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**OECD SERIES ON PESTICIDES
Number 38**

**SURVEY OF THE PESTICIDE RISK REDUCTION STEERING GROUP ON
MINOR USES OF PESTICIDES**

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OECD Environment, Health and Safety Publications

Series on Pesticides

No. 38

**Survey of the Pesticide Risk Reduction Steering Group
on Minor Uses of Pesticides**

IOMC

**INTER-ORGANISATION PROGRAMME FOR THE
SOUND MANAGEMENT OF CHEMICALS**

**A cooperative agreement among
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**Environment Directorate
ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
Paris 2007**

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

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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)

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The Pesticide Programme was created in 1992 within the OECD's Environmental Health and Safety Division to help OECD countries:

- harmonise their pesticide review procedures,
- share the work of evaluating pesticides, and
- reduce risks associated with pesticide use.

The Pesticide Programme is directed by the Working Group on Pesticides, composed primarily of delegates from OECD Member countries, but also including representatives from the European Commission and other international organisations (*e.g.* United Nations Food and Agriculture Organization, United Nations Environment Programme, World Health Organization, Council of Europe), and observers from the pesticide industry and public interest organisations (NGOs).

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

This publication was produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals (IOMC). It was approved for derestriction by the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, the governing body of the Environment, Health and Safety Division.

The Inter-Organization Programme for the Sound Management of Chemicals (IOMC) was established in 1995 by UNEP, ILO, FAO, WHO, UNIDO and the OECD (the Participating Organizations), 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. UNITAR joined the IOMC in 1997 to become the seventh Participating Organization. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organizations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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* An EU member state, but not an OECD country

EXECUTIVE SUMMARY

1. In response to a questionnaire on minor uses fifteen countries and the European Commission responded. They include Australia, Canada, Estonia¹, European Commission, Germany, Hungary, Ireland, Japan, Netherlands, New Zealand, Poland, Republic of Korea, Slovakia, Switzerland, UK, and the US.

2. The report is a collation of various aspects such as responsible regulatory authorities/agencies, data requirements, activities being pursued and regulatory mechanisms for approving minor uses in member countries.

3. Of the respondent countries many have or are in the process of developing mechanisms for addressing minor uses. Many countries have either on the regional or domestic level established expert groups or coordinators to address minor use needs, and where these groups usually contain representation from regulators, research providers and the user industry. It is clear that successful minor uses programs are underpinned by sufficient resources and representation from a range of stakeholders cooperatively involved in the process of finding solutions.

4. The criteria and guidelines for determining what constitutes a minor use varies amongst member countries, although it is largely determined by one or two key factors, either area or tonnage of production and/or dietary intake. Minor use classifications are utilised to provide things such as guidance on the number of trials required, incentives to encourage their registration (i.e. reduced assessment fees/timeframes) and qualification under grower requested registration or off-label schemes.

5. Regulatory criteria, data requirements and assessments undertaken within member countries for minor uses are in much part similar to those conducted for major uses, although increasingly specific guidelines have or are being developed to reduce the regulatory burden for minor uses. These guidelines are largely centered on principles of things such as data extrapolation, crop-grouping schemes, use of overseas data and mutual recognition and typically involve considerations of efficacy/crop safety and residues. Other data requirements such as toxicology, occupational health and safety and the environment are largely unchanged from uses already approved and which have been addressed via data assessment when the product was originally considered for registration.

6. The report contains four recommendations that are principally focused on further progressing harmonisation of data requirements and principles for assessing minor uses, assisting member countries in identifying the potential availability of supporting data (in another member country) and 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. Some member countries are already progressing initiatives to promote the generation and exchange of data that could be utilised as test cases for future consideration by the WGP in targeting key areas for further development such as principles of efficacy/crop safety and residues for minor uses.

¹ Note that Estonia is not an OECD member country.

RECOMMENDATIONS

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

1. Member countries when developing 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.
2. 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.
3. That countries and minor use contact points use the report and information links provided as an initial starting point to locate and retrieve potentially supporting data for information exchange. In particular sections covering Maximum Residue Limits (MRLs), Product labels/registration status, Newsletters and Off-label approvals could serve to identify supporting data that may exist in member countries, where those uses may be approved. Countries following identification of potential data could then contact the appropriate minor use contact point in the respective country to determine the usefulness of the data and whether or not such data can be exchanged, or to locate sources of data ownership etc.
4. The report be regularly maintained as a stand-alone information source (directory) posted to the OECD website and:
 - all member countries and minor use contact points be notified of the report and be requested to provide updates when changes occur, and
 - member countries that have not responded should be further encouraged to complete the questionnaire.

BACKGROUND

8. In November 2003, the Risk Reduction Steering Group (RRSG) convened a seminar in Canberra (Australia) to discuss ways to achieve risk reduction while addressing issues associated with minor uses.

9. The seminar aimed to identify;

- opportunities for achieving risk reduction while addressing issues associated with minor uses;
- ways to increase co-operation among governments and stakeholders; and
- recommendations or next steps for the OECD or other parties.

10. A copy of the seminar report is available on the OECD website, refer to *Report of the OECD Pesticide Risk Reduction Steering Group on Minor Uses and Pesticide Risk Reduction [ENV/JM/MONO(2005)4]*.

11. The report concluded that the potential role of the OECD would be to;

- develop a list of contact points for governments, national or regional grower groups and associations and other stakeholders to facilitate cooperation on information exchange and data generation for minor uses,
- consider ways to aid countries to simplify the generation of data (eg. by developing extrapolations, crop groupings and/or guidance documents),
- monitor progress after a few years and consider whether a workshop or other fora of stakeholders might be useful.

12. A list of minor use contact points from 21 countries plus the European Commission (EC) was established in October 2004 (and more countries have been encouraged to nominate contact points).

13. The 18th Meeting of the Working Group on Pesticides recommended that the OECD secretariat request member countries to complete a questionnaire. The questionnaire was conducted to provide a brief overview of the regulatory requirements and mechanisms available for minor uses in member countries. Appendix 1 includes a copy of the questionnaire provided to each country for completion.

14. This report provides a summary of the responses, some discussion about different approaches and recommendations for use of the report to further future developments by OECD member countries with respect to minor uses.

SUMMARY OF THE SURVEY RESULTS

I. Major Questions

1. Countries who responded as of 31 March 2006:

15. Fifteen countries and the European Commission returned completed questionnaires. They include Australia, Canada, Estonia², European Commission, Germany, Hungary, Ireland, Japan, Netherlands, New Zealand, Poland, Republic of Korea, Slovakia, Switzerland, UK, and the US.

2. Responsible Regulatory Authorities - 3. Authority/Agency Web site:

<i>Country/ Organisation</i>	<i>Regulatory Authorities</i>	<i>Relevant Website</i>
Australia	Australian Pesticides and Veterinary Medicines Authority (APVMA)	http://www.apvma.gov.au/
Canada	PMRA	http://www.pmra-arla.gc.ca/
Estonia	Estonian Plant Production Inspectorate	http://www.plant.agri.ee
EC	DG SANCO- Unit D3 (Chemicals, Contaminants and Pesticides)	http://europa.eu.int/comm/food/plant/protection/indexen.htm
Germany	Federal Office for Consumer Protection and Food Safety (BVL)	http://www.bvl.bund.de
Hungary	Central Service for Plant Protection and Soil Conservation	http://www.ontsz.hu
Ireland	Pesticide Control Service, (Department of Agriculture and Food (Gov))	http://www.pcs.agriculture.gov.ie
Japan	Ministry of Agriculture, Forestry and Fisheries (MAFF)	http://www.maff.go.jp/
Netherlands	Board for the Authorisation of Pesticides	http://www.ctb-wageningen.nl
New Zealand	New Zealand Food Safety Authority Environmental Risk Management Authority (ERMA NZ)	http://www.nzfsa.govt.nz/acvm http://www.ermanz.govt.nz
Poland	Ministry of Agriculture and Rural Development	http://www.bip.minrol.gov.pl/DesktopDefault.aspx?TabOrgId=633&LangId=0
Republic of Korea	Pesticide Safety Division, National Institute of Agricultural Science & Technology (NAST) and Agricultural Resources Division, Rural Development Administration RDA)	http://www.rda.go.kr
Slovakia	Central Controlling and Testing Institute in Agriculture (CCTIA)	http://www.uksup.sk/index.php?n=14
Switzerland	Swiss Federal Office for Agriculture	http://www.blw.admin.ch/
United Kingdom	Pesticides Safety Directorate	http://www.pesticides.gov.uk

² Note that Estonia is not an OECD member country.

USA	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); Federal Food, Drug, and Cosmetic & Act (FFDCA); and the Food Quality Protection Act (FQPA)	http://www.epa.gov/pesticides
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4. General background to minor use in my country

16. Five countries (Australia, Canada, Germany, UK and the US) provided information on existing publications or those under development as well as website links (as summarised below).

<i>Country</i>	<i>Information</i>	<i>Website link etc.</i>
Australia	Report of the OECD Pesticide Risk Reduction Steering Group on Minor Uses and Pesticide Risk Reduction (pages 26-37)	ENV/JM/MONO(2005)4
Canada	User Requested Minor Use Label Expansion (URMULE)	http://www.pmra-arla.gc.ca/english/pdf/dir/dir2001-01-e.pdf
	User Requested Minor Use Registration (URMUR)	http://www.pmra-arla.gc.ca/english/pdf/dir/dir9905-e.pdf
	Update on Registrations for Minor Crops and Uses	http://www.pmra-arla.gc.ca/english/pubs/mcu-e.html
	URMULE Update	http://www.pmra-arla.gc.ca/english/pubs/urmule-e.html
Germany	Publication in preparation, title: "Minor Uses procedures and programs to close minor use gaps in plant protection in Germany"	Not available
New Zealand	Report of the OECD Pesticide Risk Reduction Steering Group on Minor Uses and Pesticide Risk Reduction (pages 38-43)	ENV/JM/MONO(2005)4
United Kingdom	UK Minor Uses Network	http://www.pesticides.gov.uk/fg_minor_uses.asp?id=282
USA	US Environmental Protection Agency Report on Minor Uses of Pesticides	http://www.epa.gov/pesticides/minor_use/minoruserpt.pdf
	FIFRA Amendments in Food Quality Protection Act of 1996, Title II, Section 210 Minor Crop Protection	http://epa.gov/oppfead1/fqpa/fqpaiffr.htm
	IR-4 Project program overview	http://ir4.rutgers.edu/Binars/IR-4Overview.pdf

5. Past, current, and planned activities related to Minor Uses

17. On the regional level, the European Commission established an Expert Group on Minor Uses in 2002. It consists of two technical groups, one covering Northern Europe and the other, Southern Europe. Several non-European OECD countries reported their efforts in developing a regulatory framework on the domestic level while supporting international minor use projects through involvement in NAFTA and/or OECD activities, in the hope of promoting harmonisation. Yet, countries responding to the survey have not provided concrete information of their future projects on minor use.

18. Some country specific comments are summarised below:

<i>Country</i>	<i>Summary comments</i>
Australia	Federal and state governments are considering a new strategic framework, initiatives and reform for minor use in Australia.
Canada	<p style="text-align: center;">NAFTA HARMONIZATION</p> <p>The PMRA is working towards harmonizing regulatory approaches under NAFTA. Aims include; standardization of the type and scope of studies required, protocols in conducting studies, format and presentation of submissions, and methods used to evaluate submissions and prepare reports.</p> <p><u>Crop Grouping</u> Crop groupings are used on a routine basis in Canada. Work is underway with NAFTA and internationally to expand and harmonize the use of crop groupings. Canada is also exploring the use of crop groups in the context of exposure assessment and efficacy/crop tolerance</p> <p><u>Joint PMRA/US EPA Minor Use Review</u> PMRA and US EPA have developed under NAFTA a joint review process for minor uses. In 2004-2005, this was piloted with a small number of uses; this will be expanded in 2005-2006 with the hope the program will become routine.</p>
European Commission	<p><u>Directive 91/414/EEC</u> (Article 9 and 10 mutual recognition) is supposed to ease the authorization process in general and especially for minor uses and in minor crops.</p> <p style="text-align: center;">EXPERT GROUP ON MINOR USES</p> <p>In 2002 the European Commission decided to create an Expert Group on Minor Uses (recently renamed as Steering group) in order to find ways to ease these problems for the farming community. Two Technical Groups (one for North and one for Southern Europe) were also installed by the Expert Group as a platform for the execution of the actual work, i.e. obtaining of solutions for minor crop plant protection problems.</p>
Germany	Germany works in close co-operation with the EU Minor Use working group. Aim is to exchange data between member states, accompany projects (extrapolation and databases).
Ireland	<p style="text-align: center;">PAST</p> <p>TEAGASC has in the past done some developmental work in new uses for existing Plant Protection Products, exclusively concentrated on efficacy screening and trials.</p> <p style="text-align: center;">PRESENT</p> <p>The Department of Agriculture and Food has co-funded some residue trial work in conjunction with growers/grower groups. The results of this work will be made available to other authorities who can provide residue data on other crop pesticide combinations of interest to Irish growers</p> <p style="text-align: center;">FUTURE</p> <p>It is the intention (at least short term) to continue co-funding such trial work as detailed above. However no long term commitments have been made at this point.</p>

Netherlands	<p style="text-align: center;">CTB PROVIDED ONE OF THE NATIONAL COORDINATORS FOR THE EU EXPERT GROUP ON MINOR USES (NORTH), TOGETHER WITH THE PLANT PROTECTION SERVICE.</p> <p>An extrapolation document has been published http://www.ctb-wageningen.nl</p>
New Zealand	Information is available at: http://www.nzfsa.govt.nz/acvm/publications/agvetlink/issue-47/page-13.htm
Slovakia	The list of minor crops will be published during the 2 nd Q 2006. Also the communication strategy will be set. The reason is that farmers and grower organisations are not very familiar with minor use system and the fact that these persons till this time didn't use a possibility to request for extension of uses of registered PPP. Also there is a plan to publish comprehensive information on uses of registered PPPs into minor crops.
US	<p style="text-align: center;">EPA IS WORKING TO UPDATE THE CROP GROUPING REGULATION (40CFR180.41) WITH INPUT FROM THE INTERNATIONAL CROP GROUPING CONSULTING COMMITTEE COORDINATED BY THE USDA IR-4 CENTER FOR SPECIALITY CROP PEST MANAGEMENT.</p> <p>Support global harmonization through NAFTA Technical Working group and OECD Working Groups regarding Risk Reduction and Minor Uses, as well as support and promote Harmonized Crop Grouping.</p> <p><u>Biopesticides:</u> IR-4 has a grant program to promote biopesticide efficacy research in specialty crops. IR-4 and EPA also have a joint grant program to promote adoption of biopesticides in minor crops.</p> <p>IR-4 Project offers regulatory assistance involving the registration of new biopesticide active ingredients.</p>

II. Optional Sections

6. Regulatory Requirements & Guidelines

19. Responses in terms of data requirements for minor uses were largely universal in that specific toxicological, chemistry, environment and occupational data is usually not required where the proposed minor use can be considered already covered by existing data and risk assessments conducted for the product intended to be used. The two key areas where specific guidelines for minor uses have been developed were in Residues (9 respondents) and efficacy and crop safety (8 respondents). Responses are provided below, including those in relation to Residues, Efficacy and Crop Safety.

Part Response type	Provisions or guidance documents specifically available for minor uses		
	Yes	No ³	No response
Toxicology	0	15	1
Chemistry & Manufacture	0	15	1
Residues	9	6	1
Environment	0	15	1
Efficacy & Crop Safety	8	7	1
Occupational health & safety	0	15	1
Other: Biological guidelines	1	10	5

Residue guidelines

Country/ Organisation	Specific guideline established for minor uses (Y OR N)	Summary of comments - details - relevant websites etc.
Australia	YES	Guidelines (number of trials, extrapolations etc.) available via: http://www.apvma.gov.au/guidelines/guidln24.shtml AND http://www.apvma.gov.au/publications/nrafactsheet000.pdf
Canada	NO	Residue Chemistry Guidelines available via: http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802a-e.pdf http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802b-e.pdf http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802c-e.pdf
EC	YES	Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs : http://europa.eu.int/comm/food/plant/protection/resources/app-d.pdf Classification of (minor) crops not listed in the Appendix of Council Directive 90 /642: http://europa.eu.int/comm/food/plant/protection/resources/annex2.pdf
Germany	YES	For each use, also for minor uses, data concerning residues are required. The data package is normally not as large as for major crop registrations. The possibility to extrapolate results from a major to a minor crop have to be taken into account. Additional data are necessary if the minor use is not covered by the basic data set especially metabolism in plants.
Hungary	NO	Residue data should be supplied by manufacturer.
Ireland	NO	If the product is already authorised, the additional uses require residue trial data only. The number of trials required is as per EU document "Doc. 7525/VI/95- rev. 7".

³

Note that Germany and Ireland have specified that data for minor use applications are required although guidelines are not available. See the ANNEX for the detailed comments.

Japan	YES	Refer to page 13 “Test results regarding persistence in crops”, Appendix of Data Requirements for Supporting Registration of Pesticides (Notification No. 12-Nouan-8147 ,24 November, 2000) http://www.acis.go.jp/eng/testglp/8147appendix.pdf (English)
Netherlands	YES	EU-document
New Zealand	NO	Minor use normally only considered for products already approved.
Poland	NO	
Republic of Korea	YES	Supervised filed trial for residue data generation is required at least one field of the targeted crop
Slovakia	NO	Case by case approach.
Switzerland	YES	Specific guidelines for minor uses (number of trials, extrapolations etc.) have been developed. Crop grouping similar to the EU.
United Kingdom	YES	EU residues guidelines apply that include provisions for minor crops and very minor crops. Comparability, extrapolation, group tolerances and data requirements, (Doc. 7525/VI/95), 12 June 2001 (http://europa.eu.int/comm/food/plant/protection/resources/publications_en.htm)
USA	YES	Specific guidelines for residue chemistry have been developed for minor (speciality) crops for number and distribution of field trials and specific guidance for processing studies (http://www.epa.gov/docs/OPPTS_Harmonized/860_residue_chemistry_test_guidelines). Residue Chemistry Guidelines are designated as OPPTS 860.1000 Background; OPPTS 860.1500Crop Field Trials; and OPPTS 860.1520 Processed food/feed guidance.

Efficacy and Crop Safety guidelines

Country/ Organisation	Specific guideline established for minor uses (Y OR N)	Summary of comments - details - relevant websites etc.
Australia	NO	Specific efficacy and crop safety guidelines for minor uses under development during 2006. Currently crop specific data may not be required if scientific extrapolation can be justified based upon existing registrations in related major crops. May consider overseas data where deemed applicable. Current registration requirements apply: http://www.apvma.gov.au/MORAG_ag/vol_3/part_8_efficiency&safety.pdf
Canada	NO	Efficacy Guidelines for Plant Protection Products http://www.pmra-arla.gc.ca/english/pdf/dir/dir2003-04-e.pdf
EC	YES	Efficacy for third party extension in minor uses is not required (Art. 10 Directive 91/414/EEC).
Germany	YES	According to national plant protection act there must be knowledge about sufficient efficacy and crop safety for minor uses. Crops and pest which are new for the active substance are to be documented by trials, literature or expert knowledge. Liability lies with the user.

		There are no particular German guidelines available. In Germany EPPO guidelines are used for special data requirements concerning minor uses (e. g. <i>Principles of evaluation for minor uses</i> or <i>Number of efficacy trials</i>)
Hungary	NO	Efficacy trials for Minor Use are carried out free of charge by Plant Protection and Soil Conservation Service
Ireland	NO	In some instances authorisation will be granted without a full biological assessment dossier.
Japan	YES	Refer to page 15 "Efficacy tests and phytotoxicity tests", Appendix of Data Requirements for Supporting Registration of Pesticides (Notification No. 12-Nouan-8147 ,24 November, 2000) http://www.acis.go.jp/eng/testglp/8147appendix.pdf (English)
Netherlands	YES	EPPO draft guideline on Principles of efficacy requirements for minor uses.
New Zealand	NO	Minor use normally only considered for products already approved.
Poland	NO	General provision on extrapolation and specific tables concerning efficacy are in regulation of the Minister of Agriculture and Rural Development of 4 August 2004 on efficacy evaluation of plant protection products (and amendment). Links: http://bip.minrol.gov.pl/FileRepozytory/FileRepozytoryShowImage.aspx?item_id=15735 and http://bip.minrol.gov.pl/FileRepozytory/FileRepozytoryShowImage.aspx?item_id=15736
Republic of Korea	YES	Three filed data on the target pests and crops are essentially required.
Slovakia	NO	Case by case approach.
Switzerland	YES	A reduced set of data is required (especially concerning phytotoxicity). Data from similar agronomic conditions from abroad are accepted.
United Kingdom	YES	Extrapolation based on expert judgement and available guidance may be possible in which case data not required, or reduced data. http://www.pesticides.gov.uk/psd_pdfs/registration_guides/data_reqs_handbook/efficacy.pdf
USA	NO	Efficacy or product performance generally not required except for public health uses. OPPTS Series 810.

7. Crop grouping schemes

20. Nine respondents indicated that crop grouping schemes/lists are established either on a regional level (6 countries) or on a national level (5). Responses are provided below.

<i>Crop group lists exist for use in regulatory decision and extrapolation</i>	Yes	No	Notable comments
	10	5	6 → on the regional (EU or NAFTA) level 5 → on the national level (Japan, Hungary, Netherlands, New Zealand & Poland)

Summary of crop grouping/lists comments received:

Country/ Organisation	Established crop grouping scheme/ lists (Y OR N)	Summary of comments - details - relevant websites etc.
Australia	NO	Australia currently adheres to Codex Classifications. For the purposes of Data Protection Legislation crop groups (including major/minor crops) are established: http://www.apvma.gov.au/about_us/regs_amendment_no3.pdf
Canada	YES	Crop Groups are listed in the Residue Chemistry Guidelines, Directive 98-01, and are harmonized under NAFTA. http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802a-e.pdf http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802b-e.pdf http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802c-e.pdf
EC	YES	Classification of (minor) crops not listed in the Appendix of Council Directive 90 /642: http://europa.eu.int/comm/food/plant/protection/resources/annex2.pdf Doc. 7525/VI/95- rev. 7 - Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs: http://europa.eu.int/comm/food/plant/protection/resources/app-d.pdf
Germany	YES	National crop groups are available. The groups are harmonised with the residue requirements as close as possible.
Hungary	YES	Ministry order 89/2004 FVM describes crop grouping and minor crops.
Ireland	YES	As per EU document "Doc. 7525/VI/95- rev. 7".
Japan	YES	Japanese original crop group list is available on http://www.acis.go.jp/stuchi/13-3986betu1.htm (Japanese)
Netherlands	YES	For efficacy crop listing and extrapolation document on the internet.
New Zealand	YES	In the Plant Compounds Residue Standard (http://www.nzfsa.govt.nz/acvm/publications/standards-guidelines/pc-food-clearance.pdf) it provides advice in Annex 2 on crop groupings and number of residue trials. Applicants can apply to reduce or waive the number of trials specified in this Annex.
Poland	YES	General provision on extrapolation and specific tables concerning efficacy are in regulation of the Minister of Agriculture and Rural Development of 4 August 2004 on efficacy evaluation of plant protection products (and amendment). Links: http://bip.minrol.gov.pl/FileRepozytory/FileRepozytoryShowImage.aspx?item_id=15735 and http://bip.minrol.gov.pl/FileRepozytory/FileRepozytoryShowImage.aspx?item_id=15736
Republic of Korea	NO	Government-oriented study is being done to group the minor crops in consideration with crop physiology and residue patterns.
Slovakia	NO	
Switzerland	YES	Crop grouping similar to the EU.

United Kingdom	NO	Some EU extrapolations are wide enough to fit with the whole group concept, although many of the extrapolations are crop to crop specific, e.g. tomatoes to aubergine, rather than having a crop group wide extrapolation system. On some occasions the extrapolation does encompass a crop group (e.g. carrots, potatoes and sugar beet to all of the root and tuber vegetables). EU extrapolations are at: Comparability, extrapolation, group tolerances and data requirements, (Doc. 7525/VI/95), 12 June 2001: http://europa.eu.int/comm/food/plant/protection/resources/publications_en.htm
USA	YES	The current Crop Grouping Regulation has 19 established groups (Code of Federal Regulations (40CFR180.41, which is available on the internet at http://ecfr.gpoaccess.gov/) The crop groups have been approved by NAFTA including a Crop Group 20 for oilseeds. The regulation is currently undergoing a revision, which will add additional crops to the groups and establish new crop groups/subgroups. A discussion of the International crop grouping workgroup and the regulation and International Crop grouping Symposium are available under Crop grouping on the USDA IR-4 website www.ir-4.rutgers.edu

8. Criteria and/or regulatory guidelines for defining minor uses

21. Twelve respondents indicated that criteria/guidelines are established for determining minor uses (5 countries) or on a national level (3). Responses are provided below.

<i>Guidelines or criteria exist for defining/determining minor uses</i>	Yes	No	Notable comments
	11	5	5 → specific guidelines on the national level 3 → specific guideline on the EU level (Doc. 7525/VI/95) 3 → flexible depending on cases 5 → No (1 under consideration)

Country/ Organisation	Established minor use criteria (Y OR N)	Summary of comments - details - relevant websites etc.
Australia	YES	Legislation states that a minor use is: “ <i>a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose)</i> ” Guidelines for determining minor uses have been developed and encompass three schedules: <ul style="list-style-type: none"> • Schedule 1 lists those commodities and situations considered major and where anything not listed is considered a minor (crop) use,

		<ul style="list-style-type: none"> • Schedule 2 enables considerations of minor uses within major situations (<10% and do not exceed 10,000 hectares), and • Schedule 3 enables options to demonstrate a use would not produce sufficient economic return. This guideline <p>A copy of this guideline is available via: http://www.apvma.gov.au/gazette/gazette0203p39.pdf</p> <p>A revision of the guideline is being conducted and a revised version is expected during 2006.</p>
Canada	YES	<p>Refer to Directive 2001-01, User Request Minor Use Label Expansion. http://www.pma-arla.gc.ca/english/pdf/dir/dir2001-01-e.pdf</p>
Estonia	YES	<p>Plant Protection Act states that minor use is: <i>extension of field of application of plant protection products that has already been authorised to purposes other than those covered by this authorisation when it is in public interest and if the intended field of application of plant protection product is minor or the plant protection product is to be used on a crop with limited growing area</i></p> <p>The substantive and formal requirements for extension of the field of application of plant protection product and the procedure for processing applications are under the preparation.</p> <p>The Plant Protection Act is available via: http://www.plant.agri.ee</p>
EC	YES	<p>There are currently criteria to classify a crop or a product as major for residue purposes (SANCO document 7525/VI/95 rev. 7). The following criteria are used for classifying a crop or a product as major in the European Community:</p> <ul style="list-style-type: none"> • daily dietary intake contribution > 7.5 g (i.e. 7.5 g mean daily consumption over the population for a 60 kg person) and/or • cultivation area > 10000 ha and • production > 200000 tonnes per year. <p>These criteria are used equivalent for distribution of crops or products as being major or minor.”</p> <p>There are also criteria to classify a crop or a product as “very minor” for residue purposes (SANCO document 7525/VI/95 rev. 7). In some cases the dietary intake contribution and/or the cultivation area of a crop or a product is very small. In this case certain simplifications should be introduced.</p> <p>The following criteria are used for classifying a crop or a product as 'very minor' in the European Community:</p> <ul style="list-style-type: none"> • daily dietary intake contribution < 1.5 g (i.e. 1.5 g mean daily consumption over the population for a 60 kg person) and/or • cultivation area < 600 ha (less than 0.0035 % of the total cultivation area) <p>These criteria are used for classifying crops or products as being very minor with a preference on the dietary intake contribution meaning that a higher dietary intake contribution will exclude a crop or a product automatically from the classification as being very minor.”</p>

Germany	YES	<p><u>Major crops*</u>:</p> <ul style="list-style-type: none"> •Dietary intake contribution > 7,5 g mean daily consumption for a 60 kg person and/or •Cultivation area > 10.000 ha and •Production > 200.000 tonnes/year <p><u>Minor crops*</u>:</p> <ul style="list-style-type: none"> •Dietary intake contribution > 1,5-7,5 g mean daily intake consumption for a 60 kg person <p><u>Very minor crops*</u>:</p> <ul style="list-style-type: none"> •Dietary intake contribution < 1,5 g mean daily consumption for a 60 kg person and/or •Cultivation area < 600 ha (proposal for Germany, may be changed in European countries or regions) <p>* according to EU working document (Doc. 7525/VI/95-rev. 7, 12/6/2001)</p>
Hungary	YES	Ministry order 89/2004 FVM describes crop grouping and minor crops
Ireland	YES	As per EU document “Doc. 7525/VI/95- rev. 7” (refer above for EC).
Japan	YES	<p>The crops* excepting for the crops listed in appendix 3 of operational notice for Data Requirements for Supporting Registration of Pesticides. http://www.acis.go.jp/stuchi/13-3986.pdf (Japanese)</p> <p>*The crops are classified as “minor crop”, usually, the amount of the production is little (e.g. less than 30,000 t).</p>
Netherlands	YES	Taking into account size and occurrence of pest etc (major pest in minor crop and also minor pest in major crop), to determine if a third party extension of approval can be granted. For number of residu-trials see Lundehn-document.
New Zealand	NO	There is a facility for applicants to either waive or reduce the number of trials required to support claims. Once granted this provides applicants with a degree of certainty of the number of trials they are required to undertake to support label claims. More information on this can be found at http://www.nzfsa.govt.nz/acvm/publications/forms/guidelines-iw.htm#P1_44 .
Poland	NO	Exhaustive list of minor and major crops is under construction. First draft version is available on: http://bip.minrol.gov.pl/FileRepozytory/FileRepozytoryShowImage.aspx?item_id=14184
Republic of Korea	YES	Minor use(crop) defines only for the crop which is not exceed 1,000 hectares of cropping area a season.
Slovakia	NO	Plant Health Care Act (Article 10, Par. 5) No. 193/2005 Coll. states that : Persons intending to use registered plant protection products or other products in crops or against harmful organisms as are defined in the Official Journal of the Ministry of Agriculture may ask for Control Institute for the extension of its use.
Switzerland	NO	Decisions are taken case by case, based on the following criteria: Size of cultivated area, spatial or timely restricted incidence. Prioritization according to urgency for agriculture.

<p>United Kingdom</p>	<p>YES</p>	<p>Outside the residue area, no formal definition exists, but definitions include ‘Minor uses are either uses of pesticides on small area cropping or against infrequent pests’ and ‘Minor uses are those which are too small to warrant sufficient return for manufacturers to develop plant protection products for them’</p> <p>The residues guidelines give the classification criteria for major versus minor or very minor crops. According to the residue guidelines this affects the number of trials required to support MRLs for major (generally 8 trials) and minor crops (generally 4 trials).</p> <p>The EU classification criteria are within: Comparability, extrapolation, group tolerances and data requirements, (Doc. 7525/VI/95), 12 June 2001 (http://europa.eu.int/comm/food/plant/protection/resources/publications_en.htm). These are:</p> <p>“The following criteria are used for classifying a crop or a product as major in the European Community:</p> <p>Daily dietary intake contribution > 7.5 g (i.e. 7.5 g mean daily consumption over the population for a 60 kg person) and/or</p> <p>Cultivation area > 10000 ha and</p> <p>Production > 200000 tonnes per year.</p> <p>These criteria are used equivalent for distribution of crops or products as being major or minor.</p> <p>In some cases the dietary intake contribution and/or the cultivation area of a crop or a product is very small. In this case certain simplifications should be introduced.</p> <p>The following criteria are used for classifying a crop or a product as 'very minor' in the European Community:</p> <p>Daily dietary intake contribution < 1.5 g (i.e. 1.5 g mean daily consumption over the population for a 60 kg person) and/or</p> <p>Cultivation area < 600 ha (less than 0.0035 % of the total cultivation area) [Cultivation area is given on the basis of a German proposal; it may be changed for the European regions]</p> <p>These criteria are used for classifying crops or products as being very minor with a preference on the dietary intake contribution meaning that a higher dietary intake contribution will exclude a crop or a product automatically from the classification as being very minor.”</p>
<p>USA</p>	<p>YES</p>	<p>Under FIFRA Section 2(II), a minor (use) crop is defined in one of two ways: 1) It is produced on fewer than 300,000 acres or 2) It is a major crop (a crop grown on more than 300,000 acres) for which the pesticide use pattern is so limited that revenues from the expected sales will be less than the cost of registering the pesticide AND A) There are insufficient efficacious alternatives for the use; B) Alternatives pose greater risks to the environment or human health, C) The minor use is significant in managing pest resistance, or D) The minor use plays a significant part in integrated pest management (http://epa.gov/oppfead1/fqpa/fqpafifr.htm).</p>

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label				Grouping of responses on applicants	Notable comments
	Yes	No	Yes/No	No response		
Registration	15	1	-	-	Manufacturer or registrant / third party / authorisation holder	4→ same as major use 3→ some flexibility (possibility of off-label)
Minor Use Permits	3	9	2	2	Any individuals (or anyone other than approval holder) involved / manufacturer or registrant / third party	3→ no separate regulations from major use 3→ off-label under certain conditions

10. Other information sources

Maximum Residue Limits (MRLs)

22. Information is available in 13 respondents. Hungary follows EC regulation (396/2005) on MRLs.

Country/ Organisation	Web Links	Comments
Australia	http://www.apvma.gov.au/residues/mrl_standard.shtml	Includes listings of current MRL's (updated monthly).
Canada	http://www.pmra-arla.gc.ca/english/legis/maxres-e.html	
Estonia	http://www.legaltext.ee/	Includes EU and also national MRL
EC	http://europa.eu.int/comm/food/plant/protection/pesticides/index_en.htm	
Germany	http://www.verbraucherministerium.de/index-000BA9DE972D104591B36521C0A8D	
Hungary	See EU	Hungary follows 396/2005 EC regulation on MRL-s
Ireland	http://europa.eu.int/comm/food/plant/protection/pesticides/legislation_en.htm	Council Directives 76/895/EEC & 90/642/EEC as amended.
Japan	http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/zanryu2/index.html http://www.env.go.jp/water/dojo/noyaku/law_data/e348kk0046.htm#	MRLs and the relevant information. (in Japanese)
Netherlands	http://www2.rikilt.dlo.nl/vws/index.html	All Dutch MRL's are published here.

New Zealand	http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/index.htm#mrl	MRLs are specified in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2005 (No.2) and its amendments. Note where no MRL exists New Zealand has a default limit of 0.1ppm
Slovakia	http://www.zbierka.sk/periodika.asp?pr=11&id=1347 http://www.zbierka.sk/periodika.asp?pr=11&id=1293 http://www.zbierka.sk/periodika.asp?pr=11&id=1132 http://www.zbierka.sk/periodika.asp?pr=11&id=811	Under No. 100 No. 83 No. 11 No. 46
United Kingdom	http://www.pesticides.gov.uk/food_industry.asp?id=548	Includes listings of current UK MRLs
USA	http://www.epa.gov.pesticides/food/viewtols.html http://ecfr.gpoaccess.gov/	The EPA Tolerance website is currently not available. Specific tolerances can be determined by using the Federal Register under 40CFRPart180 (http://ecfr.gpoaccess.gov/). The EPA Food and Feed Commodity Vocabulary allow the user to find the correct commodity name and the EPA preferred tolerance regulatory term (http://www.epa.gov/pesticides/food/feed/). International MRL database hosted by USDA Foreign Agricultural Service is available at http://www.mrldatabase.com

Product labels/registration status etc.

23. Information was provided by twelve (12) respondents.

Country/ Organisation	Web Links	Comments
Australia	http://services.apvma.gov.au/PubcrisWebClient/welcome.do;jsessionid=DcvLTrsWL3kyYv6plS2WnPjSn9t24ZXK2jLhLT2QNHWSnp0k3Lpv!1993087504	Includes listings of all registered products and links to product labels (updated daily).
Canada	http://eddenet.pmra-arla.gc.ca/4.0/4.01.asp http://www.omafra.gov.on.ca/english/crops/minoruse/minoruse_crops.htm#group1	
Estonia	http://www.plant.agri.ee	Product labels are not available
EC		
Germany	http://www.bvl.bund.de	On the homepage all registered PPP are researchable for with all uses and all label advises.

Hungary	www.neoland.hu	Database on registered products
Ireland	http://www.pcs.agriculture.gov.ie/db.htm	Product label information is available on request. Registration status can be checked via website.
Japan	http://www.acis.go.jp/index2.htm	List of all registered products and database of the applicable table, not product labels (Japanese).
Netherlands	http://www.ctb-wageningen.nl	site has a part in English, also our databank of approvals. Authorisation complete with motivations are published.
New Zealand	http://www.nzfsa.govt.nz/acvm/registers-lists/acvm-register/index.htm	Labels may not include the claim, if it was approved in relation to a third party application – however the claim would be made available via the public register.
Poland	http://www.bip.minrol.gov.pl/DesktopDefault.aspx?TabOrgId=648&LangId=0	All labels of approved plant protection products
Slovakia	http://www.zbierka.sk/periodika.asp?pr=11&id=1218	Registration status, list of registered PPP also contains basic information on products which can be used in minor crops Product labels are not available
United Kingdom	http://www.pesticides.gov.uk/psd_databases.asp	
USA	http://oaspub.epa.gov/pestlabl/ppls.home http://www.epa.gov/opprd001/workplan/	Individual product labels for registered products are available. EPA is providing workplans for the Office of Pesticide Programs pending new chemicals, new uses and food-use inert registration candidates.

Newsletters etc. on minor use

24. Six countries provided relevant sources, including Australia, Canada, Estonia, Netherlands, UK, and US.

Country/ Organisation	Web Links	Comments
Australia	http://www.apvma.gov.au/minor_use/minor_use_news.shtml	
Canada	http://www.pmra-arla.gc.ca/english/pubs/mcu-e.html http://www.pmra-arla.gc.ca/english/pubs/urmu-e.html	
Estonia	http://www.plant.agri.ee	
Netherlands	www.ctb-wageningen.nl	General CTB newsletter

United Kingdom	http://www.pesticides.gov.uk/farmers_growers_home.asp	Location of general advice to growers and includes minor uses issues
USA	http://ir4.rutgers.edu/news.cfm http://ir4.rutgers.edu/Binars/YIR.pdf http://ir4.rutgers.edu/annreports.html	EPA has no specific newsletters on minor uses. IR-4 publishes both Newsletters and Annual Reports.

Off-label approvals

25. Five countries including Australia, Estonia, Germany, Netherlands, and the UK, provided relevant sources. For Ireland, such a source is available on request.

Country/Organisation	Web Links	Comments
Australia	http://www.apvma.gov.au/permits/permits.shtml	Database with copies of currently issued permits for minor uses (updated daily)
Estonia	http://www.plant.agri.ee	Available during limited period after approval
Germany	http://www.bvl.bund.de/cln_027/nn_492012/DE/04_Pflanzenschutzmittel/02_ZugelassenePflanzenschutzmittel/02_OnlineDatenbank/onlineDB_node.html_nnn=true	Public database with all authorisations and approvals (updated monthly).
Netherlands	www.ctb-wageningen.nl	Off label not known; Netherlands have the third party extension of use, that are put on/added to the label; to be found via this link.
United Kingdom	http://www.pesticides.gov.uk/psd_databases.asp	

General minor use information

26. The sources are provided by eight countries, considering that the question item overlaps with question number 4. Ireland responded that it is available on request.

Country/Organisation	Web Links	Comments
Australia	http://www.apvma.gov.au/minor_use/subpage_minor.shtml ENV/JM/MONO(2005)4	General information on minor uses, how to apply etc. <i>Report of the OECD Pesticide Risk Reduction Steering Group on Minor Uses and Pesticide Risk Reduction</i> (refer pages 26-37)

Canada	http://www.omafra.gov.on.ca/english/crops/minoruse/aboutminoruse.html http://www.agr.gc.ca/env/index_e.php?section=pest&page=pest http://www.agf.gov.bc.ca/pesticides/j_4.htm	
Estonia	http://www.plant.agri.ee	Legislation acts
Germany		On the homepage of the BVL all off-label approvals are available. Publication in preparation, title: "Minor Uses procedures and programs to close minor use gaps in plant protection in Germany".
Japan	http://www.maff.go.jp/nouyaku/	Status of the registration and the relevant information for minor crops.
New Zealand	Agvet Link publication	Ad hoc articles in our quarterly publication Agvet Link.
Slovakia	http://www.uksup.sk/download/legislativa/2005/20060118_nariadenie_vlady_531_2005.pdf http://www.uksup.sk/download/legislativa/2005/20060117_zakon_193_2005.pdf	Only in legislation.
Switzerland		Through extension services of the Federal Research Stations for Agriculture and the Cantons.
United Kingdom	http://www.pesticides.gov.uk/fg_minor_uses.asp?id=282	General information on minor uses
US	http://www.epa.gov/pesticides/minoruse/index.htm	

Minor Use Contact points

Country	Contact Points
Australia	Alan Norden: alan.norden@apvma.gov.au Roger Toffolon: roger.toffolon@agric.nsw.gov.au
Canada	Doug Rothwell: Doug_Rothwell@hc-sc.gc.ca
Estonia	Katrin Karelsohn: katrin.karelsohn@plant.agri.ee
EC	Contact point European Commission: Francesca Arena francesca.arena@cec.eu.int Coordinator North Technical group: Ton Roteevel: a.j.w.rotteveel@minlnv.nl Coordinator South Technical group: Jean Claude Malet: jean-claude.malet@agriculture.gouv.fr Chairman Steering group: Tim Davis: tim.davis@psd.maff.gsi.gov.uk
Germany	Sterring Group: Wolfgang Zornbach: Wolfgang.Zornbach@bmvel.bund.de Technical Working Group: Mario Wick: M.Wick@bba.de

	Technical Working Group (efficacy): Gregor Kral, Gregor.Kral@bvl.bund.de Technical Working Group (residues): Karsten Hohgardt: Karsten.Hohgardt@bvl.bund.de
Hungary	Gábor Tőkés: Gabor.Tokes@ntksz.ontsz.hu Géza Ripka: Geza.Ripka@ntksz.ontsz.hu
Ireland	Gordon Rennick: gordon.rennick@agriculture.gov.ie
Japan	Kazuo Ogura: Kazo_ogura@nm.maff.go.jp
Netherlands	J.G. Mulder: hans.mulder@ctb.agro.nl
New Zealand	Warren Hughes Warren.hughes@nzfsa.govt.nz Robin Toy Robin.toy@ermanz.govt.nz
Poland	Paweł Bichta, Pawel.Bichta@minrol.gov.pl
Republic of Korea	Mr. Hong-Kyu Oh: hkoh@rda.go.kr Mr. Jin-Bae: jimbkim@rda.go.kr
Slovakia	martin.hajas@land.gov.sk marta.galusova@uksup.sk
Switzerland	S. Sütterlin: s.sutterlin@minlnv.nl Daniel Gut: daniel.gut@faw.admin.ch
United Kingdom	Francis Daly and Fiona Fisher ('off-label' approvals and application) francis.daly@psd.defra.gsi.gov.uk Fiona.fisher@psd.defra.gsi.gov.uk
USA	Pat Cimino, EPA Minor Crops Advisor: cimino.pat@epa.gov Barbara Madden, EPA Minor Use Officer: madden.barbara@epa.gov Bernard Schneider, EPA Tolerance and Commodity Information: schneider.bernard@epa.gov Dan Kunkel, Assistant Director-Registrations, IR-4 Headquarters: kunkel@aesop.rutgers.edu Michael Braveman, IR-4 Biopesticide Coordinator: braverman@aesop.rutgers.edu

Minor Use Communications Strategy

27. Five countries provided relevant sources or contact points.

<i>Country</i>	<i>Contact Point</i>
Australia	http://www.apvma.gov.au/minor_use/comms_strategy.pdf
Estonia	http://www.plant.agri.ee
Japan	http://www.maff.go.jp/nouyaku/
United Kingdom	http://www.pesticides.gov.uk/fg_minor_uses.asp?id=275
USA	Dan Kunkel, IR-4 Headquarters: kunkel@aesop.rutgers.edu

Relevant industry websites relating to minor use

28. Australia, Republic of Korea and the US provided industry websites relating to minor use.

<i>Country</i>	<i>Industry websites</i>
Australia	Grains – http://www.grdc.com.au/projects/minoruses/ Vegetables – http://www.ausveg.com.au/resource-centre-permits.cfm
Republic of Korea	http://www.koreacpa.org
USA	Speciality Crops USDA/IR-4 http://www.ir4.rutgers.edu CropLifeAmerica http://www.croplifeamerica.org

ANNEX 1 – AUSTRALIA

1. COUNTRY: AUSTRALIA

2. RESPONSIBLE REGULATORY AUTHORITY(TIES) Australian Pesticides and Veterinary Medicines Authority (APVMA)

3. Authority/Agency Web site: <http://www.apvma.gov.au/>

4. General background to minor use in my country is available in the *Report of the OECD Pesticide Risk Reduction Steering Group on Minor Uses and Pesticide Risk Reduction* [ENV/JM/MONO(2005)4] refer to pages 26-37

5. Past, current, and planned activities related to Minor Uses (please describe here, or attach relevant documents or web-links):

The Australian federal and state governments are currently considering a proposed new strategic framework, initiatives and reform for minor use in Australia. A paper is attached which outlines the proposed strategy, key initiatives and reforms and also includes historical information on minor use permit applications lodged with the APVMA for off-label approval.

FOLLOW SECTIONS ARE OPTIONAL**6. Regulatory Requirements & Guidelines (IF AVAILABLE)**

Copies of Requirements and Guidelines may be obtained via:

http://www.apvma.gov.au/MORAG_ag/MORAG_ag_home.shtml (refer to Volume 3)

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology	N	Usually not required if the minor use involves an existing approved active constituent and/or registered product.
Chemistry & Manufacture	N	Usually not required if the minor use involves an existing approved active constituent and/or registered product.
Residues	Y	Specific guidelines for minor uses (number of trials, extrapolations etc.) have been developed available via: http://www.apvma.gov.au/guidelines/guidln24.shtml AND http://www.apvma.gov.au/publications/nrafactsheet000.pdf
Environment	N	Usually not required if the use involves an existing approved active constituent and/or registered product for use under similar conditions and use regime.
Efficacy & Crop Safety	N (guidelines under development, expected during 2006)	Data may not be required if scientific extrapolation can be justified based upon existing registrations in related major crops. May consider overseas data where deemed applicable.

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Occupational Health & Safety	N	Usually not required if the use involves an existing approved active constituent and/or registered product for use under similar conditions and use regime.
Other: Biological guidelines	N	Biological guidelines available via: http://www.apvma.gov.au/guidelines/bioagprod.pdf

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
N	Whilst no specific guideline exists Australia currently adheres to Codex Classifications, although contributions are made by Australia to the International Crop Grouping Consulting Committee (convened by IR-4).

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
Y	Legislation states that a minor use is: <i>“a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose)”</i>

	<p>Guidelines for determining minor uses have been developed and encompass three schedules:</p> <ul style="list-style-type: none"> • Schedule 1 lists those commodities and situations considered major and where anything not listed is considered a minor (crop) use, • Schedule 2 enables considerations of minor uses within major situations (<10% and do not exceed 10,000 hectares), and • Schedule 3 enables options to demonstrate a use would not produce sufficient economic return. This guideline <p>A copy of this guideline is available via: http://www.apvma.gov.au/gazette/gazette0203p39.pdf</p> <p>A revision of the guideline is being conducted and a revised version is expected during 2006.</p>
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9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	Applicant may only be the manufacturer or registrant. End users cannot apply for new uses to be added to product labels.	Data protection introduced in 2005, for new uses including incentives for minor uses. Further details regarding data protection legislation available via: http://www.apvma.gov.au/registration/data_protection.shtml (refer <i>Regulations & Distinct Uses</i>).
Minor Use Permits	N	Anyone can apply for a <i>minor use permit</i> .	This mechanism exists to allow end users to apply for “permit” approval of minor uses. Typically involves the <i>off-label</i> use of existing registered products, but may also include uses of products not currently registered in Australia.

			<p>Typically end users (growers) apply either alone, as an association or where available via a dedicated service providers such as those operating below under relevant industry websites (for grains and horticulture).</p> <p>Details regarding guidelines and requirements for minor use permits refer to: http://www.apvma.gov.au/MORAG_ag/vol_2/category_21.pdf</p>
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10. Other information sources

Information source	Web Links	Comments
Maximum Residue Limits (MRLs)	http://www.apvma.gov.au/residues/mrl_standard.shtml	Includes listings of current MRL's (updated monthly).
Product labels/registration status etc.	http://services.apvma.gov.au/Pubcri sWebClient/welcome.do;jsessionid =DcvLTrsWL3kyYv6plS2WnPjSn 9t24ZXK2jLhLT2QNHWSnp0k3L pv!1993087504	Includes listings of all registered products and links to product labels (updated daily).
Newsletters etc. on minor use	http://www.apvma.gov.au/minor_use/minor_use_news.shtml	Newsletter listing recently issued Minor Use Permits.
"Off-label" approvals	http://www.apvma.gov.au/permits/permits.shtml	Database with copies of currently issued permits for minor uses (updated daily)

Minor use information (general)	http://www.apvma.gov.au/minor_use/subpage_minor.shtml	General information on minor uses, how to apply etc. available from APVMA website
Minor Use Contact points	<p>Alan Norden alan.norden@apvma.gov.au</p> <p>Roger Toffolon roger.toffolon@agric.nsw.gov.au</p>	
Minor Use Communications Strategy	http://www.apvma.gov.au/minor_use/comms_strategy.pdf	Communications strategy for minor use released in 2005.
Relevant industry websites relating to minor use	<p>Grains – http://www.grdc.com.au/projects/minoruses/</p> <p>Vegetables – http://www.ausveg.com.au/resource-centre-permits.cfm</p>	

ANNEX 2 - CANADA

1. COUNTRY: Canada

2. RESPONSIBLE REGULATORY AUTHORITY(TIES): PMRA

3. Authority/Agency Web site: <http://www.pmra-arla.gc.ca/>

4. General background to minor use in my country is available in:

User Requested Minor Use Label Expansion (URMULE)¹

<http://www.pmra-arla.gc.ca/english/pdf/dir/dir2001-01-e.pdf>

User Requested Minor Use Registration (URMUR)²

<http://www.pmra-arla.gc.ca/english/pdf/dir/dir9905-e.pdf>

Update on Registrations for Minor Crops and Uses

<http://www.pmra-arla.gc.ca/english/pubs/mcu-e.html>

URMULE Update

<http://www.pmra-arla.gc.ca/english/pubs/urmule-e.html>

Use Site Categories and Data Codes (DACOs)

<http://www.pmra-arla.gc.ca/english/appregis/daco-e.html>

Good Laboratory Practice

<http://www.pmra-arla.gc.ca/english/pdf/dir/dir9801-e.pdf>

Residue Chemistry Guidelines

<http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802a-e.pdf>

<http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802b-e.pdf>

<http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802c-e.pdf>

¹ **The User Requested Minor Use Label Expansion (URMULE)** program considers the expansion of a label for a new minor use of a pesticide for which the active ingredient(s) and the end-use product (EP) are currently registered in Canada. This expansion can be applied for by a grower or a grower representative with the support of the product registrant.

² **The User Requested Minor Use Registration (URMUR)** program considers the registration of a product containing an active ingredient(s) that is registered in an OECD country but is not registered in Canada. The applicant in this program is the product registrant.

5. Past, current, and planned activities related to Minor Uses (please describe here, or attach relevant documents or web-links):NAFTA Harmonization

The PMRA is working towards harmonizing regulatory approaches under NAFTA. The aim of harmonization includes standardization of the type and scope of studies required to register a pesticide use, the protocol followed in carrying out these required studies, the format and presentation of the submissions provided in support of a registration application, and the methods used to evaluate submissions and prepare reports.

Crop Grouping

Crop groupings are used on a routine basis in Canada. Work is underway with NAFTA and internationally to expand and harmonize the use of crop groupings. Canada is also exploring the use of crop groups in the context of exposure assessment and efficacy/crop tolerance.

Joint PMRA/EPA Minor Use Review

PMRA and EPA have developed under NAFTA a joint review process for minor uses. In 2004-2005, this was piloted with a small number of uses; this will be expanded in 2005-2006 with the hope the program will become routine.

FOLLOWING SECTIONS ARE OPTIONAL**6. Regulatory Requirements & Guidelines (IF AVAILABLE)** Copies of Requirements and Guidelines may be obtained via <http://www.pmra-arla.gc.ca/>

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations <u>URMULE-</u> program considers the expansion of a label for a new minor use of a pesticide for which the active ingredient(s) and the end-use product are currently registered in Canada. Directive 2001-01 http://www.pmra-arla.gc.ca/english/pdf/dir/dir2001-01-e.pdf . <u>URMUR-</u> program considers the registration of a product containing an active ingredient(s) that is registered in an OECD country but is not registered in Canada. This application would enter the review stream as a new submission,
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		but may be eligible for reduced fees based on projected sales. Directive 99-05 http://www.pmra-arla.gc.ca/english/pdf/dir/dir9905-e.pdf
Toxicology	N	
Chemistry & Manufacture	N	Since a product in the URMULE stream must already be registered in Canada information would already have been submitted for chemistry and manufacturing.
Residues	N	Residue Chemistry Guidelines http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802a-e.pdf http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802b-e.pdf http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802c-e.pdf
Environment	N	If the requested use expansion fits within the current accepted use data is not required. The <u>use sites</u> and associated DACOs are on the PMRA web site. http://www.pmra-arla.gc.ca/english/appregis/daco-e.html
Efficacy & Crop Safety	N	Efficacy Guidelines for Plant Protection Products http://www.pmra-arla.gc.ca/english/pdf/dir/dir2003-04-e.pdf
Occupational Health & Safety	N	If the requested use expansion fits within the current accepted use pattern data is not required. If data is required it is typically Mixer/Loader/Applicator-Passive Dosimetry Data or Mixer/Loader/Applicator- Biological Monitoring Data and Dislodgeable Residues (Foliar, Soil and Surface).Frequently, this is related to changes in the use pattern (i.e., from field to greenhouse or seed treatments). Post application Exposure Monitoring Test Guidelines http://www.pmra-arla.gc.ca/english/pubs/pro9804-e.html
Other: Biological guidelines	N	Guidelines For the Registration of Microbial Pest Control Agents and Products http://www.pmra-arla.gc.ca/english/pdf/dir/dir2001-02-e.pdf

7. Crop grouping schemes

<u>Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)</u>	<u>Comments</u>
Y	Crop Groups are listed in the Residue Chemistry Guidelines, Directive 98-01, and are harmonized under NAFTA. http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802a-e.pdf http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802b-e.pdf http://www.pmra-arla.gc.ca/english/pdf/dir/dir9802c-e.pdf

8. Criteria and/or regulatory guidelines for defining minor uses

<u>Guidelines or criteria exist for defining/determining minor uses (Y or N)</u>	<u>Comments</u>
Y	Refer to Directive 2001-01, User Request Minor Use Label Expansion. http://www.pmra-arla.gc.ca/english/pdf/dir/dir2001-01-e.pdf

9. Regulatory mechanisms for approving minor uses

<u>Mechanism</u>	<u>Regulatory outcome results in use on label (Y or N)</u>	<u>Applicant</u>	<u>Comments</u>
Registration	Y	Agriculture and Agri-Food Canada- Pest Management Centre (AAFC-PMC) Provincial Minor Use Coordinator (PMUC) Grower/Grower Association	An end user can request that a product be placed on the national needs list. The 36 highest priority needs are submitted as URMULEs for review and the data requirements are completed by AAFC-PMC. If the product is not chosen, a PMUC may submit the minor use submission and complete the data requirements. The grower or grower association may also submit an URMULE, however due to the cost of completing many of the trials this is infrequent.
Minor Use Permits	N		Use must be registered on label

10. Other information sources

<u>Information source</u>	<u>Web Links</u>	<u>Comments</u>
Maximum Residue Limits (MRLs)	http://www.pmra-arla.gc.ca/english/legis/maxres-e.html	
Product labels/registration status etc.	http://eddenet.pmra-arla.gc.ca/4.0/4.01.asp http://www.omafra.gov.on.ca/english/crops/minoruse/minoruse_crops.htm#group1	
Newsletters etc. on minor use	http://www.pmra-arla.gc.ca/english/pubs/mcu-e.html http://www.pmra-arla.gc.ca/english/pubs/urmule-e.html	
“Off-label” approvals		Off-label uses are not permitted in Canada

Minor use information (general)	http://www.omafra.gov.on.ca/english/crops/minoruse/aboutminoruse.html http://www.agr.gc.ca/env/index_e.php?section=pest&page=pest http://www.agf.gov.bc.ca/pesticides/j_4.htm	
Minor Use Contact points	<u>Name and e-mail of contact person(s)</u> Doug Rothwell Doug_Rothwell@hc-sc.gc.ca	
Minor Use Communications Strategy	Not available	
Relevant industry websites relating to minor use		

ANNEX 3 – ESTONIA

1. COUNTRY: Estonia

2. RESPONSIBLE REGULATORY AUTHORITY(TIES): Estonian Plant Production Inspectorate

3. Authority/Agency Web site: <http://www.plant.agri.ee>

4. General background to minor use in Estonia is regulated with **Plant Protection Act**

5. Past, current, and planned activities related to Minor Uses (please describe here, or attach relevant documents or web-links):

No special activities because of very small cultivation area of minor crops.

See sections below.

FOLLOW SECTIONS ARE OPTIONAL**6. Regulatory Requirements & Guidelines (IF AVAILABLE)**Copies of Requirements and Guidelines may be obtained via [HTTP://WWW.](http://www.)_____

Not available.

In the process of minor use authorisation it is considered the toxicological, environmental and other relevant risks, also the residues using the extrapolation and available data of authorisations in Nordic countries.

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology		
Chemistry & Manufacture		
Residues		
Environment		
Efficacy & Crop Safety		
Occupational Health & Safety		
Other: Biological guidelines		

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
N	The number of minor crops applied for and approved is very small (2-3)

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
Y	<p>Plant Protection Act states that minor use is: extension of field of application of plant protection products that has already been authorised to purposes other than those covered by this authorisation when it is in public interest and if the intended field of application of plant protection product is minor or the plant protection product is to be used on a crop with limited growing area</p> <p>The substantive and formal requirements for extension of the field of application of plant protection product and the procedure for processing applications are under the preparation.</p> <p>The Plant Protection Act is available via: http://www.plant.agri.ee</p>

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	A person who is registered as an undertaking in Estonia or another Member State, or whose branch is registered in Estonia or another Member State, may apply for authorisation of plant protection product	
Minor Use Permits	N	The applicant may be the persons and scientific or research bodies involved in agricultural activities (end users)	The minor use is not added on the label (off-label use) and it is on own responsibility of end user. The plant protection product the minor use is applied for has to be already authorised in Estonia.

10. Other information sources

Information source	Web Links	Comments
Maximum Residue Limits (MRLs)	http://www.legaltext.ee/	Includes EU and also national MRL
Product labels/registration status etc.	http://www.plant.agri.ee	Product labels are not available
Newsletters etc. on minor use	http://www.plant.agri.ee	Available during limited period after approval
“Off-label” approvals	http://www.plant.agri.ee	Available during limited period after approval

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Minor use information (general)	http://www.plant.agri.ee	Legislation acts
Minor Use Contact points	Katrin Karelsohn katrin.karelsohn@plant.agri.ee	
Minor Use Communications Strategy	http://www.plant.agri.ee	Special communication strategy for minor use is not released. General information is available in website.
Relevant industry websites relating to minor use		

ANNEX 4 - EUROPEAN COMMISSION

1. **“COUNTRY”:** European Union
2. **“RESPONSIBLE REGULATORY AUTHORITY(TIES)”** European Commission – DG SANCO- Unit D3 (Chemicals, Cuntaminants and Pesticides)
3. **SANCO Web site:** http://europa.eu.int/comm/food/plant/protection/index_en.htm

4. **General background to minor use in the EU** is available in:

⇒ Directive 91/414/EEC concerning the placing of plant protection products on the market.

5. **Past, current, and planned activities related to Minor Uses** (please describe here, or attach relevant documents or web-links):

Directive 91/414/EEC (Article 9 and 10 mutual recognition) is supposed to ease the authorization process in general and especially for minor uses and in minor crops. The Article 10 only deals with active substances, which are already included in Annex 1 of the Directive. Due to the limited number of active substances placed, and the limited range of representative uses, the effect of Article 10 is today very limited. Article 9, providing the possibility of voluntary mutual recognition is also used in a very limited way.

In 2002 the European Commission decided to create an Expert Group on Minor Uses (which has been recently renamed as Steering group) in order to find ways to ease these problems for the farming community. The Expert Group has been quite active during the last three years.

Two Technical Groups were also installed by the Expert Group as a platform for the execution of the actual work, i.e. obtaining of solutions for minor crop plant protection problems.

There are two Groups: one for North and one for Southern Europe, and delineated according to the Residue Directives. However, the Groups have much in common, and joint meetings are often organised.

Numerous initiatives and projects have been undertaken and some of them are still ongoing.

FOLLOW SECTIONS ARE OPTIONAL**6. Regulatory Requirements & Guidelines (IF AVAILABLE)**Copies of Requirements and Guidelines may be obtained via HTTP://WWW._____

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology	N	
Chemistry & Manufacture	N	
Residues	Y	http://europa.eu.int/comm/food/plant/protection/resources/app-d.pdf Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs http://europa.eu.int/comm/food/plant/protection/resources/annex2.pdf Classification of (minor) crops not listed in the Appendix of Council Directive 90 /642
Environment	N	
Efficacy & Crop Safety	Y	Efficacy for third party extension in minor uses is not required (Art. 10 Directive 91/414/EEC).
Occupational Health & Safety	N	
Other: Biological guidelines	N	

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
Y	<p>http://europa.eu.int/comm/food/plant/protection/resources/annex2.pdf Classification of (minor) crops not listed in the Appendix of Council Directive 90 /642</p> <p>Doc. 7525/VI/95- rev. 7 - Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs http://europa.eu.int/comm/food/plant/protection/resources/app-d.pdf</p>

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
Y	<p>There are currently criteria to classify a crop or a product as major for residue purposes (SANCO document 7525/VI/95 rev. 7).</p> <p>“The following criteria are used for classifying a crop or a product as major in the European Community:</p> <ul style="list-style-type: none"> • daily dietary intake contribution > 7.5 g (i.e. 7.5 g mean daily consumption over the population for a 60 kg person) and/or • cultivation area > 10000 ha and • production > 200000 tonnes per year. <p>These criteria are used equivalent for distribution of crops or products as being major or minor.”</p> <p>There are also criteria to classify a crop or a product as “very minor” for residue purposes (SANCO document 7525/VI/95 rev. 7).</p> <p>“In some cases the dietary intake contribution and/or the cultivation area of a crop or a product is very small. In</p>

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	<p>this case certain simplifications should be introduced.</p> <p>The following criteria are used for classifying a crop or a product as 'very minor' in the European Community:</p> <ul style="list-style-type: none"> • daily dietary intake contribution < 1.5 g (i.e. 1.5 g mean daily consumption over the population for a 60 kg person) and/or • cultivation area < 600 ha (less than 0.0035 % of the total cultivation area) <p>These criteria are used for classifying crops or products as being very minor with a preference on the dietary intake contribution meaning that a higher dietary intake contribution will exclude a crop or a product automatically from the classification as being very minor.”</p>
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9. Regulatory mechanisms for approving minor uses – NOT APPLICABLE

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration			
Minor Use Permits			

10. Other information sources

Information source	Web Links	Comments
Maximum Residue Limits (MRLs)	http://europa.eu.int/comm/food/plant/protection/pesticides/index_en.htm	
Product labels/registration status etc.	//	
	//	

Newsletters etc. on minor use		
“Off-label” approvals	//	
Minor use information (general)	//	
Minor Use Contact points	Name and e-mail of contact person(s) ⇒ Francesca Arena (francesca.arena@cec.eu.int) – Contact point European Commission ⇒ Coordinator North Technical group: Ton Roteevel (a.j.w.rottevel@minlnv.nl) ⇒ Coordinator South Technical group: Jean Claude Malet (jean-claude.malet@agriculture.gouv.fr) ⇒ Chairman Steering group: Tim Davis (tim.davis@psd.maff.gsi.gov.uk)	
Minor Use Communications Strategy	//	
Relevant industry websites relating to minor use	//	

ANNEX 5 - GERMANY

1. **COUNTRY:** GERMANY
2. **RESPONSIBLE REGULATORY AUTHORITY(TIES)** Federal Office for Consumer Protection and Food Safety (BVL)
3. **Authority/Agency Web site:** <http://www.bvl.bund.de>
4. **General background to minor use in my country:** Publication in preparation, title: “Minor Uses procedures and programs to close minor use gaps in plant protection in Germany”
5. **Past, current, and planned activities related to Minor Uses** (please describe here, or attach relevant documents or web-links): see sections below

FOLLOW SECTIONS ARE OPTIONAL**6. Regulatory Requirements & Guidelines (IF AVAILABLE)**Copies of Requirements and Guidelines may be obtained via [HTTP://WWW.](http://www.)

Part	Required (Y or N)	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology	Y	N	Normally, additional data are not required because data were submitted with the main application; an approval for a minor use is possible when the use is covered by the registration of the product (e.g. concerning application rate, timing of application, number of application etc.).
Chemistry & Manufacture	Y	N	Normally, additional data are not required because data were submitted with the main application; an approval for a minor use is possible when the use is covered by the registration of the product (e.g. concerning application rate, timing of application, number of application etc.).
Residues	Y	Y	For each use, also for minor uses, data concerning residues are required. The data package is normally not as large as for major crop registrations. The possibility to extrapolate results from a major to a minor crop have to be taken into account. Additional data are necessary if the minor use is not covered by the basic data set especially metabolism in plants.
Environment	Y	N	Normally, additional data are not required because data were submitted with the main application; an approval for a minor use is possible when the use is covered by the registration of the product (e.g. concerning application rate, timing of application, number of application etc.). Is the use not covered by an already registered use additional data and/or additional evaluation has to be done. This can lead to particular label advices for the minor use approvals.
Efficacy & Crop Safety	Y	Y	According to national plant protection act there must be knowledge about sufficient efficacy and crop safety for minor uses. Crops and pest which are new for the active substance are to be documented by trials, literature or

			expert knowledge. Liability lies with the user. There are no particular German guidelines available. In Germany EPPO guidelines are used for special data requirements concerning minor uses (e. g. <i>Principles of evaluation for minor uses</i> or <i>Number of efficacy trials</i>)
Occupational Health & Safety	Y	N	Normally, additional data are not required because data were submitted with the main application; an approval for a minor use is possible when the use is covered by the registration of the product (e.g. concerning application rate, timing of application, number of application etc.).
Other: Biological guidelines	-	-	-

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
Y	<p>National crop groups are available. The groups are harmonised with the residue requirements as close as possible. The single crop names are always described with a code. Therefore, the EPPO code system is used. The crop group codes are on national level because there are no EPPO codes available up to now. However, the EPPO have been working on building up crop groups.</p> <p>Within the frame of a working group for minor uses of the COM an extrapolation project for efficacy data is worked on (project leader: UK). A first proposal is submitted and will be further discussed between EU-MS.</p> <p>Crop groups concerning residue extrapolations are also available based on EU guidelines. At the moment on EU level crop groups are also discussed. There is also a project ongoing within the frame of the COM working group for minor uses ((project leader: UK).</p>

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
Y	<p><u>Major crops*:</u></p> <ul style="list-style-type: none"> •Dietary intake contribution > 7,5 g mean daily consumption for a 60 kg person and/or •Cultivation area > 10.000 ha and •Production > 200.000 tonnes/year <p><u>Minor crops*:</u></p> <ul style="list-style-type: none"> •Dietary intake contribution > 1,5-7,5 g mean daily intake consumption for a 60 kg person <p><u>Very minor crops*:</u></p> <ul style="list-style-type: none"> •Dietary intake contribution < 1,5 g mean daily consumption for a 60 kg person and/or •Cultivation area < 600 ha (proposal for Germany, may be changed in European countries or regions) <p>* according to EU working document (Doc. 7525/VI/95-rev. 7, 12/6/2001)</p>

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	Applicant may only be the manufacturer or registrant.	A company can also apply for a minor use within the frame of a normal registration, of course, however, most they are not interested in because of low earnings outlook.
Minor Use Permits	Y and N (it depends on the decision of the company, when a user itself apply for an extension of use, this is not labelled)	Applicant can be the manufacturer or registrant itself, but also extension services or the user. In the last cases, the manufacturer or registrant must be listened to the extension use of their already registered product.	An off-label approval can only be granted when the product is already registered in Germany; thus, it is in every case an extension of the use of a registered product.

10. Other information sources

Information source	Web Links	Comments
Maximum Residue Limits (MRLs)	http://www.verbraucherministerium.de/index-000BA9DE972D104591B36521C0A8D	-
Product labels/registration status etc.	http://www.bvl.bund.de	On the homepage all registered PPP are researchable for with all uses and all label advises.
Newsletters etc. on minor use	-	No newsletter or regularly published document, but sending around (within National Plant Protection Service) a database of all minor use application forms in preparation and already approved.
“Off-label” approvals	http://www.bvl.bund.de/cln_027/nn_492012/DE/04_Pflanzenschutzmittel/02_ZugelassenePflanzenschutzmittel/02_OnlineDatenbank/onlineDB_node.html_nnn=true	Public database with all authorisations and approvals (updated monthly).
Minor use information (general)	-	On the homepage of the BVL all off-label approvals are available. Publication in preparation, title: “Minor Uses procedures and programs to close minor use gaps in plant protection in Germany”.
Minor Use Contact points	Wolfgang Zornbach Wolfgang.Zornbach@bmvel.bund.de (Steering Group) Mario Wick M.Wick@bba.de (Technical Working Group) Gregor Kral	BVL is the authority responsible for registration processes and final decisions about registrations and off-label approvals. BBA (Federal biological research center for agriculture and forestry) is responsible for pre-registration processes concerning minor use approvals (e. g. co-ordinating the necessity of approvals in Germany, preparation of applications, database for available trials etc.)

	<p>Gregor.Kral@bvl.bund.de (efficacy) (Technical Working Group)</p> <p>Karsten Hohgardt Karsten.Hohgardt@bvl.bund.de (residues)</p>	
Minor Use Communications Strategy	-	<p>Meeting of the working groups (arable crops, vegetables ...) "Minor Uses" (once a year): Members: heads and specialists of plant protection services of the federal states (planning of efficacy trials and field residue work). Most important basis for solutions of minor use problems. Round table meetings with several companies, authorization authority, authorities of consent and heads of working groups "Minor Uses" (once a year). Both groups are managed and co-ordinated by BBA.</p>
Relevant industry websites relating to minor use	-	-

Annex with some additional questions:

Grouping schemes of harmful organisms

National groups are available. The single organisms are always described with a code. In these cases the EPPO code system is used. The grouping codes are on national level because there are no EPPO codes available.

Special structures or working groups for solving minor use problems in your country (like in the USA IR4 or in Germany AK-Lück)

In Germany the minor use problems are discussed with the grower associations, extension services and the companies to find practical solutions. This includes funding for residue and efficacy trials every year.

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Which co operations do already exist with other countries in order to solve minor use problems?

Germany works in close co-operation with the EU Minor Use working group. Aim is e. g. to exchange data between member states, accompany projects (extrapolation and databases).

Main difficulties with regard to solving minor use problems

Main problem is the funding of trials needed for closing gaps. Data exchanges with other countries have not been so often as it was desired, e. g. because of missing data, costs for allocating data and competition.

ANNEX 6 - HUNGARY

1. COUNTRY: __HUNGARY

2. RESPONSIBLE REGULATORY AUTHORITY(TIES) : Central Service for Plant Protection and Soil Conservation

3. Authority/Agency Web site: <http://www.ontsz.hu>

4. General background to minor use in my country is available in – list and/or attach reports, documents, web download address.

5. Past, current, and planned activities related to Minor Uses (please describe here, or attach relevant documents or web-links):

In the past years CSPPSC organized and evaluated cc. 200 efficacy trials on minor use in the frame of plant protection development strategy. In appropriate cases – when analytical trials were supplied or were not needed – proposals were taken for registration.

FOLLOW SECTIONS ARE OPTIONAL**6. Regulatory Requirements & Guidelines (IF AVAILABLE)**Copies of Requirements and Guidelines may be obtained via [HTTP://WWW.](http://www.)

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology	N	
Chemistry & Manufacture	N	
Residues	N	Residue data should be supplied by manufacturer
Environment	N	
Efficacy & Crop Safety	N	Efficacy trials for Minor Use are carried out free of charge by Plant Protection and Soil Conservation Service
Occupational Health & Safety	N	
Other: Biological guidelines	N	

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
Y	Ministry order 89/2004 FVM describes crop grouping and minor crops

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
Y	Ministry order 89/2004 FVM describes crop grouping and minor crops

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	Applicant may be manufacturer or registrant	
Minor Use Permits	Y	Applicant may be manufacturer or registrant, or the CSPPSC	

10. Other information sources

Information source	Web Links	Comments
Maximum Residue Limits (MRLs)	See EU	We follow 396/2005 EC regulation on MRL-s
Product labels/registration status etc.	www.neoland.hu	Database on registered products
Newsletters etc. on minor use	----	----
“Off-label” approvals	----	----
Minor use information (general)	----	----
Minor Use Contact points	Name and e-mail of contact person(s) <u>Dr.Gábor Tőkés:</u> Gabor.Tokes@ntksz.ontsz.hu <u>Dr.Géza Ripka:</u> Geza.Ripka@ntksz.ontsz.hu	

Minor Use Communications Strategy	---	---
Relevant industry websites relating to minor use	---	---

ANNEX 7 - IRELAND

1. COUNTRY: IRELAND

2. RESPONSIBLE REGULATORY AUTHORITY(TIES) Pesticide Control Service, (Department of Agriculture and Food(Gov))

3. Authority/Agency Web site: <http://www.pcs.agriculture.gov.ie>

4. General background to minor use in my country is available in _____ Not available _____ (list and/or attach reports, , web download address.

5. Past, current, and planned activities related to Minor Uses (please describe here, or attach relevant documents or web-links):

Past

TEAGASC is the government organisation with responsibility for food and agricultural development has in the past done some developmental work in new uses for existing Plant Protection Products. This work has exclusively concentrated on efficacy screening and efficacy trials. TEAGASC has not engaged in residue trial work, and in recent years has withdrawn from any development work in the area of “minor crops”

Present

The Department of Agriculture and Food has co-funded some residue trial work in conjunction with growers/grower groups. The results of this work will be made available to other authorities who can provide residue data on other crop pesticide combinations of interest to Irish growers.

Future

It is the intention (at least short term) to continue co-funding such trial work as detailed above. However no long term commitments have been made at this point.

FOLLOW SECTIONS ARE OPTIONAL**6. Regulatory Requirements & Guidelines (IF AVAILABLE)**Copies of Requirements and Guidelines may be obtained via [HTTP://WWW.](http://www.)

Part	Required (Y or N)	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology	Y	N	No additional requirements if the product is already authorised and the method of application is the same as for existing uses of the product.
Chemistry & Manufacture	Y	N	No additional requirements if the product is already authorised.
Residues	Y	N	If the product is already authorised, the additional uses require residue trial data only. The number of trials required is as per EU document "Doc. 7525/VI/95- rev. 7".
Environment	Y	N	No additional requirements if the product is already authorised and the method of application is the same as for existing uses of the product. Scale of use may well be a consideration.
Efficacy & Crop Safety	Y	N	In some instances authorisation will be granted without a full biological assessment dossier.
Occupational Health & Safety	Y	N	No additional requirements if the product is already authorised and the method of application is the same as for existing uses of the product.
Other: Biological guidelines	N	N	

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
Y	As per EU document “Doc. 7525/VI/95- rev. 7”

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
Y	As per EU document “Doc. 7525/VI/95- rev. 7”

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	Authorisation holder may apply. This often done via other interested parties.	This results in a label recommendation.
Minor Use Permits	Y/N	Anyone may apply for an emergency use.	This results in an “off label” approval. Only granted in circumstances where no other product is available for the problem and significant losses are envisaged, by all producers of that crop. This is only valid for 120 days.

10. Other information sources

Information source	Web Links	Comments
Maximum Residue Limits (MRLs)	http://europa.eu.int/comm/food/plant/protection/pesticides/legislation_en.htm	Council Directives 76/895/EEC & 90/642/EEC as amended. These residue directives will be replaced with the “new” residues regulation.
Product labels/registration status etc.	http://www.pcs.agriculture.gov.ie/db.htm	Product label information is available on request. Registration status can be checked via website.
Newsletters etc. on minor use		Not applicable
“Off-label” approvals		Available on request. Consideration being currently given to publication on website.
Minor use information (general)		Available on request.
Minor Use Contact points	Name and e-mail of contact person(s)	Gordon Rennick gordon.rennick@agriculture.gov.ie
Minor Use Communications Strategy		Available on request.
Relevant industry websites relating to minor use		Available on request.

ANNEX 8 - JAPAN

1. COUNTRY: JAPAN**2. RESPONSIBLE REGULATORY AUTHORITY(TIES)** Ministry of Agriculture, Forestry and Fisheries (MAFF)**3. Authority/Agency Web site:** www.maff.go.jp/**4. General background to minor use in my country** is not available.**5. Past, current, and planned activities related to Minor Uses)**See Section below**6. Regulatory Requirements & Guidelines (IF AVAILABLE)**Copies of Requirements and Guidelines may be obtained via <http://www.acis.go.jp/eng/indexeng.htm> (English)

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology	N	Not required if minor uses are added to the use pattern of existing registered products.
Chemistry & Manufacture	N	Not required if minor uses are added to the use pattern of existing registered products.
Residues	Y	Refer to page 13 “Test results regarding persistence in crops”, Appendix of Data Requirements for Supporting Registration of Pesticides (Notification No. 12-Nouan-8147 ,24 November, 2000) http://www.acis.go.jp/eng/testglp/8147appendix.pdf (English)

Environment	N	Not required if minor uses are added to the use pattern of existing registered products.
Efficacy & Crop Safety	Y	Refer to page 15 “Efficacy tests and phytotoxicity tests” , Appendix of Data Requirements for Supporting Registration of Pesticides (Notification No. 12-Nouan-8147 ,24 November, 2000) http://www.acis.go.jp/eng/testglp/8147appendix.pdf (English)
Occupational Health & Safety	N	Not required if minor uses are added to the use pattern of existing registered products.
Other: Biological guidelines	N	Not required if minor uses are added to the use pattern of existing registered products.

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
Y	Japanese original crop group list is available on http://www.acis.go.jp/stuchi/13-3986betu1.htm (Japanese)

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
Y	<p>The crops* excepting for the crops listed in appendix 3 of operational notice for Data Requirements for Supporting Registration of Pesticides. http://www.acis.go.jp/stuchi/13-3986.pdf (Japanese)</p> <p>*The crops are classified as “minor crop”, usually, the amount of the production is little (e.g. less than 30,000 t).</p>

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	Applicant may only be the manufacturer or the registrant. End users can not apply for new uses to be added to product labels.	Minor uses must be registered by the Minister of AFF and added to the product labels as well as major use.
Minor Use Permits	-	-	-

10. Other information sources

Information source	Web Links	Comments
<ul style="list-style-type: none"> Maximum Residue Limits (MRLs) 	http://www.mhlw.go.jp/topics/bukyoku/iyaku/syoku-anzen/zanryu2/index.html http://www.env.go.jp/water/dojo/nouyaku/law_data/e348kk0046.htm#	MRLs and the relevant information. (Japanese)
Product labels/registration status etc.	http://www.acis.go.jp/index2.htm	List of all registered products and database of the applicable table, not product labels (Japanese)
Newsletters etc. on minor use	No	
“Off-label” approvals	No	
Minor use information (general)	http://www.maff.go.jp/nouyaku/	Status of the registration and the relevant information for minor crops
Minor Use Contact points	Kazuo Ogura (Mr.) Kazo_ogura@nm.maff.go.jp	
Minor Use Communications Strategy	http://www.maff.go.jp/nouyaku/	Status of the registration and the relevant information for minor crops
Relevant industry websites relating to minor use	No	

ANNEX 9 - NETHERLANDS

1. COUNTRY: Netherlands

2. RESPONSIBLE REGULATORY AUTHORITY(TIES) Board for the Authorisation of Pesticides, P.O. Box 217, 6700 AE Wageningen, The Netherlands, +31 317 471810 fax. + 31 317 471899

3. Authority/Agency Web site: <http://www.ctb-wageningen.nl>

4. General background to minor use in my country is available in _____ (list and/or attach reports, documents, web download address.

- documents, reports and minutes of the EU Expert group on minor uses

-

5. Past, current, and planned activities related to Minor Uses (please describe here, or attach relevant documents or web-links):

- CTB provided one of the national coordinators for the EU Expert Group on minor uses (North), together with the Plant Protection Service
- An extrapolation document has been published with in the latest update extra attention to minor uses (to be published on the website <http://www.ctb-wageningen.nl>)
- Regular contacts with national Crop growers organisation coordinators.
- Participation in a project to assist the application and authorisation of list 4

FOLLOW SECTIONS ARE OPTIONAL**6. Regulatory Requirements & Guidelines (IF AVAILABLE)**

Copies of Requirements and Guidelines may be obtained via

http://www.ctb.agro.nl/portal/page?_pageid=33,43713&_dad=portal&_schema=PORTAL

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology	N	Normal requirements
Chemistry & Manufacture	N	Normal requirements
Residues	Y	EU-document
Environment	N	Normal requirements
Efficacy & Crop Safety	Y	EPPO draft guideline on Principles of efficacy requirements for minor uses.
Occupational Health & Safety	N	Normal requirements, but if it is known that there is only a small area of a specific method of application this is taken into account in the risk-assessment.
Other: Biological guidelines	Y	Draft of biopesticide steering group on efficacy evaluation for microbial products. Further the EU guidelines on dossier requirements and dossier evaluation.

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
Y	For efficacy crop listing and extrapolation document on the internet.

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
Y	Taking into account size and occurrence of pest etc (major pest in minor crop and also minor pest in major crop), to determine if a third party extension of approval can be granted. For number of residu-trials see Lundehn-document.

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	Authorisation holder	All uses (major and minor; company and third party applications for extension of use) has to have a registration.
Minor Use Permits	Y	Third party (i.c.Trustee Special Authorisations acts as third party applicant)	All uses (major and minor; company and third party applications for extension of use) has to have a registration. Permit is actually a regular extension of the authorisation.

10. Other information sources

Information source	Web Links	Comments
Maximum Residue Limits (MRLs)	http://www2.rikilt.dlo.nl/vws/index.html	All Dutch MRL's are published here.
Product labels/registration status etc.	http://www.ctb-wageningen.nl site has a part in English, also our databank of approvals. Authorisation complete with motivations are published.	
Newsletters etc. on minor use	No specific newsletter. General CTB newsletter on www.ctb-wageningen.nl	
“Off-label” approvals	Off label not known; we do have the third party extension of use, that are put on/added to the label; to be found on the internet site www.ctb-wageningen.nl	
Minor use information (general)		
Minor Use Contact points	Name and e-mail of contact person(s) J.G. Mulder e-mail: hans.mulder@ctb.agro.nl S. Sütterlin e-mail: s.sutterlin@minlnv.nl	Ir. J.G. Mulder Board for the Authorisation of Pesticides, P.O. Box 217, 6700 AE, Wageningen, the Netherlands. Tel: +31 317 471854, fax. +31 317 471 899 Dr. Susanne Sütterlin Plant Protection Service Division Integrated Plant Protection PO Box 9102, NL 6700 HC Wageningen, The Netherlands tel. **31 (0)317 496268, fax. **31 (0)317 421701 e-mail:

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Minor Use Communications Strategy	Internet, workinggroup, newsbrief, Presentations at symposia.	
Relevant industry websites relating to minor use		

ANNEX 10 – NEW ZEALAND

1. COUNTRY: New Zealand

2. RESPONSIBLE REGULATORY AUTHORITY(TIES) New Zealand Food Safety Authority, Environmental Risk Management Authority (ERMA NZ)

3. Authority/Agency Web site: <http://www.nzfsa.govt.nz/acvm>, <http://www.ermanz.govt.nz>

4. General background to minor use in New Zealand is available in the *Report of the OECD Pesticide Risk Reduction Steering Group on Minor Uses and Pesticide Risk Reduction* [ENV/JM/MONO(2005)4] refer to pages 38-43..

An approval from ERMA NZ would not be required for a change in minor use, unless the change involved a significantly different method of application.

5. Past, current, and planned activities related to Minor Uses (please describe here, or attach relevant documents or web-links):

<http://www.nzfsa.govt.nz/acvm/publications/agvetlink/issue-47/page-13.htm>

FOLLOW SECTIONS ARE OPTIONAL**6. Regulatory Requirements & Guidelines (IF AVAILABLE)**

Copies of Requirements and Guidelines may be obtained via <http://www.nzfsa.govt.nz/acvm/publications/information-requirements/index.htm> and <http://www.nzfsa.govt.nz/acvm/publications/standards-guidelines/index.htm>

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology	No	Minor use normally only considered for products already registered. Toxicology assessment of the original registration is the responsibility of ERMA NZ. There are no additional data requirements for minor uses. No guidance documents are available.
Chemistry & Manufacture	No	Minor use normally only considered for products already approved.
Residues	No	Minor use normally only considered for products already approved.
Environment	No	Minor use normally only considered for products already approved.
Efficacy & Crop Safety	No	Minor use normally only considered for products already approved.
Occupational Health & Safety	No	Another Government Agency (ERMA NZ) is primarily responsible for this area.
Other: Biological guidelines	No	Minor use normally only considered for products already approved.

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
Yes	In the Plant Compounds Residue Standard (http://www.nzfsa.govt.nz/acvm/publications/standards-guidelines/pc-food-clearance.pdf) it provides advice in Annex 2 on crop groupings and number of residue trials. Applicants can apply to reduce or waive the number of trials specified in this Annex.

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
No	There is a facility for applicants to either waive or reduce the number of trials required to support claims. Once granted this provides applicants with a degree of certainty of the number of trials they are required to undertake to support label claims. More information on this can be found at http://www.nzfsa.govt.nz/acvm/publications/forms/guidelines-iw.htm#P1_44 .

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Yes (in most cases)	Either by the registrant or a third party	Under the ACVM Act 1997, making an application for an additional claim is not limited to the registrant of a registered product. Specifically, third parties (ie not the registrant) can make such applications. However, the registrant(s) of the product or products may or may not agree to include the third party claim on the label. For more details see article in Agvet

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			Link at (http://www.nzfsa.govt.nz/acvm/publications/agvetlink/issue-38/agvet38.pdf)
Minor Use Permits	No		

10. Other information sources

Information source	Web Links	Comments
Maximum Residue Limits (MRLs)	http://www.nzfsa.govt.nz/policy-law/legislation/food-standards/index.htm#mrl	MRLs are specified in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2005 (No.2) and its amendments. Note where no MRL exists New Zealand has a default limit of 0.1ppm
Product labels/registration status etc.	http://www.nzfsa.govt.nz/acvm/registers-lists/acvm-register/index.htm	Labels may not include the claim, if it was approved in relation to a third party application – however the claim would be made available via the public register.
Newsletters etc. on minor use	None	
“Off-label” approvals	None	
Minor use information (general)	Agvet Link publication	Ad hoc articles in our quarterly publication Agvet Link.
Minor Use Contact points	Name and e-mail of contact person(s): Warren Hughes Warren.hughes@nzfsa.govt.nz Robin Toy Robin.toy@ermanz.govt.nz	
	None	

Minor Use Communications Strategy		
Relevant industry websites relating to minor use		

ANNEX 11 - POLAND

- 1. COUNTRY: Poland**
- 2. RESPONSIBLE REGULATORY AUTHORITY: Ministry of Agriculture and Rural Development**
- 3. Authority/Agency Web site: <http://www.bip.minrol.gov.pl/DesktopDefault.aspx?TabOrgId=633&LangId=0>**
- 4. General background to minor use in Poland is available in: (not available)**
- 5. Past, current, and planned activities related to Minor Uses (not available)**

FOLLOW SECTIONS ARE OPTIONAL**6. Regulatory Requirements & Guidelines (IF AVAILABLE)**

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology		
Chemistry & Manufacture		
Residues		
Environment		So far we had very few applications concerning minor uses approvals (according to art. 49 of the law on plant protection of 18 December 2003 - http://www.bip.minrol.gov.pl/FileRepozytory/FileRepozytoryShowImage.aspx?item_id=7324), that's why they have been evaluated case by case. In the moment, there is are no specific guidelines in Poland, however we consider, that progressing process of review of active substances on EU level will increase interest in "minor uses" approvals and on the basis of gained experience specific polish guidelines will be elucidated.
Efficacy & Crop Safety		
Occupational Health & Safety		
Other: Biological guidelines		

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
Y	General provision on extrapolation and specific tables concerning efficacy are in regulation of the Minister of Agriculture and Rural Development of 4 August 2004 on efficacy evaluation of plant protection products (and amendment). Links: http://bip.minrol.gov.pl/FileRepozytory/FileRepozytoryShowImage.aspx?item_id=15735 and http://bip.minrol.gov.pl/FileRepozytory/FileRepozytoryShowImage.aspx?item_id=15736

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
N	Exhaustive list of minor and major crops is under construction. First draft version is available on: http://bip.minrol.gov.pl/FileRepozytory/FileRepozytoryShowImage.aspx?item_id=14184

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	Applicant may only be the registrant.	Regular application on extension of use may concern “minor uses”
Minor Use Permits	N	National and scientific agricultural institutes or growers organizations can apply for a specific <i>minor use approval</i> .	Approval contains special instruction for use plant protection product in applied crop/harmful organism

10. Other information sources

Information source	Web Links	Comments
Product labels/registration status etc.	http://www.bip.minrol.gov.pl/DesktopDefault.aspx?TabOrgId=648&LangId=0	All labels of approved plant protection products in Poland
Minor Use Contact points	Name and e-mail of contact person(s)	Paweł Bichta, Pawel.Bichta@minrol.gov.pl

ANNEX 12 – REPUBLIC OF KOREA

1. COUNTRY: Republic of Korea

2. RESPONSIBLE REGULATORY AUTHORITY: Pesticide Safety Division, National Institute of Agricultural Science & Technology (NAST) and Agricultural Resources Division, Rural Development Administration (RDA)

3. Authority/Agency Web site: <http://www.rda.go.kr>

4. General background to minor use in Republic of Korea

5. Past, current, and planned activities related to Minor Uses (please describe here, or attach relevant documents or web-links):

See Sections below

6. Regulatory Requirements & Guidelines

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology	N	Usually not required if the minor use involves an existing approved active constituent and/or registered product.
Chemistry & Manufacture	N	Usually not required if the minor use involves an existing approved active constituent and/or registered product.
Residues	Y	Supervised filed trial for residue data generation is required at least one field of the targeted crop
Environment	N	Usually not required if the use involves an existing approved active constituent and/or registered product for use under similar conditions and use regime
Efficacy & Crop Safety	Y	Three filed data on the target pests and crops are essentially required.
Occupational Health & Safety	N	Usually not required if the use involves an existing approved active constituent and/or registered product for use under similar conditions and use regime.

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation	Comments
N	Government-oriented study is being done to group the minor crops in consideration with crop physiology and residue patterns.

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
Y	Minor use(crop) defines only for the crop which is not exceed 1,000 hectares of cropping area a season.

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	Applicant may only be the manufacturer or registrant.	Data for efficacy, phytotoxicity and residue are generated from the special fund consisted of government, agricultural cooperatives and pesticide manufacturers.
Minor Use Permits	N	Nobody can apply for a <i>minor use permit</i> without registration.	

10. Other information sources

Information source	Links	Comments
Maximum Residue Limits (MRLs)		National MRLs for minor uses are set in cooperation with Korean FDA
Product labels/registration status etc.		National MRLs for minor uses are set in cooperation with Korean FDA
Newsletters etc. on minor use		A quarterly newsletter is available to inform a recently registered minor use registration.
“Off-label” approvals		Database with copies of currently issued permits for minor uses (updated yearly)
Minor Use Contact points	Mr. Hong-Kyu Oh: hkoh@rda.go.kr Mr. Jin-Bae: jinbkim@rda.go.kr	
Minor Use Communications Strategy		
Relevant industry websites relating to minor use	http://www.koreacpa.org	

ANNEX 13 – SLOVAKIA

1. COUNTRY: Slovakia

2. RESPONSIBLE REGULATORY AUTHORITY(TIES): Central Controlling and Testing Institute in Agriculture (CCTIA)

3. Authority/Agency Web site: <http://www.uksup.sk/index.php?n=14>

4. General background to minor use:

information is available in the tables below

5. Past, current, and planned activities related to Minor Uses (please describe here, or attach relevant documents or web-links):

Legislation frame :

Plant Health Care Act No. 193/2005 Coll. available on:

Ordinance No. 531/2005 by the Government of the Slovak Republic laying down requirements concerning placing on the market of plant protection products available on:

Further information is available in the tables below.

Planned activities:

The list of minor crops will be published during the 2nd Q 2006. Also the communication strategy will be set. The reason is that farmers and grower organisations are not very familiar with minor use system and the fact that these persons till this time didn't use a possibility to request for extension of uses of registered PPP. Also there is a plan to publish comprehensive information on uses of registered PPPs into minor crops.

FOLLOW SECTIONS ARE OPTIONAL

6. Regulatory Requirements & Guidelines (IF AVAILABLE)

Copies of Requirements and Guidelines may be obtained via

Not available.

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology		case by case approach
Chemistry & Manufacture		
Residues		
Environment		
Efficacy & Crop Safety		
Occupational Health & Safety		
Other: Biological guidelines		

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
N	-

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
N	<p>Plant Health Care Act (Article 10, Par. 5) No. 193/2005 Coll. states that :</p> <p>Persons intending to use registered plant protection products or other products in crops or against harmful organisms as are defined in the Official Journal of the Ministry of Agriculture may ask for Control Institute for the extension of its use.</p>

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	Company	<p>Plant Health Care Act (Article 10, Par. 6) No. 193/2005 Coll.</p> <p>A person who is registered as an undertaking in Slovakia or another Member State, or whose branch is registered in Slovakia or another Member State, may apply for authorisation of plant protection product</p>
Minor Use Permits	Y	Company or growers organisations and farmers	<p>Plant Health Care Act (Article 10, Par. 5) No. 193/2005 Coll. states that :</p> <p>Persons intending to use registered plant protection products or other products in crops or against harmful organisms as are defined in the Official Journal of the Ministry of Agriculture may ask for Control Institute for the extension of its use.</p> <p>Only big companies requested CCTIA for granting of authorisations into minor crops.</p> <p>Growers organisations and farmers till this time didnt use a possibility to request for extension of uses of registered PPP.</p> <p>Article 5 of Ordinance No. 531/2005 by the Government of the Slovak Republic</p> <p>The scope of use of an registered product can be extended on behalf of anybody who is seated or domiciled in a Member</p>

			<p>State and:</p> <p>a) has submitted the dossier for the said product and rationale in respect of the extension;</p> <p>b) evaluations have confirmed that such extension meets the requirements as laid down in a specific regulation ;</p> <p>c) the instructions for use will be indicated on the product's label or published in the Official Journal of the Ministry of Agriculture of the Slovak Republic.</p>
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10. Other information sources

Information source	Web Links	Comments
Maximum Residue Limits (MRLs)	http://www.zbierka.sk/periodika.asp?pr=11&id=1347 http://www.zbierka.sk/periodika.asp?pr=11&id=1293 http://www.zbierka.sk/periodika.asp?pr=11&id=1132 http://www.zbierka.sk/periodika.asp?pr=11&id=811	<p>Under No. 100</p> <p>No. 83</p> <p>No. 11</p> <p>No. 46</p>
Product labels/registration status etc.	http://www.zbierka.sk/periodika.asp?pr=11&id=1218	<p>Registration status, list of registered PPP also contains basic information on products which can be used in minor crops</p> <p>Product labels are not available</p>
Newsletters etc. on minor use	-	-
“Off-label” approvals	-	<p>Growers organisations and farmers till this time didnt use a possibility to request for extension of uses of registered PPP.</p>
Minor use information (general)	http://www.uksup.sk/download/legislativa/2005/20060118_nariadenie_vlady_531_2005.pdf	Only in legislation

	http://www.uksup.sk/download/legislative/2005/20060117_zakon_193_2005.pdf	
Minor Use Contact points	martin.hajas@land.gov.sk marta.galusova@uksup.sk	
Minor Use Communications Strategy	-	Special communication strategy for minor use is not yet released.
Relevant industry websites relating to minor use		

ANNEX 14 - SWITZERLAND

1. COUNTRY: Switzerland

2. RESPONSIBLE REGULATORY AUTHORITY(TIES) Swiss Federal Office for Agriculture

3. Authority/Agency Web site: <http://www.blw.admin.ch/>

4. General background to minor use in my country is available in _____ (list and/or attach reports, documents, web download address).

5. Past, current, and planned activities related to Minor Uses (please describe here, or attach relevant documents or web-links):

See below

Activities are coordinated with EU Expert Group on Minor Uses (Swiss Member: Daniel Gut, Swiss Federal Research Station for Horticulture, PO Box 185, CH-8820 Waedenswil).

D. Gut, E. Bosshard, October 20, 2005

FOLLOW SECTIONS ARE OPTIONAL**6. Regulatory Requirements & Guidelines (IF AVAILABLE)**Copies of Requirements and Guidelines may be obtained via [HTTP://WWW.](http://www.)

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology	N	Not required because the minor use mandatory involves an existing approved active constituent and registered product.
Chemistry & Manufacture	N	Not required because the minor use mandatory involves an existing approved active constituent and registered product.
Residues	Y	Specific guidelines for minor uses (number of trials, extrapolations etc.) have been developed. Crop grouping similar to the EU.
Environment	N	Usually not required if the proposed minor use is under similar conditions and use regime as already registered uses.
Efficacy & Crop Safety	Y	A reduced set of data is required (especially concerning phytotoxicity). Data from similar agronomic conditions from abroad are accepted.
Occupational Health & Safety	N	Usually not required if the proposed minor use is under similar conditions and use regime as already registered uses.
Other: Biological guidelines		

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
Y	Crop grouping similar to the EU.

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
N	Decisions are taken case by case, based on the following criteria: Size of cultivated area, spatial or timely restricted incidence. Prioritization according to urgency for agriculture.

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	Procedure most recently established by new legislation (May 2005); Generally: Reduction in data requirements according to Points 6-8 of questionnaire	

		<p>If: product is already registered for the same minor use in a EU country with similar agronomic and environmental conditions, or</p> <p>If: In Switzerland the product is registered for a similar indication enabling extrapolation.</p> <p>Application by registrant or growers via specific bodies (Point 10);</p>	
Minor Use Permits	N		

10. Other information sources

Information source	Web Links	Comments
Maximum Residue Limits (MRLs)		
Product labels/registration status etc.		
Newsletters etc. on minor use		
“Off-label” approvals		Not possible in Switzerland. For minor uses, growers can initialise an application for label extensions of already registered products via specific bodies of their sectors (mainly vegetables and other horticultural crops).
Minor use information (general)		Through extension services of the Federal Research Stations for Agriculture and the Cantons.

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Minor Use Contact points	Name and e-mail of contact person(s) Daniel Gut daniel.gut@faw.admin.ch	
Minor Use Communications Strategy	N	However, general acceptance of very high relevance of the minor use problem in official extension services and regulatory authorities.
Relevant industry websites relating to minor use	N	No specific site for Switzerland known.

ANNEX 15 – UNITED KINGDOM

1. COUNTRY: UK

2. RESPONSIBLE REGULATORY AUTHORITY(TIES) Pesticides Safety Directroate

3. Authority/Agency Web site: <http://www.pesticides.gov.uk>

4. General background to minor use in my country is available in http://www.pesticides.gov.uk/fg_minor_uses.asp?id=282 (list and/or attach reports, documents, web download address.

5. Past, current, and planned activities related to Minor Uses (please describe here, or attach relevant documents or web-links):
http://www.pesticides.gov.uk/fg_minor_uses.asp?id=282

FOLLOW SECTIONS ARE OPTIONAL**6. Regulatory Requirements & Guidelines (IF AVAILABLE)**

Copies of Requirements and Guidelines may be obtained via

http://www.pesticides.gov.uk/applicant_advice_home.asp

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology	N	If ADIs or ARfDs or acceptable operator exposure values have been determined previously for a major use, these will also apply to exposures arising from the minor use. If these reference values have not been derived then the evaluation will be in line with that for a major use
Chemistry & Manufacture	N	Usually not required if the minor use involves an existing approved active constituent and/or registered product.
Residues	Y	EU residues guidelines apply that include provisions for minor crops and very minor crops. Comparability, extrapolation, group tolerances and data requirements, (Doc. 7525/VI/95), 12 June 2001 (http://europa.eu.int/comm/food/plant/protection/resources/publications_en.htm)
Environment	N	The risk assessment used is based on that for major crops, however in determining whether the impact or risk is 'acceptable' then the scale of use may be taken in to account.
Efficacy & Crop Safety	Y	Extrapolation based on expert judgement and available guidance may be possible in which case data not required, or reduced data. http://www.pesticides.gov.uk/psd_pdfs/registration_guides/data_reqs_handbook/efficacy.pdf
Occupational Health & Safety	N	Not usually required if the minor use is within existing approved uses. If the minor uses goes outside these existing parameters, then the existing data packages is usually re-assessed or additional data in line with major uses is required
Other: Biological guidelines		

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
N	<p>Some of the EU extrapolations are wide enough to fit with the whole group concept, although many of the extrapolations are crop to crop specific, e.g. tomatoes to aubergine, rather than having a crop group wide extrapolation system. On some occasions the extrapolation does encompass a crop group (e.g. carrots, potatoes and sugar beet to all of the root and tuber vegetables).</p> <p>EU extrapolations are at: Comparability, extrapolation, group tolerances and data requirements, (Doc. 7525/VI/95), 12 June 2001 (http://europa.eu.int/comm/food/plant/protection/resources/publications_en.htm)</p>

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
	<p>Outside the residue area, no formal definition exists, but definitions include ‘Minor uses are either uses of pesticides on small area cropping or against infrequent pests’ and ‘Minor uses are those which are too small to warrant sufficient return for manufacturers to develop plant protection products for them’</p> <p>The residues guidelines give the classification criteria for major versus minor or very minor crops. According to the residue guidelines this affects the number of trials required to support MRLs for major (generally 8 trials) and minor crops (generally 4 trials).</p> <p>The EU classification criteria are within: Comparability, extrapolation, group tolerances and data requirements, (Doc. 7525/VI/95), 12 June 2001 (http://europa.eu.int/comm/food/plant/protection/resources/publications_en.htm).</p> <p>These are:</p> <ul style="list-style-type: none"> · The following criteria are used for classifying a crop or a product as major in the European Community: · Daily dietary intake contribution > 7.5 g (i.e. 7.5 g mean daily consumption over the population for a 60 kg

	<p>person) and/or</p> <ul style="list-style-type: none"> · Cultivation area > 10000 ha and · Production > 200000 tonnes per year. <p>These criteria are used equivalent for distribution of crops or products as being major or minor. In some cases the dietary intake contribution and/or the cultivation area of a crop or a product is very small. In this case certain simplifications should be introduced.</p> <p>The following criteria are used for classifying a crop or a product as 'very minor' in the European Community:</p> <ul style="list-style-type: none"> · Daily dietary intake contribution < 1.5 g (i.e. 1.5 g mean daily consumption over the population for a 60 kg person) and/or · Cultivation area < 600 ha (less than 0.0035 % of the total cultivation area) <p>[Cultivation area is given on the basis of a German proposal; it may be changed for the European regions]</p> <p>These criteria are used for classifying crops or products as being very minor with a preference on the dietary intake contribution meaning that a higher dietary intake contribution will exclude a crop or a product automatically from the classification as being very minor.”</p>
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9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	Approval holder for the product	Risk assessment is the same as for a major use
Minor Use Permits	N	Anyone other than the approval holder for the product	Risk assessments as for on-label major use, except that efficacy and crop safety data are not required/considered. Outcome is an “off-label” approval.

10. Other information sources

Information source	Web Links	Comments
Maximum Residue Limits (MRLs)	http://www.pesticides.gov.uk/food_industry.asp?id=548	Includes listings of current UK MRLs
Product labels/registration status etc.	http://www.pesticides.gov.uk/psd_databases.asp	
Newsletters etc. on minor use	http://www.pesticides.gov.uk/farmers_growers_home.asp	Location of general advice to growers and includes minor uses issues
“Off-label” approvals	http://www.pesticides.gov.uk/psd_databases.asp	
Minor use information (general)	http://www.pesticides.gov.uk/fg_minor_uses.asp?id=282	General information on minor uses
Minor Use Contact points	Name and e-mail of contact person(s)	Francis Daly and Fiona Fisher for enquires relating to ‘off-label’ approvals and application (francis.daly@psd.defra.gsi.gov.uk , Fiona.fisher@psd.defra.gsi.gov.uk)
Minor Use Communications Strategy	http://www.pesticides.gov.uk/fg_minor_uses.asp?id=275	Either via email to Minor use network or via PSD webpages.
Relevant industry websites relating to minor use		

ANNEX 16 – UNITED STATES

1. COUNTRY: United States of America

2. RESPONSIBLE REGULATORY AUTHORITY(TIES) Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); Federal Food , Drug, and Cosmetic Act (FFDCA); and the Food Quality Protection Act (FQPA) of 1996.

3. Authority/Agency Web site: United States Environmental Protection Agency, <http://www.epa.gov/pesticides>

4. General background to minor use in my country is available in the US Environmental Protection Agency Report on Minor Uses of Pesticides: <http://www.epa.gov/pesticides/minoruse/minoruserpt.pdf>. Also refer to, FIFRA Amendments in Food Quality Protection Act of 1996, Title II, Section 210 Minor Crop Protection (<http://epa.gov/oppfead1/fqpa/fqpaiffr.htm>).

Information is also available at the IR-4 Website: <http://ir4.rutgers.edu/>

Please see the program overview at: <http://ir4.rutgers.edu/Binars/IR-4Overview.pdf> and other pertinent information provided at the website.

5. Past, current, and planned activities related to Minor Uses (please describe here, or attach relevant documents or web-links):

- EPA is working to update the Crop Grouping Regulation (40CFR180.41, <http://ecfr.gpoaccess.gov/>) with input from the International Crop Grouping Consulting Committee coordinated by the USDA IR-4 Center for Speciality Crop Pest Management (<http://www.ir-4.rutgers.edu>). See # 7. [Crop grouping schemes](#) below for additional information.
- Continue to support the IR-4 program efforts regarding minor uses. Again refer to the IR-4 website and see <http://ir4.rutgers.edu/docs/stratplan.htm>.
- Support Global harmonization through NAFTA Technical Working group and OECD Working Groups regarding Risk Reduction and Minor Uses, as well as support and promote Harmonized Crop Grouping. Refer to Report of the OECD Pesticide Risk Reduction Group, Seminar on Minor Uses and Pesticide Risk Reduction, Canberra, Australia, 4 November, 2003 and the North American Free Trade

Agreement, Technical Working Group On Pesticides 5-Year Strategy November 5, 2003 and <http://ir4.rutgers.edu/Cropgrouping.html> for additional information.

- **Biopesticides:** IR-4 has a grant program to promote research on early stage and advanced stage biopesticide efficacy research in specialty crops. IR-4 and EPA also have a joint grant program involving on farm demonstration research to promote adoption of biopesticides in minor crops. Reports on this research can be found at: <http://ir4.rutgers.edu/Binars/BPResearchReportES.pdf>, <http://ir4.rutgers.edu/Binars/BPResearchReport2003.pdf>, <http://ir4.rutgers.edu/Binars/executivesummary05.pdf>, and <http://ir4.rutgers.edu/Binars/DemonstrationGrant2004entire.pdf>. The actual call for proposals can be found at: <http://ir4.rutgers.edu/Docs/2006callforproposals.htm>
- The IR-4 Project offers regulatory assistance involving the registration of new biopesticide active ingredients and has conducted a joint Biopesticide Registration Workshop with EPA. The proceedings can be found at: <http://ir4.rutgers.edu/RWP/index.htm>

6. Regulatory Requirements & Guidelines (IF AVAILABLE)

Copies of Requirements and Guidelines may be obtained via http://www.epa.gov/docs/OPPTS_Harmonized/

Part	Provisions or guidance documents specifically available for minor uses (Y or N)	Comments for minor use considerations
Toxicology	N	Risk assessments are required for all uses. Toxicology data is required for major crops and the databases are used for minor uses. OPPTS Series 870.
Chemistry & Manufacture	N	Use data from the existing approved active ingredient OPPTS Series 830.
Residues	Y	Specific guidelines for residue chemistry have been developed for minor (speciality crops) for number and distribution of field trials and specific guidance for processing studies (http://www.epa.gov/docs/OPPTS_Harmonized/860_residue_chemistry_test_guidelines). Residue Chemistry Guidelines are designated as OPPTS 860.1000 Background; OPPTS 860.1500Crop Field Trials; and OPPTS 860.1520 Processed food/feed guidance. Some joint reviews are coordinated between EPA, California Department of Pesticide

		Regulation (CDPR), and Canada's Pest Management Regulatory Agency (PMRA). Working with OECD and PMRA to harmonize residue chemistry guidelines.
Environment	N	Environmental fate studies are conducted for new uses. OPPTS Series 835, 840, and 850.
Efficacy & Crop Safety	N	Efficacy or product performance generally not required except for public health uses. OPPTS Series 810.
Occupational Health & Safety	N	Worker exposure assessments are conducted for all uses. OPPTS Series 875.
Other: Biological guidelines	N	No specific guidelines for minor uses but guidelines for biopesticides are listed under OPPTS Series 880 and 885. Priorities for food use are coordinated with USDA IR-4. http://www.epa.gov/pesticides/biopesticides/regtools/guidelines/microbial_gdlns.htm http://www.epa.gov/pesticides/biopesticides/regtools/guidelines/biochem_gdlns.htm http://www.epa.gov/pesticides/biopesticides/

7. Crop grouping schemes

Crop group lists exist for use in regulatory decisions and extrapolation (Y or N)	Comments
Y	The current Crop Grouping Regulation has 19 established groups (Code of Federal Regulations (40CFR180.41, which is available on the internet at http://ecfr.gpoaccess.gov/). The crop groups have been approved by NAFTA including a Crop Group 20 for oilseeds. The regulation is currently undergoing a revision which will add additional crops to the groups and establish new crop groups/subgroups. A discussion of the International crop grouping workgroup and the regulation and International Crop grouping Symposium are available under Crop grouping on the USDA IR-4 website (www.ir-4.rutgers.edu).

8. Criteria and/or regulatory guidelines for defining minor uses

Guidelines or criteria exist for defining/determining minor uses (Y or N)	Comments
Y	Under FIFRA Section 2(l), a minor (use) crop is defined in one of two ways: 1) It is produced on fewer than 300,000 acres or 2) It is a major crop (a crop grown on more than 300,000 acres) for which the pesticide use pattern is so limited that revenues from the expected sales will be less than the cost of registering the pesticide AND A) There are insufficient efficacious alternatives for the use; B) Alternatives pose greater risks to the environment or human health, C) The minor use is significant in managing pest resistance, or D) The minor use plays a significant part in integrated pest management (http://epa.gov/oppfead1/fqpa/fqpaiffr.htm).

9. Regulatory mechanisms for approving minor uses

Mechanism	Regulatory outcome results in use on label (Y or N)	Applicant	Comments
Registration	Y	Manufacturer, registrant or third parties	Applicant may be the manufacturer, registrant or third party.
Minor Use Permits	N	None	There is no separate registration process for minor uses.

10. Other information sources

Information source	Web Links	Comments
Maximum Residue Limits (MRLs)	http://www.epa.gov.pesticides/food/viewtols.html http://ecfr.gpoaccess.gov/	The EPA Tolerance website is currently not available. Specific tolerances can be determined by using the Federal Register under 40CFRPart180 (http://ecfr.gpoaccess.gov/). The EPA Food and Feed Commodity Vocabulary allow the user to find the correct commodity name and the EPA preferred tolerance regulatory term (http://www.epa.gov/pesticides/foodfeed/). International MRL database hosted by USDA Foreign Agricultural Service is available at http://www.mrlatabase.com .

<p>Product labels/registration status etc.</p>	<p>http://oaspub.epa.gov/pestlabl/ppls.home http://www.epa.gov/opprd001/workplan/</p>	<p>Individual product labels for registered products are available at http://oaspub.epa.gov/pestlabl/ppls.home EPA is providing workplans for the Office of Pesticide Programs pending new chemicals, new uses and food-use inert registration candidates at http://www.epa.gov/opprd001/workplan/.</p>
<p>Newsletters etc. on minor use</p>	<p>http://ir4.rutgers.edu/news.cfm http://ir4.rutgers.edu/Binars/YIR.pdf http://ir4.rutgers.edu/annreports.html</p>	<p>EPA has no specific newsletters on minor uses. IR-4 publishes both Newsletters and Annual Reports.</p>
<p>“Off-label” approvals</p>	<p>Not Available in the US</p>	
<p>Minor use information (general)</p>	<p>http://www.epa.gov/pesticides/minoruse/index.htm</p>	
<p>Minor Use Contact points</p>	<p>Name and e-mail of contact person(s)</p> <p>Pat Cimino, EPA Minor Crops Advisor cimino.pat@epa.gov</p> <p>Barbara Madden, EPA Minor Use Officer madden.barbara@epa.gov</p> <p>Bernard Schneider, EPA Tolerance and Commodity Information schneider.bernard@epa.gov</p> <p>Dan Kunkel, Assistant Director - Registrations IR-4 Headquarters kunkel@aesop.rutgers.edu</p> <p>Michael Braveman, IR-4 Biopesticide Coordinator braverman@aesop.rutgers.edu</p>	

Minor Use Communications Strategy	Dan Kunkel IR-4 Headquarters kunkel@aesop.rutgers.edu	As noted above, IR-4 is also considering an International Specialty Crop Website and a Global Specialty Crop Initiative to provide and share data internationally to harmonize MRL's to promote reduced risk product for imported and exported commodities.
Relevant industry websites relating to minor use	SpecialityCropsUSDA/IR-4 http://www.ir4.rutgers.edu CropLifeAmerica http://www.croplifeamerica.org	