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

Working Group on Pesticides

OECD Survey on Regulatory Incentives for the Registration of Pesticide Minor Uses: Survey Results

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This document contains the final draft report of the survey carried out in 2009 by the EGMU (Expert Group on Minor Uses) on "**Regulatory Incentives for the registration of Pesticide Minor Uses**". This survey was conducted to gather the extent of available incentives in OECD countries and to collect suggestions for new incentives to promote and encourage applicants to register products and new uses for pesticide minor uses. Seventeen responses were received from 16 countries and CropLife International.

The report contains three recommendations (in paragraph 10) that are provided to continue further dialogue and exchange of information in this area between regulators and industry on the development, improvement and implementation of incentives to enhance the registration of minor uses.

Following several rounds of comments, this survey report was approved by the members of the EGMU (deadline for comments on 11 February) and by the Registration Steering Group & Risk Reduction Steering Group (deadline for comments on 28 February 2011).

This is now circulated to the OECD WGP for approval.

Note: The WGP is invited to also refer to the "draft guidance on regulatory incentives", provided as a separate document ENV/JM/PEST(2011)6.

ACTION REQUIRED: ***The WGP is invited to:***

i. Approve the survey report, amended as appropriate; and

ii. Agree that it be forwarded to the OECD Joint Meeting on Chemicals with a request for declassification and publication in the OECD Series on Pesticides.

OECD SURVEY ON REGULATORY INCENTIVES

FOR THE REGISTRATION OF PESTICIDE MINOR USES:

SURVEY RESULTS

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EXECUTIVE SUMMARY

1. In response to an OECD survey conducted to gather the extent of available incentives in OECD countries and to collect suggestions for new incentives to promote and encourage applicants (chemical manufacturers/registrants) to register products and new uses for pesticide minor uses, seventeen responses were received. They include 16 countries Australia, Belgium, Canada, Czech Republic, Germany, Ireland, Italy, Japan, Netherlands, New Zealand, Portugal, Slovak Republic, Slovenia, Switzerland, United Kingdom and United States and CropLife International.

2. This report is a collation of regulatory incentives adopted by OECD countries for the registration of minor uses and is provided as information to national regulatory authorities in providing greater incentives to encourage applicants (manufacturers/registrants) to register new products and uses for minor uses. This report also contains suggestions made by respondents that could be considered for future areas in developing new incentives for the benefit of enhancing minor use registrations.

3. There were two main areas where regulatory incentives are provided to support or encourage minor use submissions by applicants. These included data protection extensions and fee waivers or reductions. Many countries reported that they did indeed provide some type of fee waiver for minor use registrations. These ranged from submission fees being totally waived for all possible applicants, if the intended use(s) is (are) of public interest (to show the real extreme), or partially waived if a manufacturer or applicant made the submission. Some countries have an accelerated procedure for minor use applications.

4. Many countries that have fee waivers also provide an extension of the exclusive use of data period or extend data protection period. European countries reported that the new EC regulations will also provide extended data protection when registrants make minor use submissions. In most cases where data protection is provided it has been extended by three to four years in addition to the original time period.

5. Few countries indicated that minor uses were reviewed on a "fast track" compared to reviews for standard submissions. If "off label" uses or emergency uses were allowed, they may be considered expedited reviews, however these are often temporary approvals. Data waivers were generally not provided for minor uses registrations, however in many cases greater flexibility is provided via mutually acceptable data (perhaps data from another country) or to use data extrapolations (or crop groupings) to allow minor use registrations. In 2011, in the EU, trials for efficacy/plant safety will no longer be necessary for minor uses.

6. There are very diverse approaches to the degree of government-funded programs for minor uses. In some cases such as in the United States and Canada, there are programs specifically established, designed and funded to generate data for minor uses and these programs generate the majority of data for minor uses in North America. In other cases there are "shared" programs where the government and manufacturer or grower share the cost of generating data.

7. Many countries do take advantage of existing international data, and also undertake "data mining" to provide the supporting information for minor use submissions. In some cases minor use approvals may also progressed by a "third party" i.e. not the main registrant for the product.

8. Respondents outlined that the development and implementation of incentives were a recognition for the strong need to deliver solutions that would enhance the registration minor uses and that incentives were critical in facilitating such an outcome.

9. The report contains three recommendations that are provided to continue further dialogue and exchange of information in this area between regulators and industry on the development, improvement and implementation of incentives to enhance the registration of minor uses.

RECOMMENDATIONS

10. The aim of the survey conducted was to provide an overview of regulatory incentives available to enhance the registration of minor uses. It is therefore recommended that:

(i) Member countries when considering the development and implementation of regulatory incentives for minor uses should utilise this report in considering options.

(ii) The Working Group on Pesticides through Risk Reduction Steering Group (RRSG) & Registration Steering Group (RSG) and the Expert Group on Minor Uses should consider, based upon the finding of this survey, the development of a guidance document on regulatory incentives for the registration of minor uses.

(iii) Regulators and industry should continue to:

a) progress and maintain dialogue and information exchange on the successful implementation of regulatory incentives, and in doing so continually, and

b) review existing incentives, explore improvements in existing incentives and opportunities for new incentives.

SUMMARY OF THE SURVEY RESULTS

1. Current Incentives Implemented

		Yes or No	***Responses/Summary***
1a	**Fee reductions or waivers** If YES please describe	Most reported that there are waivers. No waivers reported at: Australia, Japan, New Zealand, Netherlands, Italy.	Submission fees generally waived or reduced. Reductions may depend on submitter. If public organization (IR-4, PMC, growers) then generally fees waived. Possible reduced fees for the company submissions. EU is phasing out national waivers as new regulations come into effect (see comments below). Generally off label uses are considered in the public interest and there is no fee. For registrants (companies) there may be a graduated fee (EU/CAN). Companies may need to provide sale volume data. There may also be reduced efficacy requirements in some countries.
1b	**Extension or increased periods of data protection** If YES please describe	Most reported that there are no increased data protections in place.	Countries with increased periods of data protection included US/CAN/and EU (new regulation). All three have similar incentives that may increase the data protection period for up to 3 (US/EU) or 5 (CAN) years when minor uses are added to product labels. Although many EU countries indicated that there were no incentives, it was noted that the new regulations could allow for up to 3 years of data protection.
1c	**Liability (limitations or waivers)** If YES please describe		In the EU countries, the liability generally lies with the user. Especially with off label uses. Australia, US, Switzerland, Portugal, and Japan, were the only countries that responded that did not have a liability waiver at this time.

		Yes or No	*Responses/Summary*
1d	**Expedited review ('fast-track')?** If YES please briefly describe process		A few countries (Korea/CAN) had expedited reviews or where "off label" uses were allowed, it was considered an expedited (shortened) review. However, for most countries that responded, minor use reviews are made through normal processes and are not expedited (unless they are considered an emergency use). Generally as extensions from major crops.
1e	**Reduced data requirements, data waivers, use and acceptance of international data or registrations?** If YES please describe		Reduced data (residue and or efficacy). Many countries had "mutually accepted data" that could be used. In many cases these data were data from other countries with similar GAPs that could be used in place of data from the requesting country. Although some countries did not have reduced data requirements (US/CAN) they do allow for case by case data waivers or utilize crop group extrapolations.
1f	**Grower assisted data generation programs funded by governments?**	Mostly Yes – However, level of support varies considerably.	Many countries have programs that are funded either in part or whole by government funds. Ranged from rather large programs (US and CAN) to assistance programs where shared support from government and companies (even with regard to study conduct). Generally generate residue and efficacy data and provide regulatory support. Very little direct grower support in the form of funds. However, they do provide requests or priorities. Countries that have no programs include: Portugal, UK, Slovak Republic, Slovenia, New Zealand

		Yes or No	*Responses/Summary*
1g	**Others / additional comments** If YES please describe		Third parties and off label uses are common in many countries, they request the uses and MRLs instead of companies. Canada-PMRA has access to an international database that can assist with data mining and collaborative data generation. There continues to be a need for a system that allows minor uses to be added to labels in a short period of time (CLI).

		Responses/Summary
1h	**What was the reason or purpose to develop, provide and promote such incentive(s)?**	After it was recognized that there was a lack of interest by companies to register minor uses, these incentives were developed to encourage companies to add more minor use registrations (including off label approvals). Also used to speed the process of adding minor uses to labels. To fill gaps and increase the range of products in plant protection for minor uses and to share the responsibility to address the needs of speciality crop growers.
1i	**Are the incentives implemented on a routine basis?** (Yes or No and please describe why)	Most replied with yes (or “more or less”) to address the needs of specialty crop growers. It was unclear from some responses if this was related to data: waivers, protection, and generation; or to liability waivers. Many responses were “Yes” with no additional information provided The US noted the wide use of crop groups and extrapolation as an incentives used routinely. CLI – indicated that they were not implemented on a routine basis except for emergency needs.

		Responses/Summary
1j	**To what extent do governments and applicants (chemical companies/manufacturers) use these incentives?** Please also indicate the most frequently used incentives and provide some examples if possible.	The incentives are being used for nearly every minor use approved (Germany) and used extensively for off label/third party uses. Generally used by government or public organizations (like IR-4) with very little use by companies, except for the data protection and some waivers. In Canada the incentives are used extensively and are a big help, but further incentives or regulator help is needed. CLI – only a few countries have fully funded programs to generate data and make submissions. The incentives are not widely used by applicants because of excessive liability.

2. Suggested Incentives

2a	**Are there any proposals to implement regulatory incentives currently under consideration in your country?** If YES please describe	Responses: CAN is developing regulations for protection proprietary interests in pesticide data in Canada. US are updating/expanding crop groups. Many of the noted comments depend on the implementation of new EU regulations which will increase data protection period and intend to establish a fund to support minor uses. Switzerland is considering extending data protection when minor uses are added.
2b	**Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?**	Responses: CAN provided a long list of suggestions ranging from incentives for biopesticide products, shorter timeframes, waiving requirements for efficacy data, more funding, incentives for global registrations, have exempted or non-registered list for products that are “house-hold” products. Etc. Italy noted that since many of the incentives result from products that are registered on major crops and then extensions are provided to minor crops, that it may be useful to have incentives for products developed specifically for minor uses/crops. The example provided was for pheromones.

ANNEXES

Compilation of all responses provided by respondents

ANNEX 1: AUSTRALIA

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	No	
1b	Extension or increased periods of data protection If YES please describe	Yes	Data protection is available for new uses registered that rely on new data submitted. For existing registered products gaining new use patterns 5 years protection is granted for the use. For registrations involving new active ingredients 8 years protection is granted. For new active ingredients an additional three years (up to a maximum of 11 years protection) may be granted for the registration of minor uses. http://www.apvma.gov.au/registration/downloads/data_protection_provisions.pdf
1c	Liability (limitations or waivers) If YES please describe	No	
1d	Expedited review ('fast-track')? If YES please briefly describe process	No	

		Yes or No	*Comments*
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	Yes	On a case-by-case and as outlined in the above sections within Part 1 on efficacy and crop safety. International Work Share Projects through OECD is assisting in this regard.
1f	Grower assisted data generation programs funded by Governments?	No	
1g	Others / additional comments If YES please describe		

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	For 1b (Data Protection) one reason was to provide protection of data in support of registration applications and new use patterns. The additional years available for minor uses was specifically developed to provide incentive for registration of minor uses.
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	Yes for 1b (Data Protection) as it is a legislative requirement that the APVMA must protect submitted data. For 1e (data waivers/extrapolation etc.) it varies depending upon the situation and then also typically only in response to a request from the applicant for the waiver or extrapolation to be considered. It is not routine in that a minimum data package is known to then allow for automatic extension to a given minor use(s).
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	As noted above for data protection (1b) APVMA must protect the data. Registrants still make business case decisions on registration submissions they make. Whilst the current data protections provisions are available registrants do not routinely and/or frequently seek them.
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: NO. At least not in a formally published way, however many options are regularly discussed with both user groups and registrants.

2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments: A key focus of regulatory incentives for minor uses need to be ones that add a value (attractiveness) for registration of the minor use to a registrant. This may not necessarily or always be a direct economic value (return) from registration and sales attributed to the minor use, but may come from associated benefits of an economic nature to a registrant or where the inclusion of the use does not require significant cost, liability or resources to place the use on their label. The following suggestions may have the potential to encourage the addition of minor uses to product labels and may require one or more of those to be in place to ensure successes. • Provide for expedited reviews (reduced assessment timeframes) and/or extended periods of data protection for registration applications that include minor uses. This could encourage registrants to work more collaboratively with minor use affected industries and could be examined in various formats such as; o Formalising a listing of the top '100-200' priority minor use needs/gaps where should registrants seek to register uses for a listed minor use gap then expedited reviews and/or increased periods of data protection would apply, and/or o Issue grower industry groups/associations with an annual allocation of '*Fast-Passes*' for exchange with registrants who seek registration of minor uses of interest to the grower group(s). • Enable third parties (ie. grower associations) to apply for assessments for variations to product labels. Whereby the regulator assesses a grower request and if supported allows the registrant to update their label. This type of process currently operates in some countries. • Enable '*conditional minor use registrations*' for a period of up to 5 years for minor uses supported by a registration and/or data from overseas. It would be conditional on the registrant (perhaps in collaboration with the user industry) generating local confirmatory data and submitting for '*full registration*' during the period or within a set timeframe. • Allow for liability limitations, waivers and/or disclaimer statements on labels, for efficacy and/or crop safety, particularly where the minor use was a grower requested registration. • Provision of regulatory guidance documents for minimum data requirements for crop group registrations in areas of residues and efficacy/crop safety. Some countries already do have some guidance in this area. • Registration fee reductions or waivers for minor uses (this could be linked to similar suggestions provided above). • Provide related incentives to the above for registration of reduced risk options. • Establish grower assisted data generation programs, with components of available funding that could be utilised to enhance registrations and the above possible initiatives. The 'program' may however not be a 'regulatory' initiative but sit separate from the regulator and be managed between growers and registrants.

ANNEX 2: BELGIUM

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	Yes	Extension of use applied for by third parties are free of charge
1b	Extension or increased periods of data protection If YES please describe	No	
1c	Liability (limitations or waivers) If YES please describe	yes	Extension applied for by third parties and not accepted by the authorization holder are on the liability of the use
1d	Expedited review ('fast-track')? If YES please briefly describe process	yes	Extension of use applied for by a third party follow a parallel circuit
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	yes	Extension may be granted based on extrapolation or mutual recognition
1f	Grower assisted data generation programs funded by Governments?	yes	A fund is available finance residue trials in minor uses.
1g	Others / additional comments *If YES please describe*		

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	A lack of authorisations in minor crops
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	Yes

		Answer
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	Almost all extension in minor crops are based on third party applications
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments:
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments:

ANNEX 3: CANADA

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	Yes	The User Requested Minor Use Label Expansion program has no fees associated with the review of data. The label review sent by the registrant has a fee of $154.00.
1b	Extension or increased periods of data protection If YES please describe	Yes	See DIR 2007-03 Protection of Proprietary Interests in Pesticide Data in Canada
1c	Liability (limitations or waivers) If YES please describe	Yes	For use expansions registered under the User Requested Minor Use Label Expansion (URMULE) the registrant may put the following liability statement on their label: NOTE TO USER: READ THE FOLLOWING BEFORE USING THIS PRODUCT FOR THE INDICATED SPECIAL USE APPLICATIONS: The DIRECTIONS FOR USE for this product for the use(s) described on this Label were developed by persons other than (COMPANY NAME) and accepted for registration by Health Canada under the User Requested Minor Use Label Expansion program. (COMPANY NAME) itself makes no representation or warranty with respect to performance (efficacy) or crop tolerance (phytotoxicity) claims for this product when used on the crop(s) listed on this Label. Accordingly, the Buyer and User assume all risks related to performance and crop tolerance arising, and agree to hold (COMPANY NAME) harmless from any claims based on efficacy or phytotoxicity in connection with the use(s) described on this Label.
1d	Expedited review ('fast-track')? If YES please briefly describe process	Yes	A minor use registration involves a three step process. Step1: Pre-submission consultation. Where the PMRA assess the current database and submitted data for it's acceptability for review (97 days) Step2: Submission Review. The PMRA does a complete assessment of the available data to support the proposed use and comes to a regulatory decision on the use. (247 days) Step3: Label Verification. The PMRA reviews and approves the final label for the accepted minor use expansion and issues an amended certificate of registration for the registered product. The minor use program has slightly shorter timelines than the standard times for an addition of a minor use through our regular submission (Category B and C) programs.

		Yes or No	*Comments*
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	Yes	Data waivers and use of acceptable international data are considered on a case by case basis. Generally field trial residue data must be conducted in zones as per the Canadian Residue Chemistry requirements. The PMRA accepts scientific rationales in lieu of studies for review but reserves the decision on use of the information based on the quality of its content.
1f	Grower assisted data generation programs funded by Governments?	Yes	Agriculture and Agri-Foods Canada (AAFC) has a program that funds the generation of data for minor use submissions.
1g	Others / additional comments If YES please describe		PMRA: The Canadian Government has provided Canadian users and registrants with access to an internationally database that allows them to (i) identify pest control products that are used on similar crop/pest combinations in other countries, (ii) conduct a focussed data-mining approach in preparation of minor use data packages, and (iii) build collaborative data-mining and data generation activities with the corresponding industry sectors in other countries. Independent Researcher: Provincial grower associations in British Columbia, i.e., BC Raspberry Growers Council., BC Blueberry Council, BC Potato and Vegetable Growers Assoc., BC Greenhouse Growers; BC Landscape and Nursery Assoc. contribute research funds to generate efficacy data for minor use registrations on specific pests and crops. No annual $ are allocated specifically for this use: funding decisions are made by each grower association on a pest/crop and grower- need basis. For each crop, provincial growers, consultants, and industry reps meet twice a year and set priority needs for ORMULE and “new product” registrations in each province. National representatives meet once a year to review and rank priorities across the country. Priorities are then submitted for AAFC Minor Use funding the following year. Projects are first offered to AAFC researchers; then, if not taken up, to private contractors in a bidding process.

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	To encourage registrants to support the addition of more minor uses to the registered label
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	Registrants are responsible for informing the PMRA that they are eligible for the data extension period under the Protection of Proprietary Interests in Pesticide Data program.

		Answer
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	Quebec: As provincial government, we support the « User Requested Minor Use Label Expansion" program, once there are sufficient data or strong rationale that permits to anticipate the request will be accepted as it is. Since provincial government has very limited or no financial support/resources to generate data, Minor Use program is not used as much as it could be. Ontario: Provinces and sponsors of minor use label expansions make full use of these 'incentives' to address priority minor use needs on an on-going basis. CHC: 1) CHC: Many companies unwilling to use waiver of liability due to possible legal challenge 2) Too soon to see if the extra years of data protection will encourage more Minor Uses added by companies under PPIP 3) Fee waiver for URMULE has been good, but we have asked repeatedly to eliminate fee for 'URMUR' candidates to no avail. 4)Ambitious timelines for Minor Use have been slowed with arrears of work Alberta: The incentives I consider would be the technical assistance to develop the residue and efficacy trials required, as well as the regulatory advice/feedback for the applications. Nova Scotia: Provincial governments make good use of these incentives by coordinating and making submissions under the minor use registration program. They are also heavily involved in the Agriculture Agri-Foods minor use program. User Requested Minor Use Label Expansion. Submissions are made by or on behalf of producer associations. Provide input into the Minor Use Priority Setting process. PPMUC: Believe incentives create greater cooperation and interest in chemical companies in supporting minor use label expansions. Industry presence and support at the National Minor Use Planning Workshop is an indication of their interest. Flowers Canada: Applicants such as Flowers Canada Growers (FCG) frequently try to use the URMULE process. Unfortunately the User Requested Minor Use Registration (URMUR) process is not functional and needs to be remodelled. FCG also frequently uses AAFC funded programs for data generation. However funding research on ~30 products/year is inadequate given the soaring numbers of pest problems. Coupled with regulatory deficiencies it remains very challenging to provide products to treat existing pest outbreaks.

		Answer
1j		Saskatchewan: The waived fee (1a) for minor use applications is very important and highly utilized. Often minor use submissions for small crops are made on behalf of grower organizations or small crop industries that do not have access to funding sources for submissions. CropLife: 1j - URMULE is widely used (1a), PPIP is anticipated to drive minor use registrations though the final wording has not yet been established by the PMRA to determine which minor uses will be eligible(1b), limit of liability waiver is frequently employed but not legally tested (1c), expedited review is not noticeable (1d), international data is accepted but international reviews do not appear to be relied upon by the regulator, Acceptance of URMURs based on DERs only would be a huge incentive. Right now with the requirement for all data and DERs to be submitted, reduced efficacy and crop tolerance requirements for minor use submissions are coming into effect and would be expected to be used by Registrants (1e), AAFC program is fully subscribed although cannot begin to meet the demand, registrants are at times co-funding work with the PMC and IR4 on joint submissions (1f), PMRA: Within the first year over 150 people among the pesticide users, registrants, scientists and regulators have made repetitive use of Homologa. Independent Researcher: The URMILE program is used frequently.

	Answer
Additional comments: CHC Incentives so far are a good start but we need to see more results. Other incentives could be tried as well, even if for time-limited periods. Flowers Canada: Although we are grateful for the assistance we receive from both PMRA and AAFC, regulatory problems remain. The timelines outlined in this document (pre-populated by PMRA) seem inconsistent with our own past experience. Furthermore onerous data requirements for Canadian registrations are often voluntary or not required in other OECD nations (e.g. Dislodgeable Foliar Residue (DFR) data). This puts added financial burdens on the registrants who must submit to generating this data or face not having the product registered in Canada. Independent Researcher: The Canadian Pest Management Regulatory Agency (PMRA) requires efficacy data (a minimum of 3 trials) on each minor crop and each pest species, e.g., each species of aphids on each crop, unlike the U.S. or Europe. The PMRA requires each pest species controlled to be identified on the product label, on each crop. Nice idea: probably designed by a lawyer, not a biologist. Biology doesn't always fit into legal categories. Sometimes, this can get a bit silly. For example, as a private contractor, I am now doing 2 efficacy trials on a product for aphid control on roses. PROBLEM: the PMRA wants efficacy data on green peach aphid on roses. Green peach aphid rarely attacks roses. The efficacy trial request originated from growers and industry specialists in Ontario, who are not aphid experts: Myzus persicae is common on greenhouse vegetable crops there, so any green aphid on any crop is called a "green peach aphid." Obviously: not possible. The product should simply be evaluated for "control of aphids" on roses. Basically, if an insecticidal product controls aphids, midges or white flies, or a miticide controls two-spotted spider mites on one ornamental crop, it is likely to be equally effective for the same pest type on another crop: even if the pest species is different. There are some exceptions: e.g., occasional species of spider mites, that are less susceptible to certain products.	

	Answer
Herbicide efficacy data can be equally silly: for herbicide minor use label expansions in Canada, up to 10 efficacy trials in several crop zones are usually required with data on each weed species; not just broadleaves and grasses. Just for a label expansion: for a product already registered and in use in the U.S. or Europe for several years. *Remember, all of these examples above are not health or environmental studies for new product or major use registrations, just efficacy data required for minor use label expansions in Canada.* *As a result of the additional efficacy data requirement for minor uses, Canadian growers often do not have access to newer, safe, effective pest control products that are available elsewhere. Manufacturers are reluctant to assume the costs of additional efficacy testing only for the relatively small Canadian market.* *This is a particular problem in the Canadian ornamental and herb industry, with such a wide variety of crops, but for small-acreage vegetable and berry crops, also.*	

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: New Regulations are being developed for the Protection of Proprietary Interests in Pesticide Data in Canada
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments: <u>Quebec:</u> Acceptability of good efficacy screening trials in support of MU / Acceptability of efficacy trials with rotation of products (as used by the users to avoid resistance development)in support of MU / Determination of international (OECD) residue zones that includes North America / International (OECD - North America) harmonization of occupational exposure requirements / Addition of resistance development <u>Ontario:</u> a no fee or significantly reduced fee structure for low risk and biopesticide products. A revised fee structure for the URMUR program that more adequately reflects the minor use nature of many of these submissions. <u>CHC:</u> 1) Shortened timeframes for Cat 'A' submissions could be done on a sliding scale, dependant upon # of data-supported Minor Uses applied for here, as a % of those on the US (or other global) label 2) Fee elimination for Grower requested First Time registration for Minor Use Only registrations of new actives. 3) Waivers for crop tolerance and efficacy data and review with the inclusion of the Waiver 4) Statement for Minor Uses only. 5) Timeframe reductions for Cat 'B' and Cat 'C' submissions if for Minor Uses only. (others may be thought of by Crop Life members as well.)

		Alberta: Possibly help with a searchable database for pest issues. By this I mean for new or emerging crops it might be good to see what chemistry doesn't hurt them. Eg. The development of Artimesia extracts as a malarial chemical. It would be useful to know what chemistry/chemicals don't have an effect on that family of plants. Then, there might be some ideas on where to explore the options. I think there may be an increase in "minor"/limited acre crops for novel uses. Right now its hard to determine options for Minor Use applications for them. Nova Scotia: : Changes to the registration criteria for biopesticides ie harmonization with USA registration requirements. PPMUC: Waive requirements for efficacy data if minor use has been registered with IR-4 research results. Flowers Canada: Development of accurate and realistic residue thresholds for specialty crops similar to the work conducted by the Agricultural Re-Entry Task Force (ARTF) - Financial incentives/assistance for registrants bringing products to smaller markets - The development of surrogate crops for efficacy & residue data generation for commodities without a crop grouping – to reduce registration costs for registrants - Improvement of the URMUR process - Increased project funding for AAFC's Pest Management Center (PMC) - Improved or realistic timelines for regulatory review CropLife: 2b - if and when residue data is extended globally this will be a major incentive for registrants to pursue minor use registrations; any significant changes to crop groupings will also expand the opportunity for additional minor uses, (there is currently a concept of "super groups" being pursued for some reduced risk products but this will only be used for exceptional products); for Canada additional data to get around Value requirements is important - they are pursuing changes in efficacy and crop tolerance but for older products we are encouraging even less work or no work if the product has been registered, sold and accepted in a major market such as the US for an extended period of time; Better and more use of crop groupings for MU and reduced number of trials.:URMUR – it is great program for registration of new AIs in Canada. Should this program be implemented globally? How about the consideration of adding new use for a specialty crops under URMUR.? Also how about the cost reduction for URMUR fees, it can cost us $250000.

		PMRA: Establishment of a national and an international database of pest control needs listing the crop/site, pest, active ingredient, country, product name, registrant name and contact name of submitter. Independent Researcher: Comments: In Canada, organic pest control products such as garlic oils and solutions, cayenne pepper powder, cinnamon, sodium bicarbonate (baking soda), tee-tree oil, NEEM, etc. cannot legally be used, sold for, or recommended for pest control because these products have not been demonstrated to be effective in 3 replicated trials and no individual manufacturer is willing to conduct all the efficacy data, plus environmental and health data studies to get these products registered as 'Pest Control Products" in Canada. The PMRA does not usually prosecute these cases, but it leaves provincial gov't advisors to the organic industry and organic growers in an uncertain legal status, and legally prohibits any written recommendations, sale or use of these products for pest control. One Canadian manufacturer has submitted a NEEM formulation for registration in Canada, and AAFC is helping to generate the efficacy data needed for this product. The PMRA may waive the health and environmental studies: but we still don't know for sure. In the U.S., there is a "non-registered product list", which exempts these common house-hold products and natural products, such as NEEM, from regulation: not in Canada. I suggest, the Canadian legislation should be changed to allow these and similar products to be placed on an "exempted from regulation list", as in the U.S. The URMULE Program and AAFC Minor Use funding programs help to address this issue somewhat, but only a few efficacy trials can be funded each year. I can`t speak for the manufacturers, but I think they don't usually have a problem with a cautionary statement on the label, since the products have usually been registered and used on these crops in Europe and the U.S. for several years, before a minor use label is requested in Canada. Some progress is being made on "crop groupings", i.e., a product demonstrated to be effective for control of powdery mildew in 3 trials on one to three ornamental crops would automatically be extended to all ornamentals, with a caution on the label (with permission of the manufacturer) : "This product has not been tested on all crops. Manufacturer disclaims all liability. Test first for possible crop injury". However, progress has been slow in the ornamental/herb sectors with the PMRA wanting smaller crop groupings and the industry wanting broader groups. DFR: In recent years, the PMRA has begun asking for `Dislodgeable Foliar Residue (DFR) data on pest control products used in the ornamental nursery industry. These trials are very costly and have delayed or prohibited registration of many pest control products for the ornamental and greenhouse vegetable sectors in Canada.

ANNEX 4: CZECH REPUBLIC

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	Yes	Specific fees if the application is submitted by growers associations or state or scientific body.
1b	Extension or increased periods of data protection If YES please describe	No	
1c	Liability (limitations or waivers) If YES please describe	Yes	Liability of user of the plant protection product.
1d	Expedited review ('fast-track')? If YES please briefly describe process	No	
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	Yes	Limited number of data, large acceptance of international data od registration reports.
1f	Grower assisted data generation programs funded by Governments?	Yes	
1g	Others / additional comments If YES please describe	No	

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	Gaps in the plant protection in the area of minor uses.
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	Yes – see above

		Answer
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	The most effective incentives are the limited data requirements and reduced fees.
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: The situation is going to improve after implementation of the new EU PPPs Regulation in 2011. We do not suppose any changes before.
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments: -----

ANNEX 5: GERMANY

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	yes	for off label approvals of public interest there is no fee if the profit for the company is too high, or is the use too large (national calculation model) a graduated fee is required
1b	Extension or increased periods of data protection If YES please describe	no in future yes	In future with the upcoming EU regulation: 3 month for every minor use up to 3 years additional data protection
1c	Liability (limitations or waivers) If YES please describe	yes	liability lies with the user, the user has to test the product before it is used under his conditions
1d	Expedited review ('fast-track')? If YES please briefly describe process	yes	normally (there are exceptions) GAP for off label must be covered by a full registered GAP, thus, a fast track evaluation within about 4 months is possible. The registration of off label use ends with the registration of the product
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	yes	In principle 3 trials are necessary or studies available in literature or by extrapolation; International data can be accepted when GAP and agricultural conditions are comparable.
1f	Grower assisted data generation programs funded by Governments?	yes	Plant Protection Services of the Federal States perform trials for efficacy/plant safety and residues for off label approvals free of charge. Financing of GLP analysis of residues comes from companies, Federal States, growers and its associations.
1g	Others / additional comments If YES please describe		

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	1a: to get off label approvals, otherwise no one would deal with registrations in minor uses to enable minor use applications by third parties (authorities, growers, growers associations) 1b: companies are requested to include minor uses in their registrations (to compensate the costs) 1c: this was the prerequisite to get agreement from companies for cooperation in the national minor use programme 1d: see above 1e: according to EPPO rules 1f: off label approvals must be of public interest, Federal States do support this by trial programmes
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	Yes, see 1h
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	all incentives are being used at every minor use application, except 1b this incentive will be introduced by a new EU regulation in future
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: at present the model we use to decide if the intended use is of public interest is being revised
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments: to introduce a fund for better international cooperation of national experts at working level: to save money and time by exchange of data and by carrying out of joint trial programmes (see IR-4)

ANNEX 6: IRELAND

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	Yes	Company required to prove low sales volume sand value.
1b	Extension or increased periods of data protection If YES please describe	No	
1c	Liability (limitations or waivers) If YES please describe	Yes	Pertinent in relation to “off label” approvals.
1d	Expedited review (‘fast-track’)? If YES please briefly describe process	Yes	
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	Yes	Data from other countries is mutually recognised, however data ownership and data protection is respected. In the case of wet weather diseases, specific Irish data required.
1f	Grower assisted data generation programs funded by Governments?	Yes*	* one such initiative undertaken.
1g	Others / additional comments If YES please describe		

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	Companies slow to seek approval for marginal/minor crops leading to pest control problems in minor crops.
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	Yes. In the EU the new MRL regulations and the EU review programme has lead to an increasing number of problems in the area of minor uses. Thus we as an authority are forced to routinely implement such measures.

		Answer
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	"Off label" route used extensively by Government Agencies and Farmer organisations. We do not allow Companies to initiate "off label" approvals. Reduction in fees only sought by companies in the most extreme circumstances.
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: NO
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments: Not considered.

ANNEX 7: ITALY

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	NO	
1b	Extension or increased periods of data protection If YES please describe	NO	
1c	Liability (limitations or waivers) If YES please describe	NO	
1d	Expedited review ('fast-track')? If YES please briefly describe process	YES	Regarding minor crops treated in the interregional program for the qualitative improvement of agricultural yields "Residue control of agrochemicals products for rationalization of crop protection management: study on minor crops "the request of extension for use have to be discussed first.
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	NO	But there are requested a minor number of trials
1f	Grower assisted data generation programs funded by Governments?	YES	It exists the interregional program for the qualitative improvement of agricultural yields "Residue control of agrochemicals products for rationalization of crop protection management: study on minor crops "
1g	Others / additional comments If YES please describe		

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	The producing societies of ppp don't have economic interests to invest on minor uses

		Answer
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	NO. The interregional program for the qualitative improvement of agricultural yelds “Residue control of agrochemicals products for rationalization of crop protection management: study on minor crops ” has a limited period and fund.
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	The studies about minor crops majorly deficient in ppp, highlighted by Regions in the program indicated above, are financed.
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: yes, that the program continues
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments: that the interregional program is continuously financed.

ANNEX 8: JAPAN

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	No	
1b	Extension or increased periods of data protection If YES please describe	No	
1c	Liability (limitations or waivers) If YES please describe	No	
1d	Expedited review ('fast-track')? If YES please briefly describe process	Yes	If necessary, the examination period of a pesticide used to minor crops is shortened.
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	Yes	- Reduced number of efficacy/crop safety trials. (see comments on additional comments of Part 1) - The GLP compliance requirement for a testing facility implementing test of persistence in crops is exempted if the amount of production is low. (Appendix Table 1 (1) on item of Test results regarding persistence in crops, Notification No. 12-Nosan-8147)
1f	Grower assisted data generation programs funded by Governments?	Yes	MAFF covers fifty percent of the cost for developing data for registration (of a pesticide) applicable to minor crops upon request from relevant prefecture/growers associations.
1g	Others / additional comments If YES please describe		

	Answer

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	Minor crops are generally cultivated in limited local areas and pesticide manufacturers are less likely to develop data needed for the registration.
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	Yes
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	We receive a large number of requests from prefectural governments for facilitation of registration of minor crops.
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments:
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments:

ANNEX 9: NETHERLANDS

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	No	
1b	Extension or increased periods of data protection If YES please describe	No	
1c	Liability (limitations or waivers) If YES please describe	Yes	NL Trustee Foundation, if the applicant is the Trustee
1d	Expedited review ('fast-track')? If YES please briefly describe process	no	
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	Yes	Reduced data in relation to efficacy Reduced data in relation to residue
1f	Grower assisted data generation programs funded by Governments?	Yes	NL Fund Minor Uses
1g	Others / additional comments If YES please describe	-	

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	1. NL has a lot of minor uses (speciality crops) 2. Shared responsibility of Government, Growers' Associations and Industry 3. Industry is reluctant to invest in minor uses, due to high costs
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	More ore less, the NL Fund Minor Uses is a long term project (5 years)

		Answer
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	Third party extensions, on average 5 – 7 registration/year (2001-2008) NL Fund, on average 20 requests
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: This is depending on the implementation of the new EU Regulation
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments: Listing of major uses instead of listing minor uses; all what is not listed as a major use, is then automatically classified as minor use.

ANNEX 10: NEW ZEALAND

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	No	
1b	Extension or increased periods of data protection If YES please describe	No	
1c	Liability (limitations or waivers) If YES please describe		
1d	Expedited review ('fast-track')? If YES please briefly describe process	No	
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	Yes	Applicants can provide technical arguments to waive or reduce the amount of data required
1f	Grower assisted data generation programs funded by Governments?	No	
1g	Others / additional comments If YES please describe		Under the NZ legislation it is possible for a party, other than the registrant (known as third party), to make an application for an additional use for an already registered product. The registrant is consulted over such requests, and should they have no objections, then if approved, they can if they wish add the additional use to the label. In addition, NZFSA recognises the small size of the NZ market. Therefore, while it has the ability to restrict use to those stated on the label for a product, it allows most products to be used off label. However, it is a requirement that the end-user must ensure the treated produce complies with our NZ MRL standard. It should also be noted NZFSA has restricted use to on label approvals for a few products to manage specific risks these products have.

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	A grower organisation has used the facility of the third party applications on occasions.
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: Not at this stage, but we are considering the matter
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments:

ANNEX 11: PORTUGAL

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	Yes (minor uses); No (minor uses on labels)	The fee for minor uses applied by third parties is reduced.
1b	Extension or increased periods of data protection If YES please describe	No	
1c	Liability (limitations or waivers) If YES please describe	No	
1d	Expedited review ('fast-track')? If YES please briefly describe process	No	
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	Yes *	• On-labels: reduced data, compared to major uses : reduced number of residue and efficacy trials; recognition of trials carried out in others countries and possibility of using extrapolation. • Off-labels : efficacy data not required; communitary MRL required; recognition of registrations in others members states .
1f	Grower assisted data generation programs funded by Governments?	No	
1g	Others / additional comments If YES please describe	-	

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	

		Answer
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments:
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments: Commision funds would be very helpful, to implement projects between companies, regulatories bodies and third parts.

ANNEX 12: SLOVAK REPUBLIC

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	N/Y	N – The registration fee is the same for both authorized minor uses and the major crop. Y – Financial discount comes from the ½ cost of biology efficacy trials (see 1c, 1d). The fee is minimal (symbolic) for the off-labels.
1b	Extension or increased periods of data protection If YES please describe	N	
1c	Liability (limitations or waivers) If YES please describe	N	Responsibility exception regards the “off-labels” only. If there are no data of efficacy and safety for the crop, then the extrapolation of data will be applied. The grower uses plant protection product on his own responsibility if the efficacy of the product and its safety are concerned! The product has to be used according to the approved label (except the “instructions for use” part).
1d	Expedited review (‘fast-track’)? If YES please briefly describe process	N	
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	Y	Authorized minor uses are the same as for the major crop (for exception see 1c, 1d). The exception is requirements of dossier for “other products”, where in accordance to the type of product the expert institution will consider e.g. toxicology. Reduced requirements of data are for “off-labels” (1c).
1f	Grower assisted data generation programs funded by Governments?	N	
1g	Others / additional comments If YES please describe	N	

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	No adequate protection of some crop exists in the Slovak republic. It is regarding crop which are grown on relatively small area, resp. it is regarding pests which exist on common crop relatively scarcely. The registration holders are not usually interested in extended use from economical reasons.
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	Routine conditions for "off-labels" registration are: 1. the product is registered in the Slovak Republic. 2. there is no other protection of the crop 3. sufficient efficacy of the product against pests 4. crop safety 5. safety of consumer health The exception for ecological products of "off-labels" is that even if sufficient number of products for given use is registered registration of extended use of ecological product will be given.
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	Cooperation of chemical companies with regulatory office (ÚKSÚP) and growers: - chemical company applies for registration of authorized minor uses - grower, growers association, etc. apply for the "off-labels" registration The chemical companies are to provide data required for the "off-label" registration if they have such.
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: NO
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments: NO

ANNEX 13: SLOVENIA

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	yes	No fee for minor use registration is charged. Only administrative tax is charged (17 Euros)
1b	Extension or increased periods of data protection If YES please describe	no	New EU legislation, which should be published this year, provides for the extension of data protection for minor use
1c	Liability (limitations or waivers) If YES please describe	no	
1d	Expedited review ('fast-track')? If YES please briefly describe process	yes	Review of established MRL and authorizations in other EU Member States; no data evaluation.
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	yes	As above
1f	Grower assisted data generation programs funded by Governments?	no	
1g	Others / additional comments If YES please describe	no	

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	The lack of pesticides for specific uses.
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	Yes, by provisions of legislation.

		Answer
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	The grower associations use these incentives in the most cases. Chemical companies help if they find an interest, otherwise not. The most minor use authorizations are granted by the effort of the government to find appropriate data from other Member States.
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: Yes, new regulation on placing plant protection on the market is to be published this year. After its publications we are obliged to adopt the national legislation.
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments:

ANNEX 14: SWITZERLAND

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	y	No registration costs
1b	Extension or increased periods of data protection If YES please describe	n	
1c	Liability (limitations or waivers) If YES please describe	n	
1d	Expedited review ('fast-track')? If YES please briefly describe process	y	Submissions for registration with limited data set is possible at any time
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	y	See above, e.g. registration document from comparable EU-country MRL must be settled
1f	Grower assisted data generation programs funded by Governments?	y	National agricultural research institute (Agroscope) run minor use programs including trials for data generation and assistance to companies with respect to data acquisition from other countries and preparation of registration applications. Only very limited involvement of grower's organisations (e.g. with respect to funding)
1g	Others / additional comments If YES please describe		

	Answer

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	Demand from growers.
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	y
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	Routinely for minor uses - Assistance and motivation by Agroscope (see above) - Acceptance of international data and registrations (comparable EU-countries) - Public founded efficacy and residues trials, carried out by Agroscope
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: extended data protection (possible modes under discussion)
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments:

ANNEX 15: UNITED KINGDOM

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	Yes, but being phased out	Although supporting this approach under national authorisation rules, it is incompatible with current harmonised EC rules and is being phased out
1b	Extension or increased periods of data protection If YES please describe	No	
1c	Liability (limitations or waivers) If YES please describe	Yes	Liability for efficacy and phytotoxicity is waived. Growers use authorised products at their own risk
1d	Expedited review ('fast-track')? If YES please briefly describe process	No	
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	Yes	Efficacy and phytotoxicity data are not required
1f	Grower assisted data generation programs funded by Governments?	No	
1g	Others / additional comments If YES please describe	No	

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	These incentives were introduced in recognition of the lack of interest among pesticide companies in minor uses, because the financial returns on sales of pesticides for these uses do not justify investment in generating the necessary data
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	Yes

		Answer
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	The incentives at (a), (c) and (e) are provided as part of the application arrangements for extending authorisations to minor uses. Around 130 such applications are received each year, primarily from a grower organisation funded by horticultural growers
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: The European Community recently adopted a new Regulation for the authorisation of plant protections products. It includes specific provisions for supporting minor uses, in particular: - increased periods of data protection - development of a Community fund to support minor uses
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments:

ANNEX 16: UNITED STATES

1. Current Incentives Implemented

		Yes or No	Comments
1a	Fee reductions or waivers If YES please describe	Yes	The Pesticide Registration Improvement Act, (PRIA) created a new section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). PRIA created a registration service fee system for applications for specified pesticide registration, amended registration, and associated tolerance actions, which set maximum residue levels for food and feed. There is a provision for a waiver from the fee for minor uses however, to date, EPA has not approved a minor use fee waiver because no company has demonstrated that they will not be able to recoup the fee in a reasonable amount of time in accordance with Section 33(b)(7)(D). The US EPA and the Inter-Regional Project Number 4 (IR-4) have a long history of working together to register pesticides for minor crops. IR-4 was created to assist in the collection of residue and efficacy data in support of the registration or re-registration of minor uses. Under PRIA, if the EPA determines that a new use registration application is solely associated with a tolerance petition submitted by IR-4 and an exemption from registration service fees is in the public interest, such an application is exempt from registration service fees.
1b	Extension or increased periods of data protection If YES please describe	Yes	When a new active ingredient is first registered the data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration is provided ten years of protection and use of these data require the written permission of the original data submitter. The exclusive use period may be extended if new minor uses are registered within the first 7 years of the initiation of the exclusive use period. The new uses must meet the criteria outlined in FIFRA section 3(c)(1)(F)(ii). For each 3 minor uses registered within this timeframe that meet the necessary standards, the exclusive use period may be extended for 1 year. The maximum that the exclusive use period may be extended under this section of FIFRA is 3 years. There is also a provision under FIFRA section 3(c)(1)(F)(vi) that applies to data submitted to add a minor use to an existing registration after the initial data exclusivity period expires. It provides for a new exclusive use period for data generated by an applicant or registrant to register a new minor use. It allows registrants to request at the time they submit their application for a new minor use that the data be given exclusive use protection.
1c	Liability (limitations or waivers) If YES please describe	No	

		Yes or No	Comments
1d	Expedited review ('fast-track')? If YES please briefly describe process	No	
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	Yes	The US does not have specific provisions for reduced data requirements for minor uses. However, the number of field trials required to support a minor use is based on the total acreage grown and the dietary consumption. Therefore, most minor uses do not require as many field trials be conducted to support the registration of the minor use when compared to a major commodity such as wheat. The US also has a well-defined commodity grouping system which includes both groups and subgroups and representative commodities for the groups and subgroups (40CFR180.41; http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=a9e870a4e7e3c849923661e1d4b1fac5&rgn=div8&view=text&node=40:23.0.1.1.28.2.27.12&idno=40). An adequate data base of supervised field trials on the representative crops within the group or subgroup allows establishment of a group or subgroup tolerance (MRL) that applies to all commodities within that group or subgroup. In most groups and subgroups minor uses make up the majority of commodities and therefore this allows for registration of multiple minor crops without having to generate data for all commodities. The US will accept international data to support establishing tolerances (MRLs) in the US. This is done on a case by case basis for the chemical/crop. Request to use international data are typically presented to the Chemistry Science Advisory Council (Chem SAC) of the Health Effects Division of the Office of Pesticide Programs for consideration. For example the US has accepted European field trial data on grapes to support registrations for grapes grown east of the Rocky Mountains in the US and has accepted international data to support vegetables grown in greenhouses. The US is also actively involved in conducting global joint reviews for new active ingredients and new minor uses with its international partners.
1f	Grower assisted data generation programs funded by Governments?	Yes	The IR-4 Project is a cooperative agreement between the states and federal government in the US. IR-4's principle goal is to develop data to establish registrations for minor uses. The IR-4 Project provides the field trial and laboratory residue data necessary for EPA clearance of minor crop tolerances, and approval of new uses for pesticide labels. For additional information please visit http://ir4.rutgers.edu/index.html.
1g	Others / additional comments If YES please describe		

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	The provision to extend the exclusive use period for active ingredients based on new minor uses registered within the first 7 years of the initiation of the exclusive use period as well as the current crop grouping scheme were developed to create incentives to allow for more minor use registrations so that growers would have more tools available to control pests on minor use crops.
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	The current crop grouping scheme that the US EPA relies on to establish tolerances (MRLs) for crop groups and subgroups was codified in 1995. The petitioner must request that tolerances (MRLs) be established on the crop group. Since 1995 the establishment of tolerances on crop groups and subgroups instead of just the representative commodity has become the norm when residue data are submitted on a representative commodity. This has resulted in a large increase in the number of minor use registrations. EPA is currently in the process of revising all of the crop groups that exist in 40CFR180.41 as well as creating new crop groups. For example in December of 2007, a new crop group, Edible Fungi Group 21 was established. Revision of all crop groups and creation of new ones is occurring in increments and once this project is complete it is expected that this will allow for a greater number of minor uses to realize tolerances (MRLs) under the crop grouping scheme. Extension of the exclusive use period for minor use registrations is not automatic. Registrants must submit a request to the Agency to be considered under section 3(c)(1)(F)(ii) or section 3(c)(1)(F)(vi) of FIFRA for an extension of the exclusive use period.

		Answer
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	As discussed above, EPA has not approved a minor use fee waiver under PRIA because no company has demonstrated that they will not be able to recoup the fee in a reasonable amount of time in accordance with Section 33(b)(7)(D). However, there are a larger number of registration actions submitted in association with IR-4 petitions that have been granted an exemption from PRIA fees. Actions submitted by IR-4 make up for nearly half the new use registrations in a given year. Since 1995 the establishment of tolerances on crop groups and subgroups instead of just the representative commodity has become the norm when residue data are submitted on a representative commodity. This has resulted in a large increase in the number of minor use registrations. The provision to allow for extension of exclusive use for active ingredients based on new minor uses registered within the first 7 years of the initiation of the exclusive use period was established in 1996. In the first ten years after this provision was established few chemical companies requested extension of exclusive rights. However, in the last three to five years the number of requests submitted to the US EPA has increased and more chemical companies are taking advantage of this provision. As a result more minor uses are being registered with the initial registration of an active ingredient or within the first 7 years from the initial registration. To date few companies have requested a new exclusive use period for data generated by an applicant or registrant to register a new minor use under FIFRA section 3(c)(1)(F)(vi).
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: EPA is currently in the process of revising all of the crop groups that exist in 40CFR180.41 as well as creating new crop groups. For example in December of 2007, a new crop group, Edible Fungi Group 21 was established. Revision of all crop groups and creation of new ones is occurring in increments and once this project is complete it is expected that this will allow for a greater number of minor uses to realize tolerances (MRLs) under the crop grouping scheme.
2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments:

ANNEX 17: CROPLIFE INTERNATIONAL

1. Current Incentives Implemented

		Yes or No	*Comments*
1a	Fee reductions or waivers If YES please describe	Yes	Efficacy and residue trials: Cooperation between governments and manufacturers are frequent. or do not exist or are not that relevant (as fees are not high in some countries)
1b	Extension or increased periods of data protection If YES please describe	Yes	e.g. EU: each minor use can prolong data protection by 3 months, maximum of 3 years (12 uses) or additional data protection under the current legislation is unattainable
1c	Liability (limitations or waivers) If YES please describe	Yes	Liability waivers are possible in some countries only and only for efficacy and crop safety. In other countries the liability of the manufacturer cannot be restricted, therefore the acceptance of minor uses is less likely (but always a business decision of individual manufacturers). Crop Safety is the major challenge: One recent example for a use in flowers (few k€ turnover, due to crop damage a compensation of 10 Mio€ had to be paid!)
1d	Expedited review ('fast-track')? If YES please briefly describe process	Yes	e.g. 3 month in S. Korea or Are processed currently through normal system. Residue data requirement tends to slow down process e.g. getting MRL's set.
1e	Reduced data requirements, data waivers, use and acceptance of international data or registrations? If YES please describe	Yes	Not full data, only Effacy and MRLs e..g. (Korea), or Reducing data requirements, without solving the liability questions for manufacturers increases the burden for manufacturers Or Not because of liability. Not because of residues. Could use overseas data as supporting data for efficacy & safety and residues.
1f	Grower assisted data generation programs funded by Governments?	Yes	Many examples from EU, NAFTA, Asia Pesticide regular demand research (authority registration)

		Yes or No	*Comments*
1g	Others / additional comments If YES please describe		The need for a quick system to allow the establishment of MRLs for minor uses by the time a minor use is added to the label is of high priority.

		Answer
1h	What was the reason or purpose to develop, provide and promote such incentive(s)?	Minor crop often makes damage from agrochemical, High registration fee for small market..
1i	Are the incentives implemented on a routine basis? (Yes or No and please describe why)	No, (except, emergency authority registration)
1j	To what extent do governments and applicants (chemical companies/manufacturers) use these incentives? Please also indicate the most frequently used incentives and provide some examples if possible.	Country specific programs to share the development of the data package. Only used is by few countries are programs fully funded by governments (data generation, compilation and submission for approval). Or These incentives are not widely used by responsible applicants because they create too much liability risk to meet the stewardship objectives of responsible companies. None of these incentives are widely used – although reduced data requirements are sometimes used.
Additional comments:		

2. Suggested Incentives

2a	Are there any proposals to implement regulatory incentives currently under consideration in your country? If YES please describe	Comments: Yes. Improve the data protection scheme so that there is a better incentive for applicants to generate a full data set for minor uses and put them on the label as early as possible.

2b	Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?	Comments: 1. Change the trade practices laws so that the liability of minor uses can be shared between the applicant, the regulator and the user of the product. Minor uses that are not based on a comprehensive data set should be labelled as such, and it should be on the basis of user beware.

ANNEX 18:

SURVEY QUESTIONNAIRE

Expert Group on Minor Uses

OECD SURVEY

April 2009

Regulatory incentives

for the registration of pesticide minor uses

The following survey consists of a series of questions examining;

1. Current incentives implemented, and
2. Suggested incentives.

Background

To promote and encourage applicants (chemical manufacturers/registrants) to register agricultural pesticide products on minor uses, a number of national regulatory authorities provide incentives to add minor uses to the product labels. This survey serves as a tool to gather the extent of available incentives in OECD countries and to collect suggestions for new incentives.

1. Current Incentives Implemented

In the following table please indicate what regulatory incentives are currently available in your country to enhance the registration of minor uses.

		Yes or No	*Comments*
1a	**Fee reductions or waivers** If YES please describe		
1b	**Extension or increased periods of data protection** If YES please describe		
1c	**Liability (limitations or waivers)** If YES please describe		
1d	**Expedited review ('fast-track')?** If YES please briefly describe process		
1e	**Reduced data requirements, data waivers, use and acceptance of international data or registrations?** If YES please describe		
1f	**Grower assisted data generation programs funded by Governments?**		
1g	**Others / additional comments** If YES please describe		

1. Current Incentives Implemented (con't)

For responses above (1a-1g) where regulatory incentives are available in your country please answer the following questions:

		Answer
1h	**What was the reason or purpose to develop, provide and promote such incentive(s)?**	
1i	**Are the incentives implemented on a routine basis?** (Yes or No and please describe why)	
1j	**To what extent do governments and applicants (chemical companies/manufacturers) use these incentives?** Please also indicate the most frequently used incentives and provide some examples if possible.	
Additional comments:		

2. Suggested Incentives

2a	**Are there any proposals to implement regulatory incentives currently under consideration in your country?** If YES please describe	**Comments:**
2b	**Please list any suggestions for new regulatory incentives (apart from those listed in 1a-1f above) that could be useful if they could be implemented?**	**Comments:**

Other information: If you would like to provide more information, please attach as many additional pages as needed and where applicable reference your information with the number of the corresponding question.