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CHEMICALS AND BIOTECHNOLOGY COMMITTEE**

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OECD Guidance Document on addressing minor uses

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FOREWORD

This guidance document collates a variety of existing information regarding the registration of pesticides for minor uses in a centralised document.

Minor uses, including the majority of speciality crops, are the uses of pesticides where the potential use is on a scale not sufficiently large to justify registration of that use from an applicant's perspective alone. Typically, minor uses involve crops grown on a small scale (minor crops) and often are high value specialty crops. Additionally, minor uses can involve uses within major crops in terms of controlling minor pests and diseases. This results in a situation where speciality crop industries are either without or lacking sufficient access to pest control products to adequately protect those crops. The major factor hindering the regulatory approval of minor uses is a lack of data that is largely attributable to a lack of funding required to generate data.

Overall, the guidance document does not seek to reproduce existing information but rather briefly discusses and collates sources of information useful in addressing and solving minor use gaps. The guidance includes background on existing minor use programs and information/guidance produced by OECD through the Expert Group on Minor Uses (EGMU) and the Residue Chemistry Expert Group (RCEG), member countries and other international bodies. The guidance provides a summary of previous work and refers to databases which exist internationally. It is recommended to be read in conjunction with those materials where referenced. Finally, a section refers to incentives and another to work sharing that could encourage minor use registrations.

Australia has led the development of this guidance document and has engaged with and received input from Canada (PMRA & PMC), US (IR-4 Project), and EU (Minor Uses Coordination Facility and the Netherlands). The working document was approved by EGMU and the Working Party on Pesticides in August 2023. This document is being published under the responsibility of the Chemicals and Biotechnology Committee (CBC), which has agreed that it be declassified and made available to the public.

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1 INTRODUCTION

1. Minor use is the use of chemical pesticides or non-chemical means of crop protection where the potential use is on a scale not sufficiently large to justify registration of that use from an applicant's perspective alone. The key driver for minor uses is a lack of economic return to an applicant from registration of those uses, in particular the associated costs of generating the data required for obtaining and maintaining regulatory approval and potential liability from those uses once approved. Typically, minor uses involve crops grown on a small scale (minor crops) and often are high value speciality crops. Additionally, minor uses can involve uses within major crops in terms of controlling minor pests and diseases. This results in a situation where speciality crop industries are either without or are lacking sufficient access to pesticides to adequately protect those crops.

2. Many countries implement a number of strategies to assist in addressing the needs related to the registration minor use pesticides, including technical and policy concerns. Individual tools and strategies, in isolation, may not provide solutions, although when various technical and policy strategies are implemented, they can significantly enhance the registration of minor uses.

3. This guidance has been developed to provide a document that centralises the variety of existing information and global approaches for facilitating the registration of minor uses. It is not intended to reproduce existing information, but rather briefly discuss and collate in a single document the sources of information utilised to address and solve minor use gaps. The guidance encompasses background regarding existing minor use programs and information/guidance produced by OECD Working Party on Pesticides (WPP) through the Expert Group on Minor Uses (EGMU) and the Residue Chemistry Expert Group (RCEG), member countries and other international bodies. This guidance provides a summary of previous work and refers to several other publications and documents which exist internationally and therefore, the guidance needs to be read in conjunction with those materials where referenced.

2 MINOR USE PROGRAMS

4. One of the key strategies implemented by several countries and regions is the establishment of specific programs that work directly with growers of minor crops to identify priority needs and solutions, generate data and seek registration of crop protection solutions.
5. The programs are often structured around centralised coordination units, grower-liaison committees and work in close collaboration with regulators and product registrants. The programs, in partnership with growers, conduct regular and typically annual prioritisation workshops to identify needs and crop protection solutions. For prioritised needs the programs design and conduct research generating the necessary data to support regulatory submissions.
6. Several programs are supported through direct government funding grants allocated annually or over several years (i.e., 1-5 years). Some governments have also implemented regulatory incentives associated with submissions that originate from such programs. These can include waivers or reduction in assessment fees or qualification for additional years data protection. For more information on these aspects refer to the section on *Regulatory Incentives*.
7. The following sections provide a brief summary of some existing minor use programs.

United States IR-4 Project

8. The IR-4 Project established in 1963, has been the primary resource in the United States for facilitating registrations of conventional chemical pesticides and biopesticides on speciality food crops and non-food ornamental horticulture crops. Now into its 60th year of operation the IR-4 Project has delivered over 75,000 use registrations of chemicals and biopesticides to US growers.
9. The IR-4 Project operates in partnership with the Federal government (USDA, EPA, and Department of Defence), the land-grant universities/State Agricultural Experiment Stations (SAES), farmers/commodity associations, food processors, the crop protection/pest management industry and international partners (e.g., Canada's Pest Management Centre Minor Use Pesticides Program). The IR-4 Project serves as an intermediary between the crop protection industry and speciality crop farmers by developing research data to facilitate the regulatory approvals that meet the pest management needs of US producers/farmers.
10. Using its unique ability to partner with government, industry and growers, IR-4 develops required data to support the registration of pest management products, conducting both residue and efficacy/target safety (performance) data. The IR-4 Project accepts requests for minor use needs and conducts workshops annually to prioritise needs. These priorities are then scheduled for research in the following year throughout a network of IR-4 field research centres and analytical laboratories across the US. Following data generation and compilation of results IR-4 Project then lodge regulatory submissions to the US EPA.
11. More information about the IR-4 Project can be found here: <https://www.ir4project.org/>

Canada's Pest Management Centre's Minor Use Pesticides Program

12. The Pest Management Centre (PMC) was established in 2003 in response to Canadian producers of minor crops for improved access to pest control products. Since its inception in 2003, the PMC has achieved over 2,300 new use registrations and over 850 new uses for 33 different biopesticides for Canadian growers.

13. The objectives of the PMC are to provide benefits to Canadian producers, the environment, and consumers by focusing on:

- improving growers of minor crops access to pest control products, with emphasis on reduced-risk products; and
- providing producers with access to new pest-management technologies to improve their competitiveness domestically and internationally.

14. PMC work in partnership with growers, provinces, registrants, and crop protection experts to establish grower-selected crop and pest needs, and match them with potential solutions, particularly reduced-risk products. Like the US IR-4 Project (described above) the PMC conduct an annual priority setting workshop to identify the top national pest priorities and potential solutions (chemical and biologicals).

15. The PMC, in consultation with the Canadian Regulator (PMRA), determines the data requirements for each selected priority and then conducts field, greenhouse and growth-chamber trials that determine pesticide efficacy, crop tolerance to pesticides and for food crops especially, determination of pesticide residues. Trials are conducted in specific locations, corresponding to the crop growing zones and the likelihood of pest occurrence. Following data generation and compilation of results, PMC then lodge regulatory submissions to the PMRA.

16. More information about the PMC can be found here: <https://agriculture.canada.ca/en/science/agriculture-and-agri-food-research-centres/pest-management-centre>

Collaboration between the IR-4 Project and PMC

17. The Canadian PMC and the US IR-4 Project have a close liaison and attend one another's annual prioritisation workshops to identify mutual needs and jointly generate and prepare regulatory submissions to their respective regulatory agencies. Through these efforts, growers in Canada and the US with the same crop and pest problems have access to new minor uses of pesticides simultaneously. These efforts also reduce the amount of data that would otherwise be required if the two programs operated in isolation, through Canadian and US regulators accepting data generated in agreed zones across the two countries. Since 2003, numerous joint minor use projects have been undertaken as part of this collaborative effort.

European Minor Uses Coordination Facility

18. To address minor use needs, the European Minor Uses Coordination Facility (MUCF) was established in 2015. The MUCF was initially funded by three European countries, France, Germany, the Netherlands and the European Commission for the first three years. Since 2019, the funding of the MUCF has been relying on voluntary contributions from several European countries. The MUCF is an activity hosted by the European and Mediterranean Plant Protection Organization (EPPO). The MUCF's mission is 'to support European stakeholders in closing crop protection gaps in minor uses. It coordinates collaboration and information exchange to improve the availability of sustainable crop protection solutions.

19. The objective is to enable farmers to produce high-quality crops and contribute to sustainable European agriculture.

The MUCF work comprises a range of activities:

- the collection of minor use needs, the search for possible solutions, the support of data generation (residue/efficacy) projects.
- the facilitation of expert groups (several commodity expert groups, one horizontal expert and one residue expert group), which meet twice a year.
- the collection of national information on minor crops and minor uses on a European level.
- the maintenance and development of the European Minor Uses Database (EUMUDA).
- the communication on minor uses issues and MUCF work progress to stakeholders through the website, newsletters, social media and to the EU Standing Committee on Plants, Animals, Food and Feed (DG-Sante).

20. Different actors are involved in this work: governments (representatives from Ministries and competent authorities), policy-makers, growers' organisations, national minor uses experts, PPP industry and PPP industry associations (conventional and biological), research centres, advisory services, and European and international partners.

21. The MUCF liaises with all EU Member States, MUCF Member and Partner Countries, growers' associations and other organisations active internationally in the field of minor uses, such as the OECD and the IR-4 Project. The MUCF stimulates and supports further harmonization e.g., in relation to regulatory procedures, crop group and pest group definitions and developed a document to provide comprehensive information on European minor use procedures. In 2022, the MUCF released an explanatory note, which was endorsed by the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF), titled *Comprehensive Information on Minor Uses Procedures According to Regulation (EC) No 1107/2009*. The note is accessible under the following link: https://minoruses.eu/resources/explanatory_note

22. The MUCF maintains and further develops the European Minor Uses Database ([EUMUDA](#)) as a key structure to identify minor uses gaps, share information on them and provide an overview of ongoing projects and their status and reference lists of what are considered "minor uses and crops" in different European countries and minor uses useful links. The MUCF is supporting several commodity expert groups (MUCF commodity expert groups: Fruits and Vegetables, Seeds, Ornamentals, Hops, Tobacco, Herbs and Species, and Mushrooms) to solve minor use problems with an IPM approach. In that respect, the MUCF has established a strong link with research networks on IPM ([C-IPM ERANET](#)).

23. The European Minor Uses Coordination Facility organised in February 2020 a workshop on "Minor Uses and Speciality Crops: The way forward in Europe". This workshop aimed at enhancing regulatory harmonisation, to come to a sustainable European way forward for minor uses' work, and to establish a roadmap containing concrete actions related to (i) obstacles in minor uses work, (ii) IPM research and implementation, (iii) communication and awareness-raising, and (iv) the future organisation of minor uses' work in Europe ([Minor Uses - Meetings](#)).

24. More information about the MUCF can be found here: <https://minoruses.eu/>

Australian Government - Improved access to agricultural and veterinary chemicals program

25. The Australian Government in 2014 commenced a program to help farmers gain improved access to safe and effective agricultural and veterinary (agvet) chemicals. The Federal Department of Agriculture,

Fisheries and Forestry works closely with the Australian Pesticides and Veterinary Medicines Authority (APVMA), grower groups, rural Research and Development Corporations (RDCs) and the chemical industry to deliver this commitment.

26. The program operates an annual collaborative forum to develop a priority list of industry-nominated needs to inform the governments' allocation of grants to support data generation for the making of regulatory submissions. Participants in the annual forum include rural Research & Development Corporations (RDCs), the National Farmers' Federation, Animal Health Australia, Plant Health Australia and the Australian federal and state and territory governments. Since its inception, the program has provided grant funding support in excess of \$11.5M for 208 identified priority minor use needs.

27. The program has a range of activities:

- supporting collaboration between growers, producers and the chemical industry
- establishing an official Australian crop grouping list and associated regulatory guidelines
- migrating some uses authorised under permits to product labels
- an assistance grants program to help fund the generation of sufficient data to support regulatory submissions
- improving the prioritisation of grants to the needs of Australian agriculture

28. More information about the Australian Government initiative can be found here: <https://www.agriculture.gov.au/agriculture-land/farm-food-drought/ag-vet-chemicals/improved-access-agvet-chemicals>

Minor Use Foundation

29. The Minor Use Foundation (MUF), a non-profit private foundation, was founded in 2018 to promote minor uses and speciality crop pest management solutions for growers globally. The MUF hosts the Global Minor Use Priority setting meetings, funds research to identify and develop pest control solutions and provides training and capacity building globally. Together with its partners and cooperators the MUF identifies and implements work to expand uses, harmonise Maximum Residue Limits (MRLs), and support grower needs.

30. The MUF Mission is to: Harmonize global residue tolerances through developing and implementing research priorities set through the collaboration of universities, domestic and foreign governments, speciality crop growers and grower groups, non-profits and for-profit organisations. Facilitate and coordinate cooperation among Minor Use Organisations globally. Implement Global Minor Use priorities (Grower Plant Protection Needs) and host Global Minor Use Priority setting meetings and the Global Minor Use Summit.

31. In 2020 the MUF hosted the third Global Minor Use Priority setting meeting attended by over 180 participants representing 38 countries across the globe. During 2021-22 the MUF has hosted regional priority-setting workshops across Africa, Asia and Latin America. The MUF in collaboration with its partners has commenced a number of research projects for the generation of residue data for identified grower needs. The [Global Minor Use Portal](#) contains information and materials from the first, second and third global minor use summits conducted in 2007, 2012 and 2017.

32. The MUF in 2021 in collaboration with the Food Agriculture Organization (FAO) of the United Nations, and with the support of the United States Department of Agriculture (USDA), conducted a training workshop focused on risk analysis, supervised trials, and estimation of MRLs as contained in FAO Manual 224 *Evaluation of pesticide residues for estimation of maximum residue levels and calculation of dietary intake – Training manual*.

33. More information about the Minor Use Foundation, including videos from training workshops and regional priority setting meetings can be found here (website has material in English, Spanish and French): www.minorusefoundation.org

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DEFINING MINOR USES

34. The definition of a minor use varies globally, although most definitions are associated with providing support for crop protection uses that are not sufficiently large to generate commercial interest in seeking their registration, due to a limited return on the investment required to meet regulatory requirements. The definitions are used for various purposes but principally are for establishing regulatory requirements and policies for enhancing the registration of minor uses. Typically, they are complemented with a range of measures that are aimed to support data generation (i.e., dedicated minor use programs discussed above) and reduce the regulatory burden on registering minor uses through globally accepted and scientifically based principles (refer to section below on *Risk Assessment Tools*).

35. In 2009, the OECD published an *OECD Guidance Document on Defining Minor Uses of Pesticides* to enhance the consistency among countries in the methods used in defining minor uses. As noted by OECD in the publication:

Minor use definitions serve as an important mechanism to ensuring that minor uses that are required by agricultural producers are appropriately regulated and where applicable include mechanisms that reduce the regulatory burden and are complemented by providing regulatory incentives to enhance their registration. This may include things such as reduced data requirements (where relevant), reduced assessment fees, increased periods of data protection and expedited regulatory review.

36. The OECD guidance recommends that four key elements that should be considered in developing, using and maintaining a definition. These are:

- a) Development and implementation of minor use definitions should be conscious of and reflect the different factors that result in minor uses. In particular, the mechanism(s) should be specifically designed to enable considerations to be made for those uses that do not provide sufficient economic return for an applicant to justify registration of the use.
- b) Determinations of what are minor uses derived via an economic return approach should remain independent from determinations of regulatory risk assessment and establishing data requirements of major and minor crops derived via the risk assessment approach.
- c) Definitions and mechanism(s) of determining minor uses should be regularly reviewed to ensure that they are current and up to date with the crop protection trends and needs of agricultural producers.
- d) Minor use definitions should be complemented by regulatory incentives that are developed to encourage the registration of more minor uses.

37. A copy of the OECD guidance document can be found here: <https://www.oecd.org/chemicalsafety/pesticides-biocides/publicationsonminorusesofpesticides.htm>

38. In 2015, the Codex Committee on Pesticide Residues (CCPR) produced guidance to facilitate the establishment of MRLs for minor crops. The guidance is based on dietary consumption within the GEMS Food Cluster data and accordingly assigned commodities into three categories for the minimum number of trials necessary to support the establishment of Codex MRLs. The three categories are as follows:

- Category 1: no data in FAO Stat and No GEMS Food Cluster data: to be considered on a case by case basis
- Category 2: <0.5% worldwide and <0.5% in all of the clusters: minimum of 4 trials
- Category 3: <0.5% worldwide and >0.5% in all of the clusters: minimum of 5 trials

39. The classification of commodities into these three Categories may be obtained from the Report of the 47th Session of the CCPR (refer to Appendix XI) available here:

https://www.fao.org/input/download/report/926/REP15_PRe.pdf

4 DATABASES

40. There are many databases that contain information associated with minor uses. These can be in the form of project databases containing information on prioritisation processes and minor use projects underway or completed by minor use programs, regulatory databases containing information on the registration status of products and their uses in various countries and MRL databases.

41. These databases can be useful resources when seeking to identify solutions to minor use needs and existing data.

Project databases

42. The IR-4 Project maintains two databases that contain information on research activities and the status of projects undertaken by IR-4, including research protocols and performance (efficacy/target safety) data. Searches can be performed for crops, target pests/diseases, products and/or actives.

- IR-4 Project Food Crops Database: <https://www.ir4project.org/fc/fc-database-search-options/>
- IR-4 Project Environmental Horticulture Database: <https://www.ir4project.org/ehc/ehc-registration-support-research/environmental-horticulture-database-a-2/>

43. The Canadian Pest Management Centre maintains the following databases on projects it has initiated and results can be sorted by crop, target (pest/disease), product, active ingredient, project id or project status.

- [Integrated Pest Management Solutions](#)
Projects exploring lower-risk pest control options for specific agricultural crops
- [Minor-use pesticides](#)
Field and greenhouse projects to support product registrations for the management of weeds, insect pests and plant pathogens on specific, smaller-acreage crops
- [Biopesticides](#)
Projects investigating and promoting naturally-occurring options to control insects, weeds and plant diseases

44. The European Minor Use Coordination Facility maintains the European Minor Uses Database ([EUMUDA](#)). The information available in EUMUDA includes:

- list of minor use needs from MUCF Member and Partner countries
- overview of ongoing projects and their status.

45. Not all information on individual projects is accessible to the public. Rules for confidentiality and access rights have been implemented.

46. Results can be sorted by a number of attributes including crop, crop group, target (pest/disease), country and project status. The database can be accessed here: <https://www.eumuda.eu/>

47. EUMUDA also provides linkages to national crop areas, what crops are considered minor uses in European countries and national databases of registered plant protection products.

MRL databases

48. Various national regulatory authorities publish lists of MRLs established in their country and/or region.

- Canadian MRLs can be accessed here: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/pesticides-food/maximum-residue-limits-pesticides.html>
- US MRLs can be accessed here: <https://www.epa.gov/pesticide-tolerances/how-search-tolerances-pesticide-ingredients-code-federal-regulations> (or via the BCGlobal database mentioned below)
- MRLs established by the European Commission can be accessed here: <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/mrls>
- Australian MRLs can be accessed here: <https://apvma.gov.au/node/10806>
- New Zealand MRLs can be accessed here: <https://www.mpi.govt.nz/agriculture/agricultural-compounds-vet-medicines/maximum-residue-levels-agricultural-compounds/>
- Codex MRLs published by FAO are available at: <https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/en/>

Registration databases

49. Various national regulatory authorities maintain databases and/or lists of products registered in their country. The level of information varies from country to country. The majority of databases enable searches for crop, target pest/disease, product trade name, active ingredient and several provide links to copies of approved labels.

- Canada: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/registrants-applicants/tools/pesticide-label-search.html>
- US: <https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:1>
- Australia: Registrations: <https://portal.apvma.gov.au/pubcris>
Off-Label Approvals: <https://portal.apvma.gov.au/permits>
- UK: <https://www.hse.gov.uk/pesticides/databases/index.htm>
- New Zealand: <https://eatsafe.nzfsa.govt.nz/web/public/acvm-register/>
- European Union: refer to EUMUDA which provides links to individual MUCF Member and Partner countries at: <https://www.eumuda.eu/>

5 RISK ASSESSMENT TOOLS & GUIDELINES

50. To enhance the registration of minor uses many tools and guidelines have been developed by individual countries, OECD, FAO and APEC. These are commonly associated with risk assessment principles for the assessment of crop protection products including for minor uses and cover topics such as efficacy and target safety, crop grouping and establishing domestic and import MRLs. The purpose of tools and guidelines is to inform both applicants and regulatory officers of agreed methods in assessing minor uses, providing greater confidence and clarity in preparing and assessing submissions, whilst reducing regulatory burden in registering minor uses.

Crop grouping

51. For the purpose of scientific assessment and regulation, crops are usually grouped by similarities in botanical classification, morphology, growth habit, the portion of the commodity harvested and/or consumed, and cultural practices. This is a common practice among international regulators and is used to streamline the establishment of data guidelines and regulatory risk assessment. It is particularly important for minor crops because the data generated to register a chemical for a major crop use can be extrapolated to include uses on other minor crops in the same group – without the need for data for each crop in the group. Crop grouping schemes, once established, enable formal recognition of data generated in a subset of crops to be extrapolated to other related crops of the same crop group with little or no additional data (or assessment) required.

52. The Codex Alimentarius in its publication [Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups](#) noted the following general principles for the selection of representative commodities.

Representative commodities within each Classification commodity group and subgroup will be selected and proposed, based on consideration of all available information. The following principles will be used for the selection of representative commodities:

-A representative commodity is most likely to contain the highest residues.

-A representative commodity is likely to be major in terms of production and/or consumption.

-A representative commodity is most likely similar in morphology, growth habit, pest problems and edible portion to the related commodities within a group or subgroup.

The application of the three principles in the selection of representative commodities is based on the assumption that all of the commodities, covered by the commodity group maximum residue limit (MRL), are produced following a similar use pattern or good agricultural practice (GAP).

To facilitate the global use of the commodity groups for MRLs, alternative representative commodities may be selected giving flexibility for use of residue research conducted in different countries or regions that may vary due to regional differences in dietary consumption and/or areas of production for certain commodities.

53. Several countries maintain published lists of crop groups and key representative commodities.
- Canada: <https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/protecting-your-health-environment/pesticides-food/residue-chemistry-crop-groups.html>
 - US: <https://www.epa.gov/pesticide-registration/pesticide-tolerance-crop-grouping-revisions> see also the IR-4 Project: <https://www.ir4project.org/fc/crop-grouping/>
 - Australia: <https://apvma.gov.au/crop-groups>
 - European Commission: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0062&from=EN>
 - FAO – Codex Commodity Categories: <https://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/commodities/en/>
 - Codex Alimentarius – Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides to Commodity Groups: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B84-2012%252FCXG_084e.pdf

Crop Residue Field Trials

54. Developed by the OECD Residue Chemistry Expert Group the OECD Guidance Document on Crop Field Trials was developed to assist in the planning of residue trials and interpretation of results.

55. The guidance document focuses on and discusses various aspects including:

- Crop grouping
- Extrapolation
- Proportionality
- Conversion factors
- Formulations (equivalency of formulations)
- Geographical distribution of trials
- Number of trials
- Results from residue trials to be used in MRL estimations
- MRL estimations

56. Guidance for minor uses is aimed at reducing data generation required for a minor use by leveraging data that has been generated in other (usually major) commodities and regions.

57. These aspects are covered and discussed in detail in the four sections of the OECD Guidance Document. The sections on *Crop grouping* and *Extrapolation* explain the selection and use of data from representative commodities, thus eliminating data generation for minor commodities of the same crop group. The sections on *Geographical distribution* and *Number of trials* explain provisions for reducing data generation for field trials by as much as 40-50% and cases where the need for local field trials can offset by a larger, more comprehensive data set. However, such provisions require that the GAP and production conditions are the same for the data generation and extrapolation commodities.

MRL Calculator

58. The [OECD Maximum Residue Limit \(MRL\) Calculator](#) is a statistical procedure for setting Maximum Residue Limits (MRLs). It was developed by the OECD Residue Chemistry Expert Group with input from regulators, industry experts and academics. The objectives of the calculator are to:

- provide a practical implementation of sound statistical methods.
- be simple to use without requiring extensive statistical knowledge.
- produce clear and unambiguous MRL proposals for most data sets.
- harmonise existing procedures in use.

59. The calculator is in the form of two Excel Spreadsheets to accommodate either single data sets, or multiple data sets and is accompanied by a *User Guide* and *Statistical White Paper*.

Use of International data

Residue data

60. The OECD Guidance Document on Crop Field Trials, as discussed in the above section *Crop Residue Field Trials*, has guidance on the relevance and use of international residue data.

Efficacy and Target safety (phytotoxicity) data

61. The OECD [Guidance Document on the Exchange and Use of International Efficacy and Crop Safety Data for Minor Uses](#) provides guidance on using efficacy and crop safety data generated in other countries and regions (as well as from other sources) and evaluations conducted by other regulatory authorities. The guidance is broken into four key areas:

- Basic principles
- Principles for applications based on authorisations in another country
- Relevance of foreign data
- Use of data from other sources

62. The Canadian PMRA has a sections in its [Value Guidelines for New Plant Protection Products and Label Amendments](#) on minor uses and [Value Assessment of Pest Control Products](#) which include guidance on the use of foreign registrations and use history information.

Extrapolation

63. The above section on *Crop grouping* contains many references to guidance documents for the extrapolation of residue data between accepted related commodities. However, many countries also utilise extrapolation principles for other aspects of regulatory risk assessments, including efficacy, target safety, the environment and worker/applicator exposure. The following paragraphs reference guidance documents in these areas.

European Commission

64. The European Commission has published [Technical Guidelines](#) on data requirements for setting MRLs, comparability of residue trials and extrapolation of residue data on products from plant and animal origin.

EPPO Extrapolation Tables

65. The European and Mediterranean Plant Protection Organisation (EPPO) published efficacy and crop safety [Extrapolation tables for minor uses](#) in conjunction with the [EPPO Standard PP 1/257 Efficacy and crop safety extrapolations for minor uses](#). The tables contain specific guidance for herbicides, fungicides, insecticides, as well as specific pests and diseases and from which commodities extrapolations may be transferred to other crop commodities, in particular minor crops. These tables are available on the EPPO website in pdf format. The EPPO Secretariat is currently working on transforming the tables into a searchable database so that users can more easily retrieve information on the different possibilities for extrapolation.

OECD

66. The OECD [Guidance Document on the Exchange and Use of International Efficacy and Crop Safety Data for Minor Uses](#) contains information on the use of expert knowledge, extrapolation from other authorised uses and laboratory data for minor targets.

Risk envelope approach

67. The European Commission has published a [Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”](#). The guidance has relevance to the registration of minor uses employing similar principles to ‘crop grouping’, whereby for each area of a risk assessment, the supported uses of a product can be grouped.

The risk envelope approach, taking into account certain criteria (e.g., crop, application rate, number of applications, timing, etc.), acknowledges that an assessment can be targeted at the group rather than at individual uses, or can be extrapolated from a worst case scenario to other scenarios where the GAP is less critical or the same without the need for further data or risk assessment. The approach has the most relevance for the consideration of human health and environmental risk assessments, with limited relevance for residues. The approach is not utilised for efficacy, target safety or product chemistry. For further guidance on the extrapolation of residue, efficacy and target safety refer to the above sections.

Australia

68. The APVMA has published a guideline, [Representative crops and extrapolation principles for risk assessment and data waivers](#), that outlines where extrapolation or data waivers are possible. The document provides guidance, tables and examples where data extrapolation and waivers are accepted from either (i) representative commodities to other members of the same crop group and (ii) between related crop groups for residues, efficacy and target safety, environment and worker/operator safety.

APEC Import MRL Guideline for Pesticides

69. Commodities that are treated with pesticides are commonly traded globally, and each country has its own systems for the establishment of MRLs. Producers are regularly faced with situations where MRLs are either absent or lower in export markets compared to their own regulations and standards. These instances commonly occur where the destination market may not have the active substance registered, the commodity is not grown, the pesticide has not been considered for use on the commodity, or the use patterns for the active substance may be different resulting in different or lower residues. Increasingly, producers are seeking that countries provide efficient solutions to these issues so as to not impede trade.

70. The APEC Food Safety Cooperation Forum published the 2016 [APEC Import MRL Guideline for Pesticides](#) that outlines approaches for the establishment of import MRLs and to achieve alignment of MRLs. The guideline provides information on the import MRL assessment process and the type of information that may be required to support risk assessments for an import MRL. The guideline also provides scenarios for different situations that may arise and potential outcomes based on information available and regulatory status of the active substance. These include scenarios in the presence or absence of MRLs and Health Based Guidance Values (ADI and/or ARfD), either domestically, by Codex or JMPR and/or through recognition of other countries standards.

6 REGULATORY INCENTIVES

71. Many countries implement incentives to facilitate the registration of minor uses. The section above on *Risk assessment tools and guidelines* outlines a range of technical approaches taken by countries to reduce the regulatory burden and facilitate the registration of minor uses.

72. The OECD has published a [Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses](#) that summarises and discusses a number of approaches adopted by various countries. These include:

- economic incentives through fee reductions or waivers, expedited reviews and extension of data protection periods
- authorisation procedures through third party registrations and temporary approvals
- research through data generation assisted schemes
- promotion of safer alternatives through incentives for reduced risk pesticides, and
- liability waivers or disclaimers

7 JOINT REVIEWS / WORKSHARING

73. Several countries' regulatory agencies share the effort in assessing new regulatory submissions and exchanging assessment reports or implementing mutual recognition for existing regulatory decisions. These efforts aim to facilitate access to new markets for new active substances or extensions of use by reducing regulatory burdens and harmonising regulatory outcomes including the establishment of MRLs. The examples are the [zonal system of authorisation in the EU](#) and the [North American Free Trade Agreement's \(NAFTA\) Technical Working Group \(TWG\)](#).

74. The OECD has also published a [Guidance Document on the Planning and Implementation of Joint Reviews of Pesticides](#), where the evaluation of a pesticide dossier is shared by two or more countries. It requires that the dossier be submitted to all participating regulatory authorities simultaneously. In advance of receiving the submission, the participating authorities agree on assessment timelines and work allocation for each science discipline. Data reviews are exchanged and peer-reviewed across the participating authorities. The document provides guidance for both applicants and regulatory authorities on the steps for planning and implementing a joint review.