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FOOD AND AGRICULTURE
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JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 11

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON PESTICIDE RESIDUES

42nd Session

Xian, China, 19 - 24 April 2010

DISCUSSION PAPER ON THE GUIDANCE TO FACILITATE THE ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS FOR PESTICIDES FOR MINOR USE AND SPECIALTY CROPS

Prepared by the Electronic Working Group led by the United States of America and co-chaired by Australia and Kenya

I. BACKGROUND

At its 41st Session, the Codex Committee on Pesticide Residues (CCPR) agreed to re-establish the Electronic Working Group (EWG) on Minor Uses and Specialty Crops. The Codex Committee determined that the EWG should continue to identify and address issues related to minor uses and specialty crops by 1) identifying priority minor uses and specialty crops for maximum residue limits (MRL) setting for proposing in the CCPR priority scheduling and facilitate submissions to the Joint Meeting of Pesticide Residues (JMPR) and 2) elaborating on the definitions of minor use and specialty crops for use by the CCPR and JMPR.

The Committee agreed the re-established EWG will be co-chaired by the United States, Australia and Kenya working in English. Barbara Madden (madden.barbara@epa.gov) from the United States Environmental Protection Agency (EPA) represents the United States on this group, Alan Norden (Alan.Norden@apvma.gov.au) from the Australian Pesticides and Veterinary Medicines Authority (APVMA) represents Australia and Lucy Namu (lnamu@kephis.org) from the Kenya Plant Health Inspectorate Service represents Kenya.

In October of 2009 the chairs sent a message via the Codex Secretariat to all Codex Members and Observers as well as contacts identified in the March 2009 EWG report the chairs submitted to the Codex Committee on Pesticide Residues. This message provided a summary of the outcome of the 41st session regarding the EWG report which Lucy Namu (Kenya) presented to the Committee. In addition the message requested information from Members and Observers to further the goals assigned the EWG by the 41st Session, the Codex Committee on Pesticide Residues.

This report summarizes the activities of the group to date and proposes recommendations for future action.

II. SUMMARY OF PROPOSED RECOMMENDATIONS

The EWG on Minor Uses and Specialty Crops proposes member countries and CCPR support:

B.1. a Specialty Crops & Minor Use Interest Group of Members and Observers to work collaboratively to identify and nominate chemical/uses to the *EWG on Priorities* and collate submissions (comprising of data and product labels across member countries) to JMPR for review by:

B.1.1.a. identifying data/labels available for submission and if there are possibilities for bundling and coordinating these efforts where data for minor uses of a priority chemical have been produced in different countries but are bundled together and submitted by one lead country.

B.1.1.b. exploring mechanisms to facilitate multiple countries working collaboratively to develop the needed data to support the establishment of Codex MRLs on a minor crop. In cases where 4 residue field trial data are not available from a single country, countries should work together to develop such data provided the GAP in which the residue field trials are conducted are within the required 25% variation of the GAP.

B.1.2. requesting that JMPR formalize:

B.1.2.a. acceptance of residue field trial data available on a minor crop when there is no formal label available, but instead the data are accompanied by an official letter from a government agency that states the chemical is being used on the crop in that country and the letter outlines the use pattern (GAP) being used by growers in that country;

B.1.2.b. acceptance of submissions on priority chemicals that are bundled from multiple countries and submitted by just one country that has agreed to take the lead on behalf of others;

B.1.2.c. acceptance of residue data for the same chemical/GAP from multiple countries in order to obtain the 3 or 4 required residue field trials. Provided these data are conducted are within the required 25% variation of the GAP, the JMPR is encouraged to accept data from several countries to support the establishment of a Codex MRL; and

B.1.2.d. guidance concerning when 3 field trials might be acceptable for a minor use.

B.2. The EWG on Minor Uses and Specialty Crops proposes member countries and CCPR to continue to;

B.2.1. actively participate in and continue progress for the inclusion of new commodities into the *Revision of the Codex Classification on Foods and Animal Feeds* and

B.2.2. progress steps for suitable implementation on the *Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups*.

C.1. If the EWG on Minor Uses and Specialty Crops is asked to continue work on elaborating the definitions of minor use and specialty crops for use by the CCPR and JMPR then the EWG requests the CCPR provide additional guidance on the following:

The *OECD Guidance Document on Defining Minor Uses of Pesticides* provides a general overview of OECD member countries approaches to defining minor uses. It discusses how minor use determinations can differ depending upon the utilization of risk assessment or economic return principles and those that can occur due to country or regional differences.

The EWG would like to determine if;

- the *OECD Guidance Document on Defining Minor Uses of Pesticides* provides sufficient guidance in defining minor uses and specialty crops for acceptance by the CCPR, or
- does CCPR believe that more targeted information/guidance is required in defining minor uses in respect of issues such as residue chemistry, trade or other areas?

III. DISCUSSION

A. Participation in the EWG for Minor Uses and Specialty Crops

Similar to 2008 the response to the chair's call for participation in the EWG for Minor Uses and Specialty Crops was limited. In some respects, the level of participation in this working group has been disappointing given the level of support expressed during the Codex meetings. However, it is important to remember that the obstacles faced by many delegations in effectively participating in the Codex process are immense. These difficulties, which are long-standing in many cases, will not be eliminated quickly. However, the working group is making some progress, which we think will build upon itself if we continue to focus attention on the issues of facilitating establishment of MRLs for minor uses.

For example, the kinds of obstacles faced by many countries were clearly indicated in a Colloquium sponsored by the United States Department of Agriculture (USDA) which was held in Morocco in September 2009. This outreach was intended to serve as an encouragement for Codex Africa (CCAfrica) to more effectively participate in Codex Alimentarius Committees and as an opportunity to discuss the obstacles to their participation. Issues raised included obstacles in communication in all of its many aspects such as: receipt of Codex information by the appropriate people through the Codex Contact Point system does not work for many countries; frequent changes in delegation make-up is a major problem; the actions of the Committee itself contribute to the problems, for example, the request for comment on the MRL calculator was sent without any background information on the calculator--in essence asking non-OECD countries to comment on something they are keenly interested in but have no information about; obstacles to inter-regional communication and communication with manufacturers also need to be addressed.

Another obstacle that was identified at the Colloquium is the lack of importance or emphasis on Codex work by governments. Participating effectively in the Codex process may help to accomplish important goals for many countries, elevating the significance of Codex work and garnering the attention of the government leaders. Thus, effective participation in Codex is the best way of building support for that work in many countries and is one of the main reasons for continuing the work of this electronic working group.

B. Facilitating Submissions to the JMPR

1. Data Submission to Joint Meeting of Pesticide Residues (JMPR)

As reported by the EWG in March of 2009, a lack of available residue data was cited as the primary reason why more countries do not put forth nominations to the CCPR for review for new uses. Additionally, many countries do not always know how to appropriately generate data and present that data as required by the JMPR for its evaluations. Typically to recommend for Codex MRLs, JMPR requires submission of 4 residue field trials and a label that contains the Good Agricultural Practices (GAP) in which the residue field trials were conducted. If there is variation between the GAP (application rate, number of applications, etc.) on the label and the GAP in which the residue field trials were conducted the JMPR will usually only accept labels with a GAP that is within a 25% variation from the residue field trial data. However, for many minor crops that are important to countries for export, these data are not always available preventing the establishment of needed Codex MRLs. The chairs of the EWG contacted members of JMPR and CCPR earlier in 2009 regarding submissions to JMPR and the potential for some deviation from these requirements.

For example, if there are residue field trial data available on a minor crop but there is no formal label, the JMPR has been willing to accept submission of the data for review if it is accompanied by an official letter from a government agency that states the chemical is being used on the crop in that country and the letter outlines the use pattern (GAP) being used by growers in that country. There have also been some circumstances where data for only 3 residue field trials have been accepted on a minor crop to establish a Codex MRL. Therefore, if a country only has 3 residue field trials they were encouraged to submit these data to JMPR for consideration. The EWG believes it would be helpful for JMPR to develop some formal guidance around when 3 trials might be acceptable for a minor use.

The chairs also determined through discussions with members of the JMPR and CCPR that though the EWG can not make formal submissions to the JMPR there is an agreement that submissions can be

bundled from multiple countries and submitted by just one country. This is particularly relevant in cases where 3 or 4 residue field trial data are not available from a single country, yet where data from several countries if consolidated and of a similar GAP would collectively meet the requirements of JMPR for a minimum of 4 field trials. To facilitate this, the EWG requested that members identify any data available for a crop to potentially be submitted together. Therefore, even if there were only data for 1 or 2 residue field trials for a crop, members were encouraged to identify these data for possible submission to the JMPR. However responses to these requests were low and the EWG presumes this may have been due to a number of factors.

Firstly, the collaborative approach across several countries in identifying, submitting and developing the needed data to support the establishment of Codex MRLs is new and further work may be required in establishing a recognized process to enhance this occurring more efficiently and successfully. The EWG recommends that countries work together to develop a process that identifies and collates available data for submission to JMPR.

Secondly, amongst some member countries and potential sources of data there can be a lack of knowledge for the process and requirements of JMPR. The EWG sent a document entitled, *Minimum Requirements for Data Submissions to JMPR in Support of New Uses of Existing Codex Pesticide Compounds and Add-Ons to New Pesticide Compounds* to provide guidance on the data requirements in support of additional uses for existing Codex pesticide compounds in particular, the supervised crop field trial (CFT) study report. The EWG notes that FAO is in the process of developing a training manual that will provide guidance in the generation and submission of data to JMPR. The EWG fully supports these efforts and expects such a manual will facilitate the submission of data to establish Codex MRLs on minor uses and specialty crops.

Recommendations

The EWG on Minor Uses and Specialty Crops proposes member countries and CCPR support:

B.1. a Specialty Crops & Minor Use Interest Group of Members and Observers to work collaboratively to identify and nominate chemical/uses to the *EWG on Priorities* and collate submissions (comprising of data and product labels across member countries) to JMPR for review by:

B.1.1.a. identifying data/labels available for submission and if there are possibilities for bundling and coordinating these efforts where data for minor uses of a priority chemical have been produced in different countries but are bundled together and submitted by one lead country.

B.1.1.b. exploring mechanisms to facilitate multiple countries working collaboratively to develop the needed data to support the establishment of Codex MRLs on a minor crop. In cases where 4 residue field trial data are not available from a single country, countries should work together to develop such data provided the GAP in which the residue field trials are conducted are within the required 25% variation of the GAP.

B.1.2. requesting that JMPR formalize:

B.1.2.a acceptance of residue field trial data available on a minor crop when there is no formal label available, but instead the data are accompanied by an official letter from a government agency that states the chemical is being used on the crop in that country and the letter outlines the use pattern (GAP) being used by growers in that country;

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B.1.2.c. acceptance of residue data for the same chemical/GAP from multiple countries in order to obtain the 3 or 4 required residue field trials. Provided these data are conducted are within the required 25% variation of the GAP, the JMPR is encouraged to accept data from several countries to support the establishment of a Codex MRL; and

B.1.2.d. guidance concerning when 3 field trials might be acceptable for a minor use.

Approaches in the Absence of Commodity Specific Data

As recommended to the 41st Session of the Codex Committee on Pesticide Residues, the EWG on Minor Uses and Specialty Crops continues to recommend that CCPR actively participate in and continue progress for the inclusion of new commodities into the *Revision of the Codex Classification on Foods and Animal Feeds* and progress steps for suitable implementation on the *Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups*.

A common approach utilized and accepted by regulators to support the registration of minor uses is to allow the scientific extrapolation of data between related commodities of the same crop group. This enables MRLs to be established for either individual commodities or for an entire crop group should data from identified representative commodities of that group be available.

Current work by the CCPR Electronic Working Group on the *Revision of the Codex Classification on Foods and Animal Feeds* is proposing the inclusion of many new commodities. The inclusion of new commodities will further serve to address some of the barriers for Codex MRLs on those commodities being considered for inclusion. However the benefits for the addition of new commodities into the *Codex Classification on Foods and Animal Feeds* may only be fully realized where Codex MRLs can be established for entire crop groups.

Recommendations

B.2. The EWG on Minor Uses and Specialty Crops proposes member countries and CCPR to continue to;

B.2.1. actively participate in and continue progress for the inclusion of new commodities into the *Revision of the Codex Classification on Foods and Animal Feeds* and

B.2.2. progress steps for suitable implementation on the *Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups*.

C. Definition of Terms

1. Definition of Terms

At its 41st Session, the Codex Committee on Pesticide Residues determined that the EWG should continue to elaborate on the definitions of minor use and specialty crops for use by the CCPR and JMPR. As discussed in March 2009 by the EWG there was not agreement among all member countries as to the definitions of minor uses and specialty crops. There was acknowledgement that the definition of what crops may be “minor uses” or “specialty crops” may be different from country to country.

In October of 2009 the Organization for Economic Co-operation and Development (OECD) through its Expert Group on Minor Uses finalized a guidance document on mechanisms used amongst member countries and issues countries should be conscious of when developing a definition (or criteria) for minor uses and specialty crops. In December of 2009 the EWG circulated to Codex Members and Observers the recently published document by OECD titled: *Publication OECD Guidance Document on Defining Minor Uses of Pesticides* {ENV/JM/MONO(2009)39}. A copy of this document is attached (Attachment I) and may also be obtained from the OECD at http://www.oecd.org/department/0,3355,en_2649_34383_1_1_1_1_1,00.html

The EWG chairs asked Members and Observers to consider and comment on the OECD guidance document for the purpose of elaborating on the definitions of minor use and specialty crops for use by the CCPR and JMPR. In particular comments were requested on the suitability of aspects of the OECD guidance document in providing a basis for definitions, or if additional areas need to be considered in elaborating on such definitions for use by CCPR and JMPR.

Recommendations

C.1. If the EWG on Minor Uses and Specialty Crops is asked to continue work on elaborating the definitions of minor use and specialty crops for use by the CCPR and JMPR then the EWG requests the CCPR provide additional guidance on the following:

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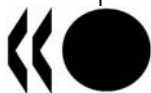
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- No. 16 *OECD Guidance for Industry Data Submissions for Pheromones and Other Semiochemicals and their Active Substances* (Dossier Guidance for Pheromones and other Semiochemicals) (2003)
- No. 17 *OECD Guidance for Country Data Review Reports for Pheromones and Other Semiochemicals and their Active Substances* (Monograph Guidance for Pheromones and other Semiochemicals) (2003)
- No. 18 *Guidance for Registration Requirements for Microbial Pesticides* (2003)
- No. 19 *Registration and Work sharing, Report of the OECD/FAO Zoning Project* (2003)
- No. 20 *OECD Workshop on Electronic Tools for data submission, evaluation and exchange for the Regulation of new and existing industrial chemicals, agricultural pesticides and biocides* (2003)
- No. 21 *Guidance for Regulation of Invertebrates as Biological Control Agents (IBCA's)* (2004)
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- No. 26 *Report of the OECD Pesticide Risk Reduction Group Seminar on Minor Uses and Pesticide Risk Reduction* (2005)
- No. 27 *Summary Report of the OECD Project on Pesticide Terrestrial Risk Indicators (TERI)* (2005)

- No. 28 *Report of the OECD Pesticide Risk Reduction Steering Group Seminar on Pesticide Risk Reduction through Good Container Management* (2005)
- No. 29 *Report of the OECD Pesticide Risk Reduction Steering Group Seminar on Risk Reduction through Good Pesticide Labelling* (2006)
- No. 30 *Report of the OECD Pesticide Risk Reduction Steering Group: The Second Risk Reduction Survey* (2006)
- No. 31 *Guidance Document on the Definition of Residue* (2006)
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- No. 46 *Report of the Seminar on Risk Reduction through Spray Drift Reduction Strategies as part of National Risk Management* (2009)
- No. 47 *OECD Survey on Countries' Approaches to the Collection and Use of Agricultural Pesticide Sales and Usage Data: Survey Results* (2009)
- No. 48 *OECD Strategic Approach in Pesticide Risk Reduction* (2009)

Published separately

OECD Guidance for Country Data Review Reports on Plant Protection Products and their Active Substances-Monograph Guidance (1998, revised 2001, 2005, 2006)

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

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

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

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

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

Report of the 2nd OECD Workshop on Pesticide Risk Indicators (1999)

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

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

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

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This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The participating organisations are FAO, ILO, UNEP, UNIDO, UNITAR, WHO and OECD. The World Bank and UNDP are observers. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

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or contact:

**OECD Environment Directorate,
Environment, Health and Safety Division**

**2, rue André-Pascal
75775 Paris Cedex 16
France**

Fax: (33-1) 44 30 61 80

E-mail: ehscont@oecd.org

FOREWORD

Minor use is the use of chemical pesticides or non-chemical means of crop protection where the potential use is on a scale not sufficiently large to justify registration of that use from an applicant's perspective alone. 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 pesticides 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.

In June 2007, the OECD through the Registration Steering Group (RSG), a sub-group of the Working Group on Pesticides (WGP) established an Expert Group on Minor Uses (EGMU), chaired by Australia and composed of experts from Austria, Belgium, Canada, Czech Republic, France, Germany, Greece, Hungary, Ireland, Japan, Netherlands, New Zealand, Slovak Republic, United Kingdom, United States, Slovenia, European Commission, FAO (UN Food and Agriculture Organization), CropLife International, IBMA (International Biocontrol Manufacturers' Association), EPPO (European and Mediterranean Plant Protection Organization) and IR-4 (US Interregional Research Project Number 4). Appendix 2 lists EGMU members.

The Guidance for Defining Minor Uses of Pesticides is provided to encourage and enhance member countries similarities in their approaches to defining minor uses, and to ensure that those needs are appropriately regulated, managed and addressed in their respective countries. It was developed by the Chair of the EGMU Alan Norden (Australia) and reviewed on several occasions by EGMU and RSG delegates.

The draft Guidance was approved by the Working Group on Pesticides by written procedure in August 2009.

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.

OECD Guidance Document on Defining Minor Uses of Pesticides

Table of Contents

Purpose	12
Introduction	13
Considerations	
○ Risk assessment and Economic return	15
○ Defining Minor Crops & Major Crops versus Minor Uses	16
○ Minor Use in a Major Crop.....	17
○ Country and Regional Differences.....	17
Developing a Minor Use Definition – The Critical Elements	18
Appendix 1: Member Country Definitions	19
Appendix 2: OECD Expert Group on Minor Uses	26

PURPOSE

This document provides member countries guidance on defining minor uses of pesticides at local or regional levels with the aim of enhancing the consistency between member countries in the methods used in defining minor uses.

Minor use definitions serve as an important mechanism to ensuring that minor uses that are required by agricultural producers are appropriately regulated and where applicable include mechanisms that reduce the regulatory burden and are complemented by providing regulatory incentives to enhance their registration. This may include things such as reduced data requirements (where relevant), reduced assessment fees, increased periods of data protection and expedited regulatory review.

This document is limited to guidance for defining minor uses of pesticides only. Further work is currently being undertaken to develop other documents including those that will provide further information on regulatory incentives for minor uses that exist amongst member countries.

INTRODUCTION

There is no one internationally or OECD accepted definition for minor use.

In 2006 an OECD ‘Survey on Minor Uses’ [ENV/JM/MONO(2007)12] reported on the *Criteria and/or regulatory guidelines for defining minor uses* in various member countries. In summary the report noted ‘*The criteria and guidelines for determining what constitutes a minor use varies amongst member countries, although it is largely determined by one or two key factors, either area or tonnage of production and/or dietary intake. Minor use classifications are utilised to provide things such as guidance on the number of trials required, incentives to encourage their registration (i.e. reduced assessment fees/timeframes) and qualification under grower requested registration or off-label schemes.*’

Appendix 1 outlines current approaches to defining minor uses in several member countries. Of specific guidelines established amongst member countries most include cut-off limits based upon volume of production (area or tonnage) and/or dietary intake of the commodity that are largely designed for purposes of regulatory risk assessment, where exposure from pesticide use is reduced and often includes comparatively reduced data requirements from those otherwise assigned to major uses. One example of this provided in Table 1 below is the European Community (SANCO document 7525/VI/95 rev. 7).

Table 1: European Union (SANCO document 7525/VI/95 rev. 7)

Criteria to classify a crop or a product as **major** for residue purposes:

- daily dietary intake contribution > 7.5 g (i.e. 7.5 g mean daily consumption over the population for a 60 kg person) and/or
- cultivation area > 10000 ha and
- production > 200000 tonnes per year.

These criteria are used equivalent for distribution of crops or products as being major or minor.”

Criteria to classify a crop or a product as **very minor** for residue purposes:

- daily dietary intake contribution < 1.5 g (i.e. 1.5 g mean daily consumption over the population for a 60 kg person) and/or
- cultivation area < 600 ha (less than 0.0035 % of the total cultivation area)

Note: these criteria are used for classifying crops or products as being very minor with a preference on the dietary intake contribution meaning that a higher dietary intake contribution will exclude a crop or a product automatically from the classification as being very minor.

NOTE: at the time of preparing this document a Regulation revising DIR91/414 has proposed a formal definition of minor use as:

“*Use of a plant protection product in a particular Member State on plants or plant products which are:*

- (a) not widely grown in that member state, or
 (b) widely grown to meet an exceptional plant protection need”.

The proposal also requires “*Member States shall establish and regularly update a list of minor uses*”. Eighteen months after publication of the revised EU legislation (which is expected in the second half of 2009) the proposed definition will apply in all European Union Member States. Details will be figured out by individual Member States. As a consequence, Appendix 1 lists current definitions and may need to be amended once the EU Regulation applies.

In addition to specific criteria established and utilised some member countries develop definitions that also include whether or not a use may provide sufficient economic return to an applicant. Three examples of this are definitions from United Kingdom, Canada and Australia, as provided in Table 2 below.

Table 2

United Kingdom	Minor uses are either: <ul style="list-style-type: none"> - uses of pesticides on small area cropping or against infrequent pests, and - those which are too small to warrant sufficient return for manufacturers to develop plant protection products for them.
Canada	A minor use is defined as a necessary use of a pest control product for which the anticipated volume of sales is not sufficient to persuade a manufacturer to register and sell the product in Canada. The definition emphasizes that it is the projected sales of the pest control product that is minor and not necessarily the size of the crop. A minor use may be registered on a major crop because the use may be needed only occasionally or is limited to a small percentage of the total area of the crop.
Australia	A minor use is a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose.)

CONSIDERATIONS

Risk Assessment and Economic Return

There are principally two approaches currently utilised for defining or assigning criteria for the purposes of determining minor uses as discussed in the previous section.

The “risk assessment” approach

The first termed (for the purposes of this document) the “risk assessment” approach is associated with the level of regulatory risk assessment required for a given use by determining at what level a crop may be considered minor or major based upon volume (area or tonnage) of production and/or dietary intake. These criteria are also often utilised by regulatory authorities to determine data requirements and where those requirements are established commensurate to the level of risk assessment required. Therefore minor crops may often have reduced data requirements compared to major crops in areas such as residues and dietary risk assessment.

The “economic return” approach

The second termed (for the purposes of this document) the “economic return” approach is associated with potential economic return to an applicant (manufacturer/registrant) from that use and where those considerations can be influenced by factors (discussed further below) other than solely regulatory risk assessment principles.

Discussion

In examining the potential economic return from a given use decisions of end users and applicants must be taken into account and where these decisions can be independent of regulatory risk assessment and data requirements. Like any market basic economic principles of supply and demand determine what crop protection products are registered. Simply defined the ‘demand’ is end users and the ‘supply’ is applicants. End users typically define minor uses as all those potential uses that are not registered but would be of value to enhancing their agricultural production, including market access requirements or opportunities. End users are constantly altering their agricultural practices and diversifying into new crops that make for an ever-changing crop protection market across hundreds if not thousands of commodities. Amongst commodities there are also significant differences influencing their attractiveness as a profitable crop protection market to an applicant, which can include but is not limited to volume of production, value of the commodity and pest or disease pressure.

The crop protection industry (applicants) pursues registration in markets that provide greatest return on investment and include amongst many things potential sales volume including competitor products (i.e. potential market share), product stewardship, patent/data protection and product liability. Simply defined applicants consider minor uses as those uses that do not provide sufficient economic return on investment, taking into account those issues noted above. These decisions not only affect what new products and registrations are pursued but also what uses may receive continued support should regulatory reviews be initiated.

In further examining end users and the crop protection industry and some of the considerations noted above, the following basic example is provided to explain how differences in minor use determinations can arise when considering the economic return approach compared to the risk assessment approach. Consider two different crops with similar volumes of production and dietary consumption. From the risk assessment approach the registration of both crops would be subject to relatively similar data requirements and costs associated in registering that use. However from the economic return approach factors such as dietary consumption often have little or no direct linkage to potential sales volume from that use when registered. Whilst the volume of production may provide some insight into the potential market size that alone may not determine which use would provide greater economic return to an applicant and therefore which is more attractive to register. This may also be influenced by factors such as (i) level of pest or disease pressure and/or (ii) value of the commodity. Firstly the crop that is subject to greater pest or disease pressure will likewise have an associated greater potential need for crop protection products and be a market of greater interest to applicants. Secondly if the value of the commodity being produced is high that in turn will determine end users decisions on input costs in producing and protecting the crop and similarly be a market of greater interest to applicants. Although the opposite can also be true for high value commodities where potential liability to an applicant may outweigh or significantly offset potential economic return.

It is therefore fair to say that there is a ‘see-sawing’ affect to determining what may be a minor use in the economic return approach, and where that may be influenced by factors other than those utilised in the risk assessment approach where the emphasis is entirely on regulatory risk assessment principles. This often results in differences where a use from one perspective could be classified as major whilst the alternative approach could classify the use as minor and vice-versa. This creates a conundrum where the risk assessment approach and the economic return approach do not always equate and is perhaps reason why differences of opinion can exist between regulators, manufacturers and end users as to what uses are minor.

Defining Minor Crops & Major Crops versus Minor Uses

The risk assessment approach utilising cut-off limits on level of production and dietary intake largely define what commodities are ‘minor crops’ or ‘major crops’ and primarily for the purposes of determining the level of regulatory risk assessment (and data) required for a given use. Whereas the economic return approach in addition to volume of production can be equally influenced by considerations of agronomic decisions of end users and business case decisions of applicants in determining what uses are ‘minor uses’.

The economic return approach also enables the ability to consider and manage minor use needs that can arise in major crops (discussed further below), that may otherwise be denied recognition if determinations were solely based upon the risk assessment approach.

However, it is important to ensure that determinations of what are minor uses (derived via the economic return approach) remain independent from determinations of regulatory risk assessment and establishing data requirements of major and minor crops (derived via the risk assessment approach). This will ensure a scientifically robust level of regulatory risk assessment is

maintained to safeguard users, consumers and the environment irrespective of the use being considered a minor use in a major crop or minor crop.

Minor Use in a Major Crop

Major crops can also be affected by minor use needs, to an extent and for very similar reasons to minor crops, where the level of economic return to an applicant may not be sufficient to justify registration. This can include minor pests or diseases that may be defined as sporadic only occurring in one season every few years and/or that only occur in certain geographical or climatic regions of a country and thereby only affect a small proportion of the countries' total volume of production.

As noted above, the risk assessment approach is unlikely to provide for such minor use considerations for major crops and it is therefore necessary that mechanisms such as those which can be determined via the economic return approach can be undertaken for major crops.

Country or Regional Differences

It is also acknowledged that a crop (or use) in one country or region classified as minor may not necessarily be minor in another region or country. These differences exist due to considerations of use at the local level for reasons of either regulatory risk assessment or economic return to an applicant.

For example from the regulatory risk assessment approach and taking residue data requirements as one example the level of data required can vary amongst member countries where a given crop may be classified as either a minor crop or major crop based upon dietary intake at the local level. Similarly the volume of production of a crop can vary significantly between countries resulting in differences in minor crop and major crop classifications for the same commodity. From the economic return approach, in addition to variations in volume of production between countries and regions, the types of pests and diseases can vary, including their abundance and impact which may be due to differences in things such as geography or climate.

DEVELOPING A MINOR USE DEFINITION: THE CRITICAL ELEMENTS

In developing a minor use definition aspects as outlined in this document should be fully considered including examining current approaches and definitions, which exist in member countries ([Appendix 1](#)). The following are four elements that should be considered in developing, using and maintaining a definition, including the need to consider complementary regulatory incentives to encourage the registration of more minor uses.

1. Development and implementation of minor use definitions should be conscious of and reflect the different factors that result in minor uses. In particular the mechanism(s) should be specifically designed to enable considerations to be made for those uses that do not provide sufficient economic return for an applicant to justify registration of the use.
2. Determinations of what are minor uses derived via an economic return approach should remain independent from determinations of regulatory risk assessment and establishing data requirements of major and minor crops derived via the risk assessment approach.
3. Definitions and mechanism(s) of determining minor uses should be regularly reviewed to ensure that they are current and up to date with the crop protection trends and needs of agricultural producers.
4. Minor use definitions should be complemented by regulatory incentives that are developed to encourage the registration of more minor uses.

Appendix 1

Current Minor Use Definitions from OECD Member Countries

Country/ Organisation	Established minor use criteria (Y OR N)	Summary of comments - details - relevant websites etc.
Australia	YES	<p>Legislation states that a minor use is: <i>“a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose)”</i></p> <p>Guidelines for determining minor uses have been developed and encompass three schedules:</p> <ul style="list-style-type: none"> • Schedule 1 lists those commodities and situations considered major and where anything not listed is considered a minor (crop) use, • Schedule 2 enables considerations of minor uses within major situations (<10% and do not exceed 10,000 hectares), and • Schedule 3 enables options to demonstrate a use would not produce sufficient economic return. <p>A copy of this guideline is available via: http://www.apvma.gov.au/gazette/gazette0203p39.pdf</p>
Canada	YES	<p>“A minor use is defined as a necessary use of a pest control product for which the anticipated volume of sales is not sufficient to persuade a manufacturer to register and sell the product in Canada. The definition emphasizes that it is the projected sales of the pest control product that is minor and not necessarily the size of the crop. A minor use may be registered on a major crop because the use may be needed only occasionally or is limited to a small percentage of the total area of the crop.”</p> <p>Reference: Directive DIR2001-01 http://www.pmra-arla.gc.ca/english/pdf/dir/dir2001-01-e.pdf</p> <p><u>2009 Update information</u> Although Canada is considering revisiting the DIR and expanding/clarifying the definition of a minor use, the above definition is the one that is currently used by Canada.</p>

Country/ Organisation	Established minor use criteria (Y OR N)	Summary of comments - details - relevant websites etc.
Germany	YES	<p><u>Major crops:</u></p> <ul style="list-style-type: none"> • Dietary intake contribution > 7,5 g mean daily consumption for a 60 kg person and/or • Cultivation area > 10.000 ha and • Production > 200.000 tonnes/year <p><u>Minor crops:</u></p> <ul style="list-style-type: none"> • Dietary intake contribution > 1,5-7,5 g mean daily intake consumption for a 60 kg person <p><u>Very minor crops:</u></p> <ul style="list-style-type: none"> • Dietary intake contribution < 1,5 g mean daily consumption for a 60 kg person and/or • Cultivation area < 600 ha (proposal for Germany, may be changed in European countries or regions) <p>- To distinguish between major / minor and very minor crop Germany uses EU working document Doc. 7525/VI/95-rev. 7</p> <p>- To have a minor use in a major crop, the pest must be minor or locally occurring, or there must be other conditions that make the intended use minor</p> <p>- The intended use must be of public interest - this means:</p> <ul style="list-style-type: none"> • " sufficient pesticides are not available to handle the problem (as a rule: less than three effective products with different active substances are available) • " the expected potential economic return for the company must be under a limit (calculated by a calculation model) • " public interest is evaluated during authorisation procedure
Hungary	YES	Ministry order 89/2004 FVM describes crop grouping and minor crops
Ireland	YES	As per EU document "Doc. 7525/VI/95- rev. 7" (refer below for EC).

Country/ Organisation	Established minor use criteria (Y OR N)	Summary of comments - details - relevant websites etc.
Italy	YES	<p>In Italy we follow the criteria of SANCO document 7525/VI/95 to classify a crop as major or minor.</p> <p>Moreover there is a Ministerial Decree (D.M. 16/09/1999) that defines “minor use”. This Decree considers minor use the use of plant protection products in small-scale or which are of minor economic importance compared to the uses for which the product is already authorized.</p> <p>Particularly minor use means:</p> <ul style="list-style-type: none"> • use on minor crops; • use of propagating material; • treatments located along portions of the plant that require limited quantities of a product plant than its normal use; • treatment and occasional limited areas to control the adversities that occur on crops other than those already authorized. <p>In this document there is, also, a list of crops and their classification in minor or major crops.</p>
Japan	YES	<p>The crops* excepting for the crops listed in appendix 3 of operational notice for Data Requirements for Supporting Registration of Pesticides. http://www.acis.go.jp/stuchi/13-3986.pdf (Japanese)</p> <p>*The crops are classified as “minor crop”, usually, the amount of the production is little (e.g. less than 30,000 t).</p>
Korea	YES	<p>Minor use (crop) defines only for the crop which does not exceed 1,000 hectares of cropping area a season.</p>
Netherlands	YES	<p>Taking into account size and occurrence of pest etc (major pest in minor crop and also minor pest in major crop), to determine if a third party extension of approval can be granted. For number of residue-trials see Lundehn-document.</p>

Country/ Organisation	Established minor use criteria (Y OR N)	Summary of comments - details - relevant websites etc.
New Zealand	NO	There is a facility for applicants to either waive or reduce the number of trials required to support claims. Once granted this provides applicants with a degree of certainty of the number of trials they are required to undertake to support label claims. More information on this can be found at http://www.nzfsa.govt.nz/acvm/publications/forms/guidelines-iw.htm#P1_44 .
Poland	NO	Exhaustive list of minor and major crops is under construction. First draft version is available on: http://bip.minrol.gov.pl/FileRepozytory/FileRepozytoryShowImage.aspx?item_id=14184
Slovak Republic	NO	Plant Health Care Act (Article 10, Par. 5) No. 193/2005 Coll. states that: Persons intending to use registered plant protection products or other products in crops or against harmful organisms as are defined in the Official Journal of the Ministry of Agriculture may ask for Control Institute for the extension of its use.
Switzerland	NO	Decisions are taken case by case, based on the following criteria: size of cultivated area, spatial or timely restricted incidence. Prioritization according to urgency for agriculture.

Country/ Organisation	Established minor use criteria (Y OR N)	Summary of comments - details - relevant websites etc.
United Kingdom	YES	<p>Outside the residue area, no formal definition exists, but definitions include ‘<i>Minor uses are either uses of pesticides on small area cropping or against infrequent pests</i>’ and ‘<i>Minor uses are those which are too small to warrant sufficient return for manufacturers to develop plant protection products for them</i>’</p> <p>The residues guidelines give the classification criteria for major versus minor or very minor crops. According to the residue guidelines this affects the number of trials required to support MRLs for major (generally 8 trials) and minor crops (generally 4 trials). The EU classification criteria are within: comparability, extrapolation, group tolerances and data requirements (Doc. 7525/VI/95), 12 June 2001 (http://europa.eu.int/comm/food/plant/protection/resources/publications_en.htm). These are:</p> <p>“The following criteria are used for classifying a crop or a product as major in the European Community:</p> <ul style="list-style-type: none"> • Daily dietary intake contribution > 7.5 g (i.e. 7.5 g mean daily consumption over the population for a 60 kg person) and/or • Cultivation area > 10000 ha and • Production > 200000 tonnes per year. <p>These criteria are used equivalent for distribution of crops or products as being major or minor.</p> <p>In some cases the dietary intake contribution and/or the cultivation area of a crop or a product is very small. In this case certain simplifications should be introduced.</p> <p>The following criteria are used for classifying a crop or a product as 'very minor' in the European Community:</p> <ul style="list-style-type: none"> • Daily dietary intake contribution < 1.5 g (i.e. 1.5 g mean daily consumption over the population for a 60 kg person) and/or • Cultivation area < 600 ha (less than 0.0035 % of the total cultivation area) <p>[Cultivation area is given on the basis of a German proposal; it may be changed for the European regions]</p> <p>These criteria are used for classifying crops or products as being very minor with a preference on the dietary intake contribution meaning that a higher dietary intake contribution will exclude a crop or a product automatically from the classification as being very minor.”</p>

Country/ Organisation	Established minor use criteria (Y OR N)	Summary of comments - details - relevant websites etc.
USA	YES	<p>Under FIFRA Section 2(II), a minor (use) crop is defined in one of two ways:</p> <ol style="list-style-type: none"> 1) It is produced on fewer than 300,000 acres or 2) It is a major crop (a crop grown on more than 300,000 acres) for which the pesticide use pattern is so limited that revenues from the expected sales will be less than the cost of registering the pesticide <p>AND</p> <ol style="list-style-type: none"> A) There are insufficient efficacious alternatives for the use, B) Alternatives pose greater risks to the environment or human health, C) The minor use is significant in managing pest resistance, or D) The minor use plays a significant part in integrated pest management. <p>(http://epa.gov/oppfead1/fqpa/fqpafifr.htm).</p>
Estonia (OECD Accession country)	YES	<p>Plant Protection Act states that minor use is: <i>extension of field of application of plant protection products that has already been authorised to purposes other than those covered by this authorisation when it is in public interest and if the intended field of application of plant protection product is minor or the plant protection product is to be used on a crop with limited growing area.</i></p> <p>The substantive and formal requirements for extension of the field of application of plant protection product and the procedure for processing applications are under the preparation.</p> <p>The Plant Protection Act is available via: http://www.plant.agri.ee</p>

Country/ Organisation	Established minor use criteria (Y OR N)	Summary of comments - details - relevant websites etc.
European Commission	YES	<p>There are currently criteria to classify a crop or a product as major for residue purposes (SANCO document 7525/VI/95 rev. 7). The following criteria are used for classifying a crop or a product as major in the European Community:</p> <ul style="list-style-type: none"> • daily dietary intake contribution > 7.5 g (i.e. 7.5 g mean daily consumption over the population for a 60 kg person) and/or • cultivation area > 10000 ha and • production > 200000 tonnes per year. <p>These criteria are used equivalent for distribution of crops or products as being major or minor.”</p> <p>There are also criteria to classify a crop or a product as “very minor” for residue purposes (SANCO document 7525/VI/95 rev.7). In some cases the dietary intake contribution and/or the cultivation area of a crop or a product is very small. In this case certain simplifications should be introduced. The following criteria are used for classifying a crop or a product as 'very minor' in the European Community:</p> <ul style="list-style-type: none"> • daily dietary intake contribution < 1.5 g (i.e. 1.5 g mean daily consumption over the population for a 60 kg person) and/or • cultivation area < 600 ha (less than 0.0035 % of the total cultivation area) <p>These criteria are used for classifying crops or products as being very minor with a preference on the dietary intake contribution meaning that a higher dietary intake contribution will exclude a crop or a product automatically from the classification as being very minor.”</p> <p>NOTE: at the time of preparing this document a draft Regulation revising DIR91/414 concerning the placing of plant protection products on the market has proposed a formal definition of minor use as: <i>“Use of a plant protection product in a particular Member State on plants or plant products which are:</i> <i>(a) not widely grown in that Member State, or</i> <i>(b) widely grown to meet an exceptional plant protection need”.</i> The proposal also requires: <i>“Member States shall establish and regularly update a list of minor uses”.</i></p>

Appendix 2

OECD Expert Group on Minor Uses (EGMU)

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Australia (lead)	Alan Norden CHAIR
	Eva Benett-Jenkins
Austria	Johan Kohl
Belgium	Anneke De Cock
Canada	Pierre Beauchamp
Czech Republic	Ivan Filkulka
	Josef Svaricek
France	Jean-Claude Malet
Germany	Mario Wick
	Gregor Kral
	Herbert Koepp
	Wolfgang Zornbach
	Karsten Hohgardt
Greece	Dimitra Gilpathi
Hungary	Janos Molnar
Ireland	Gordon Rennie
	Anne-Marie Dillon
	Dara OShea
Japan	Yukiko Yamada
Netherlands	Susanne Sütterlin
	Johan Roman
New Zealand	Warren Hughes
Slovak Republic	Zuzana Vargova
United Kingdom	David Richardson
United States	Lois Rossi
Slovenia	Simona Luskar
	Milena Koprivnikar
European Commission	Wolfgang Reinert
FAO	Mark Davis
CropLife International	Michael Kaethner
	Peter Watson
	Sandra Keller
IBMA	Ulf Heilig
EPPO	Vlasta Zlof
IR-4	Dan Kunkel
OECD Secretariat	Beatrice Grenier