Organisation for Economic Co-operation and Development

ENV/JM/MONO(2020)1

Unclassified English - Or. English

15 January 2020

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

Guidance Document on the Exchange and Use of International Efficacy and Crop Safety Data for Minor Uses

Series on Pesticides
No. 101

JT03456751

OECD Environment, Health and Safety Publications
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Environment Directorate
ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT
Paris 2020

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FOREWORD

This document provides guidance on using efficacy and crop safety data generated in other countries and regions (as well as from other sources) and evaluations conducted by other regulatory authorities. The document does not provide guidance on the generation of data itself or related scientific principles of data assessment or extrapolation but rather discusses broad principles that may be considered and possibly assist with minor use registrations.

This document has been developed in the framework of the OECD Expert Group on Minor Uses (EGMU), a sub-group of the OECD Working Group on Pesticides (WGP) that helps member countries to harmonise the methods and approaches used to assess minor uses of.

The development of this document was overseen by the Chair of the EGMU, Alan Norden (Australia) with input from EGMU members (past and present) David Richardson (United Kingdom), Daniel Kunkel (United States), Jeroen Meeussen (Netherlands) and EPPO. The present Guidance Document received final approval of the OECD EGMU in January 2019.

The draft guidance document was approved by the Working Group on Pesticides during its 34th meeting on 28-28 June 2019.

This document is being published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology, which has agreed that it be declassified and made available to the public.

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1. Summary

1. 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. That is, 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. This results in a situation where specialty crop industries are either without or are lack 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 [ENV/JM/MONO(2011)16].

2. For regions where the climatic conditions are deemed comparable, relevant to the use at the time of application, it is generally only possible to extrapolate data from one crop/pest combination to the proposed country or region where other aspects important to product performance are also comparable. Thus, it is also important to consider agronomic, and edaphic aspects such as crop husbandry and growth habit, application techniques, the varieties grown, and soil type, as well as the pest and its biology. In considering these aspects, the focus should be on comparability of only those aspects, which will impact on the performance and safety (direct and indirect) of the product. The extent of use or history of use in the country that generated the data may also be valuable. If these conditions are also shown to be comparable then use of the data may be accepted.

3. The relative importance of the different climatic and agronomic differences will be a function of the product mode of action, and proposed target. For example, differences in crop training systems resulting in substantially different canopy sizes, would need a consideration of the appropriate dose for the different growing systems. Similarly, differences in soil type may be highly significant for soil-applied products but irrelevant to foliar applied products. Where the conditions are not directly comparable but present a greater challenge to the performance of the product, or its crop safety profile, it also may be possible to justify the relevance of such data. It is also the case that it may be possible to authorise a product but with relevant restrictions (such as specific soil types, or specific varieties, where relevant).

4. Data that can be justified as relevant to the conditions occurring in the proposed country or region can be considered relevant to supporting an application for a minor use. Moreover, data from a wider area and more diverse conditions, provided they pose a similar or greater challenge to performance, can give greater confidence in performance (or any limitations on performance) of a product, than data from only those situations and conditions arising within the proposed country or region.

5. It is also possible to consider for minor uses supporting the use by extrapolation from other major crop and uses, provided an appropriate case for their relevance is made. This is a key approach where it may not be economical or practical to generate further data, but where relevant data are available from authorised major uses. Or, it may reduce the extent of data required where major authorisations and their underlying data are available.

2. Introduction

6. The 'minor uses' problem is a complex one driven by a number of factors, all leading to limited availability of control solutions for the insect pests associated with minor crops [ENV/JM/MONO(2011)16]. The main factors involved are the high costs of data generation and the regulatory costs and expertise of achieving authorisations for the use of crop protection products on minor crops (or against minor uses on major crops) linked with the relatively low return to the manufacturer or approval holder due to the small area of the crop warranting treatment. Moreover, the high value of the crop and that the high cosmetic quality requirements demand high levels of control means that the financial risk associated with crop damage - arising either from phytotoxicity or from incomplete control - to the approval holder is high. The net result means that the balance between risks and reward is commonly unfavourable to the applicant, and authorisations for minor uses are insufficiently pursued. Hence, many growers have limited products to control pests that reduces their ability to implement good sustainable integrated management programs.

7. OECD has a vision of greater harmonisation of regulatory systems such that data reviews prepared to a common format in one region or country can be used to support regulatory decisions in another country. Towards this objective, OECD has published a number of guidance documents focussing on minor uses. This includes guidance to encourage and enhance similarities in the approaches adopted in member countries to defining minor uses, and to ensure that they are appropriately regulated, managed and addressed in their respective countries [ENV/JM/MONO(2009)39]. To encourage the registration of crop protection products for minor uses, OECD published a guidance document [ENV/JM/MONO(2011)16] on regulatory incentives available in a number of countries as well as additional suggestions on possible new incentives that could be explored. In 2011, OECD published the results of a survey of member countries regarding efficacy data requirements and guidelines for minor uses. The outcome of the survey resulted in recommendations for the use of international data and for harmonisation of requirements and guidance, as well as data exchange [ENV/JM/MONO(2011)13].

8. The following document provides guidance on the assessment of efficacy and crop safety data generated in other countries and regions and evaluations conducted by regulatory authorities and information obtained from other sources. The document does not provide guidance on the generation of data itself or related scientific principles of data assessment or extrapolation but rather discusses broad principles that may be considered and possibly assist with minor use registrations.

9. Product registrants and regulatory authorities are encouraged to familiarise themselves with various guidance available for the generation and assessment of efficacy and crop safety data. This includes guidance documents which apply in the intended country of authorisation. Other publications referred to in this document include several of the following international standards published by the European and Mediterranean Plant Protection Organisation (EPPO) in the series PP1 on efficacy evaluation of plant protection products:

- Introduction to the efficacy evaluation of plant protection products PP 1/223(2)
- Design and analysis of efficacy evaluation trials PP 1/152(4)
- Principles of acceptable efficacy PP 1/214(4)
- Conduct and reporting of efficacy evaluation trials including good experimental practice PP 1/181(4)

- Number of efficacy trials PP1/226(2)
- Phytotoxicity assessment PP1/135(4)
- Principles of efficacy evaluation for minor uses PP 1/224(2)
- Efficacy and crop safety extrapolations for minor uses PP 1/257(2)
- Principles of efficacy evaluation for microbial plant protection products PP 1/276(1)
- Principles of efficacy evaluation for low-risk plant protection products PP 1/296 (1)
- Guidance on comparable climates PP 1/241(2)
- Comparable climates on global level PP 1/269(1)
- Principles of zonal data production and evaluation PP 1/278(1)
- Dose expression for plant protection products PP 1/239(2)

10. EPPO is one of the regional plant protection organisations recognised within the framework of the International Plant Protection Convention (IPPC) by the Food and Agriculture Organisation (FAO) of the United Nations. IPPC is the international standard setting mechanism recognised by the World Trade Organisation (WTO).

11. Ultimately, the consideration of the efficacy and crop safety for a minor use in a specific country or region still resides with the regulating authority taking note of the legislation, policy and/or guidelines that may exist in those regulatory regimes.

3. Basic Principles

12. Efficacy and crop safety data from a range of sources may be used to demonstrate performance of a crop protection product and thus support authorisation for use on a minor crop or against a minor target (on a minor or major crop). The sources of data available are likely to depend on whether the active substance is a relatively new substance or one which has been widely developed and used in different countries. However, the source of the data and the associated justification of relevance of those data to the conditions in other countries and regions, may be different. For any extrapolations a proper description of the Good Agricultural Practice (GAP) is important, to serve as the basis for any evaluation. The EPPO Standard *Harmonised basic information for databases on efficacy evaluation of plant protection products* [PP1/240(1)] provides a list of basic information points that should be provided to allow a detailed understanding of a registered use.

13. The first use to be registered for any product containing a new active substance is normally on a major crop and against one or more major targets. Subsequent registrations are generally for the development of the product (or related products) across a broader range of crops (or situations) and including the extension to minor crops or minor uses. However, it can also be the case that the first use registered is a minor use, especially for products specifically developed for niche crops. As a new active substance, there is generally relatively little public domain data or knowledge regarding its spectrum of activity and performance, and support for minor uses will generally be via the provision of

specific efficacy and crop safety trials data and the use of extrapolations to related pests and crops.

14. As an active substance is developed and gains authorisations on a wider range of crops and in different countries, knowledge and understanding of performance and limitations on activity increase as data sets supporting these authorisations are developed. Moreover, such development is typically accompanied by the development and registration of a more diverse range of product types with different formulations. For horticultural crops, which can be more sensitive to crop damage, particularly under protection, specific formulations with enhanced crop safety properties are often used. Additionally, for widely used active substances considerable work on performance generally becomes conducted by independent research organisations and much information is published and available in the public domain. This wider public domain information may lend additional support to authorisations of minor uses. Importantly, the authorisation of a product under a regulatory regime where efficacy and crop safety is a formal regulatory requirement provides a basis of evidence that the product and active substance are able to provide effective and consistent performance across the broad range of conditions of that country or region in line with any label restrictions or label advice.

4. Principles of an application based on an authorisation in another country

15. Where another country has granted an authorisation for a crop protection product on a crop and against a target provided it is deemed of relevance, there is scope to use not only the efficacy and crop safety data (which may be in the form of a biological assessment dossier) but also the assessment of and decision made by the evaluating regulatory authority to grant an authorisation in another country or region. The principles for the use of the efficacy and crop safety data as part of a submission and the justification of relevance to other countries and regions are discussed in the following sections. The principles apply whether the data are from individual trials or, and this is the preferred option, where they have been summarised by the applicant and presented in a biological assessment dossier. In such situations it should be noted that the data may already be from several countries and some justification of relevance to the country or region in which authorisation is sought should be provided.

16. Most regulatory authorities, when considering an efficacy submission, draft an evaluation report summarising the data and enabling a decision to be reached on whether the data substantiate the proposed use. On this basis registration is accepted or declined. Some regulatory authorities may have provisions that they may accept the approval for a limited time with a requirement to provide additional data and/or information. In addition, there will normally be a legal approval or authorisation document permitting use of the crop protection product and detailing any specific conditions associated with the use of that product, and this may be associated with an approved label providing the detailed recommendations for the use of the product.

17. The use of evaluations prepared by a regulatory authority from a different country has the potential to minimise the burden of new data generation on an applicant, the evaluation workload of the regulatory authority and to streamline the regulatory process. It is recommended that this approach be considered appropriate only from countries that have clear and well-defined requirements for the consideration of efficacy and crop safety as a component of the authorisation process.

18. It should be noted that one regulator may not automatically adopt the decision of another regulatory authority. Regulators often consider the evaluation conducted by another regulatory authority, and the decision reached, as well as the reasoned justification of relevance, and any decision made by a regulatory authority will be on the basis of the evidence available and the scientific validity of any case presented, in line with any specific legislative requirements. The regulator will also consider the relevance of the data to its own national circumstance (and may need to conduct further national risk assessments, in the case of efficacy this may be related to resistance risk). It is envisaged, however, that the opportunity to use scientific evaluations of data and decisions made as a component of the review process may provide a more efficient and rapid process.

5. Information requirements for an application made on the basis of an evaluation and authorisation in another country

19. The information likely to be necessary for submission to a regulatory authority (country A) where applicants seek to rely on an evaluation and authorisation from another regulatory authority (country B) may include:

- Draft label for use in the proposed country (country A)
- Copy of the authorisation document from the other country (country B)
- Copy of the label to which the authorisation refers (from country B)
- Copy of the efficacy and crop safety assessment dossier submitted by the applicant to country B
- Copy of the evaluation report prepared by country B
- Evidence of ownership of the efficacy data and efficacy dossier, or a letter of access to it
- Show that efficacy and crop safety is a requirement for authorisation in the evaluating country B, and provide a copy or reference to any standards required or referred to
- A reasoned justification of the relevance of the approved use, proposed targets and the efficacy data on which it is based to the intended use in the proposed country A (refer to the following section providing a reasoned justification of the relevance of foreign data)

6. Relevance of foreign data

20. Data from any location may be used to support authorisation of a minor use but it must be relevant to the proposed use (also refer to later section on *Use of data from other sources*).

21. Key to the acceptability for use of foreign data including an authorisation from another country is an understanding of the relevance of the data to the use and agroclimatic

conditions pertaining in the country or region into which authorisation is being sought. A justification for the use of foreign data should encompass climatic, agronomic and edaphic conditions, as well as a consideration of the crop and its structure/morphology, and the target pest and its biology. The argument should focus on those conditions, which are particularly relevant to the mode of action and intended use, and have the greatest influence on efficacy and crop safety of the product. For a product based on a living organism the argumentation may include consideration of its biology and ecology. The applicant should therefore provide a robust explanation of how these aspects of the use relate to the intended use.

22. Where an applicant is seeking to rely on an authorisation from another country or region the applicant should consider and discuss any specific conditions on use imposed by the country, where the product is already registered and whether they are relevant to the use in the proposed country or region where approval is being sought. For example, a restriction on the number of applications permitted for resistance risk is likely to be relevant to all countries (due to the inherent properties of a species to develop resistance). But, it may be further adapted to consider the pest pressure during the season, and how many applications of any one product is appropriate within a typical season-long treatment. Those considerations should also take account of the risk assessment of crop safety and other potential unintended impacts, and their relevance to the proposed country (e.g., existing or proposed restrictions on following crops or whether a further assessment is required to reflect specific national conditions - including any differences in crop rotations).

23. In practice, such a case for relevance should include reference to data, other supporting information and/or an evaluation report made by another regulatory authority, identifying any critical points of relevance to the proposed country or region. It is also likely that the proposed label is closely aligned to the label approved in the authorised country. However, given the use in many countries of descriptive label claims indicating the level of control that a grower might expect from use of a product, the applicant should ensure that the justification includes reference to the level of control demonstrated in the efficacy trials as part of the justification of the proposed claims made on the draft label. The label should also reflect the relevance of the proposed use, the proposed crop, and may have further specific national information on it (e.g., local monitoring requirements, thresholds for treatment, advice on resistance management).

24. Using international data and assessments (e.g., according to OECD or FAO guidelines) undertaken by other regulators is most likely to be effective when making reference to authorisations of crop protection product used against widely distributed pests. It is also more likely to be effective for crop protection products whose performance is largely unaffected by conditions, and which have good crop safety profiles. It is also more likely to be successful on crops whose agronomy and cultural practices are similar internationally. The justification for crop protection products where there is some doubt about crop safety, such as herbicides and especially persistent residual herbicides requiring limitations regarding subsequent cropping, and those crop protection products whose performance is affected by climatic or other conditions will be much more challenging and reliance solely on international data and/or another regulators assessment may prove problematic. Similarly, it will be more challenging and may not be practical for crops where the growth habit and crop canopy is substantially different in different countries.

25. EPPO standard PP 1/214 ‘Principles of a zonal data production and evaluation’ provides some guidance on consideration of which factors might affect product performance, and why, as well as how to consider the variation in factors across a

geographical region or area. However, as an EPPO Standard it covers the European and Mediterranean region and thus is written from the perspective of locating a number of efficacy trials across a region or zone to ensure relevant factors are taken into account in those trials. It does provide a good overview of the role and importance of factors that affect performance and should be referenced prior to making any justification for the use of foreign data to support a minor use. The following sections include components of this EPPO standard (Principles of a zonal data production and evaluation), and identify the factors to be considered and, where relevant, addressed as part of a justification for use of foreign data to support a minor use. The principles also apply to the use of foreign data to support a major use. These include:

- Product
- Crop
- Agronomy
- Pest
- Climatic conditions
- Edaphic conditions

6.1. Product

26. Preferably the proposed product should be the same (formulation) as the product in which the foreign data has been generated and/or authorisation granted in another country or region. As with many data sets the data generated may be from trials involving a range of different product formulations, some similar and some not.

27. In instances where the supporting foreign data has not been generated from the specific product seeking authorisation in the country or region, the applicant should provide a rationale outlining how the data is relevant to the proposed product in terms of both efficacy and crop safety. In particular, it should address how the different products and their formulations should be considered bioequivalent, where bioequivalent is considered the property wherein two plant protection products with identical active ingredients or two different dosage forms of the same plant protection product possess similar bioavailability and produce the same effect at the site of physiological activity.

28. For products based on living organisms, further information on the biology and ecology of the organism can be useful to assess the influence of these factors on the efficacy of the product.

6.2. Crop related factors

29. Crop factors that can have a bearing on efficacy and crop safety include crop structure and growth habit, varietal diversity and sensitivity to adverse effects. In addition, it is important that the method of dose expression is relevant and well-understood.

Efficacy

30. The applicant should consider and discuss the cultural practices used for the crop, and crop growth and growth habitat in the area where the trials have been conducted to identify any key differences between those and the crop in the proposed country or region sought. Substantively different growth habits and/or canopy sizes may make use of foreign data inappropriate. Varietal variability may be important, and it is therefore also important to ensure that varieties representative of those grown in the proposed country or region where approval is being sought are tested, or in the absence of data a rationale be provided as to how those are not likely to affect the products efficacy. The applicant should also consider the relevance of the proposed application methods and whether that is reflective of commercial practice (application machinery, water volumes etc.).

31. For certain 3-dimensional crops, different dose expressions may be used in trials and on national labels and it may be appropriate to ensure the dose used or the method of dose expression is relevant to and understood by growers in the proposed country or region, or to consider a conversion between the dose expression used in the trials and that intended for use in another country or region. Further information on different dose expressions and their conversion in some crops is available in EPPO guidance document PP 1/239 *Dose expression for plant protection products*.

Crop safety

32. The data set must provide a high confidence that under normal conditions of use in the proposed country or region that no adverse crop effects would be expected, and the applicant should explain the basis for this assumption. Because of the risk of damage from herbicides, a range of varieties representative of those grown in the proposed country or region should have supporting data, and if there are indications of varietal effects, then closer attention to other varieties grown in the proposed country or region may be necessary. The same principal should be applied if there have been known or observed adverse effects of certain varieties to other crop protection products such as insecticides and fungicides. Variety screens may be an appropriate test methodology as outlined in EPPO standard PP 1/135 *Phytotoxicity assessment*.

6.3. Pest related factors

33. An applicant's justification should consider issues related to pest pressure, and pest biology (for example, insect number of generations), and resistance of the target pests in the region in which the data have been generated and how those relate to the intended use and target pests in the proposed country or region. It is also important, in the interests of sustainable use of pesticides and minimising pesticide use, to consider the relevance of the target to the proposed country. For example, an insect pest may be distributed across a wide region on the same crop but, for various interacting factors, may not cause significant damage warranting control measures in every country.

34. Data from situations where the target is more challenging, for example because of high pest pressure, may be used to support use in situations of lower pest pressure. However, where there are substantive differences in for example the number of generations of a pest, the justification should include a consideration of the relevance of the data in

support of a use pattern relevant to the proposed country or region where registration is being considered. Applicants should also consider and discuss the potential levels of resistance of the target pest between the localities where the efficacy data was generated and its relevance to use in the proposed country or region. The need for a resistance management strategy, or adapting an existing one (for example, same pest on a different crop) should be considered as part of this.

6.4. Agronomic related factors

35. Linked closely with the efficacy and crop safety issues noted above, the potential for substantial variation in agronomic practices between countries make it important that the applicant ensures that foreign data is relevant to the proposed country or region. These factors include cropping practice, crop structures, rotational crops and irrigation.

36. Differences in rotational cropping between countries and regions requires careful consideration, particularly for herbicides and examination if similar rotational crops were tested and are sufficiently representative to the proposed country or region should be discussed. Different irrigation practices in the same crop may occur in different countries or regions and these can influence crop growth, product availability and pest pressure in insects, weeds and diseases. Where irrigation practices are likely to occur in the crop these aspects should be discussed.

37. The case should consider factors that are relevant to the product and crop in question and explain how they apply to the conditions likely to be encountered in the proposed country or region.

6.5. Climatic related conditions

38. Growing conditions influence crop growth and the applicant should consider and discuss whether the data ensures a robust test of the product relative to the growth habit and conditions of the crop in the proposed country or region. For example, differences in crop growth between countries and regions may occur where the climate is more conducive to crop growth and thus foliage is more sensitive to crop damage, or conversely under slower growing conditions where exposure of the crop at particular growth stages may be more prolonged.

39. Climate can affect both the product and target pests. In support of foreign data, an applicant should provide justification that the climatic conditions of the country or region where the data has been generated is comparable to the proposed country or region into which authorisation is sought and/or, if appropriate, an argument that in the case cited, climate would not be a factor.

40. Factors such as temperature, rainfall, light and pH may affect the mode of action/plant uptake of a product and of its active ingredient in turn affecting performance. Applicants should discuss the properties of the active substance and how conditions in other countries or regions provides the type of challenge the product is likely to encounter in the intended country or region of use. It should be noted that even where climate may not be comparable the data may be relevant if those aspects of climate that differ are not relevant to the performance of the product or to the interaction with the pest and crop, or if they

present a more challenging scenario than might be encountered in the actual conditions of use. In cases where differences exist, applicants should provide a justification why comparable efficacy and crop safety should be expected. However, the comparison should focus on the climatic conditions relevant to the proposed timing of application, which may be adapted to ensure comparability at the time of use. For example, differences in climate may mean treated seed is drilled in different months in different countries, but at a point where the same minimum soil temperature required for germination is reached.

41. Rather than looking at comparability of climate, climatic conditions in a relatively small area (microclimate) should be considered. This may be achieved via the provision of basic weather data from the location(s) where the trials have been conducted and a comparison with those conditions in the proposed country or region where the crop is commercially grown. If comparability can be demonstrated, then from a (micro)climatic perspective the data can be deemed relevant.

42. There are some published climatic comparability documentation that may avoid the need for detailed presentation and explanation of weather data. EPPO standards PP 1/269 *Comparable climates on a global level* and PP 1/241 *Guidance on comparable climates* are suitable reference sources for this approach.

6.6. Edaphic related conditions

43. Edaphic factors such as soil type, texture, moisture, porosity and organic matter content can have both positive and negative effects on a products efficacy and crop safety.

44. In justifying the relevance of foreign data, the applicant should provide information on the soil type or conditions under which the supporting data has been generated. This may also include a discussion of the soil conditions in the foreign country or region for the crop where authorisations exist.

45. Similar to climatic factors discussed above even where soil conditions may not be comparable the data may be relevant if those aspects that differ are not relevant to the performance of the product or to the interaction with the pest and crop, or if they present a more challenging scenario than might be encountered in the actual conditions of use. In cases where differences exist, applicants should provide a justification of why comparable efficacy and crop safety should be expected. This should include a discussion and justification relating to the product mode of action, its performance, and how it may be affected by soil type or conditions. It may be possible to propose certain restrictions, on soil type, for example where efficacy may be impacted.

7. Use of data from other sources

46. In addition to specific efficacy studies conducted with the product, either within the country or region seeking authorisation or from another country or region, other relevant data may be used to substantiate efficacy. This may reduce the total number of specific efficacy studies that need to be conducted, although the relevance of the data to the product (e.g. the relevance to the formulation of the product) and to the proposed use must be

discussed and a rationale provided why it should be considered acceptable to support the proposed use. Such data may be from one or more sources including:

- Scientifically published literature and data out of protection
- Laboratory data
- Supervised trials and grower evidence from monitored and assessed observations
- Expert knowledge and use of extrapolation

47. In the case of foreign data, it is essential that the applicant provides a justification for the use of those data to the conditions present in the country or region seeking authorisation.

48. Data that are used must be of an appropriate quality and scientifically valid and the applicant should provide a justification that this is the case. Conduct of trials in accordance with internationally accepted protocols, such as those of EPPO, would provide such justification.

7.1. Published scientific literature and data out of protection

49. Where there are public domain data using the active substance in the proposed product for the minor use, these may be used and provide supporting evidence so reducing the number of specific efficacy studies required. The relevance of the public domain data depends on the similarity of the formulation to that proposed as well as the depth of information provided on its application and dose, and on its performance. Whilst actual formulation details of any product used in the public domain study are unlikely to be available, such evidence provides knowledge of the performance of the active substance as formulated against the proposed target. Where the evidence is with a formulation of the same type (e.g. emulsifiable concentrate or wettable powder) as the proposed product, or where it is known that formulants are inert and do not play a role in the mode of action or where it is with an active substance the performance of which is known or considered to be relatively independent of formulation, then this may be used to reduce the total number of specific efficacy trials required. To be of value the evidence also needs to contain details of the nature of the assessments made as well as the results obtained.

50. The same applies to commercial out of protection data substantiating the performance of the active substances against relevant minor uses. The relevance of such data depends on the similarity of the proposed formulation and the impact of formulation on performance of the active substance. However, a substantive data set with a formulation similar to that proposed and where the performance of the active substance is largely independent of formulation may greatly reduce the number of specific efficacy trials required.

51. When using public domain data, the applicant should provide an explanation of the relevance of the data to the proposed product and to the use being sought. Depending on where the data are from, a justification of relevance of the conditions pertaining where the trials were conducted to the proposed use may also be required.

7.2. Laboratory data

52. Laboratory data is generated in tests where conditions are controlled (e.g. growth chambers) and may be considered to include the use of 'pot tests', can provide supporting evidence of either performance or crop safety. This type of data may be used to extend the data set or to demonstrate efficacy under specific conditions likely to be encountered in practice. Laboratory data may also be useful where it is used to show the relative susceptibility of two targets to a product and the proposed target pest is likely to receive the same exposure to the product as a target for which a full data set are available. In such situations this may enable extrapolation to minor targets from targets already supported by data or previously approved on the label, and make specific efficacy testing against the proposed target unnecessary. The extrapolation should refer to the original data, evaluations, country reports etc. Extrapolation from evaluations and uses where extrapolation has already been performed is not recommended.

53. Pot tests and variety screens, conducted in greenhouse and in the field, may also provide valuable evidence of either crop safety or effectiveness and enable some reduction in the total number of efficacy trials required. Applicants should give due consideration to the location of intended use – for example whether use is under protection or outdoor. Use of glasshouse data to support an outdoor use, and vice versa, needs to be considered carefully. Plant growth and leaf surfaces can be different having impact both on effectiveness and crop safety. Glasshouse grown plant material can have a 'softer' texture (and a thinner layer of surface wax) due to more rapid growth, making it more susceptible to crop damage. However, such crops when tested in protected environments may not be influenced by wider environmental conditions, such as frost, water logging etc., which may make them more sensitive to crop damage from a product when grown under normal field conditions. More stable conditions under protection may be beneficial to some target species such that pest pressure is greater, but equally the conditions may demonstrate a higher performance of a product due to the lack of interference or weathering of deposits of a product from for example rainfall. As such the use of protected data to support outdoor use and vice versa needs to be considered carefully and is at best supporting evidence. However, it may be used as part of a submission provided there is an appropriate justification of its relevance to the intended use.

7.3. Supervised trials from monitored and assessed observations

54. Useful supporting data for minor uses, and especially for minor pests that occur infrequently and/or sporadically, can also be obtained from grower trials supervised by an agronomist, or exceptionally from trials conducted by growers. Such trials may differ from conventional and statistically designed trials in having fewer replications, and even potentially larger plot sizes as they may form part of commercial treatments applied to a commercial crop. Associated untreated areas must be available to monitor target population changes in the absence of treatment, and a comparative or standard treatment should also be included. The 'standard treatment' might be the grower's applied commercial treatment. Appropriate assessments relevant to the target must be made on all treatment areas both before and after treatment with accurate recording and subsequent presentation of data.

55. Whilst data from such trials are not a substitute for data from fully replicated and randomised efficacy trials they may provide useful supporting evidence and enable a small reduction in the total number of properly conducted trials to be made.

7.4. Expert knowledge and use of extrapolation from other authorised uses

56. Where available data are limited, expert knowledge may be used to provide a soundly reasoned justification for the effectiveness or crop safety for a minor use, referring to related evidence or data and providing a reasoned argument as to why such data are relevant to the proposed use. Local expert knowledge may be especially valuable when using foreign data and making appropriate justifications to the conditions pertaining in other countries or regions. Crop protection specialists or extension service personnel may provide the relevant expertise.

57. It is a common route for commercialisation of 'minor' crops or 'minor' targets, that an extrapolation approach from existing authorised uses is applied to either support the minor use, without further data, or reduce the amount of supportive data. When considering generating data for minor uses, it is therefore important to review any existing relevant data may be available from existing authorised uses.

58. Expert knowledge may also be used to support an argument for extrapolation by providing reasoning regarding the similarity of the targets, or to data with products containing closely related active substances with the same mode of action. Extrapolation is the means by which efficacy data supporting the authorisation of a product against a target on a crop are used to justify efficacy against either the same target on a different crop or a different target on the same or different crop. Taxonomic links between targets alone are generally not sufficient evidence of similarity for extrapolation and information on the biology of crop/pest interactions should be provided. Extrapolation requires expert knowledge: an understanding of the target pest, and the relationship with the target from which extrapolation is intended. It requires an understanding of the mode of action of the product; whether it is contact in action, systemic or translaminar, or for herbicides residual or translocated, and the interaction with the target. And for extrapolation between crops, it requires and understanding of the relationship and similarity with the crop to which extrapolation is intended, and the interaction both with the product and the target.

59. Substantive information is already available internationally on extrapolation, and when considering extrapolation, applicants should in the first instance consult EPPO standard PP 1/257 Efficacy and crop safety extrapolations for minor uses. The document provides a comprehensive insight into the principles of extrapolation. Associated with this document are a series of crop group or pest group specific tables which identify extrapolations between crops or between targets that may be considered. The tables are available either focussing on effectiveness for extrapolations between targets and crops or on crop safety, for extrapolations between crops. It should be noted that these tables are under continuous development with new tables being developed and new extrapolations being added. They are also predominately focussed on targets across the EPPO region (and as such Europe) but some targets and crops (e.g. tropical crops) are relevant to other countries and regions, and the principles of extrapolation can be applied to any target or crop. In using EPPO extrapolation tables, it is important that extrapolations are considered and verified by national experts to take account of local conditions, such as different agronomic practices or resistance to products.

60. In making any extrapolation, whether from the EPPO extrapolation tables, or any other extrapolation, the applicant should provide reasoning as to why that extrapolation is acceptable. In the former situation, it may just be a citation of the fact that the extrapolation

is listed in the EPPO table, and why it is relevant for the product in question. For more complex extrapolations and those not listed in the EPPO tables, for example extrapolations between different pests and on different crops, a more comprehensive scientific justification will be required. That justification should provide a full explanation of why the extrapolation is considered appropriate, considering the biology of the targets as well as the crops in question, and the interactions with the product, the active substance and its mode of action.

61. Also for low-risk plant protection products the general principles of extrapolation for efficacy, as described above, apply. Depending on the mode of action of the low-risk plant protection product there may be scope to extrapolate between different crops and pests, resulting in a smaller efficacy data set. Trials across a limited range of proposed major crops and pests may be acceptable with appropriate descriptions and justifications. Data from worst-case circumstances (e.g. crop(s) with a dense canopy or leaf structure in case of a contact mode of action) can be used for extrapolation to less critical situations. If a product has a direct mode of action which is pest dependent the crop may be of less relevance. Extrapolation from data on a major pest in a major crop to the same pest in other major and minor crops may be possible depending on the quality of the existing data. Key factors to consider are for example, crop morphology (e.g. waxy surface or dense canopy or leaf structure), cropping system, feeding area on the plant (e.g. root or leaf), growing conditions (e.g. field or protected), application technique or timing and growing substrate. For low-risk products with an indirect mode of action the claimed pest may be less relevant. Key factors to consider are: the life cycle of the pest (e.g. targeting the same stage, biology), taxonomic relationship, plant part affected (e.g. root, leaf), type of damage, application technique or timing, behaviour (e.g. secretive habit) and feeding method (e.g. sucking, biting).

62. Extrapolation may also require specific local knowledge to take account of local conditions and practices. Even with expert knowledge there may be some element of doubt regarding a possible extrapolation. This may be either from a crop safety or an efficacy perspective. In such situations, confirmatory data may be provided to provide confidence in the performance or crop safety of the product. As such the proposed satisfaction is made via a combination of efficacy data and extrapolation. The amount of additional data required will be dependent on the level of uncertainty associated with the extrapolation, and the quality of the data.

63. It should be remembered that while expert knowledge can be used by the applicant to provide reasoning and justification in support of a minor use authorisation, regulatory authorities will still conduct an evaluation of the data and cases presented. Decision will be made on the basis of the evidence available and the scientific validity of cases presented.

8. References

EPPO Standards for the efficacy evaluation of plant protection products (PP1): http://pp1.eppo.int

OECD 2009. Publication of the OECD Guidance Document on Defining Minor Uses of Pesticides [ENV/JM/MONO(2009)39].

OECD 2011a. OECD Survey on Efficacy & Crop Safety Data Requirements & Guidelines for the Registration of Pesticide Minor Uses [ENV/JM/MONO(2011)13].

OECD 2011b. Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses [ENV/JM/MONO(2011)16].