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GUIDANCE DOCUMENT ON REGULATORY INCENTIVES FOR THE REGISTRATION OF PESTICIDE MINOR USES

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Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses

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OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances-Dossier Guidance (1998, revised 2001, 2005)

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

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

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

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

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

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

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

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FOREWORD

This document provides guidance to national regulatory authorities in providing greater incentives to encourage applicants (manufacturers/registrants) to register agricultural pesticides (including both synthetically and naturally derived products) for minor uses. This document is based upon the results of a survey conducted in 2009 by the OECD Expert Group on Minor Uses (EGMU), which detailed available incentives in OECD countries [see survey results in publication ENV/JM/MONO(2011)14].

Minor uses, including the majority of specialty crops, are the uses of pesticides where the potential use is on a scale not sufficiently large to justify registration of that use from an applicant's perspective alone, i.e. the key driver for minor uses is a lack of economic return to an applicant from registration of those uses, in particular the associated costs of generating the data required for obtaining and maintaining regulatory approval and potential liability from those uses once approved. Typically minor uses involve crops grown on a small scale (minor crops) and often are high value specialty crops. Additionally minor uses can involve uses within major crops in terms of controlling minor pests and diseases. This results in a situation where specialty crop industries are either without or are lacking sufficient access to pest control products to adequately protect those crops. The major factor hindering the regulatory approval of minor uses is a lack of data that is largely attributable to a lack of funding required to generate data. Therefore, incentives that encourage minor use registrations such as those outlined in this document may serve to alleviate some of the minor use needs.

This document is provided as guidance to countries on existing regulatory incentives available in a number of countries and additional suggestions on possible new incentives that could be explored to encourage the registration of specialty crop or minor use needs.

The development of this report was overseen by the Chair of the EGMU, Alan Norden (Australia), and was reviewed on several occasions by EGMU members as well as by delegates of the Registration Steering Group and of the Risk Reduction Steering Group, two sub-groups of the Working Group on Pesticides.

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

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

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INTRODUCTION

Summary of survey results

1. In response to an OECD survey conducted in 2009 to gather the extent of available incentives in OECD countries and to collect suggestions for new incentives to promote and encourage applicants (manufacturers/registrants) to register products and new uses for minor uses, responses were received from 16 member countries and CropLife International. A summary of survey results as provided by respondents is included at Annex 1 (the full survey report is available as a separate document – reference to be added here).

2. This document is based upon regulatory incentives identified by the survey and as reported by OECD countries for the registration of minor uses and is provided as guidance to national regulatory authorities in providing greater incentives to encourage applicants (manufacturers/registrants) to register new products and uses for minor uses. The survey also contained suggestions for future areas in developing new incentives for the benefit of enhancing minor use registrations and which are discussed in this document.

3. Countries have noted that the implementation of regulatory incentives have been in direct recognition for a strong need to have mechanisms that enhance, facilitate and encourage the registration of minor uses. Specifically incentives have been developed to encourage applicants to add more minor use registrations (including off label approvals), to speed the process of adding minor uses to product labels and in doing so ensuring that regulatory requirements for minor uses are comparative to the level of risk. Incentives have helped to fill gaps and increase the range of products available for plant protection on minor use crops and can also serve to enhance sharing the responsibility of addressing the needs of specialty crop growers. In some countries such as Germany, incentives are being used for nearly every minor use approved and are used extensively for off label/third party uses (i.e. uses not contained on the registered label or applied for by other parties than the product registrant). Incentives are generally used by government or public organizations (like the US IR-4 Project), but with more limited use by companies. However, companies are increasing their use of these incentives because of the greater value of data protection and waivers that are provided by some countries. However consensus is that more incentives are needed to further encourage minor use registrations.

4. The survey noted that 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. Although many European countries reported that they may or may not have such an incentive, they all indicated that when the new EC regulations are put into place, they will have fee waivers available for manufacturers if they provide registrations for minor uses.

5. 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 five years in addition to the original time period (usually 10 years).

6. Few countries indicated that minor uses were reviewed on a "fast track" compared to reviews for standard submissions. In countries where "off label" uses or emergency uses are allowed, they are considered expedited reviews, however they are also often only temporary approvals. Data waivers are generally not provided for minor use registrations, however in many cases greater flexibility is provided via mutually acceptable data (perhaps data from another country) or through the use of data extrapolations (or crop and pest groupings) to allow minor use registrations.

7. There are very diverse approaches amongst countries and regions as to the degree of government-funded programmes for minor uses. In some cases such as in the United States and Canada, there are programmes specifically established, designed and funded by the government to generate data for minor uses and these programmes generate the majority of data for minor uses in North America. In other cases there are "shared" programmes where the government and registrant share the cost of generating data. In nearly all cases there was very limited support for minor use approvals being provided (funded) solely by growers.

8. In many countries minor use labels can be carried by a "third party" i.e. not the main registrant for the product. This may be another registrant or a grower group that coordinates and maintains the product label for that given use. Many countries and their regulators do take advantage of existing data, including data from another country. There are also many countries and minor use programmes that use "data mining" to provide the supporting information for minor use submissions by seeking out data available internationally, both within the public and private domain.

The survey report concluded with the following recommendations:

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

(ii) The Working Group on Pesticides through its 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
   b. review existing incentives, explore improvements in existing incentives and opportunities for new incentives.

Objectives of the present guidance document

9. This document is provided in response to the second recommendation of the above-mentioned survey on the development of a guidance document and serves to further enhance delivery of the other two recommendations. It briefly discusses the various different aspects of incentives that are typically utilised including;

Economic incentives (or increased "value") for registrants

- Data protection
- Expedited reviews
- Fee reductions or waivers

Technical arrangements based on sound science

- Extrapolation and mutually accepted data
- Number of trials

Authorisation process arrangements

- Third party registrations
- Temporary approvals (off-label & emergency schemes)

Research

- Data generation assisted schemes

Promotion of safer alternatives

- Reduced risk incentives

Liability

- Liability waivers/disclaimers

CONSIDERATIONS

Economic incentives (or increased "value") for registrants

Data Protection

10. The regulatory costs associated with registering new pesticide products and their uses can be significant, in particular the costs of generating the necessary data. To provide recognition for, and encourage innovation in the registration of new products and their uses, many countries have implemented, through legislation, intellectual property protection to data submitted in support of registrations. The outcome being the provision of an identified number of months or years of data protection/exclusivity to the product registrant (data submitter). In these cases, only registrants who have access to the data are allowed to register the product and/or use pattern. Other registrants seeking similar regulatory approval must either generate their own data or compensate the data owner. Data protection is typically provided for all uses registered and periods of protection differ between member countries although they are typically in the order of between 8 and 11 years.

11. In addition to standard data protection and the periods provided, some countries have introduced increased periods of data protection for the registration of minor uses. Whilst the minor use registration in itself may still remain unattractive from an economic perspective, by registering the minor use, data protection can then be applied (extended) to all registered uses, making the minor use registration more economically attractive by the additional returns provided through exclusivity attained in other major crops on the label. To benefit from this and enhance the attractiveness of minor uses to registrants, additional periods of protection to those noted above are permitted for registrations of minor uses. The additional periods of protection provided are often in the order of between 3 and 5 years, or in other words extending the period of protection up to between 11 and 14 years. Each additional year of data protection is usually subject to the registration of a defined number of minor uses, these are typically somewhere between 3 and 5 minor uses for each additional year of protection.

Expedited Reviews

12. In many countries regulatory assessments of minor uses are subject to the same assessment timeframes and procedures as other 'major' uses seeking registration. Only when emergency uses are needed (for both minor uses and major uses) are expedited reviews provided. In these cases only a temporary use approval may be granted, with the ongoing use approval if required still subject to standard registration procedures.

13. In the survey conducted by OECD EGMU, some countries have suggested that more needs to be done to provide minor use solutions in a more timely manner, which would then tend to suggest that further examination of review timelines may provide benefits for nationally or regionally prioritised minor uses. Furthermore, it may be also worthwhile considering if expedited reviews for minor uses may also make them more economically attractive to registrants. This may be possible where a registrant is seeking expedited access to market (approval) for a major use and where a minor use if included in the same submission could provide the access to a shorter assessment timeframe. Such a 'reward' or acknowledgement for registering the minor use may

have similar benefits as does data protection, where the economic benefits are actually attributable to a major use but have a pre-requisite of requiring the minor use to attain it. It is however important that the regulatory risk assessment is conducted to the same rigour as standard registration assessments to ensure that the proposed use meets legislative requirements including human health and environmental safety.

Fee reductions or waivers

14. Most countries have implemented fee reductions or waivers to enhance the registration of minor uses noting that the economic costs of registering minor uses can be a major factor hindering their approval. Whilst costs of data generation generally far outweigh regulatory assessment costs, these provisions are seen to lessen the overall costs to some extent and are seen as a government support for minor uses.

15. Reductions or waivers may be applied to all uses be they submitted by a third party or by the registrant, or in some cases may only be applied to third parties including nationally recognised minor use programmes and are not applicable to registrants. Off-label approvals sought by third parties, emergency uses or other uses that are deemed in the public interest are generally at a reduced or nil fee.

16. In other cases there may also be provisions for registrants to seek a graduated fee or reduction against standard registration fees, and can also be on the basis of the registrant demonstrating through documentation low sales figures/volumes from the use prior to and/or following registration for a number of years. These provisions are typically subjected to a predicted calculation of likely economic return versus the regulatory assessment cost for a period extending into the initial years of registration (i.e. 3 years).

Technical arrangements based on sound science

Extrapolation & Mutually accepted data

17. Most countries utilise the concept of data extrapolation, be that in residues, efficacy and/or crop safety and worker protection (occupational health & safety). In addition to this, many countries also accept within limitations the use of data generated in other regions globally and typically where it can be demonstrated that the data is relevant to the region where the use is being sought, either by consideration of geography, climate, soil, agronomic growing conditions and a comparable use pattern.

18. In addition to extrapolation and use of international data, there is also often a lower number of trials required for minor uses (or minor crops) and generally these are in the order of between 50-75% reduction in the number of trials required compared to the registration of a major use. This is often a reflection of the fact that the product is evaluated precisely with the normal authorisation and for minor uses it only must be proved that they are similar to the uses of the basic authorisation. Combining data internationally would more than likely provide a more robust data set for these commodities overall.

19. To enhance these possibilities, many countries have published tables of crop and pest groupings that also outline in what commodities often referred to as 'representative crops' data must be generated in to attain registration for an entire crop group. The most notable of these are the activities of the International Crop Grouping Consulting Committee (ICGCC) convened by the United States IR-4 Project. ICGCC submissions are utilised in proposed changes to both crop groups utilised by US EPA and also in current work of Codex Committee on Pesticide Residues (CCPR) review of the *Classification of Food and Animal Feeds*. Historically, crop groups have been used extensively in the field of residue data generation and assessment, although increasingly more work is being done in the areas of efficacy and crop safety. Recently the European and Mediterranean Plant Protection Organisation (EPPO) has released a number of documents on data extrapolation for minor uses, including the provision of extrapolation tables for specific crop groups and their pests/diseases. Further work in this area will serve to enhance the registration of more minor uses and ensure regulatory assessments are conducted at a level comparative to their risk when compared to registered major uses.

20. Additionally under European Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market, a '*risk envelope approach*' is being developed in the European Union. The 'risk envelope approach' is based on a so called 'worst case scenario assessment', the scenario may differ for each risk assessment criterion that is taken into consideration when evaluating a plant protection product such as, physical/chemical; worker/operator protection; residue; environment or efficacy. Within a group of plant protection products (with the same active substance) and uses, for each of the relevant risk assessment criteria a given use that represents the worst case is included. There can therefore be different uses for the different risk assessment criteria/aspects. If the GAP (Good Agricultural Practice) of a minor use that is sought for, fits into the GAP of the worst case scenario assessment already undertaken, the assessment covers all (minor) uses with an equal or less impact. The advantage of this approach is that a reduction can be achieved in reviewing and assessing new uses where the risk is less than that already accommodated. For example when an application is made for an extension for a minor use and it fits the risk envelope approach, an authorization could be granted without further data requirements, as the authorization is mirrored against the initial application for that plant protection product. However, the approach is not applicable for the assessment of MRLs.

Number of trials

National/regional approach to number of trials

21. The Residue Chemistry Expert Group (RCEG) of the OECD's Registration Steering Group is concurrently developing a *Guidance Document on Crop Field Trials*. Currently this draft document is recommending up to as much as a 40% reduction of domestic trials when an application is submitted as a Global Joint Review (GJR) and a study is conducted globally and as much as 50% of the total number of trials necessary in one country/region may be replaced by trials from another country/region, provided that these trials correspond to the critical GAP and the production conditions, i.e. the comparable cultural practices. This document also contains guidance regarding crop grouping and extrapolation when conducting residue studies. It is expected that the guidance document will be released sometime in 2011.

Authorisation process arrangements

Third Party Registrations

22. Standard regulatory procedures require that an application for registration of a new product or new use be submitted by the product manufacturer/registrant. Some countries operate schemes where persons other than the registrant (termed - *third parties*) may seek to have minor uses considered for approval. This may include submissions seeking registration (on-label) or off-label approvals.

23. For registration (on-label), third parties may make regulatory submissions that are assessed by the regulatory agency(ies), and if supported, product registrants may then seek to have those uses labelled or the third party may maintain the label for the given use. In some cases, it is a requirement that the registrant must submit their proposed new label at the same time as the third party submission is lodged. It is therefore beneficial for the third party to ensure contact is made with the registrant prior to submission.

24. For countries with off-label approvals, third parties may also make regulatory submissions for assessment by the regulatory agency(ies). If supported, these approvals are authorised via the issuance of a document separate to the official (or approved) product label, which outlines the approved use pattern and typically have a defined period in which they are approved.

Temporary approvals (off-label & emergency schemes)

25. In addition to standard registration procedures, several countries also operate schemes that can allow approvals to be granted for off-label use. These mechanisms are utilised not only for minor uses but also to allow rapid responses to emergency needs.

26. Off-label provisions are provided generally to third parties where the registrant is not interested in seeking registration, including not only the data required but also the administrative regulatory effort required to compile and lodge submissions. Approvals granted by these mechanisms are typically time-limited and may in some cases also be temporarily approved with requirements on the provision of additional data during the life of the approval.

27. In some cases, temporary approvals may be granted based upon international data alone and requirements may then exist for local data to be generated during the term of the initial approval. In some cases these approvals can be a preliminary step in progressing the use to registration and in doing so provide users with temporary relief to identified priority needs whilst allowing minor data gaps to be addressed in the provision of local data and enabling field observations to be made in areas such as efficacy and crop safety. Such mechanisms enable use under real field conditions that can often provide registrants with an increased assurance in these areas in addition to, or in replace of small scale field trials that may facilitate their confidence from a liability perspective in registering a minor use. Third parties, in determining options and prior to making submissions, should discuss possible identified solutions (products and their uses) with registrants to identify those uses that are most likely to be supported by registrants and facilitate those uses proceeding to registration.

28. Off-label schemes that operate in some countries include those in the United Kingdom that are referred to as *Specific Off-Label Approvals* (SOLA) and in Australia that are termed *Minor Use Permits*.

Research

Data generation assisted schemes/programmes

29. Several countries have developed dedicated minor use programmes that are specifically designed to work with grower groups and registrants in undertaking the necessary data generation and making of regulatory submissions. These programmes may function entirely based upon government funding and/or may contain a level of co-investment between government, growers and registrants. Often times the government funds are needed to leverage private funds. In some countries grower groups have mechanisms available that generate funds through grower levies on production levels and which in turn are utilised to invest in various activities relating to research and development including data generation for minor uses.

30. These programmes are considered critical and in some cases may be the only mechanism to drive solutions for many minor uses that are not economically attractive to registrants. The most successfully recognised of these programmes is the United States IR-4 Project that has operated since 1963. In that time the programme has achieved over 10,000 approvals for use on food crops and another 10,000 on non-food ornamental crops. The IR-4 Project is internationally recognised as a model programme for other countries seeking guidance on the development of national programmes, in processes of identifying, prioritising and generating data for minor uses.

31. Most if not all programmes that operate have a significant involvement and presence of growers, University and other public personnel (Agricultural Departments) that assist in the identification and allocation of funds to priority needs, typically on an annualised basis. Programmes also ensure that they have close interactions with both the regulator and registrants in ensuring that projects undertaken are supported and conducted in a way that ensures that appropriate data are generated to satisfy both. In addition to generating data and making regulatory submissions, such programmes have also been very successful in engaging with regulators and registrants and in progressing many of the solutions or tools required to enhance the registration of minor uses and lessen the regulatory burden. These activities include championing the development of regulatory guidelines for minor uses, including the development and proposals of guidance's in areas such as crop grouping and data extrapolation and sharing.

32. Programmes are either operated by government departments or by contract or specialised providers at the specific request of grower groups.

Promotion of safer alternatives

Incentives for reduced risk pesticides

33. Some countries operate mechanisms that provide incentives for the registration of reduced risk pesticides, including biopesticides. These incentives may include fee reductions or expedited reviews. In some cases reported in the minor use survey conducted by OECD, it was proposed that such incentives should be examined in more detail for their benefit to enhance minor uses and whether or not complementary incentives that involved reduced risk or biopesticides and minor uses should be subject to even greater incentives. This could be particularly relevant as regulators are increasingly placing pressure on older chemistries through re-registration procedures and where registrants due to a lack of economic return do not support the re-registration of many minor uses.

Liability

Liability waivers or disclaimers

34. Liability from the registration of minor uses is an economic disincentive for many registrants, and in some cases may be one of the leading decisions in not seeking registration of a particular use. These decisions may not be for real but are for reasons of perceived or more correctly unknown risk. Many minor uses involve high value speciality crops where the low sales volume likely may far outweigh the potential economic liability from a use should there be problems with lack of efficacy or perhaps more concerning crop safety/damage following the use of a product. In cases where problems arise, liability costs in compensation cases can far outweigh the likely returns and for these reasons alone some registrants may choose not pursue registration.

35. To alleviate this disincentive, some countries have outlined that uses such as third party authorisations sought and off-label uses are at the risk of the end user, and commonly the registrant is still liable for other components of the product such as its quality (formulation/composition) and its risks to human health and the environment. These provisions may come in the form of general liability waivers or via the ability for the registrant to place a label disclaimer on certain uses, either at their choosing or in response to a third party registration that they may be willing to support (label).

36. It is however unclear what standing some of the provisions provide legally and in many cases there are no case studies of those being challenged in legal proceedings, so whilst the status quo may appear to be working, registrants continue to express a high level of uncertainty in this area. It may therefore be prudent for governments to examine the legal implications and status of such provisions and, if required, implement these in law to either provide exclusion of this liability or to ensure that it is capped at an appropriate level commensurate to the return from that use. Alternatively, some have suggested that schemes could be established that may allow funds to be centrally collected and available to compensate in situations of unexpected damage. In these cases, it has been muted that funding arrangements could be similar to those designed for the establishment and operation of minor use programmes via collaboratively contributions from growers, governments and the registrant community.

37. Regulators, governments, growers and registrants need to conduct further dialogue and explore issues in this area and attempt to strike a reasonable and sensible balance, particularly if the approval of uses is being made at the request of end users, and where those liability provisions may only be extended into areas such as efficacy and crop safety.

CONCLUSIONS – KEY OBJECTIVES

38. The need for and recognition by governments to adopt approaches that facilitate regulatory approvals for minor uses are evident and increasing. There are several key objectives that should be recognised and taken into consideration when developing new approaches and regulatory incentives designed to facilitate the authorization of minor uses.

1. Countries should familiarise themselves with recommendations for defining minor uses as outlined in the *OECD Guidance Document on Defining Minor Uses of Pesticides* (OECD (2009), Series on Pesticides No.49) and seek to develop regulatory incentives complementary to those definitions.
2. Regulatory risk assessments and data requirements should remain independent from minor use definitions, although incentives may be developed that reduce the regulatory burden in certain data requirements where it is scientifically acceptable to do so, through the use of extrapolation and/or mutually accepted data.
3. Incentives should be designed to facilitate the necessary research, development and registration of new uses and, in doing so, should encourage products and uses that address national or regional objectives such as those associated with reducing the risks of pesticides, including those that enhance the sustainable use of pesticides and the adoption of practices such as Integrated Pest Management (IPM).
4. Mechanism(s) should be designed specifically with the intention of increasing the 'value' a registrant may associate with the registration of a minor use whilst reducing any unnecessary regulatory burden in that process. 'Value' may not necessarily be associated with likely economic return from registration of that minor use, but may be associated in other ways.
5. Whilst a number of commonly accepted approaches are utilised in several countries, such as data protection, fee waivers and data extrapolation, these alone may not provide sufficient incentive for the registration of minor uses. Countries should also consider developing new and/or complementary approaches to raise the 'value' a registrant may associate from the registration of minor uses. For example many countries have or are considering the establishment of national programmes that work directly with affected producers to prioritise needs, generate data and make regulatory submissions. In addition to the establishment of these programmes it is recognised that complementary regulatory incentives can enhance the registration of minor uses from those programmes/schemes. Where a registrant may still not associate economic value with a minor use to justify registration, countries should have in place regulatory mechanisms that allow for third party and/or temporary authorisations to be considered and where the liability from such uses are clearly outlined.

ANNEX 1

EXPERT GROUP ON MINOR USES

OECD SURVEY – Conducted in 2009

Regulatory Incentives for the Registration of Minor Uses

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 (US IR-4, Canada 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/Canada). 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 Canada/US/ /EU (new regulation). All three have similar incentives that may increase the data protection period for up to 3 (US/EU) or 5 (Canada) 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.

		Yes or No	*Responses/Summary*
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, Japan, Portugal, Switzerland and US were the only countries that responded that did not have a liability waiver at this time.
1d	**Expedited review ('fast-track')?** If YES please briefly describe process		A few countries (Canada/Korea) 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 (Canada/US) they do allow for case by case data waivers or utilize crop group extrapolations.

		Yes or No	*Responses/Summary*
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 (Canada and US) 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: New Zealand, Portugal, Slovak Republic, Slovenia, UK.
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 (Crop Life International).

		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.
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 US-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: Canada 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: Canada 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. 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.