Initiatives and Schemes in Support of Minor Uses
The need for minor use and specialty crop registrations has triggered an increasing number of programmes and initiatives around the globe. CropLife International has developed a list of minor use initiatives and schemes and is pleased to make this information available in the form of this guide.

The guide provides an overview of key initiatives and schemes that aim to find solutions to the registration of crop protection products for minor uses and specialty crop uses. Most of them involve developing data for registration in cooperation with public and private sector stakeholders.

Part 1 of this document concerns initiatives and part 2 covers registration schemes.

Registration schemes provide regulatory incentives in two main areas to support and encourage submissions for minor use registration by applicants. These are extension of periods of data protection and waivers or reduction of registration fees. Some countries have reduced data requirements and/or an accelerated procedure for progressing applications for minor uses.

Minor use registration schemes are under discussion in China, Korea, Mexico, Argentina, Ecuador and Colombia and under review in Japan and Australia. We hope this document will provide a useful overview for stakeholders and assist interested parties to find additional information on minor and specialty use initiatives.

DISCLAIMER
This document has been compiled from public sources for informational purposes only. Please consult materials provided by each programme for verification of any details.
## Part 1: Initiatives

### Global Minor Use Summit (GMUS)
- **Leaders/Supporters:** Interregional Research Project Number 4 (IR-4), United States Department of Agriculture (USDA), United States Environmental Protection Agency (USEPA) and Food and Agricultural Organisation (FAO)
- **Objectives and Key Focus Areas:**
  - The purpose of the GMUS is to provide a forum for the international exchange of information on current activities that address minor use issues and to identify future opportunities and challenges in the area of technical and cooperative areas and in policy considerations.
  - GMUS will focus on global agreements for pesticide policy, procedure and methodology to help deal with minor use issues while providing growers with access to safe tools to grow their crops and to promote free and fair trade between nations.
- **Priority Activities:**
  - Establish and maintain the Global Minor Use Portal (www.gmup.org)
  - To discuss requirements for residue trials
  - To discuss harmonisation of data requirements
  - To support crop group classifications and promotion of international trade via Codex
  - To support countries access to advanced residue programmes

### Codex – Electronic Working Group (EWG) on Minor Uses and Speciality Crops
- **Leaders/Supporters:** CCPR (Codex Alimentarius Committee on Pesticide Residues) chaired by U.S. and co-chaired by Kenya and Thailand
- **Objectives and Key Focus Areas:**
  - The EWG was initiated to foster globally applicable MRL settings for minor uses through Codex to assist in the global trade of minor and speciality crops.
  - The EWG provides guidance to facilitate the establishment of Codex MRLs for minor uses and speciality crops.
- **Priority Activities:**
  - Draft criteria to define minor uses and specialty crops for use by the CCPR and Joint FAO/World Health Organisation (WHO) Meetings on Pesticide Residue (JMPR)
  - Identify and address issues related to minor uses and speciality crops (within the mandate of the CCPR)
  - Identify priority minor uses for MRL setting
  - Facilitate data submissions to JMPR
  - Develop criteria for use by CCPR and JMPR to determine minimum number of field trials necessary to support the establishment of MRLs for minor uses/specialty crops

### International Crop Grouping Consulting Committee (ICGCC)
- **Leaders/Supporters:** Interregional Research Project Number 4 (IR-4) and Codex
- **Objectives and Key Focus Areas:**
  - The ICGCC was initiated to drive establishment of Crop Groups and harmonisation of Crop Groups globally.
  - Crop Groups serve to extrapolate MRLs from one crop to another crop within a group.
  - Extrapolation to minor crops reduces the associated data and data needed and therefore the data generation costs for minor uses. Harmonised Crop Groups have standardised data requirements and help prevent parallel risk assessments by International and National Standard Setting Bodies.
- **Priority Activities:**
  - Identify crops and gather information to determine which crops should be included in various crop groups
  - Classify crops into groups based on botanical, taxonomical or cultural characteristics
  - Select representative crops based on dietary importance and residue exposure
  - Development of electronic databases: including zone maps, dry matters, residue trial requirement, Codex/EU/U.S.
  - Promote harmonisation in crop classification, residue extrapolation, and commodity imports/exports

### Organisation for Economic Co-operation and Development (OECD) Minor Use Effort
- **Leaders/Supporters:** Registration Steering Group (RSG) of OECD – Chaired by Australia, Industry Associations, FAO, European and Mediterranean Plant Protection Organisation (EPPO), IR-4
- **Objectives and Key Focus Areas:**
  - The ultimate goal is to assist countries, registrants and growers solve minor use problems through activities associated with baseline information, collaborative data generation, joint reviews and data sharing.
  - The long-term objective is the development of guidance documents for solving minor use data gaps.
- **Priority Activities:**
  - EGMU identified 3 key target areas:
    1. Cooperation considerations
    2. Technical considerations
    3. Policy considerations
  - Identify mechanisms that enable international cooperation on minor use issues including work-sharing
  - Supply technical guidance on preparation of data submissions for minor use
  - Assist in minimising barriers to approval of safe minor uses
## Part 1: Initiatives

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Leaders/Supporters</th>
<th>Objectives and Key Focus Areas</th>
<th>Priority Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>USDA/FAS initiative/Trade Facilitation through Capacity Building</td>
<td>USDA/FAS (Foreign Agricultural Service of US Dept. of Agriculture) Supporters: FAO, IR-4, Pesticide Initiative Programme (PIP), Association of Southeast Asian Nations (ASEAN), African Union (AU), Inter-America Institute for Cooperation on Agriculture (IICA), CropLife International</td>
<td>Facilitate the establishment of harmonised MRLs for minor use in specialty crops. Drive MRL harmonisation by establishing Codex MRLs for minor uses. Build capacity and infrastructure in developing countries to generate data required for JMPR submission/Codex MRL dossier, and harmonise regional registration requirements and crop grouping systems.</td>
<td>• Workshops held in several regions including Latin America, Africa and Asia to follow-up on GMUS 1 and to identify priority crops • Promote MRL harmonisation/ Codex MRLs • Initiate Codex MRLs for minor uses/ engage developing nations in CCPR process • Initiated pilot pesticide residue field trial programme with low-risk pesticides</td>
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<td>PIP (Pesticide Initiative Programme)</td>
<td>PIP is implemented by the Europe-Africa-Caribbean-Pacific Liaison Committee (COLEACP; an inter-professional association promoting sustainable horticultural trade between the EU and the ACP countries), and financed by the European Development Fund at the request of the ACP Group of States.</td>
<td>The Pesticides Initiative Programme, implemented by COLEACP, has completed the first phase and launched phase two in October 2009 for a period of 5 years. The goals of the programme include: • Enabling ACP producers and exporters to comply with new food safety regulations and standards, as well as sustainability standards (environment, ethical, fair trade) • Increasing the contribution made to economic growth and poverty alleviation by focusing support on disadvantaged groups (e.g. small-scale growers, rural women) • Disseminating some of the technologies, knowledge and skills developed for the export sector to benefit local, regional and processing markets • Engaging with policy-makers to improve conditions for market access and ensure that regulations and standards do not create barriers for ACP exports • Developing crop production and crop protection technologies that are cost effective and minimise pesticide residues • Ensuring sustainability by capacity building of companies &amp; service providers</td>
<td>• Organising residue trials for requests of EU import tolerances and Codex MRLs (JMPR evaluations) for exported and local ACP commodities • Organising efficacy trials needed (i) for the guides to good plant protection practises &amp; the technical itineraries and (ii) to strengthen plant protection products registration dossiers submitted by applicants at national level in ACP countries • Being an interface between applicants and national &amp; regional registration authorities • Helping to put in place harmonised (regional) registration bodies • Setting evaluation and technical protocols for the regional and local registration authorities • Building national and regional registration authorities capacities</td>
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<td>Expert Working Group (EWG) on MRLs</td>
<td>ASEAN member states</td>
<td>The objective is to harmonise MRLs for traded crops in ASEAN countries. The economics of South East Asia are committed to harmonising MRLs following the establishment of pest lists to underpin negotiations for expanding trade in agricultural commodities.</td>
<td>ASEAN members developed pest lists showing the distribution of pests in different production areas to gain access to markets for their agricultural commodities. They have also harmonised a significant number of MRLs over the years.</td>
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</tbody>
</table>
## Initiatives and Schemes in Support of Minor Uses

### Part 1: Initiatives

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Leaders/Supporters</th>
<th>Objectives and Key Focus Areas</th>
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</tr>
</thead>
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<td><strong>Interregional Research Project Number 4 (IR-4)</strong>&lt;br&gt;www.ir4.rutgers.edu&lt;br&gt;Established: 1961&lt;br&gt;Scope: U.S.</td>
<td>USDA and Rutgers University Plant Science Industry</td>
<td>To provide safe and effective pest management solutions for specialty crop growers.&lt;br&gt;IR-4 is a publicly funded research programme that develops data necessary to facilitate the registration of crop protection products for specialty crops.</td>
<td>• Successful cooperation with stakeholders to register for minor uses in U.S., Canada and Codex on ongoing basis&lt;br&gt;• Extremely active at international level, in NAFTA, Codex and OECD&lt;br&gt;• IR4 maintains Global Minor Use Portal (<a href="http://www.gmup.org">www.gmup.org</a>) as follow-up from GMUS</td>
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<td><strong>Minor Crop Farmer Alliance (MCFA)</strong>&lt;br&gt;Established: 1991&lt;br&gt;Scope: U.S.</td>
<td>Agricultural trade associations and commissions/United Fresh Produce Association</td>
<td>The Minor Crop Farmer's Alliance is a coalition of U.S. minor crop producers that work together cooperatively to address regulatory issues that might affect production and sales. The group, comprised of over 30 states, regional, and national agricultural trade associations and commissions, voluntary meets several times each year in Washington, DC and elsewhere as needed to address pending issues. The MCFA has neither an office nor staff.</td>
<td>• Advocate for the availability of pesticides for minor uses&lt;br&gt;• Monitor U.S. regulatory changes that may affect minor crops</td>
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<td><strong>North American Free Trade Agreement (NAFTA) Minor Use Joint Review Procedure</strong>&lt;br&gt;www.epa.gov/oppfeed1/international/naftatwg/&lt;br&gt;www.hc-sc.gc.ca/cps-spc/pubs/pest/_corp-plan/nafta-alena/jr07-00-1005-eng.php&lt;br&gt;Established: 2004-2010&lt;br&gt;Scope: U.S./Canada</td>
<td>U.S. Environmental Protection Agency (EPA), the Canadian Pest Management Regulatory Agency (PMRA), IR-4 under USDA and Canadian Pest Management Centre under Agriculture and Agri-Food Canada</td>
<td>To develop data and a registration process that will permit a regulatory decision of pesticide uses for the minor use grower communities in both countries simultaneously in a reduced timeframe.</td>
<td>• The first pilot candidates were successfully registered following the draft Standard Operating Procedure (SOP) developed for the new process for registering minor uses.&lt;br&gt;• A work-share process has been developed to review the residue chemistry data and ensure both EPA and PMRA agree on the level for MRLs.</td>
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<td><strong>Minor Use Pesticide Programme (MUP)</strong>&lt;br&gt;www.agr.gc.ca/prrmpup&lt;br&gt;Established: 2002&lt;br&gt;Scope: Canada</td>
<td>Pest Management Centre of Agriculture and Agri-Food Canada (AAFC)</td>
<td>The MUP Programme provides benefits to Canadian producers, the environment, and consumers by focussing on:&lt;br&gt;• Making minor use pesticide products, with emphasis on reduced-risk products, more readily available&lt;br&gt;• Providing Canadian producers with access to new pest-management technologies to improve their competitiveness domestically and internationally.&lt;br&gt;Agriculture and Agri-Food Canada support a separate minor use group known at the Pest Management Centre. This group was set up similar to IR-4 in the U.S. and develops efficacy, crop tolerance, and residue data to support minor use priorities developed by grower associations.</td>
<td>• AAFC is conducting field trials to generate the data needed to support submissions to the PMRA for registering minor use pest-control products. This activity complements the existing roles and responsibilities of pesticide manufacturers in submitting products to the PMRA for registration, and encourages manufacturers to register products in Canada.&lt;br&gt;• Annual workshop held in March to establish research priorities&lt;br&gt;• Several joint projects with IR-4 annually</td>
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## Initiatives

### European Union (EU) Initiatives

**Northern and Southern Technical Working Group on Minor Uses (TWG)**
- Established: 2003
- Scope: EU
- **Leaders/Supporters:** Directorate General Health and Consumers (DG SANCO) of the European Commission in co-operation with the national representatives for Minor Uses
- **Objectives and Key Focus Areas:**
  - Co-ordinate the minor use work in the EU.
  - Give a platform for the EU member states for discussion and co-operation in the field of minor uses.
  - Establish and harmonise the basics for an EU-wide co-operation on minor uses.
- **Priority Activities:**
  - Co-ordinate the technical activities in the EU
  - Give guidance on the development of national minor use procedures
  - Harmonise the implementation of the provisions of EU regulation 1107/2009
  - Support the development of a common EU Minor Use Database (EUMUDA)

### Expert Working Groups on Minor Uses (EWG)

- **Groups:**
  - Processed Vegetables
  - Small- & Stone Fruits
  - Fresh Vegetables
  - Ornamentals
  - Hops (planned in 2012)
- **Leaders/Supporters:** National experts on minor uses in co-operation with growers- & producers association. The groups report to the TWG.
- **Objectives and Key Focus Areas:**
  - Exchange of information on national minor use programmes, available solution, trials and other studies for minor crops and exchange of data.
  - Joint cost and labour sharing projects to close minor use gaps.
- **Priority Activities:**
  - Discussion of the national needs lists
  - Exchange information on available plant protection strategies or available registrations or studies
  - Co-ordinate common working programs and joint projects
  - Establish and maintain the common minor use database EUMUDA: www.plant-protection.eu

### Arbeitskreis Lückenindikation der ÖAIP (Working Sub-Group on minor uses of the Austrian working group on integrated plant protection (ÖAIP))

- **Leaders/Supporters:** The ÖAIP is composed of all parties having interests for crop protection including agriculture, science, authorities and industry.
- **Objectives and Key Focus Areas:**
  - Coordinate minor use registration applications.
  - The programme acts as a framework to ensure registrations at reduced investments costs.
- **Priority Activities:**
  - Application is done by the ÖAIP
  - The manufacturer involved then has to take care of the rest of the procedure
  - After the process the registration is transferred from ÖAIP to industry
  - Shared registration fees for minor uses with 83% of the registration fee covered by ÖAIP and 17% by the registrant

### Belgian Minor Use Initiative (informal)

- **Leaders/Supporters:** Private Sector
- **Objectives and Key Focus Areas:**
  - To find solutions for registration gaps in minor uses to prevent illegal use of plant protection products and to protect consumer health.
  - An informal initiative by food chain partners ("DRC" in Flanders; CRP [Regional Committee Phyto of the Catholic University of Louvain-La-Neuve] in Wallonia), including farmer unions, to identify needs and provide solutions for minor uses.
  - The overall scope of the programme is to screen minor use issues, prioritise needs to match resources, check data availability with other Member States and with the crop protection industry or request new studies to fill data gaps, in addition to completing third party requests to competent authorities.
- **Priority Activities:**
  - An annual priority list is discussed between regulatory authorities and the plant protection sector.
  - The plant protection industry endeavours to provide information and data to authorities or to food chain partners (DRC; CRP) concerning candidate products.
  - Regulatory authorities coordinate actions and submissions coming from third parties along with contacts in other countries to guide them through the registration process in a timely manner.
  - Plant protection companies provide data to authorities and/or food chain partners to evaluate the possibilities of extending the use of their products on minor crops, while asking for the protection of specific data.

## Part 1: Initiatives
## Initiatives and Schemes in Support of Minor Uses

<table>
<thead>
<tr>
<th><strong>INITIATIVE</strong></th>
<th><strong>LEADERS/SUPPORTERS</strong></th>
<th><strong>OBJECTIVES AND KEY FOCUS AREAS</strong></th>
<th><strong>PRIORITY ACTIVITIES</strong></th>
</tr>
</thead>
</table>
| **Usages Orphelins**                                | Commission on the Orphan Uses, Ministry of Agriculture, Fisheries and Landscape (DGAL)                                                                                                                                                                                                 | The objective of the programme is three-fold and includes the identification of GAPs in terms of use/crop; the identification of solutions, based on benchmark with other Member States and discussions between authorities and stakeholders regarding the priorities of action. | • Identify minor use gaps in consultation with stakeholders  
• Actively seek participation from stakeholders to realise minor use registrations  
• Coordinate and where needed generate field data for minor uses  
• Motivate registration applications for minor uses |
| **Forum Phyto**                                     | French food producers (Cerafel and maraichers nantais) Growers associations, retailers (Coop de France) and plant protection industry – Union des Industries de la Protection des Plantes (UIPP)                                                                                   | The Forum Phyto programme works in collaboration with other stakeholders such as FNSEA, Légumes de France, Bonduelle. It is a member of the Commission des Usages Orphelins (see previous). Forum Phyto serves as a representative for work sharing with EU associations (Copa-Cogeca, ECPA) as well as a good network for farmers to reach media and include communication on risks and benefits of plant protection products. | • Exchange technical information, provide analysis and weekly updates to members (electronic newsletter), common work on non-registered uses to help growers |
| **Arbeitsgruppe Lückenindikationen** (Working Group Minor Uses) | Julius Kühn Institute (JKI)                                                                                                                                                                                                                                                        | The overall objective of the programme is the registration/authorisation of pesticides for minor crops and the international cooperation in the field of minor uses. Confidentiality clauses and financial compensation can be applicable should residue data produced by farmers and/or German authorities be wished to be used by third parties. If the “minor use” is part of the authorisation of a pesticide, the data protection rules of the PflSchG apply. | • Evaluation of public interest in applications of authorisations according to art. 51(2c), Regulation (EC) No 1107/2009  
• International coordination and cooperation in the field of minor uses  
• Executive Office of the Federal State Working Group Minor Uses  
• Participation in the maintenance of a list on minor uses in Germany according to art. 51 (8), Regulation (EC) no 1107/2009 |
| **Republic of South Africa (RSA) Pesticide Initiative Programme (PIP)** | Perishable Export Control Board (PPECB) semi-government organisation                                                                                                                                                                                                                | Operates under the same framework as the PIP (see above) but is a national programme with capacity building and research activities. Its objective is to contribute to continued access to the EU market for RSA horticultural produce (especially minor crops) & minimise the detrimental impact of EU food safety & consumer protection requirements on the RSA economy as a whole. | • Research projects to adjust production practices (to meet MRL in destination market) and finding of alternative plant protection products  
• Capacity building to improve responsible pesticide handling/application |
## Part 1: Initiatives

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Leaders/Supporters</th>
<th>Objectives and Key Focus Areas</th>
<th>Priority Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expert Centre for Speciality Crops</strong>  &lt;br&gt; <a href="http://www.specialitycrops.eu">www.specialitycrops.eu</a>  &lt;br&gt; Established: 2010  &lt;br&gt; Scope: The Netherlands</td>
<td>Ministry of Economic Affairs, Agriculture and Innovation / Wageningen University / Ctgb / LTO, Plantum NL and Nefyto</td>
<td>The Expert Centre for Speciality Crops is a network to facilitate minor crops and their inputs which are of importance to keep these high-quality crops viable in the Netherlands and Europe. The Expert Centre will:  - Define and coordinate projects for minor uses (research) and data sharing and studies aiming at making authorizations possible  - Create a platform for stakeholders to discuss minor use gaps and discuss solutions</td>
<td>• The different stakeholders and authorities will collaborate together to ensure coordination between research, advice, financing and authorisations. By creating a virtual knowledge centre, it will be able to more quickly identify experts on specific sub-areas.  • For this purpose, several helpdesks have been set up i.e. a helpdesk for authorisations and a helpdesk for minor uses.  • Coordinators will prepare inventories of existing and future crop protection gaps, for which collaboration between authorities and stakeholders is undertaken to identify which plant protection products could best be used and for which subsequently an authorisation should be requested.</td>
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<td><strong>Minor Use Project</strong>  &lt;br&gt; Scope: Sweden</td>
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<td>• Studies such as scanning plant protection products in minor crops in field experiments, including pesticide residue trials for registration</td>
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<td><strong>Assistance for Minor Uses</strong>  &lt;br&gt; <a href="http://www.maff.go.jp/j/syouan/">www.maff.go.jp/j/syouan/</a> syokubo/gaicyu/index.html  &lt;br&gt; Established: 2005  &lt;br&gt; Scope: Japan</td>
<td>Food Safety and Consumer Affairs Bureau, Plant Protection Division of J-MAFF.</td>
<td>The main objective is to provide support to ensure sufficient data is available to register minor uses according to the authorities. Minor crops are generally cultivated in limited local areas and pesticide manufacturers are less likely to develop data needed for the registration.</td>
<td>Subsidies are provided by the Japanese government to prefectural governments for the following activities:  - Establishing the systematic protection method for minor crops. Under this scheme, efficacy trials and residue trials can be conducted.  - Promotion of the appropriate use of agrochemicals in terms of application rate and timing. Under this scheme, residue trials can be conducted.  - Activation of rural area in order to promote agriculture, forestry and fishery. One focus is to protect minor crops specific to the area. The subsidy can be allocated to conduct the studies for the registration of agrochemicals.  - Development of the protective method for multiple crop cultivation. Studies are usually contracted out to private organisations (laboratories) to investigate which agrochemicals are the most effective on which pests or diseases when multiple crops are cultivated at the same time. Data generated under this scheme can be used to register agrochemicals for minor crops.  - Development of novel technologies to promote new agricultural policy. New technologies include protection of crops from pests and diseases. Under the scheme, studies to promote registration of agrochemicals are highly recommended.</td>
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<tr>
<td><strong>Minor Use Registration</strong>  &lt;br&gt; (studio sulle culture minori)  &lt;br&gt; Established: 2005  &lt;br&gt; Scope: Italy</td>
<td>Ministry of Agriculture, Food and Forestry (MiPaaf) in cooperation with Italian Regions</td>
<td>Some trials for efficacy and residues are paid by the Ministry of Agriculture.</td>
<td>• The programme consists of a fast-track authorisation procedure for plant protection products and involves less study requirements.</td>
</tr>
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</table>
### Sahelian Pesticide Committee (‘Comité Sahelien des Pesticides’ or CSP), the Common Pesticide Registration Body

Established: 1973  
Scope: SAHEL Comité permanent Inter-Etats de Lutte contre la Sécheresse dans le Sahel (CILSS) Member States: Burkina Faso, Cape Verde, Chad, Guinea Bissau, The Gambia, Mali, Mauritania, Niger, and Senegal

- **Harmonised tests and field trials have been established and regional laboratories for conducting various analyses relating to pesticides are being identified.**  
The harmonisation is more likely to attract registrations for minor uses.

### U.S. Minor Use Registration Scheme

Established: 1999  
Scope: U.S.

- **Encourage minor use registrations to provide growers with increased pest control options.**  
The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) includes data protection and compensation, as well as other provisions for the registrants of pesticides. Additional regulatory incentives specific to the registration of minor uses is part of FIFRA, section 3.

- In addition to the standard 10 year period for the protection of data submitted in support of an original registration or a new use, the following is specific to Minor Uses:  
  - Protection period extended by 1 year for every 3 minor uses registered (with a maximum of 3 additional years possible; with regard to crop grouping, data submitted for each representative crop is considered 1 minor use) with a l of 13 years data protection possible for products labelled with minor uses  
  - Request for extension of data protection for the addition of minor uses must be submitted within 7 years after the date of registration  
  - In addition to the aforementioned period of data protection, data is compensable for 15 years from the date of study submission to the EPA.  
  - An offer to pay must be made to the data owner for any study another party wishes to utilize / cite that falls within said 15 year timeframe  

- Other potential minor use – specific incentives are as follows:  
  - Registration fee reduction  
  - Potential data requirement waivers

### EU Minor Use Regulation

Established: 2009/14 June 2011 (effective entry into force)  
Scope: EU

- **Providing definitions of minor uses informed by production volume. (Article 3 point 26)**  
- **Provision for listing minor uses per Member State (51.8)**  
- **Encouraging mutual recognition of minor use authorisations**  
- **Additional data protection for minor use registrations (per EU Member State) – 3 month for each MU with max.of 3 years per compound (Art. 59)**

**Additional motivation:**  
- Funding for EU minor uses (Art.51.parra7)  
- Consider for comparative assessment (Art. 50)
## Part 2: Schemes

<table>
<thead>
<tr>
<th>SCHEMES (NAME OR TITLE)</th>
<th>LEAD/REFERENCE TO LEGAL TEXT</th>
<th>OBJECTIVES AND KEY FOCUS AREAS</th>
<th>DETAILS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protection of Proprietary Interests in Pesticide Data in Canada</td>
<td>Pest Management Regulatory Agency (PMRA)</td>
<td>Extension of the period of data protection for the active ingredient based on Minor Use registrations. To provide regulated innovative crop protection solutions for minor uses in Canada. To partner with the Minor Use community and leverage the required work.</td>
<td>• 1 year extension for every 3 minor uses registered with residue and efficacy field trial data • 5 year maximum extension (15 minor uses); Minor Uses must be submitted within 7 years after the date of the initial product registration</td>
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<tr>
<td>User Requested Minor Use Registration (URMUR) policy</td>
<td>Pest Management Regulatory Agency (PMRA)</td>
<td>The purpose of the policy for URMUR is to encourage registrants to apply for the new active ingredient registration of conventional pesticides and biocides such as microbials and pheromones, that are registered in the U.S. or other OECD countries, but that due to potential low volume of sales might never be registered.</td>
<td>• Making use of acceptable foreign reviews completed in other countries, the procedures for the technical review of URMUR applications are as efficient as possible. • Registration standards for URMUR and URMULE applications are appropriate to the use, recognizing the relatively small sales volumes, use volumes and areas of use, as well as the need to maintain Canadian standards of health and environmental protection. URMULE: PMRA DIR2001-01 outlines the policy and process criteria for program consideration: • The active ingredient and the end-use product must be registered in Canada • Registrant supports the addition of the new use to its label • There must be sufficient information to assess the safety, merit and value of the proposed new use Cooperators: • Sponsors (Grower groups), Registrants, AAFC/PMC, Provincial/Forestry, Minor Use Coordinators</td>
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<tr>
<td>Additional Data Protection for Minor Uses</td>
<td>APVMA</td>
<td>A main objective is to provide protection of data in support of registration applications and new use patterns. The additional years available for minor uses were specifically developed to provide incentive for registration of minor uses. Data protection is available for new uses registered that rely on new data submitted. Major review of pesticides regulation is nearing completion. This will include proposals for minor uses. Expected end 2011</td>
<td>• A key focus of regulatory incentives for minor uses must be ones that add a value (attractiveness) for registration of the minor use to a registrant. • Data that has received 8 years protection will be extended by 1 year for each 5 distinct prescribed uses registered under this scheme.</td>
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</table>
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<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
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<td>Minor Use Permits Scheme</td>
<td><a href="http://www.apvma.gov.au/permits/">www.apvma.gov.au/permits/</a></td>
<td>This program allows user requested permits for the use of crop protectants in speciality crops. These permits are typically time limited and do not require the same level of data as a full registration.</td>
<td>A full database of existing permits may be found at <a href="http://www.apvma.gov.au/permits/search.php">www.apvma.gov.au/permits/search.php</a></td>
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</tbody>
</table>
| Minor Use Registration  | http://jppa.or.jp/ | The agricultural chemicals control law was amended in 2002 to reflect the positive list system. The amendment eventually led to the decrease of the number of agrochemicals permitted for use on minor crops. In order to keep minor crops on the market, the Japanese authorities promoted the registration of agrochemicals for minor crops through the establishment of a minor use council. | • The major role of the council is to coordinate registrations.  
• As it likely that different prefectural governments have the same request for minor use registration, the council will coordinate the necessary efficacy and residue trials to avoid duplication the studies. The council also provides the prefectural governments with the contact information of agrochemical manufacturers.  
• GLP (Good Laboratory Practice) was introduced into residue trials in Japan in 2011.  
• The number of residue trials will be increased to six for major crops in 2014. For minor crops, however, the requirement does not change and only two non-GLP trials are acceptable for registration. |

Since 1995  
Scope: Australia  

Established: 2003 (Council for promoting minor use registration established; and reorganized in 2010)  
Scope: Japan  

Council member representation from: Ministry of Agriculture, Food Safety and Consumer Affairs Bureau, Plant Protection Division  
Ministry of Agriculture, Food Safety and Consumer Affairs Bureau, Plant Products Safety Division, Agricultural Chemicals Office  
Ministry of Agriculture, Agriculture Production Bureau, Horticultural Crop Division  
Ministry of Agriculture, Agriculture, Forestry and Fisheries Research Council, Councils Secretariat  
Food and Animal Materials Inspection Center (FAMIC)  
Japan Plant Protection Association  
The Japan Association for Advancement of Phyto-Regulators  
The Institute of Environmental Toxicology  
Japan Crop Protection Association  
National Federation of Agricultural Cooperative Associations
## Part 2: Schemes

<table>
<thead>
<tr>
<th>SCHEMES (NAME OR TITLE)</th>
<th>LEAD/REFERENCE TO LEGAL TEXT</th>
<th>OBJECTIVES AND KEY FOCUS AREAS</th>
<th>DETAILS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minor Use Regulation</td>
<td>ANVISA – Brazilian Health Surveillance Agency MAPA-Ministry of Agriculture</td>
<td>Brazil published on February 24th 2011 the regulation for minor crops. This document is very important in order to start this process, but clarification is required on many specific points. The document requires refinement and specific questions need to be addressed, e.g. points such as funding, support for efficacy and residues studies, prioritisation need to be discussed.</td>
<td>• Minor use group following progress of submissions • Minor use regulations make provisions for expedited reviews</td>
</tr>
<tr>
<td>Extension of Authorisation for minor use in the United Kingdom (UK) (formerly known as ‘Scheme for Specific Off-Label Approvals (SOLAs)’)</td>
<td>UK authority (Health and Safety Executive HSE)</td>
<td>The Long Term Arrangements for Extensions of Use (LTAEU) were introduced as a temporary measure in the late 1980s to allow pesticides to be used on listed minor crops. Since that time UK pesticide approvals have gradually been transferring to EU based legislation, where specific approvals are required for all uses. The exercise to replace the LTAEU for use on edible crops by converting uses to Specific Off-Label Approvals (SOLAs), has now been completed. The LTAEU for use on edible crops expired on the 31 December 2006. Off-Label approvals for minor uses still exist in UK.</td>
<td></td>
</tr>
<tr>
<td>Minor Crop Registration Guidelines</td>
<td>Department of Agriculture, Forestry and Fisheries (DAFF)</td>
<td>To provide incentives for the registration of pesticides for minor crops/uses.</td>
<td>Data extrapolation for efficacy and phytotoxicity using Codex crop grouping is provided. The programme also provides fast tracking of registration of pesticides. The following conditions must be met: • The active ingredient and the formulation must be registered in South Africa. • The registrant supports the addition of the new use to its label. • The scientific motivation must be provided to assess the safety, efficacy and phytotoxicity of the proposed use.</td>
</tr>
</tbody>
</table>
APPENDIX I: LIST OF ABBREVIATIONS

AAFC  Agriculture and Agri-Food Canada
ACP   African, Caribbean and Pacific States
ASEAN Association of Southeast Asian Nations
AU   African Union
CCPR  Codex Alimentarius Committee on Pesticide Residues
CILSS Comité permanent Inter-États de Lutte contre la Sécheresse dans le Sahel
COLEACP  Europe-Africa-Caribbean-Pacific Liaison Committee
DG SANCO  Directorate General Health and Consumers
ECPA  European Crop Protection Association
EDF European Development Fund
EGMU  Expert Group on Minor Uses
EPPO  European and Mediterranean Plant Protection Organisation
EWG Electronic Working Group
FAO  Food and Agricultural Organisation
FAS  Foreign Agricultural Service (USDA)
FNSEA  Fédération Nationale des Syndicats d’Exploitants Agricoles (National Federation of Farmer’s Unions)
GMUS Global Minor Use Summit
ICGCC International Crop Grouping Consulting Committee
IR-4 Interregional Research Project Number 4 (IR-4)
JMPR FAO/WHO Joint Meeting on Pesticide Residue
MAFF Ministry of Agriculture, Forestry and Fisheries of Japan
MRL Maximum Residue Limits
MUP  Minor Use Pesticide Program
NAFTA North American Free Trade Agreement
OECD Organisation for Economic Co-operation and Development
PIP  Pesticide Initiative Program
PMRA Pest Management Regulatory Agency
PPECB Perishable Export Control Board (South Africa)
RSG  Registration Steering Group
SOP  Standard Operating Procedure
USDA United States Department of Agriculture
USEPA United States Environmental Protection Agency
WHO  World Health Organisation

APPENDIX II: LIST OF OECD MEMBER COUNTRIES

Australia, Austria, Belgium, Canada, Chile, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea, Luxemburg, Mexico, Netherlanda, New Zealand, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, United Kingdom, United States