	10	5	10	10	10	10	10	5	10
Alfalfa	silage	3-08-150	R	HR	40	60	25	100	40	40	40	75	40	75	75	40	75	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Barley	forage	2-00-511	R	HR	30	30	30	50	40	30	50	70	50	100	30	50	100	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Barley	hay	1-00-495	R	HR	88	25	*	100	40	*	50	65	*	70	65	*	25	*	*	10	*	*	5	*	*	*	*	*	*	*	*	*
Barley	straw	1-00-498	R	HR	89	10	30	100	10	30	20	25	60	30	25	60	30	*	*	10	*	*	10	*	*	*	*	5	*	*	*	*
Barley	silage	NA	R	HR	40	*	30	100	*	30	50	*	50	*	*	50	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Bean	vines	2-14-388	R	HR	35	30	*	60	20	20	70	30	30	*	30	30	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Beet, mangel	fodder	2-00-632	R	HR	15	*	30	*	*	25	*	*	10	*	*	10	*	*	15	*	*	*	*	*	*	*	*	*	*	*	*	*
Beet, sugar	tops	2-00-649	R	HR	23	*	20	*	*	30	*	15	20	*	20	20	*	*	10	*	*	*	*	*	*	*	*	5	*	*	*	*
Cabbage	heads, leaves	2-01-046	R	HR	15	*	20	*	*	20	*	*	10	*	*	10	*	*	10	*	*	*	*	*	*	*	*	5	*	*	*	*
Clover	forage	2-01-434	R	HR	30	30	30	100	40	40	60	85	85	100	30	30	100	*	20	*	*	*	*	*	*	*	*	10	*	*	*	*
Clover	hay	1-01-415	R	HR	89	30	30	100	40	40	60	80	80	75	20	20	35	*	20	10	*	*	10	*	*	*	*	10	*	*	*	*
Clover	silage	3-01-441	R	HR	30	30	25	100	40	40	60	85	85	75	30	30	75	*	20	*	*	*	*	*	*	*	*	10	*	*	*	*
Forages																																
Corn, field	forage/silage	3-28-345	R	HR	40	40	80	80	50	60	80	70	*	80	30	30	60	*	20	*	*	*	*	*	*	*	*	10	*	*	*	*
Corn, field	stover	3-28-251	R	HR	83	25	25	40	15	20	40	50	*	*	25	*	*	*	20	*	*	*	*	*	*	*	*	10	*	*	*	*
Corn, pop	stover	2-02-963	R	HR	85	25	25	20	15	20	20	25	*	*	25	*	*	15	20	*	*	*	*	*	*	*	*	10	*	*	*	*
Corn, sweet	forage	1-08-407	R	HR	48	40	*	80	50	*	40	75	*	25	25	*	*	15	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Corn, sweet	stover	NA	R	HR	83	25	*	40	15	*	20	70	*	30	30	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Cowpea	forage	2-01-655	R	HR	30	20	35	100	20	35	60	75	35	100	30	35	100	*	20	*	*	*	*	*	*	*	*	10	*	*	*	*
Cowpea	hay	1-01-645	R	HR	86	20	35	100	20	35	60	50	35	65	20	35	35	*	20	10	*	*	10	*	*	*	*	10	*	*	*	*
Crown vetch	forage	2-19-834	R	HR	30	20	*	100	40	*	100	80	*	95	30	*	95	*	*	*	*	*	*	*	*	*	*	10	*	*	*	*
Crown vetch	hay	1-20-803	R	HR	90	20	*	100	40	*	100	65	*	70	20	*	35	*	*	*	*	*	*	*	*	*	*	10	*	*	*	*
Grass	forage (fresh)	2-02-260	R	HR	25	60	50	100	40	60	100	95	95	100	25	50	100	*	20	*	*	*	*	*	*	*	*	10	*	*	*	*
Grass	hay	1-02-250	R	HR	88	60	50	100	40	60	60	90	90	70	15	30	25	*	20	10	*	*	10	*	*	*	*	10	*	*	*	*
Grass	silage	3-02-222	R	HR	40	60	50	100	40	60	60	90	90	75	20	50	50	*	20	*	*	*	*	*	*	*	*	10	*	*	*	*
Kale	leaves	2-02-446	R	HR	15	*	20	*	*	20	40	*	10	*	*	10	*	*	10	*	*	*	*	*	*	*	*	5	*	*	*	*
Lespedeza	forage	2-07-058	R	HR	22	20	*	20	40	*	60	80	*	*	30	*	*	*	*	*	*	10	*	*	*	*	*	10	*	*	*	*
Lespedeza	hay	1-02-522	R	HR	88	20	*	20	40	*	60	70	*	20	20	*	*	*	*	*	*	10	*	*	*	*	*	10	*	*	*	*
Millet	forage	2-03-801	R	HR	30	25	*	100	40	30	50	80	*	100	35	*	60	*	*	*	*	*	*	*	*	*	*	10	*	*	*	*
Millet	hay	1-03-119	R	HR	85	10	*	100	40	*	50	75	*	65	20	*	20	*	*	10	*	*	10	*	*	*	*	10	*	*	*	*
Millet	straw	1-23-802	R	HR	90	10	10	80	10	*	50	50	*	35	15	*	15	*	*	10	*	*	10	*	*	*	*	*	*	*	*	*

Forages																															
Oat	forage	2-03-292	R	HR	30	25	20	100	40	20	90	25	40	100	35	40	100	*	20	*	*	*	*	*	*	*	10	*	*	*	*
Oat	hay	1-03-280	R	HR	90	25	20	100	40	20	90	80	40	65	20	40	20	*	20	10	*	*	10	*	*	*	*	10	*	*	*	*
Oat	straw	1-03-283	R	HR	90	10	20	80	10	20	60	10	40	35	20	40	15	*	*	10	*	*	10	*	*	*	*	*	*	*	*	*
Oat	silage	3-03-298	R	HR	35	*	*	100	*	*	40	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Pea	vines	3-03-596	R	HR	25	20	20	60	20	20	40	75	20	90	35	20	90	*	20	*	*	*	*	*	*	*	10	*	*	*	*
Pea	hay	1-03-572	R	HR	88	20	25	100	20	30	70	75	20	70	25	20	30	*	20	15	*	*	10	*	*	*	*	10	*	*	*	*
Pea	silage	3-03-590	R	HR	40	20	25	100	20	30	40	73	20	75	35	20	70	*	20	*	*	*	*	*	*	*	*	10	*	*	*	*
Peanut	hay	1-03-619	R	HR	85	25	*	60	20	*	60	79	*	25	25	*	*	10	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Rape	forage	2-03-867	R	HR	30	20	10	100	20	10	40	50	40	90	30	40	90	*	20	*	*	*	*	*	*	*	10	*	*	*	*
Rice	straw	1-03-925	R	HR	90	10	10	60	10	5	20	10	10	20	10	10	15	*	*	10	*	*	10	*	*	*	*	*	*	*	*	*
Rye	forage	2-04-018	R	HR	30	20	20	100	20	20	20	75	40	100	30	40	100	*	20	*	*	*	*	*	*	*	10	*	*	*	*
Rye	straw	1-04-007	R	HR	88	10	20	20	10	20	20	25	40	20	10	40	20	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Sorghum,forage	see Grasses																														
Sorghum, grain	forage	2-04-317	R	HR	35	40	20	70	40	20	70	30	20	100	30	20	65	*	20	10	*	*	*	*	*	*	*	10	*	*	*	*
Sorghum, grain	stover	1-07-960	R	HR	88	20	15	70	15	15	70	30	20	*	20	20	*	*	20	*	*	*	*	*	*	*	*	10	*	*	*	*
Soybean	forage	2-04-574	R	HR	56	30	*	100	30	*	40	80	*	90	35	*	80	10	*	*	*	*	*	*	*	*	*	10	*	*	*	*
Soybean	hay	1-04-558	R	HR	85	30	*	80	30	*	40	65	*	70	20	*	25	*	*	*	*	*	*	*	*	*	*	10	*	*	*	*
Soybean	silage	3-04-581	R	HR	30	30	*	80	30	*	40	70	*	75	40	*	65	20	*	*	*	*	*	*	*	*	*	10	*	*	*	*
Sugarcane	tops	2-04-692	R	HR	25	*	*	50	*	*	25	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*

Forages																															
Trefoil	forage	2-20-786	R	HR	30	20	20	100	40	40	40	75	40	90	35	20	90	*	20	*	*	*	*	*	*	*	10	*	*	*	*
Trefoil	hay	1-05-044	R	HR	85	20	20	90	40	40	40	60	40	70	25	20	70	*	20	15	*	*	10	*	*	*	*	10	*	*	*	*
Triticale	forage	2-02-647	R	HR	30	20	20	100	40	20	70	60	40	100	30	30	100	15	20	*	*	*	*	*	*	*	*	*	*	*	*	*
Triticale	hay	NA	R	HR	88	25	20	100	40	20	70	80	40	70	20	20	25	*	20	10	*	*	10	*	*	*	*	*	*	*	*	*
Triticale	straw	NA	R	HR	90	10	20	50	10	20	70	10	40	20	10	10	15	*	*	10	*	*	10	*	*	*	*	*	*	*	*	*
Triticale	silage	3-26-208	R	HR	35	30	*	90	40	*	50	30	*	*	25	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Turnip	tops (leaves)	2-05-063	R	HR	30	50	40	80	30	20	*	65	30	75	20	30	75	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Vetch	forage	2-05-112	R	HR	30	20	25	90	40	25	35	80	30	100	30	20	100	*	*	10	*	*	*	*	*	*	*	10	*	*	*	*
Vetch	hay	1-05-122	R	HR	85	20	25	90	40	25	35	75	30	75	20	20	30	*	*	10	*	*	10	*	*	*	*	10	*	*	*	*
Vetch	silage	3-26-357	R	HR	30	35	*	90	40	*	50	80	*	*	30	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Wheat	forage	2-08-078	R	HR	25	25	20	100	40	20	60	75	40	100	30	30	100	15	20	10	*	*	*	*	*	*	*	10	*	*	*	*
Wheat	hay	1-05-172	R	HR	88	25	20	100	40	20	20	80	40	65	20	20	25	*	20	10	*	*	10	*	*	*	*	10	*	*	*	*
Wheat	straw	1-05-175	R	HR	88	10	20	80	10	20	20	25	40	20	10	40	15	*	*	10	*	*	10	*	*	*	*	10	*	*	*	*
Wheat	silage	3-05-186	R	HR	30	30	*	90	40	*	50	30	*	*	25	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Roots & Tubers																															
Carrot	culls	2-01-146	R	HR	12	10	15	5	10	15	5	20	20	*	40	20	*	*	25	10	*	25	5	*	10	*	*	10	*	*	10	*
Cassava/tapioca	roots	2-01-156	R	HR	37	*	20	*	*	15	*	*	20	*	*	20	*	*	40	*	*	40	*	*	20	*	*	15	*	*	5	*
Potato	culls	4-03-787	R	HR	20	30	30	10	10	30	10	50	30	*	40	20	*	*	50	10	*	50	*	*	10	*	*	10	*	*	20	*
Swede	roots	4-04-001	R	HR	10	*	40	10	*	20	10	*	30	80	*	30	80	*	40	5	*	40	*	*	10	*	*	10	*	*	10	*
Turnip	roots	4-05-067	R	HR	15	10	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	45	40	40	40	40	85	40	60	85	20	80	85	20	80	80	75	70	15	70	100	15	50	50	15
Bean	seed	4-00-515	PC	STMR	88	15	20	50	15	20	15	20	20	85	20	20	85	20	20	20	20	20	20	20	20	70	20	20	70	20	20	70
Corn, field	grain	4-20-698	CC	STMR	88	80	80	80	45	30	20	50	30	85	50	30	85	80	70	80	80	70	80	80	70	*	70	70	*	70	50	*
Corn, pop	grain	4-02-964	CC	STMR	88	80	*	80	45	30	20	50	30	85	50	30	85	*	*	*	*	*	*	80	*	*	70	*	*	*	*	*
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	15	15	15	10	10	10	10	10	50
Millet	grain	4-03-120	CC	STMR	88	50	40	50	40	40	50	40	30	*	40	30	*	20	70	70	20	70	70	70	70	70	60	70	60	50	50	15
Oat	grain	4-03-309	CC	STMR	89	*	40	80	*	40	10	*	40	90	*	60	90	*	70	80	*	70	80	80	70	15	70	70	15	65	50	5
Pea	seed	5-03-600	PC	STMR	90	*	20	40	*	20	20	20	20	*	20	20	*	20	20	40	20	20	40	20	20	5	20	20	5	10	20	40
Rice	grain	4-03-939	CC	STMR	88	20	*	40	20	*	20	20	*	*	20	*	*	20	*	60	20	*	65	20	*	50	20	*	50	40	*	60
Rye	grain	4-04-047	CC	STMR	88	20	40	80	20	40	*	20	40	*	20	45	*	*	70	80	*	70	70	50	70	50	35	35	35	60	60	60
Sorghum, grain	grain	4-04-383	CC	STMR	86	40	40	80	40	40	50	40	40	80	50	40	80	80	70	80	80	70	80	80	70	70	80	70	70	60	50	15
Soybean	seed	5-64-610	PC	STMR	89	15	10	20	15	10	20	25	10	40	15	20	40	25	10	10	25	20	10	20	20	15	20	15	15	15	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	80	15	*	80	15	*	80	15	60
Vetch	seed	5-26-351	PC	STMR	89	*	*	20	*	*	20	*	*	*	*	*	*	*	*	10	*	*	10	*	*	*	*	*	*	*	*	*
Wheat	grain	4-05-211	CC	STMR	89	20	40	80	20	40	20	20	40	80	20	60	80	*	70	80	*	70	80	80	70	70	70	70	55	70	50	*

By-products																																
Almond	hulls	4-00-359	R	STMR	90	10	*	10	10	*	10	*	*	*	*	*	*	10	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Apple	pomace, wet	4-00-419	CC	STMR	40	20	20	20	10	10	10	10	10	*	10	10	*	25	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Beet, sugar	dried pulp	4-29-307	R	STMR	88	20	20	*	20	20	*	15	40	*	20	40	*	15	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	30	15	20	70	30	*	40	10	*	*	10	10	*	10	10	*	10	*	*	10	*	*	10	5
Canola	meal	5-08-136	PC	STMR	88	15	*	20	15	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	*	*	10	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 bypdts	5-28-235	CC	STMR	85	50	30	15	25	30	15	35	30	*	50	30	*	60	75	70	60	75	70	60	60	*	50	50	*	50	50	20
Corn, field	hominy meal	4-03-010	CC	STMR	88	50	*	40	60	*	40	50	*	*	50	*	*	20	*	40	20	*	40	20	*	20	20	20	20	20	20	*
Corn, sweet	cannery waste	2-02-875	CC	STMR	30	10	*	30	10	*	10	30	*	*	20	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Corn gluten	feed	5-28-243	CC	STMR	40	75	30	20	50	30	*	35	30	80	50	30	80	20	20	20	25	20	20	*	10	*	*	*	*	*	*	*
Corn gluten	meal	5-28-242	CC	STMR	40	75	15	20	50	20	*	35	30	*	50	30	*	20	10	25	25	10	25	*	10	*	*	10	*	*	10	10
Cotton	meal	5-01-617	PC	STMR	89	15	5	30	15	5	15	15	15	45	10	10	45	15	10	10	15	5	10	20	5	10	20	5	10	15	10	*
Cotton	undelinted seed	5-01-614	PC	STMR	88	25	*	30	25	10	20	25	*	25	25	*	25	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Cotton	hulls	1-01-599	R	STMR	90	20	*	20	15	*	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	25	10	*	35	10	*	25	10	*	*	20	20	*	20	20	*	10	*	*	10	*	*	10	*
Flaxseed/linseed	meal	5-02-043	PC	STMR	88	10	10	10	10	15	10	15	20	*	20	10	*	20	20	10	10	20	10	30	10	*	30	10	*	15	10	*

Grape	pomace, wet	2-02-206	CC	STMR	15	*	*	20	*	*	20	*	*	*	*	*	*	*	*	10	*	*	10	b	*	*	*	*	*	*	*	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	*	25	10	*	*	*	*	*	*	*	10	10	*	10	10	*	*	*	*	*	*	*	5	10
Peanut	meal	5-03-649	PC	STMR	85	15	20	10	15	10	15	20	20	*	15	20	*	20	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	15	20	15	15	10	15	15	15	*	15	15	*	20	10	15	15	20	15	15	*	5	15	10	5	10	20	*
Rice	hulls	1-08-075	R	STMR	90	10	*	5	10	*	10	20	*	20	10	*	15	10	*	10	*	0	10	*	*	*	*	*	*	*	*	20
Rice	bran/pollard	4-03-928	R	STMR	90	15	*	40	15	20	40	*	30	*	*	30	*	*	10	30	15	0	20	25	10	20	25	5	20	25	*	15
Safflower	meal	5-26-095	PC	STMR	91	10	20	20	10	10	15	15	*	*	15	*	*	25	*	20	20	*	20	25	10	15	25	5	15	10	5	*
Sorghum, grain	asp gr fn	NA	CC	STMR	85	5	*	20	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Soybean	asp gr fn	NA	CC	STMR	85	5	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	25
Soybean	meal	5-20-638	PC	STMR	92	15	20	10	15	25	15	25	25	35	15	25	35	20	30	30	20	30	30	40	40	25	35	25	25	45	45	*
Soybean	hulls	1-04-560	R	STMR	90	20	10	*	20	10	*	50	*	20	20	*	20	*	*	10	*	*	10	20	10	5	10	5	5	2	*	*
Soybean	pollard	NA	R	STMR	?	*	*	15	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Sugarcane	molasses	4-13-251	CC	STMR	75	10	10	30	10	10	25	10	5	10	10	5	10	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*
Sugarcane	bagasse	1-04-686	R	STMR	32	*	*	20	*	*	25	*	*	10	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	15
Sunflower	meal	5-26-098	PC	STMR	92	15	20	30	15	10	15	20	20	40	20	20	40	10	10	30	20	10	30	30	10	15	25	10	15	15	10	*
Wheat	asp gr fn	NA	CC	STMR	85	5	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	*	20
Wheat gluten	meal	5-05-221	CC	STMR	40	10	15	*	10	20	*	10	30	*	10	30	*	10	10	25	10	10	25	*	10	*	*	10	*	*	10	10
Wheat	milled bypdts	4-06-749	CC	STMR	88	40	30	40	40	30	40	40	40	*	50	50	*	70	50	40	50	50	40	50	20	20	50	20	20	60	20	20

ANNEX 5

OECD FEEDSTUFFS DERIVED FROM FIELD CROPS

Example of Dose Calculation for Residues in Livestock Studies

The calculation of dose levels is conducted in several steps:

I. Selection of a livestock feed category (forage, straw, etc.) and the corresponding data from a region/country.

II. Selection of the residue levels according to the Good Agriculture Practice relevant for the region/country: highest residue (HR) for a RAC or supervised trial median residue – processed (STMR-(P)) for a by-product commodity.

III. Calculation of dose levels per animal/species using residue levels on a dry weight basis for each category. In some countries the adjustment of residues for dry matter content may not be needed for poultry and swine feed items.

IV. Selection of the feedstuff with the highest resulting dietary burden for each feedstuff category.

V. Feedstuffs are allocated a percentage of the livestock diet for each animal until no more than 100% of the diet is used.

VI. Repeat these steps for all livestock species from all countries listed in the OECD Feedstuffs Derived from Field Crops Table and select those livestock that will receive the highest dietary burden.

Example

The following example explains Step I to VI in more detail:

An active substance is intended to be registered in the United States, Canada and member states of the European Community for a broad range of food crops and feedstuffs: Wheat, Corn, Barley, Soybean, Alfalfa, Potatoes, Carrots, Grapes, Apples, Almonds.

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

STEP I. Selection of a livestock feed category and the corresponding data from a region/country. This example uses the data for Beef Cattle, residue data from United States or Canada, and feedstuff dry matter content and intake data from the OECD Feedstuffs Derived from Field Crops Table.

STEP II. Selection of the residue levels, HR or STMR-(P), according to the Good Agriculture Practice relevant for the region/country:

- The HR (or highest average field trial (HAFT) data where available) will be used for agricultural commodities from the ‘Forages’ and ‘Roots and Tubers categories.

- STMR residues values may be used for blended and/or processed agricultural commodities from the 'Cereal Grains/Crop Seeds' and 'By-Products' categories.

STEP III. Calculation of residue levels on a dry weight basis for each category.

IIIa. Category: Forages (wheat, corn, barley, alfalfa):
US/Canada Beef Cattle: Total Daily Feed Intake 9.1 kg

Forages	Commodity Category	Dry matter content [%]	Highest Residues [mg/kg]	Residue per kg dry matter [mg/kg]	Percent of daily ration	Daily Dietary Burden per animal (mg)
Alfalfa	forage	35	5	14.29	60	**78.00**
Alfalfa	hay	89	10	11.24	60	61.35
Alfalfa	meal	89	10	11.24	25	25.56
Barley	hay	88	2	2.27	25	5.17
Barley	straw	89	2	2.25	10	2.04
Corn, field	silage	40	0.02	0.05	40	0.18
Wheat	forage	25	2	8.00	25	18.20
Wheat	hay	88	1	1.14	25	2.59
Wheat	straw	88	2	2.27	10	2.07

The highest dietary burden for the forages category results from Alfalfa (forage).

IIIb. Category Roots & Tubers (Carrots, Potatoes):
US/Canada Beef Cattle: Total Daily Feed Intake 9.1 kg

Roots & Tubers	Commodity Category	Dry matter content [%]	Highest Residues /STMR [mg/kg]	Residue in dry matter [mg/kg]	Percent of daily ration	Daily Dietary Burden per animal (mg)
Carrot	culls	12	0.02	0.167	10	0.15
Potato	culls	20	0.5	2.5	30	**6.83**

The maximum dietary burden for the Roots and Tubers category results from Potato culls.

IIIc. Category Cereal grains and Crop seeds (Barley, Corn, Soybean, Wheat):
US/Canada Beef Cattle: Total Daily Feed Intake 9.1 kg

Cereal Grains/Crops Seeds	Commodity Category	Dry matter content [%]	STMR[1] [mg/kg]	Residue in dry matter [mg/kg]	Percent of daily ration	Daily Dietary Burden per animal (mg)
Barley	Grain	88	0.06	0.07	50	**0.31**
Corn, field	Grain	88	0.02	0.02	80	0.16
Soybean	Seed	89	0.04	0.05	15	0.06
Wheat	Grain	89	0.01	0.01	20	0.02

[1] The HR needs to be used in e.g. in case of post harvest treatments.
The maximum dietary burden for the Cereal grains and Crop seeds category results from Barley (grain).

IIId. Category By-Products (various by-products from food or feed processing)
US/Canada Beef Cattle: Total Daily Feed Intake 9.1 kg

Cereal Grains/Crops Seeds	**Commodity Category**	**Dry matter content [%]**	**STMR [mg/kg]**	**Residue in dry matter [mg/kg]**	**Percent of daily ration**	**Daily Dietary Burden per animal (mg)**
Almond	Hulls	90	1	1.11	10	1.01
Corn, field	aspirated grain fractions	85	2	2.35	5	1.07
Corn, field	milled by-products	85	1	1.18	50	**5.36**
Corn/wheat gluten	Feed	40	0.2	0.5	75	3.41
Corn/wheat gluten	Meal	40	0.2	0.5	75	3.41
Soybean	aspirated grain fractions	85	3	3.53	5	1.61
Soybean	Hulls	90	1	1.11	20	2.02
Wheat	aspirated grain fractions	85	2	2.35	5	1.07
Wheat	milled byproducts	88	0.3	0.34	40	1.24
Apples	pomace wet	40	0.05	0.125	20	0.23
Grapes	pomace wet	15	0.1	0.67	Nu *	0

* Nu = Not used
The maximum dietary burden for the By-products category results from Corn (field), milled by-products.

Step IV: Selection of the feedstuff with the highest dietary burden level for each feedstuff category

Forages	**Commodity Category**	**Dry matter content [%]**	**Residues [mg/kg]**	**Residue in dry matter [mg/kg]**	**Percent of daily ration**	**Daily Dietary Burden per animal (mg)**
Alfalfa	forage	35	5	14.29	**60**	78.00
Potato	culls	20	0.5	2.5	**30**	6.83
Barley	Grain	88	0.06	0.07	**50**	0.31
Corn, field	milled byproducts	85	1	1.18	**50**	5.36

The total percentages add up to more than 100% (190%), therefore, the dietary burden calculation needs to be adapted to 100%

Step V: Feedstuffs are allocated a percentage of the livestock diet for each animal until no more than 100% of the diet is used.

Feed intake and bodyweight data – See OECD Feedstuffs Derived from Field Crops Table**.**
Beef Cattle (US/CAN): Feed intake is 9.1 kg dry matter/day – Body weight is 500 kg

Crop	**Commodity Category**	**Percent of daily ration**	**Daily Dietary Burden per animal (mg)**	**Dietary burden per percent of daily ration (mg)**	**Dose in mg/kg body weight**
Alfalfa	Forage	**60**	78.00	1.30	0.156
Potato	Culls	**30**	6.83	0.22	0.014
Corn, field	Milled byproducts	**50**	5.37	0.11	0.002
Barley	Grain	**50**	0.32	0.01	0.0
					0.172

In this step the commodities are listed according to their quantitative share of the dietary burden. Adding up all intakes for all commodities would result in a feed intake of 190% (sum of alfalfa 60%, potatoes 30%, corn and barley 50% each). As the daily ration cannot exceed 100% of 9.1 kg for Beef Cattle, the total dietary burden is calculated using those commodities contributing with the highest residue level per percent of the daily ration. For alfalfa this level is 1.3 mg, the next highest value results from potatoes, namely 0.22 mg. Both, alfalfa and potatoes already cover 90% of the daily feed intake, therefore, only 10% of the intake is used from the remaining commodities. The dietary of corn milled by-products of corn is higher than for barley, therefore the remaining 10% are taken from this commodity. The dose per animal is calculated as the dietary burden per animal and commodity divided by the body weight: e.g., for alfalfa 78mg/500 kg = 0.156 mg/kg body weight. For corn, as 5.37 mg correlates with 50% of the dietary burden, one calculates 5.35/5 divided by body weight. The dose level for the commodity corn is 0.002 mg/kg body weight. In cases where summing up all categories would lead to a value of less than 100% of the daily diet, the remaining percentage would be considered free of residues.

The total dietary burden in this example for beef cattle (United States/Canada) is mg/kg bodyweight as the likely 1x dose equivalent for beef cattle for that region.

STEP VI: Repeat these steps for all livestock types from all countries listed in the OECD Feedstuffs Derived from Field Crops Table and select the livestock group with the highest dietary burden.

In this example Steps I to V are repeated for Dairy Cattle (United States/Canada, EU) and Beef cattle (EU).
Dose levels per livestock species and region

Livestock	Region	Dose level [mg/kg bw]
Beef Cattle	US/Canada	0.17
Dairy Cattle	US/Canada	0.26
Beef Cattle	EU	0.26
Dairy Cattle	EU	0.26

Obviously in this example the Dairy Cattle group from the United States/Canada and Europe and Beef Cattle from Europe receive the highest dose. Therefore the dose level of 0.26 mg/kg body weight is selected as 1X dose level for the livestock feeding study.

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.

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.

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.

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

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 under gone 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 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.

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

ANNEX 6

OECD EXPERT GROUP ON PESTICIDE RESIDUE CHEMISTRY

Australia			
Raj Bhula	APVMA		
Canada			
Ariff Ally	Pest Management Regulatory Agency (PMRA)		
Henri Bietlot	PMRA		
Louise Croteau	PMRA		
Germany			
Karsten Hohgardt	BVL		
Italy			
Roberto Dommarco	Istituto Superior di Sanita (ISS)		
Japan			
Yasuhiro Katoh	Institute of environmental Toxicology		
Kazuo Ogura	Ministry of Agriculture, forestry & Fisheries (MAFF)		
Katsuya Sato	Agricultural Chemicals Inspection Station (ACIS)		
Mituaki Kinoshita	Food Safety Commission		
The Netherlands			
Bernadette Ossendorp	RIVM		
New Zealand			
David Lunn	New Zealand Food Safety Authority		
United Kingdom			
Rebecca Scrivens	Pesticide Safety Directorate (PSD)		
Sonia Barker	PSD		
United States			
Amy Rispin (Chairperson)	EPA	***Bill Meyer***	EPA
Michael Doherty	EPA	***Christine Olinger***	EPA
Steve Funk	EPA	***Bernard Schneider***	EPA
Bill Hazel	EPA	***Charles Stafford***	EPA
George Kramer	EPA	***Jerry Stokes***	EPA
Richard Loranger	EPA		
European Commission			
Louis-Maria Smeets	EC DG Sanco		
Bas Drukker	EC DG Sanco		
Frans Verstraete	EC DG Sanco		
European Food Safety Authority (EFSA)			
Henning Bruno	EFSA Pesticide Risk Assessment		
Daniela Brocca	EFSA Pesticide Risk Assessment		
Hermine Reich	EFSA Pesticide Risk Assessment		
FAO			
Manfred Luetzov	FAO Consultant		
Gero Vaagt	FAO Plant Production & Protection Division		
BIAC/CropLife International			
Volker Bornemann	BASF, Germany		
Terry Clark	Syngenta, United Kingdom		
Michael Kaethner	Bayer CropScience, Germany		
Otto Klein	Bayer CropScience, Germany		
Kazuya Koizumi	Syngenta Japan desk, Switzerland		
David Ryan	DuPont, USA		