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ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
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OECD Survey on Efficacy & Crop Safety Data Requirements & Guidelines for the Registration of Pesticide Minor Uses: Survey Results

Series on Pesticides
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INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

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

Environment Directorate

ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT

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

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

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

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No. 25 *The Assessment of Persistency and Bioaccumulation in the Pesticide Registration Frameworks within the OECD Region* (2005)

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

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No. 38 *Survey of the Pesticide Risk Reduction Steering Group on Minor Uses of Pesticides* (2007)

No. 39 *Guidance Document on Pesticide Residue Analytical Methods* [also published in the series on Testing and Assessment, No. 72] (2007)

No. 40 *Report of the Joint OECD Pesticide Risk Reduction Steering Group EC-HAIR Seminar on Harmonised Environmental Indicators for Pesticide Risk* (2007)

No. 41 *The Business Case for the Joint Evaluation of Dossiers (Data Submissions) using Work-sharing Arrangements* (2008)

No. 42 *Report of the OECD Pesticide Risk Reduction Steering Group Seminar on Risk Reduction through Better Worker Safety and Training* (2008)

No. 43 *Working Document on the Evaluation of Microbials for Pest Control* (2008)

Guidance Document on Magnitude of Pesticide Residues in Processed Commodities - only published in the Series on Testing and Assessment, No. 96 (2008)

No. 44 *Report of Workshop on the Regulation of BioPesticides: Registration and Communication Issues (2009)*

No. 45 *Report of the Seminar on Pesticide Risk Reduction through Education / Training the Trainers* (2009)

No. 46 *Report of the Seminar on Pesticide Risk Reduction through Spray Drift Reduction Strategies as part of National Risk Management* (2009)

No. 47 *OECD Survey on Countries' Approaches to the Collection and Use of Agricultural Pesticide Sales and Usage Data: Survey Results* (2009)

No. 48 *OECD Strategic Approach in Pesticide Risk Reduction* (2009)

No. 49 *OECD Guidance Document on Defining Minor Uses of Pesticides* (2009)

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No. 51 *OECD Survey on Pesticide Maximum Residue Limit (MRL) Policies: Survey Results* (2010)

No. 52 *OECD Survey of Pollinator Testing, Research, Mitigation and Information Management: Survey Results* (2010)

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No. 56 *OECD MRL Calculator User Guide* (2011)

No. 57 *OECD MRL Calculator MRL Statistical White Paper* (2011)

No. 58 *Report of the OECD Seminar on Pesticide Risk Reduction Strategies Near/in Residential Areas* (2011)

No. 59 *Report of the OECD Seminar on Risk Reduction through Prevention, Detection and Control of the Illegal International Trade in Agricultural Pesticides* (2011)

No. 60 *Guidance Document on the Planning and Implementation of Joint Reviews of Pesticides* (2011)

Published separately

OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances-Monograph Guidance (1998, revised 2001, 2005, 2006)

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)

Report of the OECD Workshop on the Economics of Pesticide Risk Reduction (2001)

Report of the OECD-FAO-UNEP Workshop on Obsolete Pesticides (2000)

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

Report of the 2nd OECD Workshop on Pesticide Risk Indicators (1999)

Guidelines for the Collection of Pesticide Usage Statistics Within Agriculture and Horticulture (1999)

Report of the [1st] OECD Workshop on Pesticide Risk Indicators (1997)

Report of the OECD/FAO Workshop on Pesticide Risk Reduction (1995)

About the OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 34 industrialised countries in North and South 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 **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 (www.oecd.org/ehs/).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

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, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD. UNDP is an observer. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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FOREWORD

This document contains the report of a survey carried out in 2009 by the OECD Expert Group on Minor Uses (EGMU), a sub-group of the Working Group on Pesticides, on "Efficacy & Crop Safety Data Requirements & Guidelines for the Registration of Pesticide Minor Uses". The aim of the survey was to provide an overview of regulatory requirements and mechanisms pertaining to minor uses in OECD member countries.

This report is a collation of aspects pertaining to three key areas of minor uses:

1. Regulatory data requirements and/or guidelines related to efficacy and crop safety,

2. Use and/or exchange of international data, and

3. Crop and pest grouping systems adopted by OECD countries for the registration of minor uses.

The report also contains three recommendations that are principally focused on:

1. Further progressing harmonisation of efficacy & crop safety data requirements

2. Further progressing harmonisation of guidelines for assessing minor uses, and

3. Enhancing data exchange between member countries.

It is acknowledged that differences exist amongst member countries as to what constitutes a minor use, as can the use pattern, pests and diseases that may not always be suitable for exchange. Continued discussions amongst member countries on principles for assessing minor uses will enhance the potential for the exchange and use of data and data reviews where possible.

The Canada Pest Management Regulatory Agency (PMRA) designed the survey with input from EGMU members. PMRA also compiled and analysed the survey responses. The development of this report was overseen by the Chair of the EGMU, Alan Norden (Australia), and was reviewed on several occasions by EGMU members as well as by delegates of the Registration Steering Group and of the Risk Reduction Steering Group, two sub-groups of the Working Group on Pesticides.

The draft survey report was approved by the Working Group on Pesticides during its 26th meeting on 28-29 March 2011.

The Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD agreed that this document be unclassified and made available to the public. It is being published under the responsibility of the Secretary-General of the OECD.

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EXECUTIVE SUMMARY

1. In response to an OECD survey conducted in 2009 on the efficacy and crop safety data requirements and guidelines for the registration of pesticide minor uses, sixteen countries responded: Australia, Belgium, Canada, Czech Republic, Germany, Ireland, Italy, Japan, Netherlands, New Zealand, Portugal, Slovak Republic, Slovenia, Switzerland, United Kingdom and United States.

2. The report is a collation of aspects pertaining to three key areas of minor uses:

- Regulatory Data Requirements and/or Guidelines,
- Use and/or Exchange of International Data, and
- Crop and Pest Grouping Systems adopted by OECD countries for the registration of minor uses.

3. Most responding countries (14 out of 16) require efficacy and crop safety data to support minor use registration; however in six countries where off label use is allowed, efficacy and crop safety data are not required for those off label uses.

4. Guidelines are generally available for minor uses (11/16). Most countries accept 3 trials only to support a minor use although a larger number might be required in certain cases.

5. A majority of respondents (9/16) indicated that they would accept another country minor use registration; however in 7/9 countries it is limited to EU member states, e.g., zone approach. Most respondents (14/15) will accept data generated in other countries to support domestic minor use registration if the trials conditions are comparable, however it is often limited to EU member states (6/12).

6. Although the efficacy and crop safety data are considered confidential (15 & 14/16), they can be shared with other regulatory bodies (10/16). Regulatory reports and summaries are also considered confidential but can be shared with other regulatory bodies (12/16).

7. Crop and pest grouping systems are utilised in the vast majority of respondents for crops (15/16) and pests (12/16) to reduce data requirements. Generally two grouping approaches are used, the first based on the EPPO guidelines, the second on rationale considering the biology of the crop and pest.

8. Based on the results of the survey, it appears possible to exchange data and reviews to support the registration of minor uses across jurisdictions. The amount and type of data required are similar enough to support or at least facilitate minor use registration across jurisdictions.

9. The report contains three recommendations that are principally focused on (i) further progressing harmonisation of efficacy & crop safety data requirements (ii) further progressing harmonisation of guidelines for assessing minor uses, and (iii) enhancing data exchange between member countries. It is however acknowledged that differences exist amongst member countries as to what constitutes a minor use, as can the use pattern, pests and diseases that may not always be suitable for exchange. Although continued discussions amongst member countries on principles for assessing minor uses will enhance the potential for the exchange and use of data where possible.

RECOMMENDATIONS

10. The aim of the survey conducted was to provide an overview of regulatory requirements and mechanisms pertaining to minor uses in each member country. It is therefore recommended that:

(i) Member countries when developing efficacy & crop safety data requirements and guidelines for minor uses should (where possible) utilise the report in considering options with a view to harmonising data requirements for minor uses with other member countries that would facilitate data sharing and performing joint reviews for minor uses.

(ii) The Working Group on Pesticides through Risk Reduction Steering Group (RRSG) & Registration Steering Group (RSG) and other interested individual countries utilise the report as a basis for exploring options to progress harmonisation (where possible) in certain key areas universal to minor use data requirements, such as residues and efficacy/crop safety.

(iii) To support a more global approach to minor use registration, member countries should examine further work to expand information sharing agreements and consideration of foreign data and reviews across all OECD member countries.

SUMMARY OF THE SURVEY RESULTS

1. Regulatory Data Requirements and/or Guidelines

		Efficacy (Yes or No)	Crop Safety (Yes or No)	Comments
1a	**Is data required prior to registration?**	14 yes	14 yes	Note 1: 6 countries also indicated that data was not required for off-label authorisations or submissions made by persons other than the registrant. Note 2: The US EPA does not review efficacy and crop tolerance data.
1b	**Are guidelines outlining data requirements available?** *If YES then please provide website link(s) or reference(s).*	15 yes	14 yes	
1c	**Are guidelines tailored for minor uses?**	11 yes 4 no	10 yes 4 no	
1d	**Do established guidelines specify how many trials are required?** *If YES then please indicate in the following table below the numbers of trials required.*	11 yes 4 no	9 yes 4 no	
1e	**Is it common to label minor uses according to e. g. resistance or use within the framework of integrated pest management systems?**	7 yes 8 no	5 yes 8 no	
Additional comments: Not clear if questions address regular or minor use or both				

1. Regulatory Data Requirements and/or Guidelines (Continued)

1f. Numbers of efficacy & crop safety trials required

	Number efficacy trials		Number crop safety trials		Comments
	Major use	**Minor use**	**Major use**	**Minor use**	
Herbicides	5 to 15	0 to 8	5 to 10	0 to 8	For minor use 0 trials refer to off label use, use of rationale and extrapolation. Most respondent use the efficacy trials to assess crop safety in minor uses.
Insecticides	3 to 15	0 to 8	0 to 10	0 to 8	See above
Fungicides	3 to 15	0 to 8	0 to 10	0 to 8	See above
Biopesticides	3-15	0 to 4	0 to 8	0 to 4	See above
Other?	6 to 10	0 to 4	6 to 10	0 to 4	Molluscide, PGR
Additional comments: For minor use 3 trials are required in most cases					

2. Use and/or Exchange of International Data

		Yes or No	Comments
2a	**Is registration (alone) in another country acceptable to support registration of a minor use in your country?** *If YES, from any country/region or only specific countries/regions or under certain circumstances?*	9 yes 6 no	Seven respondents specified from EU countries only
2b	**Is data generated in other countries/regions acceptable to support minor use registration in your country?** *If YES, from any country/region or only specific countries/regions or under certain circumstances?*	14 yes 1 no	Most respondents indicated restriction on the geographical region or need for rationale demonstrating that conditions are comparable. Six respondents restricted acceptance to EU members
2c	**Is a regulatory authority data evaluation report (with or without the accompanying data) from other countries acceptable to support registration in your country?** *If YES, is a data evaluation report from any country (regulatory authority) acceptable or only data evaluation reports from specific countries (or regions) acceptable?*	11 yes 4 no	Five European countries restricted acceptance to within EU only.
2d	**Is the label (e.g. resistance, integrated pest management) from other countries acceptable/enough to support/deal with labelling systems for the minor use approval processes in your country?**	3 yes 11 no 1 maybe	
Additional comments:			

2. Use and/or Exchange of International Data (Continued)

		Are the following data/documents considered confidential? (Yes or No)	Can the information be shared with other regulatory bodies? (Yes or No)	If information is published please provide website link or reference	Comments
2e	**Efficacy data (submitted by applicant)**	15 yes 0 no	10 yes 5 no		
2f	**Crop safety data (submitted by applicant)**	14 yes 1 no	10 yes 5 no		
2g	**Efficacy evaluation reports and/or summaries (compiled by the regulator)**	9 yes 6 no	12 yes 3 no		
2h	**Crop safety evaluation reports and/or summaries (conducted by the regulator)**	10 yes 5 no	12 yes 3 no		
Additional comments:					

3. Crop & Pest Grouping Systems

		Between crops (for efficacy and crop safety) (Yes or No)	Between pests/diseases (for efficacy) (Yes or No)	Comments
3a	**Are grouping systems used for reduced data requirements, data evaluation and extrapolation?** *If YES and if available please provide website link or reference.*	12 yes 3 case by case	10 yes 2 no 2 case by case	All respondents use a grouping system.
3b	**Please list what you consider are the important factors/criteria in considering data extrapolation between crops and target pests/diseases.**	10 grouping	8 grouping	Generally 2 grouping approaches: EPPO guidelines or based on rationale considering the biology of the crop and pest. Expert knowledge used in many case to decide on the proposed groups.
Additional comments:				

ANNEX 1

COMPILATION OF ALL RESPONSES PROVIDED BY RESPONDING COUNTRIES (IN TABULAR FORMAT)

1. Regulatory Data Requirements and/or Guidelines

		Efficacy (Yes or No)	Crop Safety (Yes or No)	Comments
1a	**Is data required prior to registration?**			
	AUSTRALIA	YES	YES	Off label authorisation (via permit) may be through extrapolation without need for data from the precise situation (crop and/or pest). Registration may also be similarly considered and granted via extrapolation.
	BELGIUM	YES	YES	
	CANADA	YES	YES	Efficacy data are required for registration. Observations on potential phytotoxicity are also required and may be conducted within efficacy trials.
	CZECH REPUBLIC	NO	NO	* only if the application is submitted by growers associations or state or scientific body. Industry has to provide full data package.
	GERMANY	YES	YES	
	IRELAND	YES	YES	There exists the possibility of “off label” approval which does not require these data sets.

		Efficacy (Yes or No)	Crop Safety (Yes or No)	Comments
	ITALY	YES	-	
	JAPAN	YES	YES	
	NETHERLANDS	YES	YES	No data required if it concerns an extension of authorisation = Off label?
	NEW ZEALAND	YES	YES	
	PORTUGAL	YES NO (OFF LABELS)	YES NO (OFF LABELS)	Efficacy and Crop Safety Data are required when approvals are required by companies; Efficacy and Crop Safety Data are not required when approvals are required by third parties (off-labels)
	SLOVAK REPUBLIC	YES	YES	The same data are required for authorized minor uses as are for the major crops. For unauthorized minor uses ("off-labels") are required: - expertise of biological efficacy from the view of efficacy on crop and crop safety (based on available data or extrapolation or mutual recognition) and proposed use - expertise on consumers safety and health protection (based on submitted residual studies, resp. extrapolation of residues, resp. mutual recognition)
	SLOVENIA	Yes for regular registration No for minor use	Yes for regular registration No for minor use	In the case of minor use registration, the user of a pesticide takes responsibilities for efficacy and crop safety.
	SWITZERLAND	YES	YES	Quality according to EPPO-Standards, no data necessary in cases covered by question 2a (see below)
	UNITED KINGDOM	YES	YES	Off label used allowed in the UK
	UNITED STATES	NO	NO	The US EPA requires efficacy data be submitted, reviewed and approved prior to registration of Minor-Use Pesticides only in certain circumstances for the registration of public health uses, such as hospital disinfectants, rodenticides and insecticides. Otherwise, registrants are required to have efficacy data but are not required to submit the data unless requested by the EPA.

		Efficacy (Yes or No)	Crop Safety (Yes or No)	Comments
1b	**Are guidelines outlining data requirements available?** *If YES then please provide website link(s) or reference(s).*			
	AUSTRALIA	YES	YES	http://www.apvma.gov.au/MORAG_ag/vol_3/part_8_efficacyandsafety.pdf It is noted that these guidelines are undergoing a complete revision, with the intention of including more specific guidance for minor uses.
	BELGIUM	YES	YES	http:/www.fytoweb.fgov.be/indexfr.htm
	CANADA	YES	YES	DIR2003-04: Efficacy Guidelines for Plant Protection Products. Note that these guidelines are in the process of being updated.
	CZECH REPUBLIC	YES	YES	www.srs.cz
	GERMANY	YES	YES	EPPO standards as follows: PP 1/181(3) Conduct and reporting of efficacy trials incl. good experimental practice PP1/226 Number of efficacy trials Web page: www.eppo.org
	IRELAND	YES	YES	www.eppo.org
	ITALY	YES	-	Guidelines of OEPP
	JAPAN	YES	YES	Data Requirements for Supporting Registration of Pesticides(Notification No. 12-Nosan-8147) http://www.acis.famic.go.jp/eng/shinsei/index.htm
	NETHERLANDS	YES	YES	EPPO Standard PP 1/224 Principles of efficacy for minor uses
	NEW ZEALAND	YES	YES	Only relates to design of trials and whether we require this information or not with an application.

		Efficacy (Yes or No)	Crop Safety (Yes or No)	Comments
	PORTUGAL	YES	YES	Use existing guidelines (from EPPO) PP 1/ 224 (Principles of efficacy evaluation for minor uses) PP 1/ 257 (Efficacy and crop safety extrapolations for minor uses) http://www.eppo.org/PPPRODUCTS/extrapolation/tables.htm (extrapolation tables)
	SLOVAK REPUBLIC	YES	YES	www.uksup.sk Some parts are being redone
	SLOVENIA	Yes for regular registration www.furs.si No for minor use	Yes for regular registration No for minor use	No written guidance for minor use exists, however, MRL for the crop concerned have to be established in EU Regulation on MRL and active substance has to be authorized in a EU Member State
	SWITZERLAND	YES	YES	Data requirements for major uses (but see 2a), EPPO-Standards, case-by-case expert decision may allow approval based on less data
	UNITED KINGDOM	YES	YES	http://www.pesticides.gov.uk/applicant_advice.asp?id=643&link=%2Fpsd%5Fpdfs%2Fregistration%5Fguides%2Fdata%5Freqs%5Fhandbook%2Fefficacy%2Epdf http://www.pesticides.gov.uk/applicant_advice.asp?id=733
	UNITED STATES	-	-	

		Efficacy (Yes or No)	Crop Safety (Yes or No)	Comments
1c	**Are guidelines tailored for minor uses?**			
	AUSTRALIA	NO	NO	The data required to support minor uses are largely equivalent to those required for major uses. Although, as noted above (1a) extrapolation is possible for registration where the data is relevant and generally from related major commodities and pests.
	BELGIUM	YES	YES	Only for some crops e.g. ornamentals, babyleaf,... Http://www.fytoweb.fgov.be/indexfr.htm (info for industry)
	CANADA	YES	YES	There is a section in DIR2003-04 specific to minor use.
	CZECH REPUBLIC	YES	YES	
	GERMANY	YES	YES	EPPO standards as follows: PP 1/257 (1) Efficacy and crop safety extrapolations for minor uses
	IRELAND	YES	YES	Less number of trials required for minor crops as opposed to major crop.
	ITALY	YES		not always
	JAPAN	YES	YES	
	NETHERLANDS	YES	YES	EPPO Standard PP 1/224 Principles of efficacy for minor uses
	NEW ZEALAND	NO	NO	
	PORTUGAL	YES	YES	
	SLOVAK REPUBLIC	YES	YES	Data requirements for minor crops are the same as for the major crops. The only difference is that only half number of trials is required.
	SLOVENIA	NO	NO	

		Efficacy (Yes or No)	Crop Safety (Yes or No)	Comments
	SWITZERLAND	NO	NO	
	UNITED KINGDOM	YES	YES	They cover both major and minor uses
	UNITED STATES	-	-	

		Efficacy (Yes or No)	Crop Safety (Yes or No)	Comments
1d	**Do established guidelines specify how many trials are required?** If YES then please indicate in the following table below the numbers of trials required			
	AUSTRALIA	NO	NO	The number of trials required are not specifically stated. Applicants are advised that the number need to be sufficient to achieve a statistically valid result, generally be for every host/pest combination, performed at three rates (lower, proposed and double) over two seasons, different pest pressures and in the major growing regions. Due to these variables and the proposed use seeking registration, numbers of trials required can vary.
	BELGIUM	YES	YES	We refer to the EPPO guidelines
	CANADA	YES	YES	
	CZECH REPUBLIC	YES	YES	
	GERMANY	YES	YES	EPPO standards as follows: PP1/226 Number of efficacy trials
	IRELAND	NO	NO	
	ITALY	YES		The references are always the guidelines of OEPP
	JAPAN	YES	YES	
	NETHERLANDS	YES	YES	EPPO Standard PP 1/224 Principles of efficacy for minor uses National guideline: Htb 1.0 via www.ctgb.nl
	NEW ZEALAND	NO	NO	
	PORTUGAL	YES	YES	
	SLOVAK REPUBLIC	YES	YES	Half number of trials is required for minor uses.

		Efficacy (Yes or No)	Crop Safety (Yes or No)	Comments
	SLOVENIA	no for minor use	no for minor use	
	SWITZERLAND	YES	YES	Same as data requirements for major uses
	UNITED KINGDOM	YES	-	Both UK guidance as above and EPPO guidance on numbers of trials
	UNITED STATES	-	-	

		Efficacy (Yes or No)	Crop Safety (Yes or No)	Comments
1e	**Is it common to label minor uses according to e. g. resistance or use within the framework of integrated pest management systems?**			
	AUSTRALIA	NO	NO	However product labels do carry Mode of Action symbols (groups) and advice for users to rotate between groups. Some labels may contain restrictions on the number of applications allowed per crop/season/year for resistance management reasons and may also refer to industry developed Resistance Management Plans where available for key pests.
	BELGIUM	NO	NO	
	CANADA	YES	YES	
	CZECH REPUBLIC	YES	YES	
	GERMANY	YES	YES	Labels often are given at product level not on use level, e. g. effect on natural enemies or effects on honey bees. The label is valid also for the minor use extension because, normally, use (application rate, numbers of application, technique etc.) is covered by authorisation. Resistance label, of course, is on use level also for minor use extensions.
	IRELAND	NO	NO	
	ITALY	YES		Sometimes
	JAPAN	NO	NO	
	NETHERLANDS	NO	NO	
	NEW ZEALAND	NO	NO	
	PORTUGAL	YES	YES	The minor uses on label are evaluated on similar procedures of major uses. So, resistance and integrated pest management systems are also considered in the evaluation of minor uses. In relation to resistance, the enemy and product risk are considered.

		Efficacy (Yes or No)	Crop Safety (Yes or No)	Comments
	SLOVAK REPUBLIC	YES	YES	It is common only for preparations which are registered since the year of 2007.
	SLOVENIA	NO	NO	
	SWITZERLAND	NO	NO	Most of this type of information is not included in the label but published elsewhere
	UNITED KINGDOM	YES	-	Certainly a resistance consideration is made for minor uses on product labels. Advice or warnings may also be made or even imposed on the number of permitted applications of a particular substance or mode of action.
	UNITED STATES	-	-	

Additional comments:
SLOVENIA: It is not clear from the questions whether they ask for data on regular authorization or specifically on minor use; or both
UNITED KINGDOM: All the comments made in this section relate to on label use. Interested parties may apply for off label use of a product for a specific purpose provided they hold appropriate safety data, approval can be granted without efficacy or crop safety data.

1. Regulatory Data Requirements and/or Guidelines (Continued)

1f. Numbers of efficacy & crop safety trials required

	Number efficacy trials		Number crop safety trials		Comments
	Major use	**Minor use**	**Major use**	**Minor use**	
Herbicides					
AUSTRALIA	3 studies*/ season / location.	< 3 studies if a new weed	Soil independent: 1 study/ major growing area over 2 seasons Soil dependent: 2 studies/ major growing area/major soil type over 2 seasons Additional trials may also be required to study cultivar susceptibility.	Same requirements as a major crop (in the absence of current guidance).	A recent guideline has been published for herbicides used in forestry. *A study is defined as a group of trials consisting of at least four replicate trials with equivalent Type 1 and/or Type 2 controls. However, the minimum number of replicate trials is governed by number of variables being investigated. As a minimum, trials must examine each crop/rate/disease combination. Guidelines state that as a general rule a minimum of 20 degrees of freedom should be available to allow for statistical analysis.
BELGIUM	NA	NA	NA	NA	
CANADA	Minimum of 5.	Minimum of 3.	Minimum of 5.	Minimum of 3.	- Number of trials reflect current approach and where the application rates fall within the presently registered use pattern.- Scientific rationales may be acceptable where appropriate
CZECH REPUBLIC	8	0* - 4	8	0* - 4	Only if the application is submitted by growers associations or state or scientific body. Industry has to provide full data package

	Number efficacy trials		Number crop safety trials		Comments
	Major use	Minor use	Major use	Minor use	
GERMANY	ca. 10	ca. 3	ca. 8	usually only observations	according to EPPO guideline
IRELAND	6-15	2-6	8	3	Crop safety data can be taken from effectiveness trials. If phytotoxic effects are seen at N rates then specific crop safety trials containing N and 2N rates should be conducted
ITALY	8	4	8	4	
JAPAN	at least six (*1)	at least two (*2)	at least six (*1)	at least two (*2)	
NETHERLANDS	2 x 6	-	2 x6*1	-	
NEW ZEALAND	-	-	-	-	
PORTUGAL	10 (6 to15)	3 (2 to 6)	**	**	* For protected crop the number is 6 (between 4 and 8) ** number of efficacy trials also include crop safety trials
SLOVAK REPUBLIC	min.8	min.4	min.8	min.4	
SLOVENIA	5	0	6	0	Efficacy: Results of five trials for each major weed and results of three trials for each minor weed listed on the label. Safety: Special crop safety trials are required for each crop in ”non weed situation”
SWITZERLAND	8	8	8	8	EPPO-Standards
UNITED KINGDOM	10	3	10	3	Specific crop safety trials with herbicides and PGRs required
UNITED STATES	-	-	-	-	

	Number efficacy trials		Number crop safety trials		Comments
	Major use	Minor use	Major use	Minor use	
Insecticides					
AUSTRALIA	NA	NA	NA	NA	The number of trials required are not specifically stated. Applicants are advised that the number need to be sufficient to achieve a statistically valid result, generally be for every host/pest combination, performed at three rates (lower, proposed and double) over two seasons, different pest pressures and in the major growing regions. Due to these variables and the proposed use seeking registration, numbers of trials required can vary.
BELGIUM	NA	NA	NA	NA	
CANADA	Minimum of 3 trials per crop-pest combination	See comments 0-3	See comments 0	See comments 0	Observations of potential phytotoxicity may be made within the efficacy trials. If phytotoxic effects are observed, dedicated trials may be required. Number of trials for minor use depends on whether extrapolation is possible from major use. In certain cases, no trials will be needed if crop and pest grouping with an acceptable rationale is sufficient. In other cases, such as for completely new uses, 1-3 confirmatory trials could be sufficient provided the application rate is within the range already established. Scientific rationales may be acceptable where appropriate
CZECH REPUBLIC	8	0* - 4	8	0* - 4	
GERMANY	ca. 10	ca. 3*)	usually only observations	usually only observations*)	according to EPPO guideline
IRELAND	6-15	2-6	8	3	crop safety data can be taken from effectiveness trials. If phytotoxic effects are seen at N rates then specific crop safety trials containing N and 2N rates should be conducted
ITALY	8	4	8	4	
JAPAN	at least six (*1)	at least two (*2)	at least six (*1)	at least two (*2)	

	Number efficacy trials		Number crop safety trials		Comments
	Major use	**Minor use**	**Major use**	**Minor use**	
NETHERLANDS	2 x 4	-	2 x4*[2]	-	
NEW ZEALAND	--	-	-	-	
PORTUGAL	10 (6 to15	3 (2 to 6)	**	**	* For protected crop the number is 6 (between 4 and 8) ** number of efficacy trials also include crop safety trials
SLOVAK REPUBLIC	min.8	min.4	min.8	min.4	
SLOVENIA	10 (min 6)	0	6	0	Crop safety data from efficacy trials are acceptable
SWITZERLAND	8	8	8	8	EPPO Standard
UNITED KINGDOM	10	3	10	3	For insecticide and fungicides, some specific crop safety work, but much of this can be done once the safety profile is established with specific crop safety studies on one or two crops by assessment in the efficacy studies.
UNITED STATES	-	-	-	-	
Fungicides					
AUSTRALIA	NA	NA	NA	NA	The number of trials required are not specifically stated. Applicants are advised that the number need to be sufficient to achieve a statistically valid result, generally be for every host/pest combination, performed at three rates (lower, proposed and double) over two seasons, different pest pressures and in the major growing regions. Due to these variables and the proposed use seeking registration, numbers of trials required can vary.
BELGIUM	NA	NA	NA		

	Number efficacy trials		Number crop safety trials		Comments
	Major use	**Minor use**	**Major use**	**Minor use**	
CANADA	Minimum of 3 trials per crop-pest combination	See comments	See comments	See comments	Observations of potential phytotoxicity may be made within the efficacy trials. If phytotoxic effects are observed, dedicated trials may be required. Number of trials for minor use depends on whether extrapolation is possible from major use. In certain cases, no trials will be needed if crop and pest grouping with an acceptable rationale is sufficient. In other cases, such as for completely new uses, 1-3 confirmatory trials could be sufficient provided the application rate is within the range already established. Scientific rationales may be acceptable where appropriate.
CZECH REPUBLIC	8	0* - 4	8	0* - 4	
GERMANY	ca. 10	ca. 3*)	usually only observations	usually only observations *)	according to EPPO guideline
IRELAND	6-15	2-6	8	3	crop safety data can be taken from effectiveness trials. If phytotoxic effects are seen at N rates then specific crop safety trials containing N and 2N rates should be conducted
ITALY	8	4	8	4	
JAPAN	at least six (*1)	at least two (*2)	at least six (*1)	at least two (*2)	
NETHERLANDS	2 x 4	-	2 x4*[2]	-	
NEWZEALAND	-	-	-	-	
PORTUGAL	10 (6 to15)	3 (2 to 6)	**	**	* For protected crop the number is 6 (between 4 and 8) ** number of efficacy trials also include crop safety trials
SLOVAK REPUBLIC	min.8	min.4	min.8	min.4	
SLOVENIA	10 (min 6	0	6	0	Crop safety data from efficacy trials are acceptable.

	Number efficacy trials		Number crop safety trials		Comments
	Major use	Minor use	Major use	Minor use	
SWITZERLAND	8	8	8	8	EPPO Standards
UNITED KINGDOM	10	3	10	3	For insecticide and fungicides, some specific crop safety work, but much of this can be done once the safety profile is established with specific crop safety studies on one or two crops by assessment in the efficacy studies.
UNITED STATES	-	-	-	-	
Biopesticides					
AUSTRALIA	NA	NA	NA	NA	The number of trials required are not specifically stated. Applicants are advised that the number need to be sufficient to achieve a statistically valid result, generally be for every host/pest combination, performed at three rates (lower, proposed and double) over two seasons, different pest pressures and in the major growing regions. Due to these variables and the proposed use seeking registration, numbers of trials required can vary.
BELGIUM	NA	NA	NA		
CANADA	Minimum of 3 trials per crop-pest combination	New Use: Minimum of 3 trials per crop-pest combination	See comments	See comments	Observations of potential phytotoxicity may be made within the efficacy trials. If phytotoxic effects are observed, dedicated trials are required. Number of trials for minor use depends on whether extrapolation is possible from major use. Scientific rationales may be acceptable where appropriate
CZECH REPUBLIC	8	0* - 4	8	0* - 4	
GERMANY	ca. 10	ca. 3*)	-	-	according to EPPO guideline
IRELAND	6-15	2-6	8	3	
ITALY	8	4	8	4	

	Number efficacy trials		Number crop safety trials		Comments
	Major use	Minor use	Major use	Minor use	
JAPAN	at least six (*1)	at least two (*2)	at least six (*1)	at least two (*2)	
NETHERLANDS	2 x 4	-	2 x4*[2]	-	
NEW ZEALAND	-	-	-	-	
PORTUGAL	10 (6 to15)	3 (2 to 6)	**	**	Evaluation may be more simplified
SLOVAK REPUBLIC	min.8	min.4	min.8	min.4	
SLOVENIA	10 (min 6)	0	6	0	Limited experiences. Crop safety data from efficacy trials are acceptable
SWITZERLAND	-	-	-	-	
UNITED KINGDOM	10	3	10	3	For insecticide and fungicides, some specific crop safety work, but much of this can be done once the safety profile is established with specific crop safety studies on one or two crops by assessment in the efficacy studies.
UNITED STATES	-	-	-	-	
Other					
AUSTRALIA					Efficacy guidelines exist for antifouling products, pool and spa sanitisers, adjuvant products and herbicides for use in forestry.
CZECH REPUBLIC	8	*0 - 4	8	*0 - 4	
GERMANY (molluscides)	ca.10	ca. 3*)	usually only observations	usually only observations *)	according to EPPO guideline
SLOVAK REPUBLIC	min.6	min.4	min.6	min.4	

	Number efficacy trials		Number crop safety trials		Comments
	Major use	Minor use	Major use	Minor use	
UNITED KINGDOM	-	-	-	-	Ag PGR's = herbicides - considered above

Additional comments:

AUSTRALIA:: A study is defined as a group of trials consisting of at least four replicate trials with equivalent Type 1 and/or Type 2 controls. However, the minimum number of replicate trials is governed by number of variables being investigated. As a minimum, trials must examine each crop/rate/disease combination. Guidelines state that as a general rule a minimum of 20 degrees of freedom should be available to allow for statistical analysis

BELGIUM: EPPO guidelines for major use and expert judgment case by case for minor use

GERMANY: *) For off label approvals, by law, no trials are required. However, in Germany authority must be able to evaluate efficacy and crop safety. So, in cases where extrapolation is not possible and in particular for new products/actives and for new uses, 3 trials are required. Plant safety can also be demonstrated by efficacy and residue trials, by literature or in cases where trials are very difficult (e.g. wireworm) by expert judgement of the Plant Protection Service of Federal States.

IRELAND: Both the crop safety trials and the efficacy trials should be carried out over 2 seasons

NETHERLANDS:-
*[1] herbicides incl. 2^N dosage
[2]Indoor specific phytotoxicity, incl. 2^N dosage; for outdoor the crop safety is included in the efficacy trials
* = only in the situation of a third party extension and when applying a so-called simplified extension. Otherwise based on extrapolation or reduced data required

NEW ZEALAND: There is no specific advice in our information requirements on number of trials for efficacy/crop safety. However, there is an expectation that the number of trials for a major use/crop will be more than for a minor use/crop.

SWITZERLAND: Since minor uses are rarely covered by 8 trials, expert judgement decides on the minimum fo data required

UNITED KINGDOM: Numbers of trials is a guide. It actually in reality refers to supportive results, rather than trials. See also EPPO PP 1/226 – similar figures but a bigger range. Scope for extrapolation is also possible.

2. Use and/or Exchange of International Data

		Yes or No	Comments
2a	**Is registration (alone) in another country acceptable to support registration of a minor use in your country?** *If YES, from any country/region or only specific countries/regions or under certain circumstances ?*		
	AUSTRALIA	NO	
	BELGIUM	YES	From neighbouring countries for extension of a well known product
	CANADA	NO	
	CZECH REPUBLIC	YES	From the Central EU zone
	GERMANY	NO	at least registration by mutual recognition is required. In that procedure recognition is possible according to the directive 91/414/EEC when the use (GAP) is comparable in the regarding countries and the agricultural conditions are comparable.
	IRELAND	YES	Within the EU, however, some Irish data required for full label approval of a weather disease fungicide
	ITALY	NO	
	JAPAN	NO	
	NETHERLANDS	In principle yes	Mutual recognition
	NEW ZEALAND	NO	
	PORTUGAL	YES	Until March of this year, we accepted trials carried out in others countries (ex: South European countries). The registration in another country was an important tool to be used in our evaluation, but it did not support alone the registration of a minor use in our country. From April of this year, we are implementing in our country the Mutual Recognition for the registration of Plant Protection Products already registered in another country (South European countries). However, this procedure is only applied to products based on active substances included in Annex I and uses approved according to uniform principles
	SLOVAK REPUBLIC	YES	It is, from the south-eastern zone of the EU. From the north-eastern zone of the EU, it is only under comparable circumstances.
	SLOVENIA	YES	EU Member States only
	SWITZERLAND	YES	GAP (dosage, pre-harvest interval, …) has to be identical. Only if conditions (climate, cropping system) in this country are comparable to those in Switzerland (expert judgement). This often the case for neighbouring countries. More often for insecticides, fungicides, less often for herbicides
	UNITED KINGDOM	YES	From countries of comparable climate. Note this is subject to a case of relevant agronomy and pest situation/status.
	UNITED STATES	-	

		Yes or No	Comments
2b	**Is data generated in other countries/regions acceptable to support minor use registration in your country?** *If YES, from any country/region or only specific countries/regions or under certain circumstances?*		
	AUSTRALIA	YES	Provided the data can be scientifically demonstrated as relevant for Australian conditions. Controlled environment situations lend more favourably to this. Local trials could be reduced by utilising additional overseas data to supplement a package.
	BELGIUM	YES	From countries with the same agro-climatic conditions
	CANADA	YES	A rationale describing the applicability of the trial results to Canadian conditions is required.
	CZECH REPUBLIC	YES	From the Central EU zone
	GERMANY	YES	north zone of EU, countries with comparable conditions/climate and data for all uses in greenhouses or storage rooms
	IRELAND	YES	However the geo/climatic conditions must be comparable.
	ITALY	YES	If conditions are comparable
	JAPAN	NO	
	NETHERLANDS	YES	North-West Europe, France up to Loire (not for greenhouse cultivation)
	NEW ZEALAND	YES	Where the GAP for the use, climate and environment are similar to that in New Zealand
	PORTUGAL	YES	Until March of this year, we accepted trials carried out in others countries (ex: South European countries). The registration in another country was an important tool to be used in our evaluation, but it did not support alone the registration of a minor use in our country. From April of this year, we are implementing in our country the Mutual Recognition for the registration of Plant Protection Products already registered in another country (South European countries). However, this procedure is only applied to products based on active substances included in Annex I and uses approved according to uniform principles
	SLOVAK REPUBLIC	YES	It is, from the south-eastern zone of the EU. From the north-eastern zone of the EU, it is only under comparable circumstances.
	SLOVENIA	YES	EU Member States only
	SWITZERLAND	YES	Only if conditions (climate, cropping system) in this country are comparable to those in Switzerland (expert judgement).
	UNITED KINGDOM	YES	Provided trials are from officially recognised organisations (other EU States), or are conducted to suitable standards (non EU Countries) and they are relevant agronomically and climatically.
	UNITED STATES	-	

		Yes or No	Comments
2c	**Is a regulatory authorities data evaluation report (with or without the accompanying data) from other countries acceptable to support minor use registration in your country?** *If YES, is a data evaluation report from any country (regulatory authority) acceptable or only data evaluation reports from specific countries (or regions) acceptable ?*		
	AUSTRALIA	NO	The data in addition to the report should also be made available.
	BELGIUM	YES	
	CANADA	YES	This would be considered on a case specific basis. A rationale is required to explain why the data evaluation report is applicable to Canadian conditions.
	CZECH REPUBLIC	YES	From the Central EU zone
	GERMANY	YES	Evaluation report is very helpful, but is not enough for recognition purposes. Additionally, comparability of uses (GAP) and agricultural conditions must be given. Experience: reports in different countries are very different.
	IRELAND	YES	However the underlying data must be made available to us.
	ITALY	NO	
	JAPAN	NO	
	NETHERLANDS	YES	Data often not available due to e.g. confidentiality
	NEW ZEALAND	NO	
	PORTUGAL	YES	Until March of this year, we accepted trials carried out in others countries (ex: South European countries). The registration in another country was an important tool to be used in our evaluation, but it did not support alone the registration of a minor use in our country. From April of this year, we are implementing in our country the Mutual Recognition for the registration of Plant Protection Products already registered in another country (South European countries). However, this procedure is only applied to products based on active substances included in Annex I and uses approved according to uniform principles
	SLOVAK REPUBLIC	YES	Yes, some date of review report is acceptable from the entire EU, but there are some data (biological efficacy) which are acceptable only from the south-eastern zone of the EU and from the north-eastern zone of the EU only under comparable circumstances.
	SLOVENIA	YES	EU Member States only
	SWITZERLAND	YES	Registration document: Only for minor uses. NO
	UNITED KINGDOM	YES but	Subject to a case for relevance an evaluation report plus copy of approved label should be sufficient. We require that applicants provide also an explanation of the relevance of the use and label to the UK. From other EU MS, subject to relevance
	UNITED STATES	-	

		Yes or No	Comments
2d	**Is the label (e.g. resistance, integrated pest management) from other countries acceptable/enough to support/deal with labelling systems for the minor use approval processes in your country?**		
	AUSTRALIA	NO	
	BELGIUM	YES	If compatible with national GAP's of other pests on the same crop or same pest on other crops
	CANADA	NO	
	CZECH REPUBLIC	Not generally	
	GERMANY	NO	Label systems in the different countries are different. There are also some national specialities and laws concerning labelling, in Germany e. g. the label for effects on honey bees (special German law).
	IRELAND	NO	
	ITALY	NO	But it could be useful to support
	JAPAN	NO	
	NETHERLANDS	In principle yes	
	NEW ZEALAND	NO	
	PORTUGAL	NO	For selection of ppp in integrated pest management we have specific criteria based on toxicity to man, beneficial and environment. The resistance is a area which is evaluated according to the situation in our country.
	SLOVAK REPUBLIC	YES	Usually it is, but there are cases of diametrically different differences in efficacy or crop safety (mostly herbicides) even within the same zone
	SLOVENIA	NO	
	SWITZERLAND	NO	Useful as background information
	UNITED KINGDOM	Possibly	We would consider resistance as a country issue and may require additional advice or warnings regarding resistance.
	UNITED STATES	-	
Additional comments:			

2. Use and/or Exchange of International Data (Continued)

		Are the following data/documents considered confidential? (Yes or No)	Can the information be shared with other regulatory bodies? (Yes or No)	If information is published please provide website link or reference.	Comments
2e	**Efficacy data (submitted by applicant)**				
	AUSTRALIA	YES	NO	YES	Since 2005 the APVMA is required to publish summaries of applications it has received which include a listing of studies provided (not actual studies or data themselves). Further details available at: http://www.apvma.gov.au/data_protection/appl_summaries.shtml
	BELGIUM	YES	YES		
	CANADA	YES	YES		2e-2h Response are specific to situation where the minor use is registered through the minor use program. Data protection may apply when the minor use is registered through a regular submission
	CZECH REPUBLIC	No (but not available to publics *(Interpreted as Yes*)	Yes but with EU Member States only	NO	
	GERMANY	YES (if not open source data)	YES		the owner of data must agree
	IRELAND	YES	YES		
	ITALY	YES	YES		Data can be shared with the other Authorities behind a motivated request and guarantee that they will be maintained confidential

		Are the following data/documents considered confidential? (Yes or No)	Can the information be shared with other regulatory bodies? (Yes or No)	If information is published please provide website link or reference.	Comments
	JAPAN	YES	NO		
	NETHERLANDS	YES	YES		-Mutual recognition -Exchange of data amongst EU member states
	NEW ZEALAND	YES	Yes – provided it is for the purpose that the other regulatory body is charged with.	NO	-
	PORTUGAL	YES	No (data) Yes (approvals; use conditions)	Approvals are available in our website	
	SLOVAK REPUBLIC	YES	YES	-	-
	SLOVENIA	YES	NO		EU system of data protection; 10 years + additional 5 years for renewal if new studies, and if requested by the applicant (directive 91/414/EEC)
	SWITZERLAND	YES	NO		Only the registration is published
	UNITED KINGDOM	YES	YES		
	UNITED STATES	-	-		

		Are the following data/documents considered confidential? (Yes or No)	Can the information be shared with other regulatory bodies? (Yes or No)	If information is published please provide website link or reference.	Comments
2f	**Crop safety data (submitted by applicant)**				
	AUSTRALIA	YES	NO	YES	Since 2005 the APVMA is required to publish summaries of applications it has received which include a listing of studies provided (not actual studies or data themselves). Further details available at: http://www.apvma.gov.au/data_protection/appl_summaries.shtml
	BELGIUM	YES	YES		
	CANADA	NO	YES		2e-2h Response are specific to situation where the minor use is registered through the minor use program. Data protection may apply when the minor use is registered through a regular submission
	CZECH REPUBLIC	No (but not available to public) *(Interpreted as Yes*)	Yes but with EU Member States only	NO	
	GERMANY	YES (if not open source data)	YES		The owner of data must agree
	IRELAND	YES	YES		
	ITALY	YES	YES		Data can be shared with the other Authorities behind a motivated request and guarantee that they will be maintained confidential
	JAPAN	YES	NO		
	NETHERLANDS	YES	YES	-	Exchange of data amongst EU member states

		Are the following data/documents considered confidential? (Yes or No)	Can the information be shared with other regulatory bodies? (Yes or No)	If information is published please provide website link or reference.	Comments
	NEW ZEALAND	YES	Yes – provided it is for the purpose that the other regulatory body is charged with.	NO	
	PORTUGAL	YES	No (data) Yes (approvals; use conditions)	-	
	SLOVAK REPUBLIC	YES	YES	-	
	SLOVENIA	YES	NO		EU system of data protection; 10 years + additional 5 years for renewal if new studies, and if requested by the applicant (directive 91/414/EEC)
	SWITZERLAND	YES	NO		Only the registration is published
	UNITED KINGDOM	YES	YES		
	UNITED STATES	-	-		

		Are the following data/documents considered confidential? (Yes or No)	Can the information be shared with other regulatory bodies? (Yes or No)	If information is published please provide website link or reference.	Comments
2g	**Efficacy evaluation reports and/or summaries (compiled by the regulator)**				
	AUSTRALIA	NO	YES	YES	Since 2005 the APVMA is required to publish summaries of applications it has received which include a listing of studies provided (not actual studies or data themselves). Further details available at : http://www.apvma.gov.au/data_protection/appl_summaries.shtml
	BELGIUM	NO	YES		
	CANADA	NO	YES		2e-2h Response are specific to situation where the minor use is registered through the minor use program. Data protection may apply when the minor use is registered through a regular submission
	CZECH REPUBLIC	NO	YES	NO	
	GERMANY	NO	YES		Reports may be non-confidential, partly
	IRELAND	YES	YES		
	ITALY	YES	YES		Data can be shared with the other Authorities behind a motivated request and guarantee that they will be maintained confidential
	JAPAN	YES	NO		
	NETHERLANDS	YES	YES	www.ctgb.nl	

		Are the following data/documents considered confidential? (Yes or No)	Can the information be shared with other regulatory bodies? (Yes or No)	If information is published please provide website link or reference.	Comments
	NEW ZEALAND	YES	Yes – provided it is for the purpose that the other regulatory body is charged with.	NO	
	PORTUGAL	NO	YES	Approvals are available in our website: http://www.dgadr.pt/default.aspx	From 2010, efficacy evaluation reports will be available for products based on active substances included in Annex I.
	SLOVAK REPUBLIC	YES	YES	-	
	SLOVENIA	YES	NO		EU system of data protection; 10 years + additional 5 years for renewal if new studies, and if requested by the applicant (directive 91/414/EEC)
	SWITZERLAND	YES	NO		Only the registration is published. Summaries are published in extension documents
	UNITED KINGDOM	YES	YES		
	UNITED STATES	-	-		

		Are the following data/documents considered confidential? (Yes or No)	Can the information be shared with other regulatory bodies? (Yes or No)	If information is published please provide website link or reference.	Comments
2h	**Crop safety evaluation reports and/or summaries (conducted by the regulator)**				
	AUSTRALIA	NO	YES	YES	Since 2005 the APVMA is required to publish summaries of applications it has received which include a listing of studies provided (not actual studies or data themselves). Further details available at: http://www.apvma.gov.au/data_protection/appl_summaries.shtml
	BELGIUM	NO	YES		
	CANADA	NO	YES		2e-2h Response are specific to situation where the minor use is registered through the minor use program. Data protection may apply when the minor use is registered through a regular submission
	CZECH REPUBLIC	NO	YES	NO	
	GERMANY	NO	YES	reports may be non-confidential, partly	
	IRELAND	YES	YES		
	ITALY	YES	YES		Data can be shared with the other Authorities behind a motivated request and guarantee that they will be maintained confidential
	JAPAN	YES	NO		
	NETHERLANDS	YES	YES	www.ctgb.nl	

		Are the following data/documents considered confidential? (Yes or No)	Can the information be shared with other regulatory bodies? (Yes or No)	If information is published please provide website link or reference.	Comments
	NEW ZEALAND	YES	Yes – provided it is for the purpose that the other regulatory body is charged with.	NO	
	PORTUGAL	YES	YES	Approvals are available in our website: http://www.dgadr.pt/default.aspx	
	SLOVAK REPUBLIC	YES	YES	-	
	SLOVENIA	YES	NO		EU system of data protection; 10 years + additional 5 years for renewal if new studies, and if requested by the applicant (directive 91/414/EEC)
	SWITZERLAND	YES	NO		Only the registration is published. Summaries are published in extension documents
	UNITED KINGDOM	YES	YES		
	UNITED STATES	-	-		
Additional comments:					

3. Crop & Pest Grouping Systems

		Between crops (for efficacy and crop safety) (Yes or No)	Between pests/diseases (for efficacy) (Yes or No)	Comments
3a	**Are grouping systems used for reduced data requirements, data evaluation and extrapolation?** *If YES and if available please provide website link or reference.*			
	AUSTRALIA	YES (Case by Case)	YES (Case by Case)	Although no crop or pest tables exist. Extrapolation is considered on a case-by-case basis and depending upon the data available
	BELGIUM	YES	YES Extrapolation tables from EPPO	Only for some crops e.g. ornamentals babyleaf, herbs,... Http://www.fytoweb.fgov.be/indexfr.htm (infor pour l'industrie)
	CANADA	YES	YES	This would be considered on a case specific basis. An acceptable rationale is required to extrapolate uses. Grouping scheme to be incorporated in the updated value guideline.
	CZECH REPUBLIC	Case by case	Case by case	
	GERMANY	YES	YES	EPPO is working on an extrapolation paper (EPPO standard); EPPO will do further work on grouping systems; MS within the EU have different grouping systems.
	IRELAND	YES	YES	
	ITALY	YES	YES	Guidelines of OEPP PP226/1
	JAPAN	YES	NO	Data Requirements for Supporting Registration of Pesticides" (Appendix Table 2, Notification No. 13-Seisan-3986)
	NETHERLANDS	YES	YES	www.ctgb.nl EPPO Guidelines for minor uses is being developed

		Between crops (for efficacy and crop safety) (Yes or No)	Between pests/diseases (for efficacy) (Yes or No)	Comments
	NEW ZEALAND	YES	YES	No formal documents, but the applicant can provide arguments to support such groupings.
	PORTUGAL	YES	YES	EPPO documents (website link has already been mentioned): - Crop group definitions - EPPO extrapolation tables In a few cases, technical and scientific knowledge and practical experience, is used.
	SLOVAK REPUBLIC	YES	YES	www.uksup.sk
	SLOVENIA	No for regular authorization Yes for minor uses	NO	
	SWITZERLAND	YES	-	For MRL according EU guidelines For Efficacy and crop safety until now according expert judgement. New EPPO extrapolation tables will serve as a rule.
	UNITED KINGDOM	YES	YES	http://www.pesticides.gov.uk/psd_pdfs/registration_guides/data_reqs_handbook/efficacy.pdf http://www.pesticides.gov.uk/uploadedfiles/Web_Assets/PSD/SANCO_D3_S12-395857.pdf eppo guidelines on extrapolation; PP 1/257 see http://pp1.eppo.org/getnorme.php?n=257 from www.eppo.org
	UNITED STATES	-	-	

		Between crops (for efficacy and crop safety) (Yes or No)	Between pests/diseases (for efficacy) (Yes or No)	Comments
3b	**Please list what you consider are the important factors/criteria in considering data extrapolation between crops and target pests/diseases.**			
	AUSTRALIA	Chemical characteristics, crop morphology, botanical similarity, growth stage and crop competitiveness, pest /crop interactions, GAP, and cultivation practices.	Pest life cycle, morphology, host range and specificity, virulence and ability to damage crops (ie. pest /crop interactions) and cultivation practices.	This is not documented in policy or guidance but are the important factors considered when supporting extrapolation between crops and or pest species. Additionally the amount and quality of data being extrapolated from is important.
	BELGIUM	Crop safety	Efficacy	
	CANADA	Insecticides: For efficacy: plant structure, crop damage by pest, pest management practices -mode of action of pesticide Fungicides: Similarities in causative pathogen, pathogen biology crop biology, disease development and crop production methods Herbicides: - may consider based on the application timing (i.e., ppi, pre vs post-application)	-pest feeding damage, pest behaviour, crop/pest interaction -mode of action of pesticide Similarities in pathogen biology crop biology, disease development and fungicide mode of action.	-For insecticides, crop grouping scheme is for foliar application only; other applications (e.g., seed treatments) are considered on a case specific basis. - The Insecticides section does not have a crop grouping scheme for crop safety. Phytotoxicity concerns may be addressed using a rationale or observations within efficacy trials. Phytotoxicity concerns may be addressed using a rationale or observations within efficacy trials. There is no crop grouping method for crop safety. Also consider herbicide chemistry (i.e., mode of action). Refer to the Efficacy guidelines.
	CZECH REPUBLIC	Crop and pest type and biology; comparable agronomical practice	Crop and pest type and biology; comparable agronomical practice	
	GERMANY	-		Basics will be published in the upcoming EPPO standard, see 3a

		Between crops (for efficacy and crop safety) (Yes or No)	Between pests/diseases (for efficacy) (Yes or No)	Comments
	IRELAND	EU Guidance Document on Minor Uses, EPPO Guidance	EU Guidance Document on Minor Uses, EPPO Guidance	Proposals for extending and harmonizing efficacy and crop safety extrapolations to reduce the need for efficacy trials on minor crops. EPPO guideline PP1-226(1)
	ITALY	Define an indicator crop from which extrapolate data of other crops	Define an indicator pest from which extrapolate data	
	JAPAN	botanical taxonomy plant morphology, crop cultivation commonality Pest commonality		
	NETHERLANDS	-	-	Comparable crop; same crop family; comparable production; same growing type
	NEW ZEALAND	Similar: growing conditions and crop shape and size (i.e. coverage)	Same genus or family	This is done on a case by case basis, based on technical arguments provided by the applicant
	PORTUGAL	See comments	See comments	Crop : (morphology, botanical family, growth pattern); Disease/pest (taxonomy relationship, biology, behaviour, plants parts attacked(/ weed (taxonomy relationship, biology, behaviour, growth stage) Product (biological properties, use conditions); Agronomic conditions (growing conditions and cultivation techniques, type of soil) Expert judgement Extrapolations are usually accepted for same or similar use conditions of the product, based on similarity of the crops or pests (taxonomy, biology and damage caused) and same agronomic conditions.

		Between crops (for efficacy and crop safety) (Yes or No)	Between pests/diseases (for efficacy) (Yes or No)	Comments
	SLOVAK REPUBLIC	YES	YES	- crop relationship, growth phase of the crop, development stage of pests, diseases and weeds, number of generations, soil requirements and climate conditions; - purpose of growing of the crop, at what stage the crop is harvested;
	SLOVENIA	For minor uses the same family	NO	
	SWITZERLAND	-	-	Crop: Plant morphology, growing period and season, cropping technique, pesticide application technique Pest/disease: biology (feeding mode, life span, population dynamics, mode of infestation, …), taxonomic relationship (same family or even genus), period of infestation (seasonality)
	UNITED KINGDOM	Similarity, structure and canopy, competiveness	Similarity, biology, life cycle,	The key criteria are detailed in the above documents.
	UNITED STATES	-	-	
Additional comments:				

ANNEX 2

Survey Questionnaire

Expert Group on Minor Uses

OECD SURVEY

April 2009

Efficacy and crop safety data requirements and guidelines for registration of pesticide minor uses

The following survey consists of a series of questions examining:

1. Regulatory Data Requirements and/or Guidelines,
2. Use and/or Exchange of International Data, and
3. Crop and Pest Grouping Systems.

The survey is particularly targeted at obtaining information on the requirements and/or guidelines adopted by OECD member countries for the registration minor uses. It is however anticipated that some member countries may not have specific guidelines established for minor uses and where requirements may revert to guidelines established for major uses and/or registration in general. Despite this, countries are encouraged to provide responses to the survey although they may not be specifically tailored for minor uses and these should be noted in responses/answers provided.

NOTE:
"Crop safety" is equivalent to "crop phytotoxicity", "adverse effect on crops" and "crop tolerance".

1. Regulatory Data Requirements and/or Guidelines

NOTE: It is recognised that some countries may stipulate different data requirements for label authorisations compared to authorisations for off-label approvals. Where this is applicable respondents are requested to specify differences in these cases in the fields/sections provided above.

		Efficacy (Yes or No)	**Crop Safety (Yes or No)**	**Comments**
1a	**Is data required prior to registration?**			
1b	**Are guidelines outlining data requirements available?** *If YES then please provide website link(s) or reference(s).*			
1c	**Are guidelines tailored for minor uses?**			
1d	**Do guidelines established specify how many trials are required?** *If YES then please indicate in the following table below the numbers of trials required.*			
1e	**Is it common to label minor uses according to e. g. resistance or use within the framework of integrated pest management systems?**			
Additional comments:				

1. Regulatory Data Requirements and/or Guidelines (Continued)

	Number of efficacy trials		Number of crop safety trials		Comments
	Major use	**Minor use**	**Major use**	**Minor use**	
Herbicides					
Insecticides					
Fungicides					
Biopesticides					
Other?					
Additional comments:					

2. Use and/or Exchange of International Data

		Yes or No	Comments
2a	**Is registration (alone) in another country acceptable to support registration of a minor use in your country?** *If YES, from any country/region or only specific countries/regions or under certain circumstances?*		
2b	**Is data generated in other countries/regions acceptable to support minor use registration in your country?** *If YES, from any country/region or only specific countries/regions or under certain circumstances?*		
2c	**Is a regulatory authorities data evaluation report (with or without the accompanying data) from other countries acceptable to support registration in your country?** *If YES, is a data evaluation report from any country (regulatory authority) acceptable or only data evaluation reports from specific countries (or regions) acceptable?*		
2d	**Is the label (e.g. resistance, integrated pest management) from other countries acceptable/enough to support/deal with labelling systems for the minor use approval processes in your country?**		
Additional comments:			

2. Use and/or Exchange of International Data (Continued)

		Are the following data/ documents considered confidential? (Yes or No)	Can the information be shared with other regulatory bodies? (Yes or No)	If information is published please provide website link or reference.	Comments
2e	**Efficacy data (submitted by applicant)**				
2f	**Crop safety data (submitted by applicant)**				
2g	**Efficacy evaluation reports and/or summaries (compiled by the regulator)**				
2h	**Crop safety evaluation reports and/or summaries (conducted by the regulator)**				
Additional comments:					

3. Crop & Pest Grouping Systems

		Between crops (for efficacy and crop safety) (Yes or No)	Between pests/diseases (for efficacy) (Yes or No)	Comments
3a	**Are grouping systems used for reduced data requirements, data evaluation and extrapolation?** *If YES and if available please provide website link or reference.*			
3b	**Please list what you consider are the important factors/criteria in considering data extrapolation between crops and target pests/diseases.**			
Additional comments:				