

GLOBAL MINOR USE SUMMIT 2

FOOD AND AGRICULTURE
ORGANIZATION OF
THE UNITED NATIONS (FAO)
HEADQUARTERS
Rome, 21–23 February 2012

PROGRAMME

**Pathways to
Pesticide Registrations and
MRLs for Minor Uses**



TUESDAY (21 FEBRUARY, 2012)-MORNING

Chair: Jerry Baron, United States

09:00 – 09:30 **WELCOME AND OPENING SESSION:**
i) Opening remarks by USEPA
Recalling achievements of GMUS I
Lois Rossi, United States
ii) Opening Remarks by China
Wei Qiwen, China
iii) Opening remarks by Brazil
Luis Rangel, Brazil
iv) Opening remarks by USDA-FAS
Jason Sandahl, United States
v) Welcome and opening remarks by FAO
Mark Davis, FAO

09:30 – 10:30 **REGIONAL UPDATES**
NEW REGULATORY
CHALLENGES/OPPORTUNITIES:
Africa
Lucy Namu, Kenya and
M. Diarra Amadou, Western Africa
Asia
Nuansri Tayaputch, Thailand
Australia/New Zealand/Oceania
Nikki Johnson – New Zealand

10:30 – 11:00 **HEALTH AND COFFEE BREAK**

11:00 – 12:00 **REGIONAL UPDATES**
NEW REGULATORY
CHALLENGES/OPPORTUNITIES
(CONTINUED)
Europe
Francesca Arena, EU Commission
North America
Jerry Baron, United States and
Manjeet Sethi, Canada
Latin America
Luis Rangel, Brazil

12:00 – 13:00 **GROWERS /INDUSTRY PERSPECTIVES ON**
MINOR USE ISSUES
Moderator: Luc Peeters, COPA-COGECA

COLEACP PIP grower (Central Africa)
Jan Prins, Jittu Horticulture, Ethiopia
VitaCress
Shaun Clarkson, United Kingdom
A view from German growers
Dr. Brinkjans and Dr. Stallknecht, Germany
US Minor Crop Farmer Alliance
Jim Cranny, United States

13:00 – 14:15 **LUNCH BREAK**

TUESDAY (21 FEBRUARY, 2012)- AFTERNOON

Chair: Dan Kunkel

14:15 – 14:30 **EPPO UPDATE**
Chair: Dan Kunkel
EPPO - Update on minor use activities
Vlasta Zlof and Robert Sunley, EPPO

14:30 – 15:15 **INDUSTRY PERSPECTIVES ON**
MINOR USE ISSUES
Moderator: Philip Brindle, BASF
CropLife International
A Partner in finding minor use Solutions for a varied food basket
Peter Watson, Dow and
Tanya Tocheva, Syngenta
Biopesticides
David Cary, Executive Director of the International
Biocontrol Manufacturers Association (IBMA)

15:15 – 16:10 **PANEL DISCUSSION:**
GLOBAL MINOR USE COLLABORATIONS
Moderator: Alan Norden, Australia
OVERVIEW OF COLLABORATION AND
COOPERATION INTERNATIONALLY THAT HAS
TAKEN PLACE SINCE THE LAST SUMMIT
Codex Electronic Working group on
Minor uses and Crop Grouping
Pisan Pongsapitch, Thailand
OECD activities - Expert Group on
Minor Uses - EGMU
Alan Norden, Australia
MRL calculator, Field guidance
Karsten Hohgardt, Germany
Improving Global capacity to enhance global
collaboration
Geoffrey Onen, Uganda
International Conference for Heads of
Regulatory Authorities
John Worgan, Canada
Joint Reviews and Pilot Projects
Lois Rossi, US EPA

16:10 – 16:30 **HEALTH AND TEA BREAK**

16:30 – 17:30 **PANEL DISCUSSION: DATA GENERATION,**
DATA SHARING AND DATABASES
Moderator Mark Davis, FAO
AN UPDATE ON GLOBAL PROJECTS AND OTHER
DATA GENERATION PROJECTS AND EXAMPLES

Global Residue Study and data sharing
Michael Braverman, United States
Global Data Generation an Industry perspective
Carmen Tiu, Dow
Capacity Development in support of
data generation
Jason Sandahl, United States
EU database on Minor Uses
Mario Wick, Germany
East and Comesa region database
Ester W. Muchiri, EAPIC

17:30 – 18:00 **WRAP-UP DAY 1**
REVIEW DAY 2 SCHEDULE AND
PRESENTATION OF BOG CHAIRS

18:30 – 20:30 **COCKTAIL RECEPTION**
KEYNOTE SPEAKER ALAN NORDEN,
REGULATORY INCENTIVES FOR MINOR USES

WEDNESDAY (22 FEBRUARY, 2012)

09:00 – 12:00 **BREAKOUT SESSIONS WITH WORKING GROUPS**

10:30 – 11:00 **HEALTH AND COFFEE BREAK**

1) **CONCRETE PLANNING FOR DEALING WITH MINOR USE ISSUES (REGISTRATIONS AND MRLS FOR TRADE), USING TROPICAL FRUITS AS AN EXAMPLE**

Chair: Lois Rossi, United States

Co-Chairs: JC Malet, France and Dr. Im, Korea

This session will focus on the mutual needs of commodity groups, using tropical fruits as one example of how pesticide MRLs affect trade. This breakout group will consider perspectives from growers, chemical industry, retailers and regulators, and will discuss the major issues and possible resolutions. This group should take the position that data needs and data generation will address in a separate breakout session. Questions to consider include:

- What systems are in place in various countries such as default MRLs, mutual recognition of MRLs from other countries or authorities?
- What is the level of coordination and cooperation by regulatory authorities?
- What alliances and cooperation currently exist and how can these cooperation develop and evolve to be more effective?
- Why are some chemical manufactures reluctant to put minor uses on product labels?
- Is product liability an issue?
- What is the impact from secondary standards? Discuss examples of where data were collected and submitted to address an issue. The goal will be to outline possible steps to address and resolve such issues and identify where better coordination and cooperation can occur. These factors will be included in the development of a five year plan to address these needs.

2) **CAPACITY DEVELOPMENT AND DATA GENERATION**

Chair: Mark Davis, FAO

Co-Chair: Jason Sandahl, United States and David Kapindula, Zambia

This session will review training and data generation activities, national and international crop grouping schemes, and OECD and Codex activities including work sharing. The group will consider existing capacity limitations in exporting countries and propose ways in which these can be addressed to allow them to participate equitably in trading agricultural commodities. Opportunities and examples for alternative approaches to dealing with MRL non-compliance such as replacement of pesticides with non-chemical options will be explored. The group will also discuss the use of tools, such as proportionality, and decline residue studies, to assist with data collation and data sharing. The group will outline possible steps to address and resolve issue and identify where better coordination and cooperation can occur.

3) **DATA SHARING, DATA NEEDS AND DATABASES**

Chair: Jerry Baron, United States

Co-Chairs: Craig Hunter, Canada, Johan Roman, The Netherlands and Esther W. Muchiri, Kenya

Panel Discussion – to review Tuesday afternoon session along with other information brought to the meeting including Homaloga database with Miles Thomas and MRL Database with James Christie and Others.

Some questions to considered are:

- What data are most needed by national authorities (in developed and developing countries) and how are the data used? (eg. Regulatory data, only residue, residue and performance - data relevant to minor use programs and minor use registrations.)
- Are exposure, decline, climate/zone data also needed?
- Are there existing data that can be used and if so, is it accessible to all?
- Are their confidentiality and data ownership issues?
- Is there a system to track data?

Following discussions and considerations the group will develop options for efficient data sharing and data generation among stakeholders that meets the needs of national authorities (in developing and developed countries) to provide access to products and ease trade.

4) **REGULATORY INCENTIVES AND POLICY CONSIDERATIONS**

Chair: Alan Norden, Australia

Co-Chair: John Worgan, Canada

This group will Review possible incentives such as data protection, expedited reviews, and fee waivers for minor uses. They will also discuss technical and research areas such as data extrapolation and data sharing incentives. For example, Canadian regulatory incentives including data protection, expedited reviews and fee reductions that applies to minor uses. Provide examples of incentives that have been successfully used by chemical manufactures and regulators. Review incentives outlined in the OECD guidance document. Determine if additional or wider improvements or incentives could be provided to further encourage registration and MRLs for minor uses. Would there be possibilities to streamline or simplify the minor use authorization process? What considerations should be made by regulatory authorities when developing and implementing regulatory incentives? To close the session the group will consider how the incentives discussed could be used regularly and consider how they could be expanded upon. Are other incentives presented? What policy considerations can be developed to add 'value' to minor uses?

**WEDNESDAY (22 FEBRUARY, 2012) - AFTERNOON
BREAKOUT SESSION**

14:00 – 16:00 **DISCUSS, COLLATE, RECOMMENDATIONS
AND CONTINUED DISCUSSION**

16:00 – 16:30 **HEALTH AND COFFEE BREAK**

16:30 – 18:00 **REFINEMENT OF CONCLUSIONS AND
RECOMMENDATIONS
WITHIN BREAKOUT GROUPS**

**THURSDAY (23 FEBRUARY, 2012)
DEVELOPING A 5-YEAR PLAN:**

Chair: Manjeet Sethi, Canada

9:00 – 10:00 **GROUPS REPORT CONCLUSIONS AND
RECOMMENDATIONS TO THE
PLENARY SESSION**

10:00 – 11:00 **DISCUSSION**

11:00 – 11:30 **HEALTH AND COFFEE BREAK**

11:30 – 12:45 **DISCUSSIONS WITH FURTHER REFINEMENT
OF RECOMMENDATIONS**

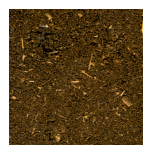
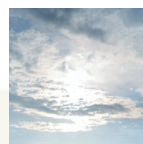
12:45 – 14:15 **LUNCH BREAK**

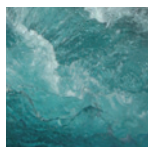
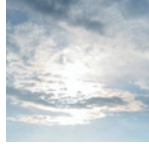
14:15 – 14:45 **PRESENTATION OF FINAL
RECOMMENDATIONS PRESENTED AS A
GUIDANCE DOCUMENT/FIVE YEAR PLAN**

14:45 – 16:00 **DISCUSSIONS**

16:00 – 16:30 **HEALTH AND COFFEE BREAK**

18:15 – 18:30 **CLOSING REMARKS
(USDA/U.S. EPA/IR-4 PROGRAM/FAO)**





GLOBAL MINOR USE SUMMIT 2

FOOD AND AGRICULTURE
ORGANIZATION OF
THE UNITED NATIONS (FAO)
HEADQUARTERS
Rome, 21-23 February 2012



The designations employed and the presentation of material in this information product do not imply the expression of any opinion whatsoever on the part of the Food and Agriculture Organization of the United Nations (FAO) concerning the legal or development status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. The mention of specific companies or products of manufacturers, whether or not these have been patented, does not imply that these have been endorsed or recommended by FAO in preference to others of a similar nature that are not mentioned. The views expressed in this information product are those of the author(s) and do not necessarily reflect the views of FAO.

All rights reserved. FAO encourages reproduction and dissemination of material in this information product. Non-commercial uses will be authorized free of charge, upon request. Reproduction for resale or other commercial purposes, including educational purposes, may incur fees.

Applications for permission to reproduce or disseminate FAO copyright materials, and all queries concerning rights and licences, should be addressed by e-mail to copyright@fao.org or to the Chief, Publishing Policy and Support Branch, Office of Knowledge Exchange, Research and Extension, FAO, Viale delle Terme di Caracalla, 00153 Rome, Italy.

© FAO 2012

This publication contains contributions which are being published with permission from the original authors and, in these cases, copyright remains with the original copyright holder.

Cover artwork prepared with royalty free photos, except for "U" letter: © FAO/G. Bizzarri

BACKGROUND AND OBJECTIVES of Global Minor Use Summit II

Background

The first Global Minor Use Summit (GMUS) was held in Rome, Italy, in December 2007, co-organized by FAO, USDA, US-EPA and IR-4. The purpose of the first Global Minor Use Summit was to highlight many of the issues and obstacles that growers of minor or specialty crops face. It was critically important that participants at the GMUS share knowledge of existing programmes and information, and thus develop a foundation for future cooperation. Four main action items identified at the first GMUS were:

- (1) Improve international communications and information exchange.
- (2) Increase capacity building efforts for developing countries.
- (3) Engage the Codex Committee on Pesticide Residues (CCPR) to better support minor use crops.
- (4) Enhance research efforts through collaborative pilot projects and initiatives.

Various countries have made great strides and contributed to the progress of these four action items: a global minor use portal (<http://ir4.rutgers.edu/GMUS/GMUSportal2.htm>) was established, with important information regarding technical and policy issues relating to minor uses; a number of workshops and training sessions in Africa, Asia and Central and South America were conducted by FAO and USDA; the Codex electronic working group on minor uses has been formed and has provided a number of papers to help assist Codex and member countries in developing more MRLs for minor uses; and a global joint review of a new pesticide is now being considered by JMPR, as part of a Codex pilot review project. As well, there is an ongoing pilot global residue study to look into the possibility of multiple countries working together to develop data to support minor uses. Despite this progress, there is still much work to be done to keep the minor use issues and the action items moving forward. At the same time, many of the issues that growers were facing at the time of the first GMUS remain, such as access to tools to protect their crops and international trade in their commodities. The co-sponsors of the first GMUS are willing to facilitate another international forum to further the progress of minor use issues by sponsoring the Second Global Minor Use Summit (GMUS-2). This GMUS will further engage with FAO member countries (particularly developing country members) to ensure that their major issues of concern are reflected in the Summit programme. The aim of GMUS-2 will be to continue improving the availability of newer, safer and more effective crop protection tools for specialty crop growers in both industrialized and developing countries through data generation and data sharing, facilitating the trade of agricultural commodities internationally, and learning from existing specialty crop programme models.

Purpose of GMUS-2

The next GMUS will focus on global agreements for pesticide policy, procedure and methodology to help deal with minor use issues while providing growers with access to safe tools to grow their crops and to promote free and fair trade between nations. The purpose of the summit is to provide a forum for the international exchange of information on current activities that address minor use issues, and to identify future opportunities and challenges in the area of technical and cooperative areas and in policy considerations.

Summit objectives are addressed below.

Updates on the action items from the first summit.

- To raise awareness of recent advances in: international communication and information exchange, capacity building efforts, the work of the Codex Committee on Pesticide Residues electronic working group on minor uses and other international initiatives.

Technical and cooperative areas

- To enhance existing or develop new working groups to address issues of common interest, for example, how to cooperate on new pesticide registrations (international data generation) to maximize minor uses and enhance outcomes that facilitate trade in those commodities.
- To facilitate open discussions for international data sharing and research collaboration (data development) to conserve and maximize benefit from limited resources relating to minor uses and to limit duplication of efforts, while still providing robust data.
- To promote enhanced involvement of all stakeholders, especially specialty crop growers and commodity associations, in identifying needs and facilitating solutions to minor use problems.
- To strengthen working groups and capacity building networks to more efficiently address other items noted under technical issues.

Policy considerations

- Advance the topic of international harmonization through cooperation and transparency in establishment of MRLs and risk assessment by regulators. Establish criteria standards (in association with Codex CCPR) to recognize minor uses.
- Discuss policy aspects to enhance the registration of minor uses including areas such as:
 - development of dedicated minor use programmes (including models and funding to establish such programmes);
 - incentives from regulatory authorities to encourage registrants to register minor uses; and
 - management of product liability to facilitate minor use registrations, such as sharing of efficacy and crop safety data.

Structure of the summit

The Second Summit will have plenary sessions and group discussions.

- The initial plenary session will provide updates from various minor use and government agencies regarding progress on the key action items identified in the first Summit. This will be followed by an overview of technical and policy considerations.
- Breakout sessions for working groups will focus on the key areas of interest, that are still being determined by the organizing committee. Some topics for consideration include: data generation; data sharing and databases; and policy considerations such as regulatory incentives and harmonization.
- On the final day, in plenary, each group will provide summaries and recommendations from their sessions, and then the attendees will identify key action items to carry forward.

Participants

It is expected that over 200 participants from approximately 50 countries will attend the summit. The Organizers expect strong participation from all parties listed below, especially by developing countries.

- Governmental pesticide regulators.
- Agricultural producers and their representatives.
- Pesticide industry representatives.
- Consumer and environmental groups.

Sponsorship

FAO, the USDA Foreign Agricultural Service (FAS), the US Environmental Protection Agency (EPA) and the USDA/IR-4 Project (IR-4).

Abbreviations used in the texts

AAFC	Agriculture and Agri-Food Canada
ACP	African, Caribbean and Pacific States
ADI	Allowable Daily Intake
ALARA	As Low As Reasonably Achievable
APVMA	Australian Pesticides and Veterinary Medicines Authority
ARfD	acute reference dose
ASEAN	Association of South-East Asian Nations
AU	African Union
BCA	biocontrol agent
CAC	Codex Alimentarius Commission
CCPR	Codex [Alimentarius] Committee on Pesticide Residues
CILSS	Comité permanent Inter-Etats de Lutte contre la Sécheresse dans le Sahel
COLEACP	Europe-Africa-Caribbean-Pacific Liaison Committee
CPAC	Community of Central Africa Countries
DG SANCO	[EU] Directorate General Health and Consumers
EAC	East African Community
EAPIC	East Africa Phytosanitary Information Committee
ECOWAS	Economic Community of West African States
ECPA	European Crop Protection Association
EDF	European Development Fund
EGMU	[OECD] Expert Group on Minor Uses
EPA	US Environmental Protection Agency
EPPO	European and Mediterranean Plant Protection Organization
EWG	[EU] Expert Working Group
EWG	Electronic Working Group
FAO	Food and Agriculture Organization of the United Nations
FAS	[USDA] Foreign Agricultural Service
FNSEA	Fédération Nationale des Syndicats d'Exploitants Agricoles (National Federation of Farmer's Unions)
GAP	Good Agricultural Practice
GJR	Global Joint Review
GLP	Good Laboratory Practice
GMUS	Global Minor Use Summit
GRDC	Grains Research and Development Corporation
HAL	Horticulture Australia Limited
HR	high residue
ICGCC	International Crop Grouping Consulting Committee
IESTI	international estimate of short-term intake

IPDN	International Plant Diagnostic Network
IPM	integrated pest management
IPPC	International Plant Protection Convention
IR-4	Interregional Research Project No. 4
JMPR	Joint FAO/WHO Meetings on Pesticide Residues
LAN	local area network
LOQ	Limit of Quantitation
MAFF	Ministry of Agriculture, Forestry and Fisheries
MRL	Maximum Residue Limit
MUP	Minor Use Pesticide [programme]
MUPP	Minor Use Pesticides Programme
MUPPS	Minor Use Pesticides Programme System [database]
NAFTA	North American Free Trade Area
NCSU	North Carolina State University
NPPO	National Plant Protection Organization
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PIMS	Pest Information Management System
PIP	Pesticide Initiative Programme
PMC	Pest Management Centre
PMRA	Pest Management Regulatory Agency
PPECB	Perishable Products Export Control Board [South Africa]
PPP	Plant protection product
PRA	Pest Risk Assessment
PSMS	Pesticide Stock Management System
QA/QC	Quality Assurance and Quality Control
QuEChERS	Quick–Easy–Cheap–Effective–Rugged–Safe
R&D	Research and development
REA	Rapid Environmental Assessment
RSG	Registration Steering Group
SAES	State Agriculture Experiment Station
SARP	Strategic Agrichemical Review Process
SOP	Standard Operating Procedure
SPRT	Supervised Pesticide Residue Trial
STMR	Supervised trial median residue
US EPA	United States Environmental Protection Agency
USDA	United States Department of Agriculture
WHO	World Health Organization

GLOBAL MINOR USE SUMMIT II (GMUS-2)

Organizing and Advisory Committees

GLOBAL MINOR USE SUMMIT II (GMUS-2) – 1. ORGANIZING COMMITTEE

COUNTRY	NAME	AFFILIATION
Australia	Alan Norton	Australian Pesticide and Veterinary Medicines Authority (APVMA) and Chair, OECD Expert group on Minor Uses
Brazil	Luis Rangel	Pesticide Coordinator, Ministry of Agriculture
Canada	Manjeet Sethi	Executive Director, Pest Management Centre (PMC), AAFC
China	Mr Shan Wei Li	Director of Residues Division, ICAMA
FAO	Mark Davis Renata Clarke YongZhen Yang	Senior Officer, Plant Production and Protection Division Senior Officer, Nutrition and Consumer Protection Division JMPR Secretary, Plant Production and Protection division
Kenya	Lucy Namu	Kenya Plant Health Inspectorate Service
Netherlands	Wim Van Eck	Food and Consumer Product Safety Authority
Thailand	Pisan Pongsapitch	Director of the Office of Commodity and System Standards
USA	Dan Kunkel (Chair) Jerry Baron Lois Rossi Jason Sandahl Sherrilynn Novack	Associate Director, IR-4 Executive Director, IR-4 Registration Division Director, US EPA Senior Program Manager, USDA-FAS Communications Manager, IR-4

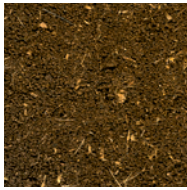
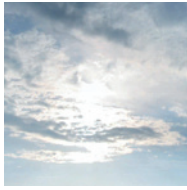
GLOBAL MINOR USE SUMMIT II (GMUS-2) – 2. ADVISORY COMMITTEE

COUNTRY OR ASSOCIATION	NAME
Australia	Peter Dal Santo – Horticulture Australia Kevin Bodnaruk – Grains Research and Development Corporation Janine Clark – Growcom and Ausveg, Pest Management Industry
Canada	Anne Fowlie – Canadian Horticultural Council Peter Isaacson – Canadian Nursery Landscape Association Cary Gates – Flowers Canada Shirley Archambault – Pest Management Centre, Agriculture and Agri-Food Canada Pat Curry – Pest Management Regulatory Agency
China	Qiao Xiongwu – Shanxi Academy of Agricultural Sciences Wenjun Zhang – Institute for the Control of Agrochemicals, Ministry of Agriculture Zhi XU – Chinese Academy of Tropical Agricultural Sciences
Colombia	Maria Christine Torres – Instituto Colombiano Agropecuario Adriana Velez – Política de Tierras y Desarrollo Rural, Programa de Políticas Públicas
Costa Rica	Roger Ruiz Zapata – Ministerio de Agricultura y Ganadería
Ghana	John Pwamang – Environmental Protection Agency, Ghana
New Zealand	Nikki Johnson – Market Access Solutionz Ltd Warren Hughes – Approvals and ACVM Group, Ministry of Agriculture and Forestry
EU	Luc Peeters – COPA-COGEA WP Euros Jones – European Crop Protection Association Ringolds Arnis – European and Mediterranean Plant Protection Organization Vivian Powell – HDC Crop Protection, UK Jean-Claude Malet – Ministère de l'Alimentation de l'Agriculture et de la Pêche, DGAL-SDQPV, France Wolfgang Zornbach – Federal Ministry of Food, Agriculture and Consumer Protection, Germany
Indonesia	Sri Noegrohati – Gadjah Mada University Yogyakarta Sri D. Kusumawardhani – Agriculture Industries & Natural Resources, ASEAN
Mali	Amadou Diarra – Institut du Sahel
Mexico	Alma Liliana Tovar Díaz – General Direction of Agri-food, Aquaculture and Fisheries Safety
South Africa	Thilivhali Nephumbada – Department of Agriculture, Forestry and Fisheries
South Korea	Moo Hyeog Im – Korea Food and Drug Administration Mi-Gyung Lee – Andong National University
Tanzania	Bakari Kaoneka – Tropical Pesticides Research Institute
Thailand	Nuansri Tayaputch – Center for Food and Agriculture, Thailand
Uganda	Geoffrey Onen – Directorate of Government Analytical Laboratories

(...) →

→ (...)

COUNTRY OR ASSOCIATION	NAME
USA	Dan Botts – Florida Fruit & Vegetable Association Jim Cranny – California Citrus Quality Council Mark Rasmussen – USDA-FAS
ASEAN	Suriyan Vichitlekan – Agriculture Industries and Natural Resources of the ASEC
Crop Protection Industry	Sheridawn Schoeman – DowAgroSciences, UK Pierre Petelle – CropLife Canada Vassilia Sgouri – Bayer CropSciences Angel Saavedra – DowAgroSciences, Mexico Vasant L. Patil – CropLife ASEAN Philip Brindle – BASF, USA Ray McAllister – CropLife America
OECD	Sylvie Poret Beatrice Grenier
COLEACP-PIP	Christine Moreira



**BACKGROUND PAPER ON THE JMPR ESTIMATION
OF MRLS FOR MINOR CROPS**

Yong Zhen Yang

**CONSIDERATION OF MINOR CROPS IN THE
CODEX COMMITTEE ON PESTICIDE RESIDUES**

Gracia Brisco

**PRINCIPLES AND GUIDANCE ON THE SELECTION OF
REPRESENTATIVE COMMODITIES FOR
THE EXTRAPOLATION OF MRLS TO COMMODITY GROUPS**

Bill Barney and Dan Kunkel

Background paper on the JMPR estimation of MRLs for minor crops

Yong Zhen Yang

Introduction

According to the FAO Manual “Submission and evaluation of pesticide residues data for the estimation of maximum residue levels (MRLs) in food and feed”¹, the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) estimates MRLs for minor crops following special principles, in addition to its general procedures.

Data generation and number of trials requested (Section 3.5, FAO Manual)

MRLs are largely derived from residue data obtained from supervised trials designed to determine the nature and level of residues resulting from the registered or approved use of the pesticide. Supervised field trials (crop field trials) are conducted to determine pesticide residue levels in or on raw agricultural commodities, including feed items, and should be designed to reflect pesticide use patterns that lead to the highest possible residues.

The term ‘supervised trials’ covers the application of a pesticide approximating targeted or authorized use, including studies for residues in crops grown in fields, e.g. outdoor, in greenhouses (glass or plastic covering) and in crops treated after harvest, e.g. stored grains, wax or dip treatment of fruits, and involves careful management of the trial procedure and reliable experimental design and sampling. Residue trials performed along the lines described in the OECD Test Guideline^{2,3} are considered by the JMPR as supervised trials. New supervised trials should be planned, implemented, documented and reported according to the OECD (or comparable) GLP principles (OECD, 1995–2002) or in compliance with national regulations that ensure the quality of residue data.

-
- 1 FAO. 2009. Submission and evaluation of pesticide residues data for the estimation of maximum residue levels (MRLs) in food and feed. 2nd edition. [FAO] *Plant Production and Protection Series*, No. 197. Available at http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/FAO_manual2nded_Oct07.pdf
 - 2 OECD Draft Test Guideline: Crop Field Trial.
 - 3 Draft Revised Guidance Document on Overview of Residue Chemistry Studies (Series on Testing and Assessment, No. 64).

The JMPR performs the evaluation of the submitted information and estimates MRLs if the database is considered sufficient, regardless of whether it represents worldwide use or is limited to a region. The number of trials (generally a minimum of 6 to 10) and samples is dependent on the variability of use conditions, the consequent scatter of the residue data, and the importance of the commodity in terms of production, trade and dietary consumption. Residue data should be available from trials, preferably carried out in at least two separate years or at least representative of different weather conditions in accordance, or approximately in accordance, with Good Agricultural Practice. If uses are authorized in regions with substantially different climatic conditions, trials should also be carried out in each region. Residue data from only one season may be considered sufficient provided that crop field trials are located in a wide range of crop production areas such that a variety of climatic conditions and crop production systems are taken into account.

The general principles that should be considered in planning, conducting and reporting supervised trials are briefly described in the FAO Manual (Section 3.5.1).

Regarding number of trials, currently there is no international agreement on the minimum number of trials to be provided for the estimation of supervised trial median residues (STMRs), high residue (HRs) and MRLs. Different countries have determined the minimum number of crop field trials required for registration of a use on a crop and for establishment of a suitable MRL. Geographical distribution of field trials within a country or region serves to ensure that data will be available for trials in key crop production areas, and a sufficient variety of horticultural practices may be represented in a crop field trial data set.

The JMPR has not specified the minimum number of trials required for estimation of MRLs, HRs and STMRs. The evaluation of the experience gained with the application of statistical methods for supporting the estimation of MRLs (see FAO Manual Section 6.10) indicated, however, that a minimum of 15 valid residue data would be required to obtain a realistic estimate for MRL using the statistical method.

The OECD Working Group on Pesticides elaborated guidance on the minimum number of trials⁴ which should be generated for registration of a pesticide in all OECD countries where the target Good Agricultural Practice (GAP) is uniform, i.e. maximum of 25% deviation in one of the key parameters. The number of supervised trials required in various OECD countries and the number of trials recommended for a comprehensive submission, is as follows:

TRIAL RECOMMENDATION	COUNTRY OR REGION					
	USA AND CANADA	EU	JAPAN	AUSTRALIA	NEW ZEALAND	TOTAL
Number required by legislation	24	16	2	8	4	54
Number with 40% reduction	14	10	2	5	2	33

4 Draft Revised Guidance Document on Overview of Residue Chemistry Studies (Series on Testing And Assessment, No. 64).

JMPR does not require a specified number of trials, so adherence to the OECD guidance may be a safe way to decide on the minimum number of outdoor field trials to be submitted for evaluation.

Estimating group MRLs to cover minor crops (Section 6.7, FAO Manual)

The establishment of commodity group MRLs has been considered as acceptable procedure at both the national and international levels. In principle, the approach recognizes that adequate data for the major crops of a group may be sufficient to estimate MRLs for the whole group, which may include minor crops.

Some pesticides may behave differently in different circumstances. Consequently, it is not possible to define precisely those commodities on which trials will always provide data that can lead to a group MRL. If the “highest residue” situation can be identified, however, the relevant data can be extrapolated to other crops with confidence, although it is recognized that this approach may result in an overestimate of residues in some commodities.

Extrapolation requires a detailed knowledge of local agricultural practices and growth patterns. In view of the large differences in commodity surface texture, shape, plant growth habits, rate of growth and seasonal cultivation, and the significant role played by the surface-to-weight ratio, the JMPR has emphasized that decisions to extrapolate should be made on a case-by-case basis when adequate relevant information is available.

As many factors can influence a decision to propose a group MRL the JMPR approaches the issue of setting group or individual MRLs on a case-by-case basis. The potential complexity of the process is highlighted by the current lack of international consensus on suitable criteria. These considerations have prevented the JMPR from developing specific guidance for group MRL estimation that might be applied at the international level.

Although no specific guidance is available, the following general principles and observations reflect the current views of the JMPR on estimating group MRLs.

- The use pattern (rate, application method, timing, pre-harvest interval (PHI)) should be the same and applicable for the whole crop group. Crops within a crop group should have similar physical nature, growth pattern and production characteristics, similar cultural practices and similar pests that require the same pesticide treatment.
- The nature of residues: systemic or non-systemic; degradation and disappearance rate.
- Relevant and adequate residue data should be available for at least one major commodity of the group. However, all relevant data for the commodities of the group should be taken into account, including residue levels measured across several crop or commodity types.
- The JMPR continues to rely on the Codex Classification of Foods and Feeds as the primary basis for recommending MRLs for individual or grouped commodities.
- Generally, the JMPR now refrains from estimating MRLs for large Codex ‘classes’ of foods or feeds, such as fruits, vegetables, grasses, nuts and seeds, herbs and spices, or mammalian products.

- In some cases the JMPR may, in the absence of sufficient data for one commodity, use data from a similar crop for which GAPs are similar to support estimates of MRLs, e.g. pears and apples; or broccoli and cauliflower.
- After dietary intake assessment, commodity group MRLs may be proposed on the following minimum conditions:
 - The pesticide is registered or authorized for use on the crop group.
 - Relevant and adequate residue data are available for at least one major commodity of the group. However, all relevant data for the commodities of the group should be taken into account. If the recommended group MRL is subsequently found to be inadequate for some commodities and their registered uses, there would be no impediment to submission of further data to amend the group MRL or to propose specific commodity MRLs.
 - In line with the alternative GAP proposal, if the international estimate of short-term intake (IESTI) calculations suggested that short-term intake would exceed the acute reference dose (ARfD) of the compound for one or more commodities in the group, the JMPR would examine and recommend alternative proposals, including alternative GAP and single commodity MRLs.
- If other considerations permit, data on residues in one or more of the major commodities with the potential for high residues within a group may allow estimates of MRLs to be extrapolated to minor crops in the group.
- When residue levels in a number of commodities in a group vary widely, separate recommendations should be made for each commodity. A limit for a group 'except one or more commodities' which are known to deviate from the norm may be justified, e.g. citrus fruits, except mandarins; in such cases separate MRLs should be estimated for the exceptional commodities.
- Residue data for a crop growing quickly in summer cannot be extrapolated to the same or related crops growing slowly under less favourable conditions, e.g. from summer to winter squash.
- In establishing group MRLs, detailed knowledge of the metabolism or mechanism of disappearance of a pesticide in one or more crops must be taken into account.
- Group MRLs recommended by the JMPR that generally appear to be acceptable include those listed in Table 6.1 in the FAO Manual.
- All else being equal, data may sometimes be extrapolated from a crop picked when immature but which grows quickly to maturity, to a closely related species with a lower surface area:weight ratio. Thus, because of dilution by crop growth, estimated MRLs can be extrapolated from gherkins to cucumbers, but not vice versa.
- Individual MRLs can be extrapolated more readily to groups when there is no expectation that terminal residues will occur and when this is supported by studies of metabolism. Examples are early treatments, seed treatments and herbicide treatments in orchard crops.

While the JMPR generally follows these principles on a case-by-case basis, it recognizes certain difficulties or limitations in the acceptance of group limits at the international level. A primary weakness is the lack of formal criteria or an agreed mechanism to determine the members of a group for which data are needed before a group MRL can be established. One approach, as occasionally used at the national

level, is to identify commodities of a group (often botanical) that represent both major crops within the group and those most likely to contain the highest residues. The factors used to determine whether a crop is a major or representative member of the group include its dietary significance as a food or feed.

The premise of this approach is that if data are available for representative crops, and if GAP and cultural practices among the individual members are similar, the residue levels should not vary widely, then an MRL can be estimated that will suffice for those members of the group for which no data are available. This approach is necessitated by the economics of data generation, and evaluation requires the use of common sense and expert judgment.

While the JMPR acknowledges advantages in this approach, there is unfortunately no consensus at the international level on the selection of representative commodities for estimating MRLs for groups. Similarly, while the JMPR bases its recommendations on the Codex Classification of Foods and Feeds, this classification has not been uniformly adopted at the national level.

Until agreement is reached at the international level, the JMPR will continue to make judgements on a case-by-case basis, using the general policy summarized above or as it may be subsequently amended.

Extrapolation of residue data to minor crops (Section 6.8, FAO Manual)

Building on Section 6.7 in the FAO Manual, that outlines the process involved in the estimation of group MRLs, examples are provided and limitations discussed. Data considered adequate for the estimation of an MRL of a major crop, of a group, are considered generally sufficient to estimate MRLs for the whole group, including the minor crops of that group.

However, decisions to extrapolate from one or more major crops to minor crops are taken by JMPR on a case-by-case basis when adequate information is available. Adequate information includes information on GAP for the relevant crops, a reference to the residue data used to support the original MRL, and an explanation of the logic for the extrapolation.

The data submitted to support extrapolation to a minor crop must include the following information:

- background information on the reasons for describing the crop as minor, the importance of the use of the pesticide in terms of pests controlled, the extent of its use on the minor crop, and the nature of the problems or potential problems for international trade;
- a description of the cultural practices for the production of the major crop and the approved or registered uses of the pesticide on the major crop from which extrapolation is proposed;
- a description of the cultural practices for the production of the minor crop, the approved or registered uses of the pesticide on the minor crop, and the reasons for expecting similar residue levels on the minor crop to those of the major crop; and
- supervised residue trials on the major crop supporting the MRL or reference to the JMPR Evaluations, if trials data have previously been reviewed by the JMPR.

The data submission should also include the following supporting information where available:

- data on supervised trials with approved or registered uses on the minor crop;
- a copy of the label describing the registered or approved uses and an English translation of the instructions for use; and
- monitoring data from selective surveys on the minor crop produced under typical commercial conditions where the pesticide is known to have been used.

JMPR special considerations for spices

As a special case, the Codex Committee on Pesticide Residues (CCPR) agreed for dried chilli peppers, a very minor crop, that a generic factor can be used for conversion of residues from fresh peppers to dried chilli peppers.

Estimation of MRL, HR and STMR values in spices

The 2004 CCPR accepted the definition of spices irrespective of whether they were classified as spices in the Codex Classification, and agreed to the setting of MRLs for spices on the basis of monitoring data⁵. It was further clarified that chilli peppers, herbs⁶ and tea are excluded from the definition of spices, and GAP and corresponding supervised trial data should be used for estimation of MRLs for these commodities.

5 Consideration of the elaboration of MRLs for spices. Paras 235–247, *in*: Report of the Thirty-Sixth Session of the Codex Committee on Pesticide Residues. ALINORM 04/27/24. http://www.codexalimentarius.net/download/report/616/al04_24e.pdf

6 Proposed draft MRLs for spices. Paras 177–182, *in*: Report of the Thirty-Seventh Session of the Codex Committee on Pesticide Residues. ALINORM 05/28/24. http://www.codexalimentarius.net/download/report/641/al28_24e.pdf

Consideration of minor crops in the Codex Committee on Pesticide Residues

Gracia Brisco

Codex Alimentarius Commission

The Codex Alimentarius Commission (CAC) is an intergovernmental international body that implements the Joint FAO/WHO Food Standards Programme, which aims at developing international food quality and safety standards to protect consumers' health and to ensure fair practices in the food trade.

Codex Committee on Pesticide Residues

The Codex Committee on Pesticide Residues (CCPR) is a subsidiary body of the Commission responsible for the establishment of maximum residue limits (MRLs) for pesticide residues in food and feed moving in international trade, including the establishment of extraneous MRLs for environmental and industrial contaminants showing chemical or other similarity to pesticides in food. The Committee is also responsible for the preparation of priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and the consideration of methods of analysis and sampling for the determination of pesticide residues in food and feed.

CCPR and minor crops

Consideration of specific issues related to the establishment of MRLs for pesticides for minor uses and specialty crops was first considered by the Committee in 2008 as a follow-up to the Global Minor Use Summit held in Rome in December 2007. The Summit identified a lack of Codex MRLs for these crops as a core problem for international trade in these commodities. A recommendation was then made that the Committee on Pesticide Residues establish a working group on minor uses and specialty crops to address problems on MRL setting for these crops on a regular basis at a global level. Following this recommendation, the Committee established a working group to provide guidance to Codex and JMPR to facilitate the establishment of MRLs for minor uses and specialty crops.

In 2009, the Committee considered a number of recommendations from the working group. Those recommendations related to, amongst others, including new commodities in the Classification of Foods and Feeds; encouraging the development

of representative commodities for the extrapolation of MRLs for commodity groups; fostering collaboration to develop and promote submissions to JMPR for prioritizing minor uses and specialty crops; supporting the development and use of a global MRL calculator; and proposing suitable definitions for minor uses and specialty crops.

These recommendations, including the continuous identification of issues related to minor uses and specialty crops within the mandate of CCPR, and in particular the identification of priority minor uses and specialty crops for inclusion in the priority list for evaluation by JMPR, and mechanisms to facilitate their submission to JMPR in order to allow the setting of MRLs for these commodities, led to the re-establishment of the working group in 2009 and at subsequent sessions of the Committee (2010, 2011).

In 2010, the Committee endorsed several additional recommendations from the working group. These included recommendations to encourage Codex members and observers to continue to identify and nominate chemicals and uses on minor uses and specialty crops to CCPR; to submit data for JMPR evaluation, including the possibility for multiple countries working collaboratively to develop data to support the establishment of MRLs on minor uses and specialty crops; and the possibility that one lead country can present the bundling of such data to JMPR for evaluation, with the understanding that, if no labels are available, an official letter should cover all information on the registered good agricultural practices (GAPs). The bundling of data would be possible provided the data are for the same compound or commodity and match the critical GAP. In addition, it was agreed that the Committee should continue to progress the work on inclusion of new commodities in the Classification, and for the suitable implementation of the Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups in order to facilitate the establishment of MRLs for minor uses and specialty crops. The working group would meanwhile continue to identify priority minor uses and specialty crops for MRL setting, and to facilitate data submission to JMPR, including proposals for definitions of minor uses and specialty crops for use by CCPR and JMPR.

In 2011, the collaborative work between the CCPR Working Group on Minor Use and Specialty Crops and the Pesticide Initiative Programme (PIP) in the identification of priority minor uses and specialty crops for inclusion in the priority scheduling for evaluation by JMPR led to the consideration of MRLs for Bifenthrin in mango, okra and papaya, and Difenoconazole in papaya, which will be considered for finalization by the next session of the Committee, in 2012 .

With regard to a definition of minor uses and specialty crops, no agreement could be reached in the Committee. This was due to the fact that the Committee did not endorse the recommendation for guidance from JMPR on the number of residue field trials necessary to perform the evaluation, as there was not an agreed international definition nor any agreed data requirements for minor uses due to difficulties in reaching consensus on what could be considered a minor use and specialty crop in relation to the production and consumption of the same commodity in different countries and regions. It was considered that criteria, as opposed to a definition, for use by CCPR and JMPR to determine the minimum number of field trials necessary to support the establishment of MRLs for minor uses and specialty crops could be

more appropriate to assist member countries in the identification of minor uses and specialty crops, and the submission of data to JMPR. The development of criteria could later assist in the elaboration of a definition for minor uses and specialty crops. The next session of the Committee (2012) would focus its discussion on these criteria.

In this regard, it was noted that there should be clear differentiation between the terms “minor use”, “minor crops” and “specialty crops” vis-à-vis the establishment of the minimum number of field trials for JMPR evaluation. Furthermore, the term “minor use” in certain countries is related to the economic return on the use of a pesticide in relation to the registration costs, which in no case would reduce the number of trials required for the establishment of MRLs for the minor crop. In this framework, there could be major crops with minor use and vice-versa; therefore, a clear understanding on the use of the different terms was necessary for the purposes of MRL setting by CCPR.

CCPR and related work on minor crops has focused on Revision of the Classification for Foods and Feeds, and completion of the Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups.

Although work on minor crops as such was started in 2008 as a follow-up of the Global Minor Use Summit, the problems faced by Codex members, in particular developing countries, in exporting minor crops due to the lack of suitable Codex MRLs was a matter of discussion for many sessions of the CCPR, dating back to early 2000. This problem was in turned linked to the possibility of establishing group MRLs through the identification of representative commodities for extrapolation of MRLs, and the subsequent revision of the Classification of Foods and Feeds to provide the commodity grouping for many tropical and sub-tropical fruits and vegetables, and other crops that are not currently covered by the Classification, in order to prevent trade disruption in such commodities.

The Principles and Guidance establishes the criteria for the selection of representative commodities and provides examples of representative commodities for residue extrapolation to estimate residue levels on related commodities in the same commodity group or subgroup for which residue field trials have not been conducted. This document will therefore assist Codex members in ensuring that data requirements to conduct risk assessment by JMPR would not become unnecessarily burdensome, especially for minor crops. The document has been completed by the Committee and was put on hold waiting for the finalization of the revision of the Classification, particularly for the fruit commodity groups. It was expected that the next session of the Committee would finalize all the commodity groups in order to advance both the revised Classification (fruit commodity groups) and the Principles and Guidance, for final adoption by the Codex Alimentarius Commission in 2012.

It is also foreseen that work on the revision of the Classification will continue on the vegetable commodity groups by including “new crops” and “crop groups”, in close cooperation and coordination with the International Crop Grouping Consulting Committee (ICGCC). This joint revision is aimed at ensuring a harmonized crop classification system that would assist JMPR and CCPR in the establishment of MRLs for harmonized crop groups, hence facilitating trade in agricultural commodities. In order to ensure coordination of work between ICGCC and Codex, the Chairperson of

the ICGCC and the lead country of the CCPR Working Group on the Revision of the Classification of Foods and Feeds have worked closely together in developing joint proposals for a comprehensive revision of the Codex Classification.

While the revision of the Classification goes beyond the sole objective of considering minor crops, work on the Classification and the accompanying Principles and Guidance for the Selection of Representative Commodities for the Extrapolation of MRLs, together with Criteria for use by CCPR and JMPR to determine the minimum number of field trials necessary to support the establishment of MRLs for minor and specialty crops, in order to facilitate data submission to JMPR, will greatly facilitate the establishment of Codex MRLs for minor and specialty crops.

Principles and Guidance on the Selection of Representative Commodities for the Extrapolation of MRLs to Commodity Groups

Bill Barney and Dan Kunkel

IR-4 Headquarters

Introduction

Residue extrapolation is the process by which the residue levels on representative commodities are utilized to estimate residue levels on related commodities in the same commodity group or subgroup for which trials have not been conducted. Representative commodities are chosen based on their commercial importance and the similarity of their morphology and residue characteristics to other related commodities in the group or subgroup. Ideally representative commodities are the most economically important commodities in production and/or consumption in a group or subgroup and have a greater dietary burden and have residue characteristics similar to other members of the group or subgroup. Residue extrapolation is a common consideration utilised by regulators internationally for ensuring that data requirements are only at a level that is scientifically justified in conducting risk assessment and to ensure the regulatory process does not become unnecessarily burdensome especially for minor crops.

The objective of this document is to (1) propose criteria for the selection of representative commodities; (2) propose example representative commodities and (3) provide a detailed justification for the selection of the representative commodities.

General Principles

Representative commodities within each Codex Classification commodity group and subgroup will be selected and proposed, based on consideration of all available information. The following principles will be used for the selection of representative commodities:

- A representative commodity is most likely to contain the highest residues.
- A representative commodity is likely to be major in terms of production and/or consumption.
- A representative commodity is most likely similar in morphology, growth habit, pest problems and edible portion to the related commodities within a group or subgroup.

The application of the three principles in the selection of representative commodities is based on the assumption that all of the commodities, covered by the commodity group MRL, are produced following a similar*(refer to FAO manual) use pattern or GAP.

To facilitate the global use of the commodity groups for MRLs, alternative representative commodities may be selected giving flexibility for use of residue research conducted in different countries or regions that may vary due to regional differences in dietary consumption and/or areas of production for certain commodities.

Note: Table 1 in this document is provided to (1) separate the selection of representative commodities from the Codex Classification itself; (2) propose examples of representative commodities in parallel with the respective Codex commodity grouping classification revisions; (3) provide flexibility on the selection of representative crops and (4) provide guidance not only to CCPR and CCPR members, but also to JMPR, product manufacturers and other data generators.

Detailed background information regarding production, consumption, MRLs and characteristics and justification for selection of the representative commodities according to the indicated principles were provided in working documents considered by the Committee when developing the representative commodities for each commodity group.

Guidance and Procedures

As proposals for the revision of the Codex Classification are made and revised commodity groupings are developed and provided to the CCPR for their review, proposals on representative commodities will also be provided in parallel with the respective commodity grouping revisions and will advance through the CCPR step process for adoption by the CAC.

As comments are addressed on the revisions of the classification and the proposed representative commodities and these are approved by the CCPR and accepted by the CAC, two separate documents will be created and maintained: (1) the revised Codex Classification (without mention of representative commodities) and (2) principles and guidance on the selection of representative commodities.

The JMPR may be advised to use the representative commodities adopted by the CAC. However, JMPR may use other representative commodities (including those which may be specifically requested by member nations) on a case-by-case basis. The JMPR will be requested to provide to the CCPR justification for the use of any alternative representative commodities, based on all available data.

Alternative Representative Commodities

To facilitate the global use of the commodity groups for MRLs, alternative representative commodities may be selected giving flexibility for use of residue research conducted in different countries or regions that may vary due to regional differences in dietary consumption and/or areas of production for certain commodities. Table 1 in this document proposes examples of representative

commodities for commodity groups. Depending on country or regional differences, alternative representative commodities may be proposed by a country. For example, leeks may be proposed as an alternative representative commodity for green onions in the green onion subgroup of Bulb Vegetables.

Precedence in Selection of Representative Commodities

In situations where a representative commodity does not meet all three of the above principles, a representative commodity should at least meet the first two principles (likely to contain the highest residues and also major in terms of production and/or consumption).

Definition of Similar Residues

When representative commodities are utilized to extrapolate to other members of a commodity group, it is based on the assumption that the representative commodities will have similar residues. "Similar residues" are difficult to define numerically, because this would require knowing actual residues for all commodities in a group. Rather, the expectation of similar residues is based upon consideration of all of the information available. This information will be prepared for each commodity group and will form the basis of the proposals for representative commodities.

Use and Combination of Data Sets

When representative commodities are utilized to extrapolate MRLs to other members of the commodity group, then MRLs may be calculated as either the highest MRL calculated for any of the individual representative commodities (considering the ALARA principle) or the residue data may be combined and the MRL calculated from the larger combined data set.

Wider Extrapolations

A representative commodity should meet at least the first two principles described above, i.e. likely to contain the highest residues and also major in terms of production and/or consumption. However, it may not always fit well with the growth habits, or pest problems of morphology within one group or subgroup. In such situations, extrapolations beyond the members of a commodity group may be appropriate. These can be considered on a case-by-case basis when commodities (with similar GAPs) have similar size, shape and surface area. Examples of these possible wider extrapolations include (1) translation of certain stone or pome fruit MRLs to a tropical fruit; (2) where residues are all <LOQ for pre-emergent herbicide uses and (3) seed treatments for non systemic pesticides.

Table 1. SELECTION AND EXAMPLES OF REPRESENTATIVE COMMODITIES

CODEX GROUP / SUBGROUP	EXAMPLES OF REPRESENTATIVE COMMODITIES ^{1,2}	EXTRAPOLATION TO THE FOLLOWING COMMODITIES
GROUP 001 CITRUS FRUITS	Lemon or Lime and Mandarin and Orange; and Pummelo or Grapefruit	Citrus Fruit (FC 0001): Australina blood lime; Australian desert lime; Australian round lime; Bergamot; Bigarade; Blood orange; Brown River finger-lime; Calamondin; Chinotto; Chironja; Citron; Clementine; Cleopatra mandarin; Dancy mandarin; Grapefruit; Kaffir Lime; King mandarin; Lemon; Lime; Lime, Sweet; Malta orange; Mandarin; Mediterranean mandarin; Mexican Lime; Mount White-lime; Myrtle-leaf orange; Natsudaïdai; New guinea wild lime; Orange, Bitter; Orange Sour; Orange, Sweet; Pomelo; Pummelo; Russell River-lime; Satsuma mandarin; Seville Orange; Shaddock; Tachibana orange; Tahiti Lime; Tangelo (small and medium cultivars); Tangelo (large size cultivars); Tangelodo; Tangerine; Tangors; Tankan mandarin; Trifoliolate orange; Ugli/Uniq Fruit; Unshu orange; Willowleaf mandarin; Yuja
SUBGROUP 001A, LEMONS AND LIMES	Lemon or Lime	Lemons and Limes (FC 0002): Australina blood lime; Australian desert lime; Australian round lime; Brown River finger-lime; Citron; Kaffir Lime; Lemon; Lime; Lime, Sweet; Mexican Lime; Mount White-lime; New guinea wild lime; Russell River-lime; Tahiti Lime; Yuzu
SUBGROUP 001B, MANDARIN	Mandarin	Mandarins (FC 003): Calamondin; Clementine; Cleopatra mandarin; Dancy mandarin; King mandarin; Mandarin; Mediterranean mandarin; Satsuma mandarin; Tangelo (small and medium size cultivars); Tangerine; Tangors; Tankan mandarin; Unshu orange; Willowleaf mandarin
SUBGROUP 001C, ORANGES, SWEET, SOUR	Orange	Oranges, Sweet, Sour (FC 004): Bergamot; Bigarade; Blood orange; Chinotto; Chironja; Malta orange; Myrtle-leaf orange; Orange, Bitter; Orange Sour; Orange, Sweet; Seville Orange; Tachibana orange; Trifoliolate orange
SUBGROUP 001D, PUMMELOS	Pummelo or Grapefruit	Pummelos and Grapefruit (FC 005): Grapefruit; Natsudaïdai; Pomelo; Pummelo; Shaddock; Tangelo (large size cultivars); Tangelodo; Ugli/Uniq Fruit

1 Alternative representative commodities may be selected based on documented regional/country differences in dietary consumption and/or areas of production.

2 Detailed information considered at the 43rd session of the Codex Committee on Pesticide Residues

OECD GUIDANCE DOCUMENT ON DEFINING MINOR USES OF PESTICIDES

Alan Norden

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

OECD Series on Pesticides No. 63 – ENV/JM/ON0(2011)16

Dan Kunkel and Alan Norden

OECD MAXIMUM RESIDUE LIMIT CALCULATOR

Jane Stewart and Domingo Salazar

GUIDANCE DOCUMENT ON CROP FIELD TRIALS

Summary discussion of OECD Series on
Pesticides No. 66 – ENV/JM/MON0(2011)50

Karsten Hohgardt

OECD guidance document on defining minor uses of pesticides

Alan Norden¹

The OECD Guidance Document on Defining Minor Uses of Pesticides² published by the OECD in 2009 states:

“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.”

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

Therefore, this document provides guidance on defining minor uses of pesticides at local or regional levels with the aim of enhancing the consistency between countries in the methods used in defining minor uses. It is limited to guidance for defining minor uses of pesticides only, and does not provide an OECD definition.

In particular, the document outlines and discusses the two prominent yet alternative approaches used amongst OECD member countries in defining minor uses and refers to these as:

1. the ‘risk assessment’ approach, and
2. the ‘economic return’ approach

The risk assessment approach is described as being 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 or dietary intake, or both. The criterion is also often utilized 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 with major crops in areas such as residues and associated dietary risk assessment. Whilst the economic

¹ Alan Norden (Australia; EGMU Chair) was the primary author of the draft OECD Guidance document, which was then reviewed and approved by all OECD countries before publication.

² OECD. 2009. OECD guidance document on defining minor uses of pesticides. Doc. no. ENV/JM/MONO(2009)39. *OECD Environment, Health and Safety Publications Series on Pesticides*, No. 49. Available at [http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO\(2009\)39&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO(2009)39&doclanguage=en)

return approach is described as considerations associated with uses that would not produce sufficient economic return to an applicant for registration of those uses.

The document discusses and provides some reasons and a hypothetical example as to how the two different approaches may result in different classifications of a use being a minor or major use. Where whilst a use may require significant regulatory risk assessment due to dietary consumption or production levels it may also be considered to be of too low economic return to justify the necessary investment by a registrant.

The guidance therefore notes that there can be a 'see-saw' effect in determining what might be a minor use 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.

The guidance notes that the risk assessment approach largely defines 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 provides the ability to consider and manage minor use needs that can arise in major crops that might otherwise be denied recognition if determinations were solely based upon the risk assessment approach. Such minor uses in major crops typically involve minor pests or diseases that may be sporadic and only occur in one season every few years, 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.

The guidance also acknowledges that a crop (or use) in one country or region classified as minor may not necessarily be minor in another region or country, and that these differences can exist due to considerations of use at the local level. This may include differences in the volume or area of production of a crop between countries and the types of pests and diseases, their abundance and impact, which may differ due to geography or climate.

The guidance concludes with four critical elements that should be considered in developing, using and maintaining a definition. The four critical elements are:

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 for 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.

Guidance document on regulatory incentives for the registration of pesticide minor uses

OECD Series on Pesticides No. 63 –ENV/JM/MONO(2011)16¹

Dan Kunkel and Alan Norden²

Background

The *Guidance Document on Regulatory Incentives for the Registration of Pesticide Minor Uses* published by OECD in June 2011 states:

“Countries have noted that the implementation of regulatory incentives have been in direct recognition for a strong need to have mechanisms that enhance, facilitate and encourage the registration of minor uses. Specifically, incentives have been developed to encourage applicants to add more minor use registrations (including off-label approvals), to speed the process of adding minor uses to product labels and in doing so ensuring that regulatory requirements for minor uses are comparative to the level of risk. Incentives have helped to fill gaps and increase the range of products available for plant protection on minor use crops and can also serve to enhance sharing the responsibility of addressing the needs of specialty crop growers.”

The document was developed as guidance for national regulatory authorities in areas where greater incentives could be provided to encourage applicants (manufacturers or registrants) to register agricultural pesticides (including both synthetically and naturally derived products) for minor uses. The guidance was based upon the results of a survey conducted in 2009 by the OECD Expert Group on Minor Uses (EGMU) [See publication ENV/JM/MONO(2011)14³].

¹ [http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO\(2011\)16&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO(2011)16&doclanguage=en)

² The authors of this summary paper are Dan Kunkel (US IR-4, and member of the OECD Expert Group on Minor Uses – EGMU) and Alan Norden (Australia, and EGMU Chair). Both were the primary authors of the draft OECD Guidance that was then reviewed and approved by all OECD countries before publication.

³ [http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO\(2011\)14&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO(2011)14&doclanguage=en)

The guidance document discusses a range of different areas where incentives for the registration of minor uses could be examined. Specifically the guidance discusses the various aspects of existing incentives that are typically utilized, including:

- Economic incentives (or increased “value”) for registrants.
- Technical arrangements based on sound science.
- Authorization process arrangements.
- Research,
- Promotion of safer alternatives,
- Liability,

The following is provided as an overview of the OECD guidance document.

Economic incentives (or increased “value”) for registrants

Data protection

To provide recognition for, and encourage innovation in the registration of new products and their uses, many countries have implemented, through legislation, intellectual property protection for data submitted in support of registrations, typically in the order of between 8 and 11 years. To incentivize minor use registrations, additional periods of protection to those noted are commonly provided. The additional periods of protection provided are often of the order of between 3 and 5 years, or in other words, extending the period of protection up to between 11 and 14 years, with generally between 3 or 5 minor uses required for each additional year of data protection.

Expedited reviews

In most countries, regulatory assessments of minor uses are subject to the same assessment timeframes and procedures as other ‘major’ uses seeking registration. The guidance noted that many OECD member countries considered that more needs to be done to provide minor use solutions in a more timely manner, and suggests that nationally or regionally prioritized minor uses could benefit from ‘expedited review’ pathways. To this end it suggests that expedited reviews for minor uses may also make them more economically attractive to registrants and may have similar (economic) benefits to data protection.

Fee reductions or waivers

Whilst the costs of data generation generally far outweigh regulatory assessment fees, most countries report that they have implemented fee reductions or waivers for minor uses. These provisions are considered to lessen the overall costs and thus aid in facilitating registrations, and are also considered as government support for minor uses.

Technical arrangements based on sound science

Extrapolation and mutually accepted data

In conducting risk assessments, regulators utilize scientifically valid principles of data extrapolation (i.e. where available, data can be accepted as supportive for another similar, related situation). To enhance extrapolation, many countries have published tables of crop and pest groupings that outline in what commodities ('representative crops') data may be generated to attain registration of an entire crop group. The most notable of these are activities of the International Crop Grouping Consulting Committee (ICGCC), convened by the United States IR-4 Project, that develops crop groups that are considered by US EPA and are also being utilized in the current revisions of the Codex Committee on Pesticide Residues (CCPR) *Classification of Food and Animal Feeds*. Please see the other GMUS-2 summary document on Codex papers detailing crop groups and extrapolations.

Additionally, under European Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market, a 'risk envelope approach' is being developed. Here, if the Good Agricultural Practice (GAP) of a minor use fits into the GAP of the 'worst case scenario' assessment already undertaken, that assessment then covers all (minor) uses with an equal or less impact. The advantage of this approach is that a reduction can be achieved in reviewing and assessing new uses where the risk is less than that already accommodated.

Number of trials

The OECD's Residue Chemistry Expert Group (RCEG) has recently developed a Guidance Document on Crop Field Trials⁴ which is proposing up to as much as a 40% reduction in domestic trials where an application is submitted as a Global Joint Review (GJR). Additionally, it is proposed for studies conducted globally that as much as 50% of the total number of trials necessary in one country or region may be replaced by trials from another country or region, provided that these trials correspond to the critical GAP and the production conditions, i.e. there are comparable cultural practices.

Authorization process arrangements

Third-party registrations

Standard regulatory procedures require that an application for registration of a new product or new use be submitted solely by the product manufacturer or registrant. However, some countries operate schemes where persons (termed *third parties*) other than the registrant may submit a regulatory package to have minor uses considered for approval, either via a (1) registrant through a supported on-label approval; or (2) under an authorized off-label approval.

⁴ OECD Series on Pesticides No. 66 [ENV/JM/MONO(2011)50]. Available at [http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO\(2011\)50&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO(2011)50&doclanguage=en)

Temporary approvals

Some countries also allow temporary approvals (i.e. off-label and emergency uses) whilst further local data is generated. Temporary approvals may be granted based upon international data alone, with requirements for local data to be generated during the term of the initial approval. In some cases these approvals can be a preliminary step in progressing the use to registration, and in doing so provide users with temporary relief to priority needs whilst allowing minor data gaps to be addressed in the provision of local confirmatory data.

Research

Data generation assisted schemes and programmes

Several countries have developed dedicated minor use programmes that are specifically designed to work with grower groups and registrants in undertaking the necessary data generation and making of regulatory submissions. These programmes may function entirely based upon government funding or may contain a level of co-investment between government, growers and registrants.

Promotion of safer alternatives

Incentives for reduced-risk pesticides

Some countries specifically provide incentives for the registration of reduced-risk pesticides, including biopesticides. These may include fee reductions or expedited reviews. In the minor use survey conducted by OECD, it was proposed by some that such incentives should be examined in more detail for their benefits, and whether or not complementary incentives that involved reduced risk or biopesticides should be subject to even greater incentives.

Liability

Liability for registrants may be one of the leading decisions in not seeking registration of a use, particularly for minor uses. Many minor uses involve high-value specialty crops where the low volume of pesticide sales far outweigh the potential economic liability from a use should there be problems with lack of efficacy or crop safety. In cases where problems do arise, liability costs in compensation cases can far outweigh the likely returns, and for this reason alone some registrants may choose to not pursue registration. To alleviate this disincentive, some countries have outlined that uses such as third party authorizations and off-label uses are at the risk of the end user, whilst the registrant is still liable for other components of the product, such as its quality (formulation or composition) and its risks to human health and the environment. It is however unclear what 'standing' some of the provisions provide legally. It may therefore be prudent for governments to examine the legal implications and status of such provisions and, if required, implement these in law to either provide exclusion of this liability or to ensure that it is capped at an appropriate level commensurate to the return from that use.

Conclusions – key objectives

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

1. Countries should familiarize themselves with recommendations for defining minor uses as outlined in the OECD Guidance Document on Defining Minor Uses of Pesticides⁵ (see other summary paper on this OECD Guidance) and seek to develop regulatory incentives complementary to those definitions.
2. Regulatory risk assessments and data requirements should remain independent from minor use definitions, although incentives may be developed that reduce the regulatory burden in certain data requirements where it is scientifically acceptable to do so, through the use of extrapolation or mutually accepted data.
3. Incentives should be designed to facilitate the necessary research, development and registration of new uses and, in doing so, should encourage products and uses that address national or regional objectives, such as those associated with reducing the risks of pesticides and enhance the sustainable use of pesticides and the adoption of practices such as Integrated Pest Management (IPM).
4. Mechanism(s) should be designed specifically with the intention of increasing the 'value' a registrant may associate with the registration of a minor use, whilst reducing any unnecessary regulatory burden in that process. 'Value' may not necessarily be associated with likely economic return from registration of that minor use, but may be associated in other ways.
5. Whilst a number of commonly accepted approaches are utilized in several countries, such as data protection, fee waivers and data extrapolation, these alone may not provide sufficient incentive for the registration of minor uses. Countries should also consider developing new or complementary approaches, or a combination, to raise the 'value' a registrant might associate with the registration of minor uses. For example, many countries have or are considering the establishment of national programmes that work directly with affected producers to prioritize needs, generate data and make regulatory submissions. In addition to the establishment of these programmes, it is recognized that complementary regulatory incentives can enhance the registration of minor uses from the programmes or schemes. Where a registrant might still not associate economic value with a minor use to justify registration, countries should have in place regulatory mechanisms that allow for third party or temporary authorizations to be considered and where the liability from such uses are clearly outlined.

5 OECD Series on Pesticides No. 49 [ENV/JM/MONO(2009)39]. Available at [http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO\(2009\)39&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=ENV/JM/MONO(2009)39&doclanguage=en)

OECD Maximum Residue Limit Calculator

*Jane Stewart (BASF Corporation) and
Domingo Salazar (Syngenta Crop Protection)*

Introduction

Recently a new statistical procedure for setting maximum residue limits (MRLs) has been adopted by the OECD¹. This procedure is based on the lessons learned from previous statistical methodologies for MRL calculation used around the world, and insights achieved from rigorous testing and experiences with regulatory policy from Europe, the United States, Canada and other OECD countries. What follows is a description of the methodology itself, and a brief discussion about its development, including some of the alternatives that were considered, but not implemented.

The OECD MRL Calculator

To compute a MRL for a particular crop, a residue dataset is developed by measuring the pesticide levels in samples taken from field trials carried out according to the maximum use pattern proposed for the pesticide label. An MRL calculator target is a high percentile of the residue distribution, typically the 95th or 99th percentile. This means that most residues levels produced when following the labelled use pattern will be below the MRL, with a small probability for residue levels exceeding the MRL. The OECD MRL calculator is designed to produce an estimate above the 95th percentile for most residue datasets (see discussion in the next section). A minimum of three field trials is required for MRL estimations using the OECD approach. If more than one sample is taken from a field trial, the mean residue of those samples should be computed and used as the field trial representative value. At the same time, no procedure for discarding suspected “outliers” is included as part of the calculation. When residue measurements are below the limit of quantification (LOQ) for an analytical method the result is called a “censored value”. A dataset made exclusively of censored data is called “fully censored” and the OECD calculator sets the MRL of a fully censored dataset to the highest LOQ of all the analytical methods used.

1 OECD MRL calculator webpage. It has links to the user guide and statistical white paper, plus the single and multiple dataset spreadsheets: http://www.oecd.org/document/8/0,3746,en_2649_34383_47259976_1_1_1_1,00.html (accessed 26 January 2012).

For datasets where at least one measurement is above the LOQ of its corresponding analytical method (e.g. not a “fully censored” dataset), all censored values are set to the value of their respective LOQs and the MRL is set at the rounded maximum of three quantities:

- Mean + 4 × Standard Deviation (SD)
- Highest Residue (HR)
- 3 × Mean × CF (CF = correction factor for censoring – see below)

The “Mean + 4×SD” method was selected as the “root” calculation because it turns out to be a surprisingly robust estimator for a high percentile of typical residue distributions, even for small datasets or those with a high proportion of censored data (see below). The highest residue (HR) was introduced into the computation to address regulatory authority requirements that MRL estimates be at least as high as the HR, even for large datasets that contain high residue values that may already be above the 95th or even 99th percentiles. The same requirement also motivated the MRL setting approach for fully censored datasets. Finally, the “3×Mean” value is computed to provide a “floor” to the calculation; in this case to guarantee that the sample coefficient of variance (CV = standard deviation/mean) used in the calculation is at least 0.5, a condition observed in most large residue datasets. This method is useful for small datasets where the standard deviation of the underlying residue population is often underestimated. Unfortunately, the “3×Mean” method is not as robust as the “Mean + 4×SD” method when dealing with highly censored datasets, and a correction factor (CF) was added because the mean is overestimated for highly censored datasets. CF is equal to $1 - 2/3 \times (\text{fraction censored data})$.

So the proposed MRL for not fully censored datasets is the rounded maximum of: HR, “Mean + 4 × SD” and “3 × Mean × CF”.

Two spreadsheets are available from the OECD to carry out the calculations (see footnote 1). One of them can be used to estimate MRLs for single datasets, while the other was designed to allow the estimation of MRLs for multiple datasets in the same spreadsheet, facilitating comparison of results. The spreadsheets show both the non-rounded and rounded MRL estimates. MRL proposals are normally rounded up following a set of MRL classes recently adopted in the EU (see SANCO 10634/2010). When an unrounded MRL estimate is only slightly above an MRL class, the spreadsheet rounds it down to that MRL class.

Discussion

The calculator was born of the desire to harmonize MRL calculations across the OECD. In 2008, the Residue Chemistry Expert Group (RCEG), part of the OECD Working Group on Pesticides, commissioned an expert group to develop the new MRL calculation procedure. The guiding principles of this procedure were:

- The procedure must be a practical implementation of sound statistical methods.
- It must be simple to use without requiring extensive statistical knowledge from a user.
- It should produce a clear and unambiguous MRL proposal for most residue datasets produced by field trials.
- It should harmonize the EU and NAFTA procedures as much as possible.

Over the course of the project the expert group working on the calculator grew until it included regulators, industry experts and academics from around the world, and with expertise in statistics, applied mathematics, analytical chemistry, residue studies and risk assessment.

After two years of work and a considerable amount of testing of various approaches, the group produced a simple yet robust statistical methodology to compute MRLs. Previous methodologies assumed that residues measurements belong to a normal or Gaussian distribution (EU Pesticide Regulations, Appendix I) or to the log-normal distribution (US EPA & PMRA 2005). The normal distribution is symmetric around its mean value, but the log-normal distribution is right-skewed, i.e. it has a tendency to include residue values much higher than the mean (this behaviour is observed in many residue datasets). The calculator working group started by testing both the above procedures in addition to one derived from the Weibull distribution, which is less right-skewed than the log-normal distribution. So it came as a surprise to the group to find that a non-distributional approach like the “Mean + 4×SD” method outperformed the distributional approaches described above, for both small and large datasets, even for synthetic data simulated from the corresponding distributions (see white paper).

For a large enough sample extracted from any distribution with finite mean and variance, the “Mean + 4×SD” method provides an estimate above the 93rd percentile. This conclusion is based on a theoretical result called “the Chebyshov’s inequality” (see Grimmett and Stirzaker, 2001). For the log-normal distribution in particular, the estimate will be above the 99th percentile. The “Mean + 4×SD” method also has been found to be robust to the presence of a large proportion of censored values in a dataset. In those cases, the mean tends to be overestimated and the SD tends to be underestimated, and the method benefits from this compensation. This makes it unnecessary to “impute” censored data (to substitute them with values produced by a distributional assumption) as has been done in the past.

Finally, the “Mean + 4×SD” method also behaves robustly for small datasets (nine to sixteen residue measurements; see white paper for details). Inevitably, though, both underestimations and overestimations of high percentiles do happen for some of the very small datasets tested (three to eight residue measurements). Given the desire to produce an MRL above the 95th percentile of the residue distribution, even for these very small datasets, the “3×Mean×CF” method was introduced.

In addition to the distributional approaches and the “Mean + 4×SD” method, other alternatives were considered but discarded by the working group. This included other non-distributional methods used in the past (EU Method II; UPL Median 95) as well as more sophisticated statistical approaches like kernel methods. Variants like the “Mean + k×SD” method with the parameter k depending on dataset size were explored, but it did not prove more precise than the “Mean + 4×SD”. The white paper describes in much more detail the extensive testing that took place, both using synthetic and real data. It also provides the rationale behind the decision to average field replicates and answers some questions raised by the RCEG review of the procedure.

Conclusions

The OECD calculator is a simple yet robust tool to estimate MRLs and was developed through joint collaborations between regulators, industry experts and academics. It emerged from lessons learned during the development and use of previous EU and NAFTA methodologies. Broad adoption of the calculator has the potential to harmonize international pesticide MRLs, which is an important step to meet local regulations and support global trade.

Guidance document on crop field trials

Summary discussion of OECD Series on Pesticides, No. 66 – ENV/JM/MONO(2011)50¹

Karsten Hohgardt

Introduction

The Guidance Document on Crop Field Trials published by the OECD in September 2011 states:

“Crop Field Trials (also referred to as supervised field trials) are conducted to determine the magnitude of the pesticide residue in or on raw agricultural commodities, including feed items, and should be designed to reflect pesticide use patterns that lead to the highest possible residues. While the OECD Guideline for the Testing of Chemicals on Crop Field Trial (TG 509 published in September 2009) provides a harmonized approach to conducting and reporting crop field trials in OECD countries, this Guidance Document on Crop Field Trials will help in planning the trials in OECD countries and in interpreting the results.”

The document was developed by the Residue Chemistry Expert Group of the OECD Working Group on Pesticides, with the aim to help planning residue trials in OECD countries and to interpret the results. To accommodate these aims it focuses on:

- Crop grouping
- Extrapolation
- Proportionality
- Conversion factors
- Formulations (Equivalency of formulations)
- Geographical distribution of residue trials
- Number of trials
- Results from residue trials to be used in MRL estimations
- MRL estimations

As far as possible national/regional approaches and the Codex approach are included.

¹ The full document is available at <http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono%282011%2950&doclang=en>

Crop grouping

Crop grouping is similar in different national and regional approaches. It is used for exposure assessment and MRL setting, both for individual crops and crop groups. While for crop grouping it is botanical aspects, morphological aspects and similarity of residues that play a major role, the basis for representative crops within a crop group or subgroup is more based on consumption and production on the one hand and expectation of highest residues on the other hand. Existing crop groups as well as criteria for crop groups in national governments are set out in two appendices.

Differences in crop grouping may hamper the use of one data set for establishing group tolerances in different regions, and it may lead to trade disruptions due to a misinterpretation by members belonging to a certain crop group in a specific region of the world.

OECD proposed use of the new Codex approach. In an appendix, the new proposed Codex Crop Groups, representative crops and extrapolations are described as far as available.

Extrapolation

To reduce the number of trials necessary to set MRLs, countries extrapolate results from residue trials on one commodity to one or several other commodities. The background for this approach is a crop grouping system, and the definition of representative commodities within the different crop groups. The underlying assumption for extrapolation is the same GAP (to read as being similar within 25 percent variation) for all crops of a crop group or subgroup.

Due to different approaches within regions, results from representative crops are not always used to set group tolerances when no (critical) GAP for all members of a crop group or a subgroup is available. A second difference occurs when results from more than one representative crop of a crop group or subgroup give different MRL estimates. Both cases relate to the same crucial point, namely the interpretation of the ALARA principle (= As Low As Reasonably Achievable).

For the comparison of data sets, it is proposed to use the Mann-Whitney U-test, as discussed in JMPR and described in the FAO Manual².

Existing extrapolations are set out in an appendix.

Also wider extrapolations — beyond crop groups or subgroups — are discussed and may be considered.

Proportionality

The new concept of proportionality is discussed. Before the concept can find wider acceptance, further investigations are necessary.

2 FAO, 2009. Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed ('FAO Manual', 2nd Edition). *FAO Plant Production and Protection Paper*, No. 197. Available at <http://www.fao.org/docrep/012/i1216e/i1216e.pdf>

Conversion factors

Especially for exposure assessment, conversion factors are sometimes needed. The following factors are mentioned in the document, as they can be derived from the available data set:

- conversion from the residue definition for enforcement to the residue definition for risk assessment;
- conversion factor from residue in the raw agricultural commodity to the edible part of the commodity; and
- processing factors.

Only the first and the second factor are discussed in this document, while the third one is discussed in Guidance Document on Magnitude of Pesticide Residues in Processed Commodities, OECD Series on Testing and Assessment No. 96 (ENV/JM/MONO(2008)23)³.

Formulations (equivalency of formulations)

The type of formulation may have an influence on the magnitude of residues. Therefore one chapter covers equivalence of formulations. It covers formulations diluted in water (including water-soluble bags), formulations applied intact, formulations used for seed treatments, controlled-release formulations, and formulations containing active substances as nanomaterials. The chapter describes where results from one formulation can be used for the assessment of another formulation.

Formulations diluted in water are considered equivalent when used early in the vegetation period. For late season foliar treatments (PHI less than 7 days) at least a differentiation between formulations containing organic solvents or oils and other formulations diluted in water is necessary. Formulations applied intact, i.e. granular formulations, will generally require a complete data set regardless of what data are already available for other formulation types.

The results from formulations used for seed treatment uses may be translated between each other.

Complete new data set are necessary for controlled-release formulations and formulations containing active substances as nanomaterials.

Geographical distribution of residue trials

Based on a recommendation of the 1999 workshop 'Developing Minimum Data Requirements for Estimating MRLs and Import Tolerances', a small group of residue experts from OECD and FAO Member countries developed a concept of a global zoning scheme to define areas in the world where pesticide trials data could be considered comparable. The results from this project are discussed. From the discussion, it is

³ Guidance document on magnitude of pesticide residues in processed commodities. *Series on Testing and Assessment*, No. 96. Available at <http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono%282008%2923&doclang=en>

recommended to reduce the number of trials for a comprehensive OECD submission by 40 percent, and in individual cases to a maximum of 50 percent.

Further expert consultations might be useful.

Number of trials

The national and regional approaches concerning the number of trials necessary for exposure assessment and MRL setting differ, and remain in place. Nevertheless, it might be possible to replace a maximum of 50 percent of the total number of trials required by a regulatory authority by trials effected by another regulatory authority, provided that these trials correspond to the critical GAP and the production conditions, i.e. comparable cultural practices.

In the case of a comprehensive submission in all OECD countries with a uniform GAP (i.e. within the 25 percent variation) it is possible to reduce the total number of trials by 40 percent. This is the maximum reduction possible. Nevertheless, some limiting factors have to be respected:

- A reduction below two trials is not possible.
- The minimum total number of trials for any crop is eight.
- The total number of trials should not be lower than the required number for the entire crop in any country or region.
- The proposal covers only outdoor crop field trials.

An example is given in the text and an appendix covers a huge number of crops.

For greenhouse and post-harvest trials, geographical distribution is of minor importance. Therefore, for a comprehensive submission to OECD countries, with similar critical GAPs, a minimum of eight greenhouse trials is needed. The minimum number of post-harvest trials with similar critical GAPs is four, provided the application techniques, storage facilities and packaging materials used are comparable.

Results from residue trials to be used in MRL estimations

For MRL estimations, all data from residue trials conducted according to critical GAP and considered valid should be taken into account for MRL setting. Nevertheless, a few questions often arise. The main ones being:

- handling of outliers;
- multiple component residues including examples;
- independent supervised residue trials;
- handling of replicates; and
- handling of residues at harvest.

These are discussed in the text. The discussion follows the lines of the FAO Manual (2nd edition).

MRL estimations

It is recommended to use the OECD calculator as a tool on which to base MRL estimations. Spreadsheets for single and multiple data sets, as well as a User Guide and White Paper, were published in March 2011⁴.

Conclusions

The OECD Guidance Document on Crop Field Trials provides a couple of proposals that helps in planning residue trials in OECD countries and in interpreting the results. As a guidance document, it leaves some flexibility for countries for their own interpretations.

In addition, it is a living document. Due to recent developments it is subject to review. The points to be covered are:

- incorporation of new EU-Extrapolation rules; and
- update of Codex Crop Grouping.

Also, some further discussion on proportionality has been taking place. It was proposed to start a survey in OECD countries to investigate whether any regulatory authority or agency is using the proportionality principle and to report on their experience. Also some investigations on newer active substances should start to investigate whether available data are suitable for broadening the database used by MacLachlan and Hamilton.

⁴ OECD Maximum Residue Limit Calculator. Available at http://www.oecd.org/document/8/0%2C3746%2Ce_n_2649_34383_47259976_1_1_1_1%2C00.html

OVERVIEW OF PROGRESS SINCE FIRST GLOBAL MINOR USE SUMMIT

Lois Rossi

MINOR USE CAPACITY BUILDING INITIATIVES

Jason Sandahl and Yong Zhen Yang

FOR SUSTAINABLE DEVELOPMENT OF THE ACP HORTICULTURAL TRADE – COLEACP PIP

A European Cooperation Programme for
the ACP horticultural industry

Christine Moreira

FAO PESTICIDE REGISTRATION TOOLKIT

Mark Davis

GLOBAL RESIDUE STUDY – A PILOT PROJECT ON TOMATO FOR THE FEASIBILITY OF INTERNATIONAL RESIDUE TRIAL ZONES

Michael Braverman, Dan Kunkel and Jerry Baron

INITIATIVES AND SCHEMES IN SUPPORT OF MINOR USES

CropLife International

CROP RESIDUES HOMOGENEITY ACROSS GLOBAL REGIONS

Carmen Tiu and J. Barnekow

Overview of progress since first Global Minor Use Summit

Lois Rossi

Director, Registration Division, Office of Pesticide Programs,
U.S. Environmental Protection Agency

The first Global Minor Use Summit (GMUS) was held in Rome, Italy, in December 2007. The purpose of the first summit was to highlight many of the issues and obstacles that growers of minor or specialty crops face. It was critically important that participants at the GMUS share knowledge of existing programmes and information to develop a foundation for future cooperation. Four major actions items identified at the first GMUS were to:

- 1) Improve international communications and information exchanges.
- 2) Increase capacity building efforts for developing countries.
- 3) Engage the Codex Committee on Pesticide Residues to better support minor use crops.
- 4) Enhance research efforts through collaborative pilot projects and initiatives.

Considerable progress has been made regarding these four action items.

To improve international communications and information exchanges, a global minor use portal (<http://www.gmup.org/>) was established, which contains important information regarding technical and policy issues relating to minor uses.

FAO, USDA and other partners have sponsored numerous workshops, training sessions and seminars in Africa, Asia and Latin America in order to strengthen the technical and regulatory capacities of developing countries on minor-use issues. The goal is to enhance participation within Codex, and ultimately for more countries to contribute to the MRL standard-setting process. As a direct result since the first Global Summit, over 50 distinct activities have taken place to support capacity building efforts with developing countries. More details of these activities are provided in a separate document (see summary paper on Minor Use Capacity Building Initiatives for more details).

The Codex Committee on Pesticide Residues (CCPR) has made considerable progress to better support minor crops. The CCPR first agreed to establish an Electronic Working Group on Minor Uses and Specialty Crops (EWG) during the April 2008 meeting, and agreed to re-establish this EWG again in 2009, 2010 and 2011. The EWG has provided a number of papers to assist Codex and member countries in developing more MRLs for minor uses. An update on the activities of the EWG is discussed in a separate document (see summary paper on Consideration of Minor Crops in the Codex Committee on Pesticide Residues for more details).

During the 2010 Session, the CCPR approved a proposal described as the 'pilot project,' which outlined a process for the evaluation of new chemicals by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) concurrently with national review and registration (Achieving Globally Harmonized MRLs through Codex). The toxicology and residue chemistry databases of the new active ingredient, sulfoxaflor, were considered by JMPR during the September 2011 meeting as part of this Codex pilot project. To date, we cannot fully evaluate the pilot project since the global joint review is not completed and final regulatory decisions are not expected until later in 2012. However, the completion of the JMPR review for this chemical should help inform the national authorities regarding allowable daily intakes (ADIs) and MRLs.

Additionally, as part of their review for sulfoxaflor, JMPR considered not only regional zones (the method currently used), but also the global dataset method for estimating MRLs. Three commodities—carrot, dry bean and common bean—did not receive MRL recommendations based on the regional dataset method due to insufficient field trial data. However, using the global dataset method, MRLs were recommended for all three commodities since all trials were considered for MRL setting purposes. The acceptance of the global dataset method, considered appropriate when a globally harmonized GAP is available, is an important step for minor crops and will also support collaborative efforts for developing residue data. Finally, it was noted that the global dataset method was likely to result in more robust MRL recommendations than would be expected from the regional dataset method, since the global approach uses larger residue datasets in the statistically-based OECD MRL calculator.

In March of 2011, the OECD MRL Calculator was made public. The OECD MRL Calculator was developed with the goal of harmonizing the calculation of MRLs across the OECD. During the development of this tool a circular letter containing a questionnaire was sent to all Codex Members in order to have more inclusiveness in the development of the OECD calculator, with the expectation that JMPR and CCPR might agree to use this tool as well to further meet the goal of harmonizing the calculation of MRLs. JMPR and CCPR both participated in the review and testing process of this tool. JMPR experts also actively took part in the development of relevant OECD Guidelines, including the calculation method. CCPR agreed that further actions of the CCPR on the OECD calculator would be determined at a later stage when the final version of the calculator became available. Since the OECD MRL Calculator was distributed in March 2011, JMPR used this tool for estimating MRLs during the September 2011 meeting, and intends to continue its use in future meetings.

The CCPR continues to work on the Revision of the Codex Classification of Foods and Animal Feeds. Ten revised crop groups for Tree Nuts, Herbs and Spices, Bulb vegetables, Fruiting vegetables (other than cucurbits), Berries and small fruits, Edible fungi, Citrus fruits, Pome fruits, Stone fruits, and Oilseeds are at Step 7, pending the finalization of the revision of the Classification. However, the CCPR has agreed to consider advancing all commodity groups within a particular commodity type to allow for the early completion of the revision of the Classification so that the revised commodity groups could be implemented in international trade as soon

as possible. This would assist in promoting MRL harmonization and in removing technical barriers to trade. In particular all the fruit types, including Berries and small fruits, Citrus fruit, Pome fruit, Stone fruit, Tropical and Sub-tropical Fruits, could be completed by the next CCPR session, in April 2012, and could all be advanced together. The Committee agreed that if all of the fruit types were completed by 2012, consideration would be given to advancing them to Step 8, for inclusion in the Classification system. This is a major step forward in this important effort.

The CCPR will also consider during the next session the Proposed Draft Principles and Guidelines for the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Commodity Groups. The document has been revised to incorporate proposed representative commodities for all of the fruit types. The paper was revised to concentrate on the proposals for the fruit types so that these are completed when the revision of the Classification for fruit types is completed. Gaining support for these proposals is critical because using representative commodities allows establishment of MRLs for many minor crops based on the residue data from the representative commodities. The revision of the Classification and the institution of the use of crop groupings and representative crops to establish MRLs are very important, especially for minor crops. Yet unless the guidance on the selection of representative commodities is adopted along with the revision to the Classification, having the revision to the Classification is of limited usefulness.

Finally, during the April 2011 meeting CCPR recommended that the JMPR should provide more examples of the application of the proportionality concept that was introduced in the 2010 meeting. Specifically, when considered appropriate, JMPR would apply scaling factors to residue data not matching the critical GAP so that additional data would be available to support MRL recommendations. This approach would give greater flexibility to JMPR in the use of residue field trial data and would allow MRL estimates to be made in more situations. JMPR was asked to further test the concept of proportionality to ensure reliable results before the Committee will endorse this approach for use by JMPR. The draft summary report from the September 2011 meeting provides recommendations for MRLs for five chemical and commodity combinations that otherwise would not receive MRL recommendations. Acceptance of the proportionality concept is expected to be another important tool for the establishment of Codex MRLs.

Regarding efforts to enhance research through collaborative pilot projects and initiatives, there is one ongoing project and several planned that will be discussed during the second Global Minor Use Summit. A pilot global residue study is underway (for more complete details see the summary paper on Global Residue Study – A pilot project on tomato for the feasibility of international residue trial zones). The goal of this project is to have multiple countries work together to develop data to support the establishment of MRLs for minor uses. There are also regional projects planned where countries in three regions, including Latin America, Asia and Africa, will work together to develop residue field trial data that can be bundled together into joint JMPR submissions, supporting initiatives for the consideration of global datasets.

Even with all of this progress, there remains much to be done to thoroughly address the action items that were prioritized during the First Global Minor Use Summit, and to resolve many of the problems that growers face. Therefore, the Second Global Minor Use Summit is being held to facilitate another international forum to take stock of lessons learned from existing specialty crop programmes and activities and to further resolve issues faced by minor and specialty crop growers.

Minor Use capacity building initiatives

Jason Sandahl (USDA-FAS) and Yong Zhen Yang (FAO)

Introduction

The first Global Minor Use Summit identified capacity building as one of the core follow-up action items. Developing country participants noted that in order to participate in the various global initiatives put forward at the Summit, developing country regulatory officials and technical experts would need to receive specialized training in minor use issues. These participants also expressed concern that less data from the developing world contribute to the MRLs established by Codex, and therefore these MRLs do not necessarily reflect use pattern demands in their regions. They also noted the irony that while most residue data is generated in industrialized countries, it is the developing countries that primarily rely on Codex as a basis for the adoption of standards.

Four primary capacity building themes emerged from the first Summit:

- Greater understanding of biopesticides and reduced-risk pesticides (registration requirements and risk assessments for non-conventional chemicals).
- Greater participation in multilateral review efforts.
- Increase regional coordination and cooperation efforts.
- Increase abilities to generate residue data (field trials, laboratory analysis, development of submission documents) and participate in Codex MRL establishment.

Following the first Summit, the United States Department of Agriculture's Foreign Agricultural Service (USDA/FAS) and the Food and Agriculture Organization of the United Nation (FAO) offered to help lead these capacity building efforts by prioritizing minor-use pesticide trainings for developing countries in their international outreach programmes.

Since the first Summit, over 75 training events in Africa, Latin America and Asia have taken place in order to increase regulatory and technical knowledge and skills related to minor-use issues. Capacity building activities have covered the following topics:

- Regulatory reviews and risk assessments to support the registration process.
- Regulatory coordination at both the national and regional levels.
- Understanding the Codex process for MRL establishment.
- Conducting supervised residue trails and operating under Good Laboratory Practices (GLP).
- Laboratory analysis and working toward accreditation.

Much of the regulatory and technical support has been provided by experts within USDA, FAO/JMPR, IR-4, the US Environmental Protection Agency (EPA), the US Food and Drug Administration (FDA), CropLife (International, Asia, Latin America, African and the Middle East), and the Europe-Africa-Caribbean-Pacific Liaison Committee (COLEACP).

Since the first Summit, much of the capacity building efforts has focused on increasing general knowledge and skills (i.e. getting countries up to speed). As many developing countries now have better established foundations in minor-use issues, future capacity building efforts should move towards implementation of minor-use programmes and engagement in collaborative multilateral projects.

The core capacity building programmes initiated by USDA/FAS and FAO leading toward this goal are described below.

USDA/FAS efforts on capacity building

Following the first Global Minor Use Summit, USDA/FAS made a commitment to incorporate and prioritize minor-use capacity building in its various international outreach programmes. Since that time, USDA/FAS has provided over 75 training events, workshops, roundtables, consultations, etc., in the area of pesticide management and minor-use issues, for over 325 individuals from more than 60 developing countries. These pesticide programmes were developed around the core capacity building themes identified at the first Summit, as listed above. Much of the regulatory and technical expertise used to deliver these programs was provided in-kind by dedicated partners from FAO, EPA, IR-4, CropLife International and its regional affiliations, and individual pesticide manufacturers.

From USDA's perspective, the primary goal of this initiative has been to facilitate global agricultural trade by reducing technical barriers (e.g. MRLs), opening communications and establishing networks between global regulatory authorities, and increasing overall technical knowledge and skills in the area of pesticide management and analysis. Below is a description of the various activities that USDA/FAS has implemented since the first Summit.

Biopesticides and reduced-risk pesticides

At the first Summit, many developing country participants expressed a need to better understand biopesticides and how they are evaluated for registrations. To address this request, USDA/FAS held a series of workshops in Africa specifically targeting biopesticide registrations, with emphasis on aflatoxin control in groundnuts and maize as a case study. As a result of these initial workshops, USDA/FAS has enhanced international interest in aflatoxin biocontrol, and is now partnering with the US Agricultural Research Service (ARS), the International Institute of Tropical Agriculture (IITA), the Bill and Melinda Gates Foundation, the US Agency for International Development (USAID), the Meridian Group, and other partners in a long-term commitment to develop and register biocontrol products to control aflatoxin in Africa.

Regulatory reviews, risk assessments, and the Codex MRL process

Also identified during the first Summit was a need to strengthen skills in conducting general risk assessments and develop better understanding of the Codex MRL establishment process. Since 2009, USDA/FAS, FAO and the US Codex Office have held a series of workshops around the world to strengthen the capacity of regulatory authorities in conducting risk assessments, and to also better engage in the CCPR. In addition to risk assessments, other related issues were emphasized, such as crop grouping, use of the MRL calculator, development of national minor-use programmes, and participation in the Global Joint Review process. In 2011, USDA/FAS partnered with FAO to deliver three regional workshops specifically on the establishment of Codex MRLs and risk assessments of pesticide residues, in Africa, Asia and Latin America (described in detail in the FAO section below).

Regulatory coordination

Most of the USDA/FAS-led capacity building activities have been conducted at the regional level, which helps support overall goals of regional harmonization. As part of these regional events, discussions have taken place on how to better harmonize residue standards, data requirements and registration processes across regions. Regional coordination (mutual recognition of efficacy and residue data) is a significant limiting factor for new product registrations in developing countries, and many regions are actively working toward harmonization of requirements and standards. USDA/FAS will continue to encourage and facilitate these regional initiatives.

Laboratory analyses and accreditation

Many developing countries have recently acquired extremely sophisticated analytical laboratories, but require some guidance on how to optimize the use of their analytical instruments and how to receive laboratory accreditation. The USDA/FAS laboratory programmes have generally consisted of:

- initial visits and evaluations of the national pesticide laboratories;
- guidance on laboratory management to support accreditation (establishing and maintaining SOPs, Quality Assurance and Quality Control (QA/QC) structures, and laboratory information management systems;
- instrument maintenance; and
- training in specific analytical techniques, such as QuEChERS [Quick–Easy–Cheap–Effective–Rugged–Safe].

Supervised residue trials

One of the primary concerns raised at the first Summit was the lack of residue data from developing countries used for establishing Codex MRLs. There are many reasons for this discrepancy, including (to name but a few): poor infrastructure for conducting supervised field trials at or near GLP; lack of marketing interests by major pesticide manufacturers; and lack of resources and oversight to carry out such work. All of the USDA/FAS minor-use capacity building programmes mentioned above have worked toward establishing a firm foundation for developing countries to participate in global data generation initiatives to support Codex MRLs for crop+pesticide combinations

pertinent to their needs. As much of this foundation is beginning to form, USDA/FAS will focus future capacity building efforts on a global data generation pilot project for tropical fruits. Four pesticides have been selected for the project: azoxystrobin (Syngenta), spinetoram (Dow), pyriproxyfen (Sumitomo) and chlorantraniliprole (Dupont). The objective of the project is to work through regional and global coordination issues that arise with “bundled” data packages (residue data provided by multiple countries) for JMPR submissions. It is expected that data from Asia, Africa, Latin America (and other countries wishing to join) will be generated for the representative crops of the tropical fruits group, and then coordinated, with joint data packages being submitted to the JMPR.

FAO efforts in capacity building for MRLs

In order to enhance developing country participation in the establishment of international standards and to strengthen the capabilities of scientists from these countries in residue risk assessment for MRL establishment and evaluation of residue dossiers for pesticide registrations, FAO in recent years has undertaken a series of capacity building activities for increasing participation of developing countries in the Codex MRL-setting process.

Revision of the FAO Manual

The *FAO Manual on submission and evaluation of pesticide residues data for the estimation of maximum residue levels*¹ was revised and published in 2009. The current (2nd edition) of the FAO Manual describes the basic principles currently applied by the FAO Panel in the evaluation of pesticide residues for recommending MRLs. These guidelines and guidance documents have been included in the references cited in the Manual. In cases where more detailed information relating to a specific subject was considered to be particularly useful for the reader, the reference to the relevant guideline is provided.

Development of the FAO Training Manual

The need for training in the evaluation of pesticide residues has become apparent in recent years as procedures have become more complex and interest in the operations of JMPR and the CCPR has increased. In 2010, at the request of Codex member countries, particularly developing countries, FAO developed the *FAO Training Manual on the Evaluation of pesticide residues for MRLs and calculation of dietary intake*².

The Training Manual is intended to be suitable for use in training workshops, and also for self-guided study. The main objectives of the training programme are:

- To train scientists to become potential members for the FAO Panel of Experts. Participants will be trained in the process of evaluation of residue data for estimation of MRLs and estimation of dietary exposure.

1 FAO. 2009. Manual on submission and evaluation of pesticide residues data for the estimation of maximum residue levels. 2nd edition. [FAO] *Plant production and Protection Paper*, No. 97. Available at: http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/FAO_manual2nded_Oct07.pdf

2 FAO. 2011. Evaluation of pesticide residues for estimation of maximum residue levels and calculation of dietary intake. Training manual. Available at: http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/TrainingManualJMPR.pdf

- To respond to the requests of developing countries to play a greater role in establishing Good Agricultural Practices (GAP) and health-based pesticide criteria for their own countries that are more reflective of local diets.
- To augment the experience of developing countries in the working procedures of the JMPR, and thereby increase their effective participation in the international forums that regulate pesticide residues in international trade.

The trial edition of the Training Manual was published in 2010, and has been used for an international training course and three regional training workshops in Asia, Africa and Latin America.

International training workshops

FAO held an international training workshop on the establishment of MRLs and risk assessment of pesticide residues on 8–12 November 2010, in Budapest, Hungary. The objectives of this training workshop were to strengthen the capabilities of scientists from developing countries in the techniques of pesticide evaluation for the establishment of MRLs, and to update their knowledge of the assessment of risks associated with dietary intake of pesticide residues. The specific training objectives were to familiarize the participants with the JMPR and CCPR pesticide review process; to conduct hands-on training on the evaluation of supervised trial data as defined by the principles of Good Agricultural Practice (GAP) and related residue chemistry data; and to increase the list of knowledgeable candidates included in the roster of experts for membership of the JMPR Expert Panel.

Fifteen trainees from 13 countries participated in the workshop, of which 13 trainees were from developing countries. The participants indicated that the workshop substantially expanded their views, improved their understanding of the complex subject, and all participants reported that the knowledge and skills they acquired from the training would be helpful for their future work.

Following the pilot training event in Budapest, FAO partnered with USDA/FAS to provide three additional workshops in 2011:

- Latin America (16–20 May), with 23 participants representing 11 countries;
- Africa (6–10 June), for 20 participants representing 14 countries; and
- Asia (8–12 August), with 33 participants representing 13 countries.

These FAO activities have been fully recognized by member countries as very important in strengthening the capabilities of scientists from developing countries in the techniques of pesticide evaluation for the establishment of MRLs, and in updating their knowledge of the assessment of risks associated with dietary intake of pesticide residues for promoting food safety and international trade of agriculture products.

For sustainable development of the ACP horticultural trade – COLEACP PIP

A European Cooperation Programme for the ACP horticultural industry

Christine Moreira

EU ACP Regulation Expert, COLEACP PIP

Introduction

The Pesticide Initiative Programme (PIP) was rolled out in 2001 (Phase 1). A second phase of PIP was then launched in October 2009, with a proposed duration of 5 years, funded by the European Development Fund and managed by the Europe-Africa-Caribbean-Pacific Liaison Committee (COLEACP), the association for African-Caribbean-Pacific (ACP) exporters and EU importers of horticultural produce.

PIP CROP PROTOCOLS AND GUIDES http://pip.coleacp.org/en/pip/production-guides	
Avocado (conventional & organic systems)	French beans
Mango (conventional & organic systems)	Snow peas
Papaya (conventional & organic systems)	Dasheen (<i>Colocasia esculenta</i>) & Macabo (<i>Xanthosoma sagittifolium</i>)
Passion fruit	Cassava
Lychee	Sweet potato
Coconut	Yam
Pineapple (conventional & organic systems)	Tomato
Baby and sweet corn	Eggplant
Melon	Okra (Lady fingers)
Cucumber & Courgette	Cabbages
Chilies and Sweet Peppers	Baby-Carrot
Ginger	Baby-Leek
Amaranth	Baby leaves
Butternut and watermelon	

- The aims of the PIP Programme are:
- to respond to concerns of European consumers;
 - to contribute to sustainable and safe food for local markets;
 - to overcome international trade barriers; and
 - to work towards minimal pesticide residues.

Disseminating good practice

COLEACP-PIP publishes Crop Protocols and Guides that promote integrated pest management (IPM) strategies, ensure minimal pesticide residues, and promote environmentally-friendly production.

The PIP Guides to Good Plant Protection Practice focus on recommended pest management strategies. The more detailed Crop Protocols cover all recommended agronomic practices.

For those exporting to Europe, following the protocols and guides enables ACP growers to ensure their produce complies with EU regulations, including pesticide maximum residue limits (MRLs).

For those supplying local and regional markets, the documents are modified to enable compliance with Codex MRLs.

Six new guides are under development: Ethnic bananas and matoke (plantain); Garlic, onions and shallots; Potato; Citrus; Guava; and Tamarillo.

Supporting biocontrol agent (BCA) research and development

Efficacy trials to develop environmentally friendly pesticides with zero residues

In order to make available the tools to protect their fruit and vegetables for farmers in the ACP countries and to try to find appropriate solutions for minor crops for the local market and for export to the European Union (EU), several efficacy tests and determinations of pesticide residues were made on several crops, including tomato, mango, French beans, peas, papaya, pineapple and passion fruit, in ACP countries (Côte d'Ivoire, Kenya, Mali and Senegal) in collaboration with the plant protection products (PPPs) industry. The data generated during the efficacy trials supported the efforts of plant protection products manufacturers wishing to obtain registration certificates in countries individually or in a sub-region (CILSS; Central Africa; Eastern Africa). In its goal to find more and more sustainable agricultural solutions, a search was conducted by PIP to identify bio-pesticides with potential for use on tropical horticultural crops. Discussions are now taking place with 19 BCA companies keen to collaborate with COLEACP-PIP in developing their products in ACP countries.

During 2011, efficacy trials of four bio-pesticides were conducted in Ghana on mealy bug on papaya. This is a serious pest in West Africa, with few available control options.

Additional trials are under development for:

- Biocontrol agents on vegetables in Senegal.
- Alternatives to sulphur fumigation for lychee post-harvest treatments in Madagascar.

- Control of fruit fly (*Bactrocera invadens*) on mango in Africa.
- Thielaviopsis [pineapple butt rot] and other post-harvest diseases of pineapple in West Africa.
- Fungicides to control passion fruit decay post-harvest in Kenya.
- Anthracnose and other post-harvest diseases on mango in West Africa
- *Cryptophlebia (Thaumatotibia) leucotetra* [false codling moth] on avocado in Kenya.

Building capacities

In parallel with R&D, COLEACP-PIP supports capacity building of BCA manufacturers in ACP countries (e.g. Kenya Biologics; Real IPM), as well as local consultants and trainers offering services to growers in IPM and pesticide safe use.

Understanding the legislation and facilitating registration

Information systems

COLEACP-PIP explains the main EU food safety regulations, and gives regular updates and access to information on new regulations, including new MRLs as well as approvals and withdrawals of active substances. It is also the role of COLEACP-PIP to keep its beneficiaries informed of changes in global trade standards and export requirements, and the consequences for their crop management and production.

Developing ACP capacities

The programme develops the capacity of ACP regulatory authorities in order to facilitate the registration of plant protection products in ACP countries. This is essential, first, to ensure that growers and exporters have access to PPPs, and can comply with the demands of EU buyers, and, second, to help ACP regulatory bodies to be part of international trade decisions and standards setting (Codex, GlobalGap, etc.). Activities include training of registration officers and developing information technology systems.

Securing import tolerances and extrapolations

If EU or Codex MRLs are not available for PPPs that are essential to give ACP growers safe and affordable pest control options, COLEACP- PIP works with national governments and the PPP manufacturers to develop and submit dossiers for import tolerances or extrapolations by performing residues trials in collaboration with local authorities and service providers according to EU and international guidelines, and to apply for EU or Codex MRLs in collaboration with the PPPs manufacturers. Over 30 import tolerances and one Codex MRL have been obtained by the programme. For Codex MRL requests, PIP often faces the reality of lack of registrations (i.e. certificates and labels) at national level in ACP countries, which are a legal requirement for Codex submissions. This is a key issue for minor crops in ACP countries.

Harmonization of PPP registrations

Harmonization of registration systems could speed up and facilitate PPP and bio-pesticide registration, as well as reducing costs and maximizing use of available resources. COLEACP-PIP is investigating and advising on development of harmonized systems in four ACP sub-regions:

- West Africa, through ECOWAS (Economic Community of West African States);
- East Africa, through EAC (Eastern African Community);
- Central Africa, through CPAC (Community of Central Africa Countries); and
- the Caribbean.

Fast track registrations

A fast-track procedure to implement trials for registration was developed with the Comité Sahélien des Pesticides for the 9 CILSS countries (Burkina Faso, Cape Verde, Chad, Gambia, Guinea Bissau, Mali, Mauritania, Niger and Senegal). Following development of a list of priority active substances for Sahelian and humid zones, a similar procedure is being discussed with the ECOWAS countries and the CPAC Comité Inter-Etats des Pesticides en Afrique Centrale.

FAO Pesticide Registration Toolkit

Mark Davis

Plant Production and Protection Division, FAO

Rationale

Sustainable intensification of agricultural production and sound disease vector management in developing countries require that any pesticides used are effective but pose a low risk to human health and the environment. The proper evaluation and registration of pesticides, before they are authorized for use, is an important mechanism to ensure that only appropriate pesticides enter the national market. This is even more so since post-registration awareness building, training, compliance monitoring and enforcement tend to be relatively weak in many developing countries.

The FAO/WHO Guidelines for Registration of Pesticides¹ were published in 2010 as an umbrella guideline that describes structure, organization and process of pesticide registration. Under the umbrella guideline, a registrar will need specific technical guidance on various topics related to pesticide registration, such as dossier composition, data requirements, testing methods, data evaluation methods, acceptability criteria, etc.

However, pesticide registration authorities in most developing countries tend to have very limited human resources. This means that copying approaches for pesticide dossier evaluation as applied in countries with more resources is not an option. Technical guidance on pesticide registration in developing countries will require innovative ‘outside of the box’ thinking on approaches to evaluate the efficacy and risk of a pesticide product for local use conditions. For instance, bridging and extrapolation approaches need to be developed between assessments carried out by resource-rich registration authorities on the one hand, and specific situations in developing countries on the other. Also, scientifically sound ‘shortcuts’ for risk assessment need to be identified, which can be applied in a limited time-span and with limited resources.

What is the Pesticide Registration Toolkit?

The FAO Pesticide Registration Toolkit is a decision-support system for pesticide registrars in developing countries. It will assist registrars in the evaluation and authorization of pesticides.

¹ The various documents associated with this topic can be found at <http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/code/guidelines/en/>

The Toolkit can best be considered a web-based registration handbook intended for day-to-day use by pesticide registrars. The Toolkit is not an automated system for the evaluation of pesticides. It supports and facilitates informed decision-making by registrars, but does not take decisions for registrars.

- Registrars can use the Toolkit to support various of their regular tasks, including:
- Assessing what data may be required for the evaluation of a specific type of pesticide for a particular use. Data requirements can be selected through a dynamic selection procedure and tailored to the specific situation a registrar needs to assess. Registrars will also be able to access internationally defined testing guidelines that are available for the generation of those data.
 - Obtaining guidance on how to evaluate the various technical aspects of the pesticide registration dossier submitted by the applicant, to ensure that only pesticides are approved for use that are effective but do not pose unacceptable risks to human health and the environment.
 - Determining whether other countries have registered a specific pesticide, and for what uses. Where available, registrars will also be able to access evaluations carried out by other registration authorities.
 - Monitoring the dossier evaluation process and checking its progress. The Toolkit will provide flow charts and check lists to help determine the most appropriate processes to be followed. In addition, standardized evaluation summary forms can be downloaded to structure and document pesticide evaluations.

Assessments at different resource levels

Since registration authorities in many developing countries have limited staff and relatively little experience in pesticide evaluation, the Pesticide Registration Toolkit provides, as much as possible, assessment methods at different levels of complexity. These range from generic methods requiring less resources, to more location-specific risk and efficacy assessment methods. As a registration authority builds up staff resources and gains (access to) scientific capacity for pesticide evaluation, the Toolkit will allow increasingly complex but more precise methods to be chosen.

A partial test-version of the Toolkit is currently under development, in which different options for its structure, functionalities and contents are being evaluated.

Select one item each in the pesticide group, pesticide type, intended use, type of registration and evaluation topic, which most closely approaches the situation that you are reviewing.

Main topic	Sub-topic
Identity	Risk from exposure to the a.i. or its impurities
Physical & chemical properties	Risk following dietary exposure
Details of use & further information	Risk following occupational exposure
Classification & labelling	Risk following bystander exposure
Methods of analysis	
Impact on human health	
Residues	
Fate & behaviour in the environment	
Effects on non-target species	
Efficacy	
Overall conclusions	

Risk following occupational exposure

Exposure to a pesticide likely to occur under the proposed conditions of use should not have any adverse effect on persons using the pesticide. Therefore, an occupational risk assessment needs to be carried out. Such a risk assessment should take into account the dose, application method and frequency, climatic conditions, and personal protective equipment, among others. Risk assessments should in principle be done for all proposed uses of the pesticide.

Occupational risk assessments are generally done for operators and for workers. Operators are those persons who handle and apply the pesticide (e.g. mixing, loading, spraying). Workers are those persons that work in an environment where pesticides have been applied (e.g. weeding, crop maintenance, harvesting). Risk assessments for these two groups are different.

The following assessment methods are available.

1. Occupational hazard assessment
2. Generic occupational risk assessment
3. Extrapolation of existing occupational risk assessments
4. Specific, local, occupational risk assessment

These methods increase in order of complexity, and the time and expertise needed for their execution. But they also become more realistic, approaching the specific use conditions in the country more closely.

[<< Back](#)

The project

The development of the full Pesticide Registration Toolkit is expected to take about two years. It will involve close collaboration among registrars in developing countries and subject experts from more resource-rich pesticide registration systems. Optimal use will be made of existing guidance documents and materials, both internationally and at the national level. FAO will coordinate the elaboration of the contents of the Toolkit, as well as ensure the design, development and maintenance of the Toolkit Web site.

The Pesticide Registration Toolkit will be made available through the FAO Web site. An extensive training programme for registration authorities in developing countries is part of the project.

Global Residue Study – A pilot project on tomato for the feasibility of international residue trial zones

Michael Braverman, Dan Kunkel and Jerry Baron

IR-4 Project Headquarters, Princeton, NJ, USA

Background

As with growers in many countries, United States growers of fruits, vegetables, herbs and other specialty crops often have legal access to some of the newest, lower-risk pesticides that can be used to protect their high value crops against insects, mites, fungi, bacteria, weeds, nematodes and other plant pests.

Within the United States, many of the specialty crop pesticide registrations are supported by the efforts of the IR-4 Project, which develops the data needed to establish pesticide tolerances (Maximum Residue Level – MRLs) and registrations with the US Environmental Protection Agency (EPA). Unfortunately, in many cases, there are not corresponding MRLs to support trade in many of the commodities when these new products are used, because of disparities among countries. This also results in the reluctance of growers to use these safer products. The United States specialty crop growers have clearly articulated that they want full access to the newest generation of pest management products and that they want to be able to use those products for commodities for the domestic and international markets.

The goal of this project was to develop a robust data set that would demonstrate the magnitude of residues from a wide variety of locations and climatic zones from around the world, with other factors remaining constant, such as spray volume, fruit size, etc. The underlying hope is that, in the future, regulatory decisions could be made using robust data sets generated globally, and result in a unified decision when establishing MRLs.

Partner organizations

IR-4 Project Headquarters at NJ AES/Rutgers University in Princeton, New Jersey, has taken the lead on this project. Participating and partnering in the study is the IR-4 Northeast Regional Laboratory at New York State Agricultural Experiment Station in Geneva, New York; EPA Office of Pesticide Programs in Arlington, Virginia; and the EPA Analytical Laboratory in Fort Mead, Maryland. Syngenta Crop Protection NAFTA Headquarters in Greensboro, North Carolina, is another participant. Also participating

is International Agriculture Group, which is assisting in sample shipping. Funding for the project was provided by the United States Foreign Agricultural Service. The study also involved many researchers from various universities or government agencies from around the world.

Methodology

The International Harmonization of MRLs on Specialty Crops through Global Zoning of Residue Data project involved establishing supervised field trials at 27 locations, where four pesticides were applied to the foliage and fruit of the test crop (outdoor staked fresh market tomato), with residue samples harvested, frozen, transferred to a single analytical laboratory and analysed for pesticide residues. All activities in this study were designed to determine how the geographical location of the crop affects the ultimate residue of the four chemicals and their metabolites in or on the tomato fruit.

Processes were put into place to reduce or eliminate many variables other than environment (such as sprayer, fruit size, etc.).

A majority of the researchers in the study were university faculty or government officials. The researchers were familiar with field crop research, but most had never conducted supervised residue trials or conducted any research in a good laboratory (GLP)-like system. In some cases, such as India, Kenya and Nigeria, on-site training was provided as part of capacity development training. IR-4 also posted a training module on the internet to help cooperators in this study to successfully conduct the work. In order to reduce variation in calibration, a specific plot size, calibration volume, walking speed and dilution mixing volume were predetermined, and specified in the protocol. A protocol was developed and an explanation on how to conduct the research was posted as YouTube videos¹ that provide great detail for conducting these studies.

Significant time and consideration was put into providing a useable spray system that could deliver a consistent and uniform application without the use of a tractor or bottled gases for each site. A backpack pump sprayer was initially tested but was unable to maintain a sufficiently uniform pressure. The addition of pressure regulating nozzle bodies attached to a 3 nozzle aluminum boom and an in-line pressure regulating valve greatly improved performance and uniformity of the pump sprayer. The boom was shaped as an inverted U so that it could direct the spray to a single row of staked tomatoes. The boom contained one nozzle to spray over the top of the row and one nozzle on each side facing inward toward the tomato plant. The four pesticides were contained in 2 pre-mix commercially formulated products, namely Endigo (Lambda-cyhalothrin and thiamethoxam) and Revus Top (Mandipropamid and Difenoconazole), along with Agri-Dex surfactant. The material was pre-measured and shipped to each site. Identical backpack pump sprayers, booms and pre-measured test substance was shipped to each trial site. In addition, safety equipment, harvest sample bags and a metronome was included to promote a uniform walking speed. A Field Data Notebook was also provided to prompt the researchers in documenting and collecting all the information generated during the course of the study.

1 See: <http://www.youtube.com/watch?v=o23QUBJm7rc>

Duplicate tomato samples were harvested at 1 hour, 24 hours and 72 hours after application. The largest challenge in this study has been the transfer of frozen residue samples from foreign sites through customs and into the United States. This has been complicated by local regulations, airline rules regarding dry ice in cargo, and Patriot Act provisions. Successful trials have been completed in trials representing

- Temperate zones (Australia; Maryland, USA; Ontario, Canada, and British Columbia, Canada; Japan; two sites in Republic of Korea; Poland; South Africa; France; and Guangzhao, China;
- Arid zones (Yemen; Beijing, China; Mexico; and India;
- Tropical (Brazil; Nigeria; Kenya; Colombia; and Costa Rica); and
- Mediterranean (Australia; California, USA; Spain; Italy; and Turkey).

They have successfully completed their trial, shipped the samples to the United States and completed a field data notebook. The notebooks were lightly reviewed by an IR-4 Quality Assurance reviewer, and questions were resolved with the researcher. The samples were in secure frozen storage at an IR-4 facility or EPA Analytical Laboratory in Fort Mead, Maryland.

The EPA Analytical Laboratory has successfully validated the analytical method in tomato fruit for all four chemicals and their metabolites. Analysis has been completed for a majority of samples.

Results and market assessment update

Of the samples analysed to date, a vast majority of the samples had similar levels of residues in fruit collected at time zero, as well as at 24 and 72 hours after application. The climatic zone does not appear to play a major role in affecting residue levels. For future studies it will be important to examine samples taken at longer intervals to determine if climate and location have an effect on residue values. This project has been presented at a number of forums and will probably be published to support the establishment of global residue zones and allow rationalization of global residue data generation to establish pesticide MRLs. This study has been presented at the Codex Committee on Pesticide Residues (CCPR) 2011 meeting, at OECD meetings, and at various Crop Life and European Crop Protection Association meetings, and will be presented at the Global Minor Use Summit II.

The ultimate goal of the International Harmonization and data generation is to facilitate the harmonization of registrations for specialty crops and ultimately promote the use of safer products. Concurrently, several companies have begun to make global submissions for new products routine, with global joint reviews occurring among regulatory agencies. For example, DuPont participated in a pilot project with a number of OECD member countries that reviewed a single submission supporting registration of a new insecticide, Chlorantranilprole. Dupont was successful in gaining registration in many of the countries from that single submission and now the product is registered in more than 60 countries worldwide. Other companies, including BASF, Bayer, Makhteshim-Agan and Dow Agrosiences are all taking similar approaches for broad use of data to support registration in multiple countries.

Initiatives and schemes in support of Minor Uses

CropLife

CropLife International, Brussels, Belgium

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

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

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

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

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

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

Part 1. Initiatives

INITIATIVE	LEADERS AND SUPPORTERS	OBJECTIVES AND KEY FOCUS AREAS	PRIORITY ACTIVITIES
<p>Global Minor Use Summit (GMUS)</p> <p>http://ir4.rutgers.edu/GMUS/</p> <p>Established: 2007</p> <p>Scope: Global</p>	<p>Interregional Research Project Number 4 (IR-4); United States Department of Agriculture (USDA); United States Environmental Protection Agency (US EPA); and Food and Agriculture Organization of the United Nations (FAO)</p>	<p>The purpose of the GMUS is to provide a forum for the international exchange of information on current activities that address minor use issues and to identify future opportunities and challenges in the area of technical and cooperative areas and in policy considerations.</p> <p>GMUS will focus on global agreements for pesticide policy, procedure and methodology to help deal with minor use issues while providing growers with access to safe tools to grow their crops and to promote free and fair trade between nations.</p>	<ul style="list-style-type: none"> • Establish and maintain the Global Minor Use Portal (www.gmup.org) • To discuss requirements for residue trials • To discuss harmonization of data requirements • To support crop group classifications and promotion of international trade via Codex • To support country's access to advanced residue programmes
<p>Codex – Electronic Working Group (EWG) on Minor Uses and Speciality Crops</p> <p>www.codexalimentarius.net</p> <p>Established: 2008</p> <p>Scope: Global</p>	<p>Codex Committee on Pesticide Residues (CCPR) chaired by USA and co-chaired by Kenya and Thailand</p>	<p>The EWG was initiated to foster globally applicable MRL settings for minor uses through Codex to assist in global trade in minor and speciality crops.</p> <p>The EWG provides guidance to facilitate the establishment of Codex MRLs for minor uses and speciality crops.</p>	<ul style="list-style-type: none"> • Draft criteria to define minor uses and specialty crops for use by the CCPR and JMPR • Identify and address issues related to minor uses and speciality crops (within the mandate of the CCPR) • Identify priority minor uses for MRL setting • Facilitate data submissions to JMPR • Develop criteria for use by CCPR and JMPR to determine minimum number of field trials necessary to support the establishment of MRLs for minor uses and specialty crops
<p>International Crop Grouping Consulting Committee (ICGCC)</p> <p>http://ir4.rutgers.edu/Other/USDACropGroupingSymposium.pdf</p> <p>http://ir4.rutgers.edu/Other/ICGCCMeeting.htm</p> <p>Established: 2004</p> <p>Scope: Global</p>	<p>Interregional Research Project Number 4 (IR-4) and Codex</p>	<p>The ICGCC was initiated to drive establishment of Crop Groups and harmonization of Crop Groups globally. Crop Groups serve to extrapolate MRLs from one crop to another crop within a group.</p> <p>Extrapolation to minor crops reduces the associated data and data needed, and therefore the data generation costs for minor uses. Harmonized Crop Groups have standardized data requirements and help prevent parallel risk assessments by international and national standard setting bodies.</p>	<ul style="list-style-type: none"> • Identify crops and gather information to determine which crops should be included in various crop groups • Classify crops into groups based on botanical, taxonomical or cultural characteristics • Select representative crops based on dietary importance and residue exposure • Development of electronic databases, including zone maps, dry matter, residue trial requirements, Codex/EU/USA. • Promote harmonization in crop classification, residue extrapolation, and commodity imports/exports

(...) →

→ (...)

INITIATIVE	LEADERS AND SUPPORTERS	OBJECTIVES AND KEY FOCUS AREAS	PRIORITY ACTIVITIES
<p>Organisation for Economic Co-Operation and Development (OECD Minor Use Effort) Expert Group on Minor Uses (EGMU)</p> <p>www.oecd.org/document/17/0,3746,en_2649_34383_41042065_1_1_1_1,00.html</p> <p>Established: 2007</p> <p>Scope: OECD member countries</p>	<p>Registration Steering Group (RSG) of OECD, chaired by Australia.</p> <p>Industry Associations, FAO, European and Mediterranean Plant Protection Organization (EPPO), IR-4</p>	<p>The ultimate goal is to assist countries, registrants and growers to solve minor use problems through activities associated with baseline information, collaborative data generation, joint reviews and data sharing.</p> <p>The long-term objective is the development of guidance documents for solving minor use data gaps.</p>	<p>EGMU identified 3 key target areas:</p> <ol style="list-style-type: none"> 1. Cooperation considerations 2. Technical considerations 3. Policy considerations <ul style="list-style-type: none"> • Identify mechanisms that enable international cooperation on minor use issues, including work-sharing • Supply technical guidance on preparation of data submissions for minor use • Assist in minimizing barriers to approval of safe minor uses
<p>USDA/FAS initiative on Trade Facilitation through Capacity Building</p> <p>Established: 2009</p> <p>Scope: Developing countries and Codex members</p>	<p>USDA/FAS (Foreign Agricultural Service of US Dept. of Agriculture)</p> <p>Supporters: FAO, IR-4, Pesticide Initiative Programme (PIP), Association of Southeast Asian Nations (ASEAN), African Union (AU), Inter-American Institute for Cooperation on Agriculture (IICA), CropLife International</p>	<p>Facilitate the establishment of harmonized MRLs for minor use in speciality crops.</p> <p>Drive MRL harmonization by establishing Codex MRLs for minor uses.</p> <p>Build capacity and infrastructure in developing countries to generate data required for JMPR submission and Codex MRL dossier, and harmonize regional registration requirements and crop grouping systems</p>	<ul style="list-style-type: none"> • Workshops held in several regions, including Latin America, Africa and Asia to follow-up on GMUS-1 and to identify priority crops • Promote MRL harmonization and Codex MRLs • Initiate Codex MRLs for minor uses and engage developing nations in CCPR process • Initiated pilot pesticide residue field trial programme with low-risk pesticides

(...) →

→ (...)

INITIATIVE	LEADERS AND SUPPORTERS	OBJECTIVES AND KEY FOCUS AREAS	PRIORITY ACTIVITIES
<p>PIP (Pesticide Initiative Programme)</p> <p>www.coleacp.org/pip</p> <p>Established: 2001 (Phase 1: 2001–2009) (Phase 2: 2009–2014)</p> <p>Scope: ACP (African, Caribbean and Pacific Countries)</p>	<p>PIP is implemented by the Europe-Africa-Caribbean-Pacific Liaison Committee (COLEACP – an inter-professional association promoting sustainable horticultural trade between the EU and the ACP countries), and financed by the European Development Fund at the request of the ACP Group of States</p>	<p>PIP, implemented by COLEACP, has completed the first phase and launched Phase 2 in October 2009 for a 5 year period. The goals of the programme include:</p> <ul style="list-style-type: none"> • Enabling ACP producers and exporters to comply with new food safety regulations and standards, as well as sustainability standards (environmental, ethical, fair trade) • Increasing the contribution made to economic growth and poverty alleviation by focusing support on disadvantaged groups (e.g. small-scale growers, rural women) • Disseminating some of the technologies, knowledge and skills developed for the export sector to benefit local, regional and processing markets • Engaging with policy-makers to improve conditions for market access and ensure that regulations and standards do not create barriers for ACP exports • Developing crop production and crop protection technologies that are cost effective and minimize pesticide residues • Ensuring sustainability by capacity building of companies and service providers 	<ul style="list-style-type: none"> • Organizing residue trials for requests of EU import tolerances and Codex MRLs (JMPR evaluations) for exported and local ACP commodities • Organizing efficacy trials needed (1) for the guides to good plant protection practices and the technical itineraries; and (2) to strengthen plant protection products registration dossiers submitted by applicants at national level in ACP countries • Being an interface between applicants and national and regional registration authorities • Helping to put in place harmonized (regional) registration bodies • Setting evaluation and technical protocols for the regional and local registration authorities • Building capacity of national and regional registration authorities
<p>Expert Working Group (EWG) on MRLs</p> <p>www.asean.org</p> <p>Established: 1997</p> <p>Scope: Association of Southeast Asian Nations (ASEAN)</p>	<p>ASEAN member state</p>	<p>The objective is to harmonize MRLs for traded crops in ASEAN countries.</p> <p>The economies of Southeast Asia are committed to harmonizing MRLs following the establishment of pest lists to underpin negotiations for expanding trade in agricultural commodities</p>	<p>ASEAN members developed pest lists showing the distribution of pests in different production areas to gain access to markets for their agricultural commodities. They have also harmonized a significant number of MRLs over the years.</p>
<p>Interregional Research Project Number 4 (IR-4)</p> <p>www.ir4.rutgers.edu</p> <p>Established: 1961</p> <p>Scope: USA</p>	<p>USDA and Rutgers University, plant science industry</p>	<p>To provide safe and effective pest management solutions for speciality crop growers.</p> <p>IR-4 is a publicly-funded research programme that develops data necessary to facilitate the registration of crop protection products for specialty crops</p>	<ul style="list-style-type: none"> • Successful cooperation with stakeholders to register for minor uses in USA, Canada and Codex on an on-going basis • Extremely active at international level, in NAFTA, Codex and OECD • IR4 maintains Global Minor Use Portal (www.gmup.org) as follow-up from GMUS-1

(...) →

→ (...)

INITIATIVE	LEADERS AND SUPPORTERS	OBJECTIVES AND KEY FOCUS AREAS	PRIORITY ACTIVITIES
<p>Minor Crop Farmer Alliance (MCFA)</p> <p>Established: 1991</p> <p>Scope: USA</p>	<p>Agricultural trade associations and commissions, United Fresh Produce Association</p>	<p>The Minor Crop Farmer's Alliance is a coalition of USA minor crop producers that work together cooperatively to address regulatory issues that might affect production and sales. The group, comprising over 30 state, regional, and national agricultural trade associations and commissions, meets several times each year in Washington, DC, and elsewhere as needed to address pending issues. The MCFA has neither an office nor staff.</p>	<ul style="list-style-type: none"> • Advocate for the availability of pesticides for minor uses • Monitor USA regulatory changes that may affect minor crops
<p>North American Free Trade Agreement (NAFTA) Minor Use Joint Review Procedure</p> <p>www.epa.gov/oppfead1/international/naftatwg/</p> <p>www.hc-sc.gc.ca/cps-spc/pubs/pest/_corp-plan/nafta-alena/jr07-00-1005-eng.php</p> <p>Established: 2004–2010</p> <p>Scope: USA and Canada</p>	<p>US Environmental Protection Agency (EPA), the Canadian Pest Management Regulatory Agency (PMRA), IR-4 under USDA, and Canadian Pest Management Centre under Agriculture and Agri-Food Canada</p>	<p>To develop data and a registration process that will permit a regulatory decision on pesticide uses for the minor use grower communities in both countries simultaneously in a reduced timeframe</p>	<ul style="list-style-type: none"> • The first pilot candidates were successfully registered following the draft Standard Operating Procedure (SOP) developed for the new process for registering minor uses. • A work-share process has been developed to review the residue chemistry data and ensure both EPA and PMRA agree on the level for MRLs.
<p>Minor Use Pesticide Programme (MUP)</p> <p>www.agr.gc.ca/prrmup</p> <p>Established: 2002</p> <p>Scope: Canada</p>	<p>Pest Management Centre of Agriculture and Agri-Food Canada (AAFC)</p>	<p>The MUP Programme provides benefits to Canadian producers, the environment and consumers by focusing on:</p> <ul style="list-style-type: none"> • Making minor use pesticide products more readily available, with emphasis on reduced-risk products. • Providing Canadian producers with access to new pest-management technologies to improve their competitiveness domestically and internationally. <p>Agriculture and Agri-Food Canada support a separate minor use group known at the Pest Management Centre. This group was set up similar to IR-4 in the USA, and develops efficacy, crop tolerance and residue data to support minor use priorities developed by grower associations</p>	<ul style="list-style-type: none"> • AAFC is conducting field trials to generate the data needed to support submissions to the PMRA for registering minor use pest-control products. This activity complements the existing roles and responsibilities of pesticide manufacturers in submitting products to the PMRA for registration, and encourages manufacturers to register products in Canada. • Annual workshop held in March to establish research priorities • Several joint projects with IR-4 annually

(...) →

→ (...)

INITIATIVE	LEADERS AND SUPPORTERS	OBJECTIVES AND KEY FOCUS AREAS	PRIORITY ACTIVITIES
<p>European Union (EU) Initiatives</p> <p>Established: 2003 (Phase 1)</p> <p>Northern and Southern Technical Working Group (Phase 2)</p> <p>Scope: Regional EU</p>	<p>Directorate General Health and Consumers (DG SANCO) of the European Commission</p>	<p>Bring innovative solutions to minor and speciality crop producers in the EU.</p> <p>Conceptual and coordination (Phase 1): Bringing stakeholders together and coordinate to influence policy considerations by Technical Expert Groups and Steering Committees. Survey among stakeholders to receive guidance for the scope of a formal programme.</p> <p>Formal support programme (Phase 2): Support priority setting of minor uses and support collaboration between Member States and, possibly, data generation for minor use registrations</p>	<ul style="list-style-type: none"> Operational Technical Expert Groups for North and South to coordinate Member State requirements for minor use registrations EC established dedicated posts within DG SANCO To administer Technical Expert Groups Activities pending approval of the formal project programme
<p>Arbeitskreis Lückenindikation der ÖAIP (Working Sub-Group on minor uses of the Austrian working group on integrated plant protection (ÖAIP))</p> <p>www.oeaip.at</p> <p>Scope: Austria</p>	<p>The ÖAIP is composed of all parties having interests for crop protection, including agriculture, science, authorities and industry.</p>	<p>Coordinate minor use registration applications.</p> <p>The programme acts as a framework to ensure registrations at reduced investments cost</p>	<ul style="list-style-type: none"> Application is done by the ÖAIP The manufacturer involved then has to take care of the rest of the procedure After the process the registration is transferred from ÖAIP to industry Shared registration fees for minor uses, with 83% of the registration fee covered by ÖAIP and 17% by the registrant
<p>Belgian Minor Use Initiative (informal)</p> <p>Scope: Belgium</p>	<p>Private Sector</p>	<p>To find solutions for registration gaps in minor uses to prevent illegal use of plant protection products and to protect consumer health.</p> <p>An informal initiative by food chain partners (“DRC” in Flanders; CRP [Regional Committee Phyto of the Catholic University of Louvain-La-Neuve] in Wallonia), including farmer unions, to identify needs and provide solutions for minor uses.</p> <p>The overall scope of the programme is to screen minor use issues, prioritize needs to match resources, check data availability with other Member States and with the crop protection industry, or request new studies to fill data gaps, in addition to completing third-party requests to competent authorities</p>	<ul style="list-style-type: none"> An annual priority list is discussed between regulatory authorities and the plant protection sector. The plant protection industry endeavours to provide information and data to authorities or to food chain partners (DRC; CRP) concerning candidate products. Regulatory authorities coordinate actions and submissions coming from third parties along with contacts in other countries to guide them through the registration process in a timely manner. Plant protection companies provide data to authorities and/or food chain partners to evaluate the possibilities of extending the use of their products on minor crops, while asking for the protection of specific data.

(...) →

→ (...)

INITIATIVE	LEADERS AND SUPPORTERS	OBJECTIVES AND KEY FOCUS AREAS	PRIORITY ACTIVITIES
<p>Usages Orphelins</p> <p>http://agriculture.gouv.fr/produits-phytosanitaires</p> <p>Established: 2008</p> <p>Scope: France</p>	<p>Commission on Orphan Uses, Ministry of Agriculture, Fisheries and Landscape (DGAL)</p>	<p>The objective of the programme is three-fold and includes the identification of GAPs in terms of use or crop; the identification of solutions, based on benchmarks other Member States and discussions between authorities and stakeholders regarding priorities for action.</p>	<ul style="list-style-type: none"> • Identify minor use gaps in consultation with stakeholders • Actively seek participation from stakeholders to realize minor use registrations • Coordinate and, where needed, generate field data for minor uses • Motivate registration applications for minor uses
<p>Forum Phyto</p> <p>www.forumphyto.fr</p> <p>www.forumphyto.fr/en</p> <p>Established: 2009</p> <p>Scope: France</p>	<p>French food producers (Cerafel and maraichers nantais), Grower associations, retailers (Coop de France) and plant protection industry – Union des Industries de la Protection des Plantes (UIPP)</p>	<p>The Forum Phyto programme works in collaboration with other stakeholders such as FNSEA, Légumes de France, Bonduelle. It is a member of the Commission des Usages Orphelins (see above).</p> <p>Forum Phyto serves as a representative for work sharing with EU associations (Copa-Cogeca, ECPA) as well as a good network for farmers to reach media and include communication on risks and benefits of plant protection products</p>	<ul style="list-style-type: none"> • Exchange technical information, provide analysis and weekly updates to members (electronic newsletter), collaborate on non-registered uses to help growers
<p>Arbeitsgruppe Lückenindikationen (Working Group Minor Uses)</p> <p>http://www.jki.bund.de/no_cache/en/startseite/institute/strategien-folgenabschaetzung/arbeitsgruppen/lueckenindikation.html</p> <p>Established: 1992</p> <p>Scope: Germany</p>	<p>Julius Kühn Institute (JKI)</p>	<p>The overall objective of the programme is the registration or authorization of pesticides for minor crops, and international cooperation in the field of minor uses. Confidentiality clauses and financial compensation can be applicable should residue data produced by farmers or German authorities be requested by third parties. If the “minor use” is part of the authorization of a pesticide, the data protection rules of the PflSchG apply.</p>	<ul style="list-style-type: none"> • Evaluation of public interest in applications of authorizations according to Art. 51(2c) of Regulation (EC) No 1107/2009 • International coordination and cooperation in the field of minor uses • Executive Office of the Federal State Working Group Minor Uses • Participation in the maintenance of a list of minor uses in Germany according to Art. 51 (8) of Regulation (EC) no 1107/2009
<p>Republic of South Africa (RSA) Pesticide Initiative Programme (PIP)</p> <p>www.ppecb.com/initiatives/sa-pip%202</p> <p>Established: 2004 (Phase 1)</p> <p>2010 (Phase 2)</p> <p>Scope: South Africa</p>	<p>Perishable Products Export Control Board (PPECB), a semi-governmental organization</p>	<p>Operates under the same framework as the PIP (see above) but is a national programme with capacity building and research activities.</p> <p>Its objective is to contribute to continued access to the EU market for RSA horticultural produce (especially minor crops) and to minimize the detrimental impact of EU food safety and consumer protection requirements on the RSA economy as a whole.</p>	<ul style="list-style-type: none"> • Research projects to adjust production practices (to meet MRL in destination market) and to find alternative plant protection products • Capacity building to improve responsible pesticide handling and application

(...)

→ (...)

INITIATIVE	LEADERS AND SUPPORTERS	OBJECTIVES AND KEY FOCUS AREAS	PRIORITY ACTIVITIES
<p>Expert Centre for Speciality Crops</p> <p>www.specialitycrops.eu</p> <p>Established: 2010</p> <p>Scope: The Netherlands</p>	<p>Ministry of Economic Affairs, Agriculture and Innovation; Wageningen University; Ctgb; LTO; Plantum NL; and Nefyto</p>	<p>The Expert Centre for Speciality Crops is a network to facilitate minor crops and their inputs which are of importance to keep these high-quality crops viable in the Netherlands and Europe.</p> <p>The Expert Centre will:</p> <ul style="list-style-type: none"> • Define and coordinate projects for minor uses (research) and data sharing and studies aiming at making authorizations possible • Create a platform for stakeholders to discuss minor use gaps and discuss solutions 	<p>Coordination between research, advice, financing and authorizations. By creating a virtual knowledge centre, it will be able to more quickly identify experts on specific sub-areas. For this purpose, several helpdesks have been set up, i.e. a helpdesk for authorizations and a helpdesk for minor uses.</p> <ul style="list-style-type: none"> • Coordinators will prepare inventories of existing and future crop protection gaps, for which collaboration between authorities and stakeholders is undertaken to identify which plant protection products could best be used and for which subsequently an authorization should be requested
<p>Minor Use Project</p> <p>Scope: Sweden</p>	<p>—</p>	<p>The overall aim of the initiative is to find practical solutions for minor uses and speciality crops.</p> <p>Therefore, any actions directed to this aim could be covered such as studies for residues data etc</p>	<ul style="list-style-type: none"> • Studies such as scanning plant protection products in minor crops in field experiments, including pesticide residue trials for registration

(...) →

→ (...)

INITIATIVE	LEADERS AND SUPPORTERS	OBJECTIVES AND KEY FOCUS AREAS	PRIORITY ACTIVITIES
<p>Assistance for Minor Uses</p> <p>www.maff.go.jp/j/syouan/syokubo/gaicyu/index.html</p> <p>Established: 2005</p> <p>Scope: Japan</p>	<p>Food Safety and Consumer Affairs Bureau, Plant Protection Division of J-MAFF</p>	<p>The main objective is to provide support to ensure sufficient data is available to register minor uses according to the authorities. Minor crops are generally cultivated in limited local areas and pesticide manufacturers are less likely to develop the data needed for registration.</p>	<p>Subsidies are provided by the Japanese government to prefectural governments for the following activities:</p> <ul style="list-style-type: none"> • Establishing the systematic protection method for minor crops. Under this scheme, efficacy trials and residue trials can be conducted. • Promotion of the appropriate use of agrochemicals in terms of application rate and timing. Under this scheme, residue trials can be conducted. • Activation of rural area in order to promote agriculture, forestry and fishery. One focus is to protect minor crops specific to the area. The subsidy can be allocated to conduct the studies for the registration of agrochemicals. • Development of protective methods for multiple crop cultivation. Studies are usually contracted out to private organizations (laboratories) to investigate which agrochemicals are the most effective on which pests or diseases when multiple crops are cultivated at the same time. Data generated under this scheme can be used to register agrochemicals for minor crops. • Development of novel technologies to promote new agricultural policy. New technologies include protection of crops from pests and diseases. Under the scheme, studies to promote registration of agrochemicals are highly recommended.
<p>Minor Use Registration (Studio sulle culture minori)</p> <p>Established: 2005</p> <p>Scope: Italy</p>	<p>Ministry of Agriculture, Food and Forestry (MiPaaf) in cooperation with Italian Regions</p>	<p>Some trials for efficacy and residues are funded by the Ministry of Agriculture.</p>	<p>The programme consists of a fast-track authorization procedure for plant protection products and involves less study requirements</p>

(...) →

→ (...)

INITIATIVE	LEADERS AND SUPPORTERS	OBJECTIVES AND KEY FOCUS AREAS	PRIORITY ACTIVITIES
<p>Sahelian Pesticide Committee (Comité. Sahélien des Pesticides – CSP), the Common Pesticide Registration Body</p> <p>www.insah.org/index.cfm?menuID=2&sb=02</p> <p>Established: 1973</p> <p>Scope: SAHEL Comité permanent Inter-Etats de Lutte contre la Sécheresse dans le Sahel (CILSS) Member States: Burkina Faso, Cape Verde, Chad, Guinea Bissau, The Gambia, Mali, Mauritania, Niger and Senegal</p>	<p>Sahelian Pesticide Committee (CSP)</p>	<p>Harmonized tests and field trials have been established and regional laboratories for conducting various analyses relating to pesticides are being identified.</p> <p>The harmonization is more likely to attract registrations for minor uses</p>	<p>—</p>
<p>U.S. Minor Use Registration Scheme</p> <p>www.epa.gov/opp00001/minoruse/</p> <p>www.epa.gov/agriculture/lfra.html</p> <p>Established: 1999</p> <p>Scope: USA</p>	<p>US EPA</p>	<p>Encourage minor use registrations to provide growers with increased pest control options.</p> <p>The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) includes data protection and compensation, as well as other provisions for the registrants of pesticides. Additional regulatory incentives specific to the registration of minor uses are part of FIFRA, section 3.</p>	<p>In addition to the standard 10-year period for the protection of data submitted in support of an original registration or a new use, the following is specific to Minor Uses:</p> <ul style="list-style-type: none"> • Protection period extended by 1 year for every 3 minor uses registered (with a maximum of 3 additional years possible; with regard to crop grouping, data submitted for each representative crop, is considered 1 minor use) with 13 years data protection possible for products labelled with minor uses • Request for extension of data protection for the addition of minor uses must be submitted within 7 years after the date of registration. <p>In addition to the aforementioned period of data protection, data is compensable for 15 years from the date of study submission to the EPA.</p> <ul style="list-style-type: none"> • An offer to pay must be made to the data owner for any study another party wishes to utilize or cite that falls within said 15-year timeframe • Other potential minor use – specific incentives are as follows: <ul style="list-style-type: none"> • Registration fee reduction • Potential data requirement waivers

(...) →

→ (...)

INITIATIVE	LEADERS AND SUPPORTERS	OBJECTIVES AND KEY FOCUS AREAS	PRIORITY ACTIVITIES
<p>EU Minor Use Regulation</p> <p>Established: 2009/14 June 2011 (effective entry into force)</p> <p>Scope: EU</p>	<p>DG SANCO</p> <p>(Articles 49–51 of 1107/2009)</p>	<p>In recognition of the need for minor use registrations and responding to farmer requests, the European Commission included provisions for minor uses during the recent revision of its authorization legislation. The incentives are designed to motivate industry to register more compounds for minor uses in Member States.</p> <p>Policy affects zonal and Member State level, but not the authorization of the compound at EU level.</p>	<ul style="list-style-type: none"> • Providing definitions of minor uses informed by production volume (Article 3 point 26) • Provision for listing minor uses per Member State (51.8) • Encouraging mutual recognition of minor use authorizations • Additional data protection for minor use registrations (per EU Member State) – 3 month for each MU with maximum of 3 years per compound (Art. 59) <p>Additional motivation:</p> <ul style="list-style-type: none"> • Funding for EU minor uses (Art.51.para7) • Consider for comparative assessment (Art. 50)

Part 2. Schemes

SCHEME (NAME OR TITLE)	LEAD OR REFERENCE TO LEGAL TEXT	OBJECTIVES AND KEY FOCUS AREAS	DETAILS
<p>Protection of Proprietary Interests in Pesticide Data in Canada</p> <p>Established: 2007</p> <p>(amended in 2010 to include the extension of the AI data protection based on MUs)</p> <p>Scope: Canada</p>	<p>Pest Management Regulatory Agency (PMRA)</p> <p>DIR 2007-03 Protection of Proprietary Interests in Pesticide Data in Canada</p>	<p>Extension of the period of data protection for the active ingredient based on Minor Use registrations.</p> <p>To provide regulated innovative crop protection solutions for minor uses in Canada.</p> <p>To partner with the Minor Use community and leverage the required work.</p>	<ul style="list-style-type: none"> • 1 year extension for every 3 minor uses registered with residue and efficacy field trial data • 5 year maximum extension (15 minor uses); Minor Uses must be submitted within 7 years after the date of the initial product registration
<p>User Requested Minor Use Registration (URMUR) policy</p> <p>Established: 1999</p> <p>www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir99-05/index-eng.php</p> <p>User Requested Minor Use Label Expansion (URMULE)</p> <p>www.hc-sc.gc.ca/cps-spc/pubs/pest/_pol-guide/dir2001-01/index-eng.php</p> <p>www.hc-sc.gc.ca/cps-spc/pubs/pest/_training-formation/urmule-pepudu/index-eng.php</p> <p>Scope: Canada</p>	<p>Pest Management Regulatory Agency (PMRA)</p>	<p>The purpose of the policy for URMUR is to encourage registrants to apply for the new active ingredient registration of conventional pesticides and biopesticides such as microbials and pheromones, that are registered in the USA or other OECD countries, but that due to potential low volume of sales might never be registered</p>	<ul style="list-style-type: none"> • Making use of acceptable foreign reviews completed in other countries, the procedures for the technical review of URMUR applications are as efficient as possible. • Registration standards for URMUR and URMULE applications are appropriate to the use, recognizing the relatively small sales volumes, use volumes and areas of use, as well as the need to maintain Canadian standards of health and environmental protection. <p>URMULE: PMRA DIR2001-01 outlines the policy and process criteria for programme consideration:</p> <ul style="list-style-type: none"> • The active ingredient and the end-use product must be registered in Canada • Registrant supports the addition of the new use to its label • There must be sufficient information to assess the safety, merit and value of the proposed new use <p>Cooperators:</p> <ul style="list-style-type: none"> • Sponsors (Grower groups), Registrants, AAFC/PMC, Provincial/Forestry, Minor Use Coordinators

(...) →

→ (...)

SCHEME (NAME OR TITLE)	LEAD OR REFERENCE TO LEGAL TEXT	OBJECTIVES AND KEY FOCUS AREAS	DETAILS
<p>Additional Data Protection for Minor Uses</p> <p>www.apvma.gov.au/morag_ag/index.php Since 2005</p> <p>Scope: Australia</p>	<p>Australian Pesticides and Veterinary Medicines Authority (APVMA)</p>	<p>A main objective is to provide protection of data in support of registration applications and new use patterns. The additional years available for minor uses were specifically developed to provide incentive for registration of minor uses.</p> <p>Data protection is available for new uses registered that rely on new data submitted.</p> <p>Major review of pesticides regulation is nearing completion. This will include proposals for minor uses. Expected end 2011</p>	<ul style="list-style-type: none"> • A key focus of regulatory incentives for minor uses must be ones that add a value (attractiveness) for registration of the minor use to a registrant. • Data that has received 8 years protection will be extended by 1 year for each 5 distinct prescribed uses registered under this scheme.
<p>Minor Use Permits Scheme</p> <p>www.apvma.gov.au/permits/index.php Since 1995</p> <p>Scope: Australia</p>	<p>Australian Pesticides and Veterinary Medicines Authority (APVMA)</p>	<p>This programme allows user-requested permits for the use of crop protectants in speciality crops. These permits are typically time limited and do not require the same level of data as a full registration.</p>	<p>A full database of existing permits may be found at www.apvma.gov.au/permits/search.php</p>

(...) →

→ (...)

SCHEME (NAME OR TITLE)	LEAD OR REFERENCE TO LEGAL TEXT	OBJECTIVES AND KEY FOCUS AREAS	DETAILS
<p>Minor Use Registration</p> <p>http://jppa.or.jp/membership/list.html</p> <p>Established: 2003 (Council for promoting minor use registration established; and reorganized in 2010)</p> <p>Scope: Japan</p>	<p>Council member representation from: Ministry of Agriculture, Food Safety and Consumer Affairs Bureau, Plant Protection Division, Ministry of Agriculture, Food Safety and Consumer Affairs Bureau, Plant Products Safety Division, Agricultural Chemicals Office, Ministry of Agriculture, Agricultural Production Bureau, Horticultural Crop Division, Ministry of Agriculture, Forestry and Fisheries Research Council, Councils Secretariat Food and Animal Materials Inspection Center (FAMIC), Japan Plant Protection Association, The Japan Association for Advancement of Phyto-Regulators, The Institute of Environmental Toxicology, Japan Crop Protection Association, National Federation of Agricultural Cooperative Associations</p>	<p>The agricultural chemicals control law was amended in 2002 to reflect the positive list system. The amendment eventually led to a decrease in the number of agrochemicals permitted for use on minor crops.</p> <p>In order to keep minor crops on the market, the Japanese authorities promoted the registration of agrochemicals for minor crops through the establishment of a minor use council.</p>	<ul style="list-style-type: none"> • The major role of the council is to coordinate registrations. • As it likely that different prefectural governments have the same request for minor use registration, the council will coordinate the necessary efficacy and residue trials to avoid duplication of studies. The council also provides prefectural governments with the contact information of agrochemical manufacturers. • GLP (Good Laboratory Practice) was introduced into residue trials in Japan in 2011. • The number of residue trials will be increased to six for major crops in 2014. <p>For minor crops, however, the requirement does not change and only two non-GLP trials are acceptable for registration.</p>
<p>Minor Use Regulation</p> <p>Established: 2010</p> <p>Scope: Brazil</p>	<p>ANVISA – Brazilian Health Surveillance Agency</p> <p>MAPA – Ministry of Agriculture</p>	<p>Brazil published on 24 February 2011 a regulation for minor crops. This document is very important in order to start the process, but clarification is required on many specific points. The document requires refinement and specific questions need to be addressed, e.g. points such as funding, support for efficacy and residues studies, and prioritization.</p>	<ul style="list-style-type: none"> • Minor use group following progress of submissions • Minor use regulations make provisions for expedited reviews

(...) →

→ (...)

SCHEME (NAME OR TITLE)	LEAD OR REFERENCE TO LEGAL TEXT	OBJECTIVES AND KEY FOCUS AREAS	DETAILS
<p>Extension of Authorisation for minor use in the United Kingdom (UK) (formerly known as Scheme for Specific Off-Label Approvals (SOLAs))</p> <p>https://secure.pesticides.gov.uk/off-labels/search.asp</p> <p>Established: 1980–2006</p> <p>Scope: United Kingdom</p>	<p>UK authority (Health and Safety Executive – HSE)</p>	<p>The Long-Term Arrangements for Extensions of Use (LTAEU) were introduced as a temporary measure in the late 1980s to allow pesticides to be used on listed minor crops. Since that time UK pesticide approvals have gradually been transferring to EU-based legislation, where specific approvals are required for all uses.</p> <p>The exercise to replace the LTAEU for use on edible crops by converting uses to Specific Off-Label Approvals (SOLAs) has now been completed. The LTAEU for use on edible crops expired on 31 December 2006. Off-Label approvals for minor uses still exist in UK.</p>	<p>—</p>
<p>Minor use registration</p> <p>Established: 2009</p> <p>Scope: Republic of South Africa</p>	<p>Department of Agriculture, Forestry and Fisheries (DAFF)</p>	<p>Offer farmers and small-scale farmers tools for crop protection.</p>	<ul style="list-style-type: none"> • Provisions for fast-track registration, reduced registration fee and reduced data requirements to accommodate stakeholders wishing to register for a minor use

Appendix 1. Abbreviations used in the tables

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

Appendix 2. List of OECD member countries

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

Crop residues homogeneity across global regions

C. Tiu and J. Barnekow

Abstract

This project has confirmed crop residue data homogeneity and that variability across subsets from different regions is not greater than within any region. The concept also known as “Global Zoning” has been developed since 2000 based on analysis of JMPR-data, and published by the OECD/FAO Zoning Project (May, 2003). Since data reported at JMPR has rarely been generated at consistent Good Agricultural Practices (GAP) at different regions, Dow AgroSciences used internal data to validate the concept for a globally generated residue programme. Data analyzed consisted of residues levels obtained from field experiments where GAP’s (application rate, pre-harvest interval-PHI) were the same across geographical regions/zones, and data has been generated in more than 2 regions. Variables included in this study were geographical zone, trial and replicate within trial, in a nested approach by using JMP statistical software.

KEY WORDS: PESTICIDES, RESIDUES, REGIONS, ZONES, HOMOGENEITY, VARIABILITY.

Objective

Comparative assessment of pesticide residues datasets homogeneity by crop and variability across experiments from different geographical regions (zones) to support global residue programmes and harmonized maximum residue levels (MRLs).

Introduction

Based on the conclusion of the OECD (2003) publication about the OECD/FAO Zoning Project, it is considered that “pre-harvest climatic conditions were not major factors influencing residue variability in comparable residue trials” and therefore “a residue zoning scheme, based on climatic differences alone, could not be proposed because of the high variation in residues reported from comparable trials even within the same climatic zone”. This precedent allowed advancements supporting the development of global residue programmes.

There are, however, precedents for building rationale to support extrapolating crop data between countries (OECD, 2003; Bourma, 2005). It was initially developed for Europe, but it may apply equally to the rest of the world. As the Abstract for the Bourma (2005) paper developed for EPPO says:

“Data on the efficacy and crop safety of plant protection products can be used for registration purposes in other countries, provided crop growth conditions are

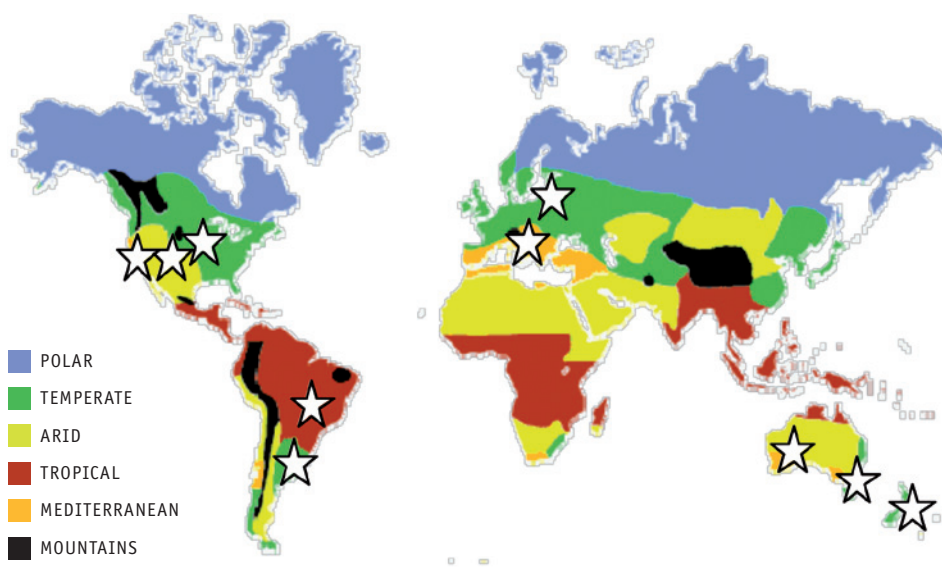
comparable. This article identifies the main conditions which are relevant in this respect, with particular emphasis on climatic conditions. Comparison of several systems of agro-climatic classification developed for the EPP0 region, particularly the climate diagrams of Walter and Lieth, the climate classification system of Köppen and Geiger, the agro-climatic areas of Thran and Broekhuizen and natural vegetation maps, has led to a division of the EPP0 region (Europe, Mediterranean area, Middle East) into four agro-climatic zones (Mediterranean, Maritime, North-east, Central) within which conditions can be considered comparable.”

Indeed, there is almost a perfect overlap of the global biomes over the global climate map, which confirms the theory that certain crops are hosted by the same climate anywhere on the globe (Worldbiomes, 2004; USDA, 1994).

The first regulation to establish the concept of comprehensive global residue programmes was published in September, 2009, in the OECD Residue Guideline 509 (OECD, 2009). This guideline sets out a framework for conduct 40 percent fewer trials for global programmes, while generating a more robust data package than required by any particular regulation, and is yet more representative and inclusive of the global regions.

This particular example of a global residue programme aimed to provide at least 8 trials for each crop from at least 2 regions, from 4 regions typically conducting larger local residue programmes for MRLs setting (US and Canada; Europe; Brazil; Australia and New Zealand); in most cases global programmes had 16 to 30 trials, with a maximum of 44 trials, per crop. Residue data was generated for foliar application of the active ingredient sulfoxaflor over a 2 to 3-year period in four regions of the world (Europe; North America; Australia and New Zealand; Brazil) for 39 crops, to support the OECD global joint review, Codex MRLs and multiple national registration processes. Five representative crops were selected for this statistical analysis of the data: wheat, cabbage, tomato, grape and apple; root crops were not considered due to very low or not detected (ND) residues.

Figure 1. LOCATIONS OF TRIALS IN THE GLOBAL RESIDUE PROGRAMME SUPERIMPOSED ON CLIMATIC ZONES
(CLIMATE ZONE IMAGE COURTESY OF THE UK METEOROLOGICAL OFFICE)



Results of the data analysis should be considered extrapolable then from a few representative crops to all other tested crops, in the same way as is accepted for extrapolating metabolism in crops, rotational crops, storage stability and analytical methods.

Locations of trials in the global residue programme are shown in Figure 1. It should be noticed that residue data is typically generated (in compliance with existing regulations) on crops growing in either temperate, Mediterranean or tropical climates. All are climates that are typically inappropriate for growing most representative crops.

Methods

Before trying to prove homogeneity of the outputs of the global residue programme, inputs have first to be confirmed for homogeneity.

There are two main aspects of inputs relative to the impact on homogeneity and variability on a global residue programme. First, GAPs have been harmonized, by crop and groups, across all regions and labels. This is often a challenge due to regional and seasonal differences in the spectrum of pests and levels of infestation. However, harmonized GAPs are the foundation of harmonized residue data, MRLs, facilitating pest management programmes, and trading of agricultural commodities globally. Second, study plans were standardized and, on a global basis, study monitoring across regions was centralized to comply with the most conservative requirements among regulations, and to ensure consistency of the results across regions.

In order to prove the homogeneity and variability of the outputs from a global residue programme, there are also two main conditions to be fulfilled. First, homogeneity of residue data subsets by regions have to be checked for similarity through several statistical tests: U-test, Wilcoxon, and analysis of variance (ANOVA). All analyses successfully passed the tests for the five selected representative crops: wheat, cabbage, tomato, grape and apple. Similarity should be considered extrapolable then to all other tested crops, based on the same criteria typically accepted when extrapolating data for metabolism in crops, rotational crops, storage stability and analytical methods. Second, crop data analysis for variability must be tested by a multi-level, nested approach (variables: zone, trial, replicates), and has demonstrated consistently that variability across trials (within any zone) is by far the highest contributor to the overall variability.

Therefore, proper methods were considered for systematically harmonizing inputs for the global residue programme, and output results satisfy multiple statistical test methods for homogeneity, similarity and variability. Thus, this analysis includes the methods to present scientific evidence and confirm the validity of global residue programmes to support harmonized MRLs, based on global datasets.

Results from statistical analyses

Residues data from different regions were analysed for eight commodities from the five selected crops: wheat, cabbage, tomato, grape and apple. These crops and commodities are considered representative of the majority of all possible others. Statistical analysis of data was performed by using JMP-9 software (SAS. 2010). Normality and homogeneity of variance of data sets were tested prior to ANOVA

analysis. Residue datasets for this active ingredient showed the best goodness of fit for log normal distribution (68%), followed by normal distribution (21%) and unknown distributions (11%).

Homogeneity of variance was tested using the unequal variance test on the raw residue data, as well as the log, square root and inverse transformations in order to accomplish general linear models and ANOVA assumptions. The data set has homogeneity of variance when $P > 0.05$ for one of the four tests (O'Brien; Brown-Forsythe; Levene; Bartlett). The data set with the highest P value, when $P > 0.05$, was used in the multilevel model.

Below there is a summary table (Table 1) displaying the outputs for residues on the wheat grain dataset to illustrate the methodology to prove homogeneity of variance (best fit is underlined). The global dataset of 35 total trials consists of 5 trials from regions in Australia and New Zealand, 4 trials from regions in Brazil, 12 trials from regions in Europe, and 14 trials from regions in the USA.

The effect of the regions on residues data (i.e. differences between regions) was analysed by a general linear mixed model, with zone as fixed factor and trial as random factor. Trial was nested within zone. This type of design is sometimes called multilevel or hierarchical design, and follows EPA recommendations from the Global Zoning Project Improvement (P. Villanueva, EPA-CLA REWG Meeting, 2008).

To compare residues variability between and within zones (i.e. variability of trial nested within zone), both trial and zone were modelled as random factors. Evaluation of variability within zone and trial was possible because at least 2 residue samples and analysis (replicates) were made at each trial.

The multilevel ANOVA model was run using the transformed residue data that achieved homogeneity of variance across regions.

To illustrate the sequence used by the model, an example is presented below (Figure 2) for the residues on grape square root transformed dataset. In the left column below, the REML variance components estimates show the nested effect in the model for trial and replicate. The Fixed effects test shows whether or not the differences between regions are significant. Since $P > 0.05$, the differences between regions are not significant and data is homogenous. In the right-hand column, the results of the Tukey test show how the means compare between the regions. The test shows all the regions connected by the same letter, which shows there is no significant difference between the means of the residue data by regions.

Results for all crops showed consistently that data analysed for variance by ANOVA is statistically similar across the different regions and zones ($P > 0.05$). A summary of all data analysed by ANOVA test is presented in Table 2.

A variability chart was also produced using the raw data residue values and the parameters: zone, trial and replicate within a nested model type, in JMP, to show the variability of the data and individual contribution from each of the three parameters. In all cases, the variability between trials within any zone was higher than the variability between regions, representing on average 78 percent contribution from trials versus 12 percent average contribution from zone. The remaining 10 percent variation is assumed to be a residual effect proceeding from duplicate samples, analytical variability, etc.

There was only one exception noticed from this common trend. For the wheat forage dataset, the variability between regions had a greater contribution than trials within regions. A closer look at the particular dataset showed that one particular

Table 1. SULFOXAFLOR DATA ON WHEAT GRAIN (LOG TRANSFORM)

TEST	TRANSFORMATION			
	RESIDUE	LOG (residue)	SQRT (residue)	INVERSE (Residue)
O'Brien	0.2560	0.2526	0.2627	0.0085*
Brown-Forsythe	0.4912	0.4909	0.4916	0.0015*
Levene	0.0787	0.0802	0.0761	0.0003*
Bartlett	0.0277	0.0310*	0.0222*	<0.0001*

Notes: * = P>0.05; indicates homogeneity of variance

Figure 2. ANALYSIS OF RESIDUES VARIANCE ON GRAPE

(29 GLOBAL TRIALS: 12 LOCATED IN AUSTRALIA AND NEW ZEALAND, 8 IN EU; AND 9 IN USA)

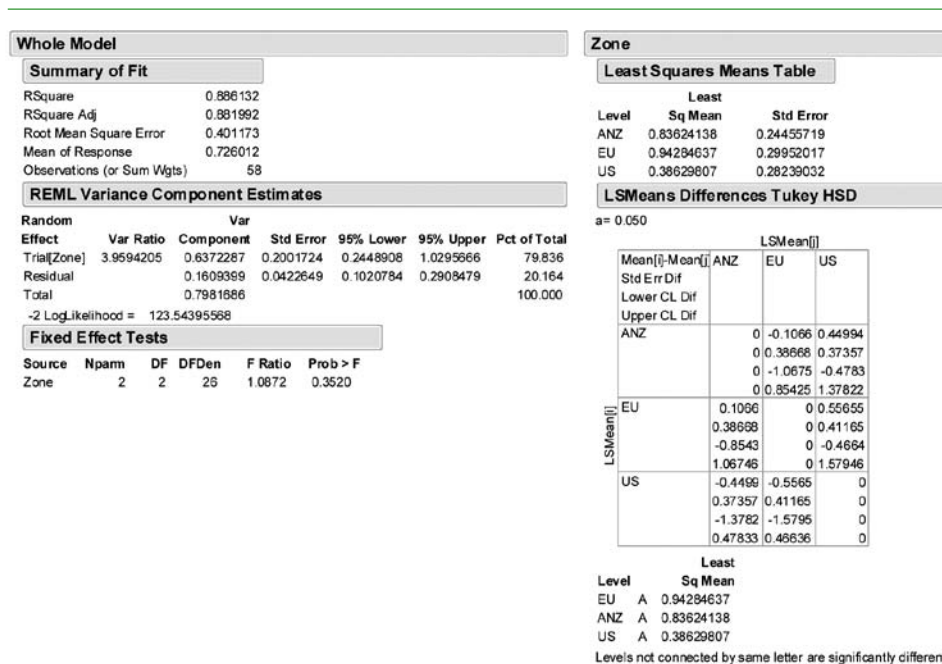


Table 2. SUMMARY OF ANOVA TEST FOR SULFOXAFLOR RESIDUES ACROSS CROP COMMODITIES AND REGIONS

MOLECULE	CROP	REGIONS	No. of TRIALS	F	DF	DFDen	P*
Sulfoxaflor	Apple	ANZ; EU; USA	6; 4; 6	1.1319	2	13	0.3522
Sulfoxaflor	Cabbage	ANZ; EU; USA	2; 6; 6	0.0167	2	11	0.9834
Sulfoxaflor	Grape	ANZ; EU; USA	12; 8; 9	1.0872	2	26	0.3520
Sulfoxaflor	Tomato	ANZ; BRZ; EU; USA	6; 4; 12; 8	1.3274	3	26	0.2869
Sulfoxaflor	Wheat Grain	ANZ; BRZ; EU; USA	5; 4; 12; 14	0.5270	3	31.02	0.6670
Sulfoxaflor	Wheat Forage	ANZ; BRZ; EU; USA	2; 4; 13; 14	0.8831	3	29.07	0.4613
Sulfoxaflor	Wheat Hay	BRZ; EU; USA	4; 14; 14	2.8060	2	29	0.0769
Sulfoxaflor	Wheat Straw	ANZ; BRZ; EU; USA	5; 4; 13; 14	0.0382	3	32	0.9898

Notes: ANZ = Australia and New Zealand; BRZ = Brazil; EU = European Union
 * = P>0.05; indicates similarity of variance across regions

sample was taken at field moisture content corresponding to hay (average 17 percent). To ensure consistency across forage data, the particular data point can be adjusted by a conservative factor of 4 to bring it up to the average moisture content in forage samples from the same study, or all data can be brought to the common denominator, as on a dry basis. Thus, it can be concluded that, in all cases, the variability due to zone is the least contributor to the overall variation across datasets.

An example of variability of residues on wheat forage, across regions is presented below. The example presents comparatively both the original dataset, as well as the adjusted set, to account for outlier moisture content of one sample (that corresponded to hay).

Figure 3. SULFOXAFLOR RESIDUES VARIABILITY CHART BY REGIONS – WHEAT FORAGE (ORIGINAL DATASET)

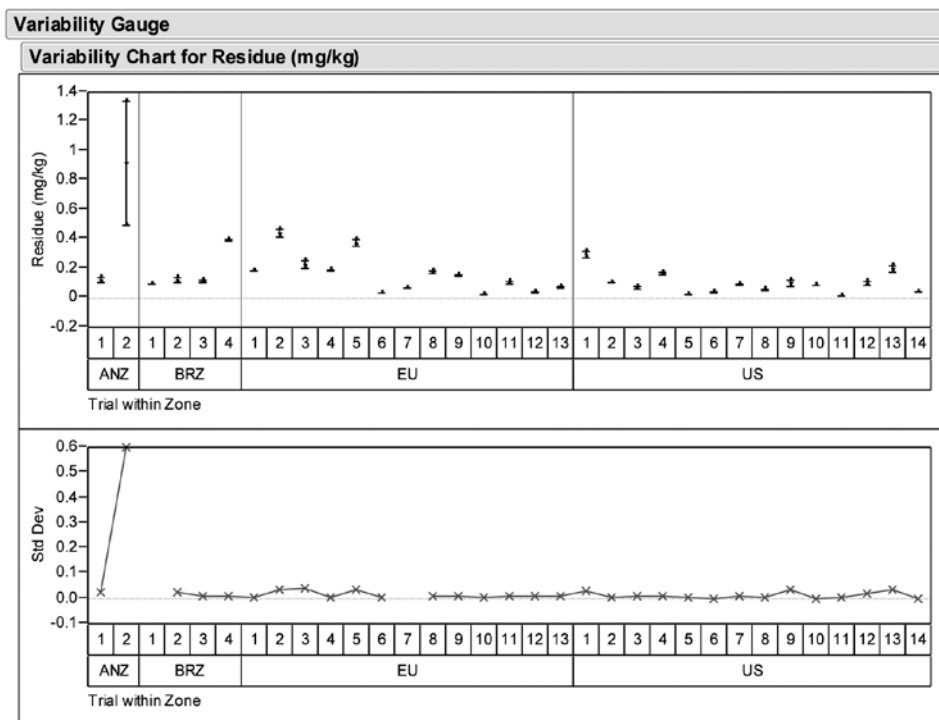


Figure 4. SULFOXAFLOR RESIDUES VARIABILITY OF PARAMETER – WHEAT FORAGE (ORIGINAL DATASET)

REML Variance Component Estimates

Random Effect	Var Component	Pct of Total
Zone	0.0227793	44.159
Trial[Zone]	0.0170177	32.989
Residual	0.0117882	22.852
Total		100.000

-2 Log Likelihood = -48.58011843

Variance Components

Component	Var Component	% of Total	Sqrt(Var Comp)
Zone	0.02277933	44.2	0.15093
Trial[Zone]	0.01701766	33.0	0.13045
Within	0.01178818	22.9	0.10857
Total	0.05158517	100.0	0.22712

Figure 5. SULFOXAFLORES RESIDUES VARIABILITY CHART BY REGIONS – WHEAT FORAGE (ADJUSTED MOISTURE ONE HAY SAMPLE)

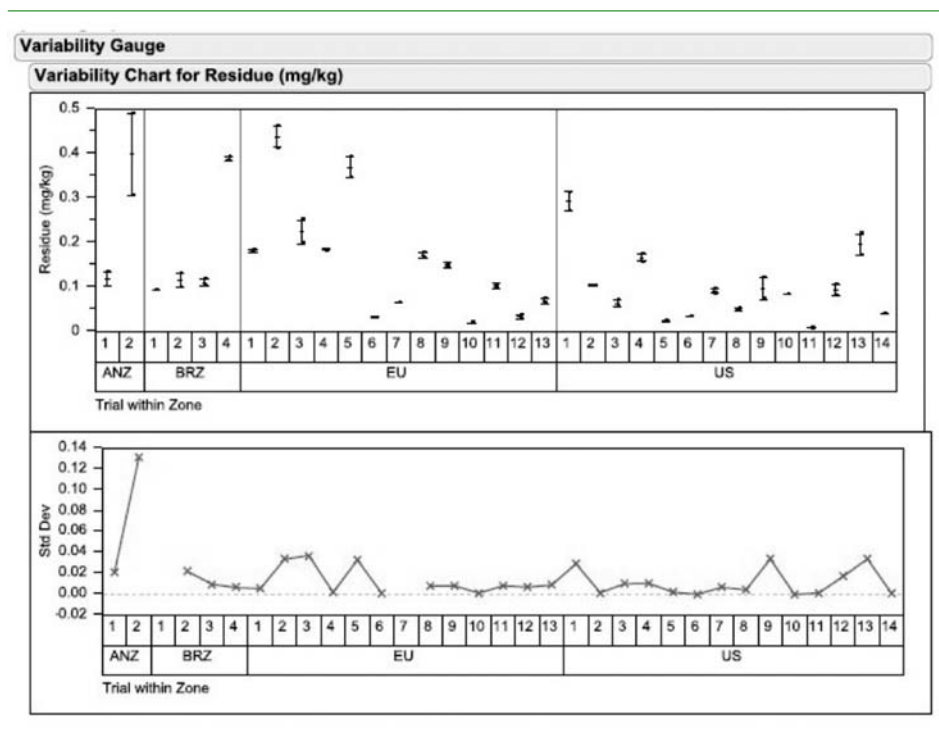
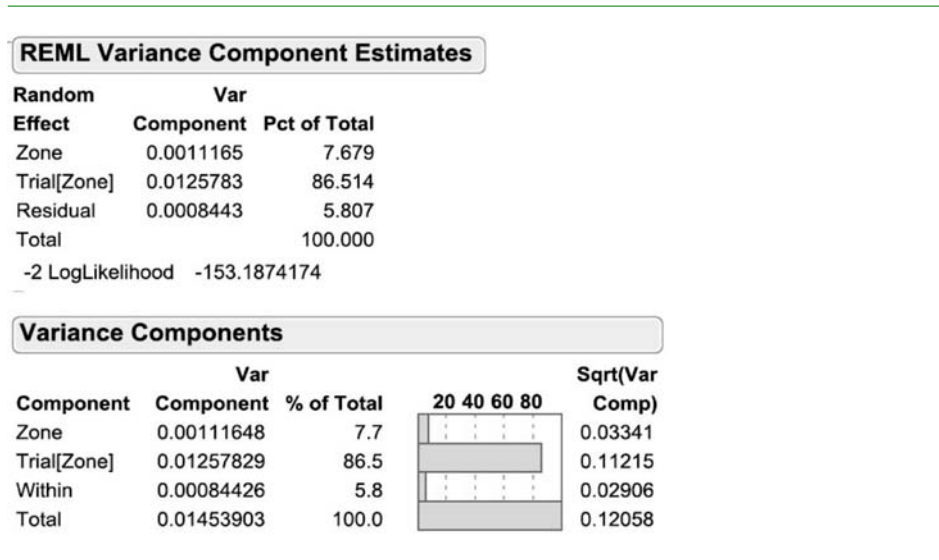


Figure 6. SULFOXAFLORES RESIDUES VARIABILITY OF PARAMETERS – WHEAT FORAGE (ADJUSTED MOISTURE ONE HAY SAMPLE)



The JMP outputs are summarized in the next page across crops, commodities and regions (Table 3). It confirms the consistency of results for all crops, the greatest variance proceeding from variability of trials within either region, while variability between regions is contributing to a much less extent (by 2-20x).

Table 3. SUMMARY RESULTS FROM VARIABILITY PLOTS, ACROSS CROP COMMODITIES

MOLECULE	CROP/PHI/ RATE	REGIONS	NO. OF TRIALS	% VAR. ZONE	% VAR. TRIAL [ZONE]	% VAR. RESIDUAL
Sulfoxaflor	Apple	ANZ; EU; USA	6; 4; 6	29.0	55.0	16.0
Sulfoxaflor	Cabbage	ANZ; EU; USA	2; 6; 6	9.2	65.9	24.9
Sulfoxaflor	Grape	ANZ; EU; USA	12; 8; 9	5.8	84.9	9.3
Sulfoxaflor	Tomato	ANZ; BRZ; EU; USA	6; 4; 12; 8	5.9	87.9	6.2
Sulfoxaflor	Wheat grain	ANZ; BRZ; EU; USA	5; 4; 12; 14	5.3	86.8	7.9
Sulfoxaflor	Wheat straw	ANZ; BRZ; EU; USA	5; 4; 13; 14	4.4	93.9	1.7
Sulfoxaflor	Wheat hay	BRZ; EU; USA	4; 14; 14	31.7	59.3	9.0
Sulfoxaflor	Wheat forage	ANZ; BRZ; EU; USA	2; 4; 13; 14	44.2	33.0	22.9
Sulfoxaflor	Wheat forage (adjusted)	ANZ; BRZ; EU; USA	2; 4; 13; 14	7.7	86.5	5.8

Notes: ANZ = Australia and New Zealand; BRZ = Brazil. EU = European Union

Conclusions

Residues data from a comprehensive and harmonized global residue package produced in four different regions of the world were analysed for eight commodities representing five selected crops: wheat, cabbage, tomato, grape and apple. These crops and commodities are considered representative of the majority of all possible others. Statistical analysis of data was performed using JMP-9 software. Residue datasets for this active showed the best goodness of fit for log normal distribution (68%), followed by normal distribution (21%) and unknown distributions (11%). Homogeneity of variance was tested using the unequal variance test. Results for all crops showed that data analysed by ANOVA is statistically similar across the different regions and zones ($P > 0.05$). The results of the Tukey test shows there is no significant difference between the means of the residue data by regions.

The effect of the regions on residues data was analysed by a general multilevel linear mixed model with zone as fixed factor and trial as random factor. Trial was nested within zone. Variability between trials within a zone was higher than the variability between regions (2-20x). It represented on average 78 percent versus 12 percent average contribution from zone. The remaining 10 percent variation is assumed to be a residual effect proceeding from duplicate samples, analytical variability, etc.

Since the residue data has been produced in a harmonized way and the output results satisfy all statistical tests, it is concluded that data is homogeneous across regions and variability between regions is smaller than the variability of trials within individual regions. Therefore, global datasets by crops consolidating residue data across regions can be used as such, to propose harmonized MRLs (e.g. at JMPR 2011 pilot project, as recommended by the first Global Minor Use Summit in December 2007). When GAPs across regions can be aligned and similar residue study designs are used, this approach can facilitate the use of shared residue data across regions and zones, resulting in a more robust dataset than available for individual regions, and applicable to harmonization of MRLs for crops that are traded between countries as a result of the globalization of agricultural production.

References

- Bourma, E.** 2005. Development of comparable agro-climatic regions for the international exchange of data on the efficacy and crop safety of plant protection products. *Bulletin OEPP/EPPO Bulletin*, 35(2): 233–238.
- OECD [Organisation for Economic Co-operation and Development].** 2003. Registration and Work Sharing. Report of the OECD/FAO Zoning Project. ENV/JM/MONO(2003)4. *OECD Series on Pesticides*, No. 19.
- OECD.** 2009. OECD Guideline for the testing of chemicals, TG 509: Crop Field Trial.
- SAS.** 2010. JMP Pro. Version 9.0.1. Computer software from SAS Institute Inc., Cary, NC, USA, used under licence by The Dow Chemical Company.
- USDA [United States Department of Agriculture].** 1994. Major World Crop Areas and Climatic Profiles. USDA, World Agricultural Outlook Board, Joint Agricultural Weather Facility. *Agricultural Handbook* No. 64. Revised September 1994.
- Worldbiomes.** 2004 [Online]. See: <http://www.worldbiomes.com/>

MINOR USE DEVELOPMENTS IN COLOMBIA AND THE ANDEAN REGION

Maria Cristina Torres Villamil

OVERVIEW OF MINOR USE ACTIVITIES WITHIN AUSTRALIA

Kevin Bodnaruk, Janine Clark, Peter Dal Santo and Alan Norden

OVERVIEW OF BRAZILIAN MINOR USE ACTIVITIES

Luis Rangel and Juliano dos Santos Maly

CANADIAN MINOR USE PESTICIDES PROGRAMME

Manjeet Sethi and Shirley Archambault

USER-REQUESTED MINOR USE PROGRAMMES OF THE HEALTH CANADA – PEST MANAGEMENT REGULATORY AGENCY

John Worgan

EU MINOR USE PROGRAMME – EU EXPERT GROUP ON MINOR USES

Johan Roman and Jean-Claude Malet

ORPHAN USES COMMITTEE

Jean-Claude Malet

EXPERT CENTRE FOR SPECIALITY CROPS

Johan Roman

THE UNITED STATES IR-4 PROJECT

Dan Kunkel, Jerry Baron and Diane Infante

CHALLENGES RELATED TO SPECIALTY CROPS AND MINOR USES OF PESTICIDES IN AFRICA AN EAST AFRICAN PERSPECTIVE

Lucy Namu

MINOR USE INCENTIVE SCHEMES GLOBALLY INDUSTRY PERSPECTIVE OF SUCCESS

Vassilia Sgouri and Sandra Keller

Minor Use developments in Colombia and the Andean region

Maria Cristina Torres Villamil

There is a clear need for appropriate data and the sharing of that data for the benefit of countries like Colombia and the Andean Community (CAN; Bolivia, Ecuador and Perú) in South América. The area has a great range of biodiversity, there are enormous difficulties in registering specific chemical pesticides for agricultural use, not to mention the difficulties inherent in establishing maximum residue limits (MLRs), and these are barriers that limit exports and competitiveness.

The countries have a wide range of crops. Colombia, for example, lists 117 crops, of which 89 are minor crops (76 percent of total number of varieties grown), especially fruits, vegetables and herbs. For these minor crops, 47 have no pesticides registered, and therefore have no MRLs and yet they are a basis of the diverse diet and consumption pattern. However, there is no possibility that the chemical industry will register pesticides for each of them, because cultivated areas are not very extensive. For these reasons, collaboration among producers, countries, governments, industries and organizations is needed. Examples of this are the regulatory modifications in the Andean Community to benefit the register of pesticide for minor crops, which were formalized with Decision 767 of the Andean Community Commission on 7 December 2011. The most important elements of that are to:

1. Determine the validity of the registration of Pesticidas Químicos de Uso Agrícola (PQUA; Agricultural Chemical Pesticide Use).
2. Make possible the importation into the countries of the Andean Sub-Region of substances codified as 'under development' for the purpose of investigating their value for local agricultural use, if suitable national capacities exist to assure that the risks for health and environment are minimized.
3. Extend authorization for import, production, formulation and use of chemical pesticides for agricultural use that are not registered in the country, but only in the case of phytosanitary emergency officially declared by the National Authority for a specific crop-pest combination and only for the duration of the emergency.
4. Make possible a new registration for a product , but with a different name.
5. Modify the National Register of a Chemical Pesticide for agricultural use if there is:
 - a change in record title;
 - addition of a manufacturer, product formulator or the country of origin, to the registration holder;
 - removal or addition of applications (introduction of new crops or pests to be treated) for which the product was registered, or when the dosage of the formulated product is modified; or
 - a toxicological re-classification of a product.

Another example is the official acceptance of the codex MRL in countries like Colombia, but with restrictions on tropical crops typical of the region. At this point it is important to note that the collaborative work between countries with similar crops and industry will serve to facilitate permission for field trials to provide the basic data required for the establishment of the MRLs, thus benefiting many crops and countries.

The type of data required is considered to be the list of countries interested in participating, the list of priority crops (particularly tropical fruits in the local context), information on pests, substances for which MRLs need to be determined, procedures to implement the field trials necessary to support the establishment of MRLs for minor and specialty crops in order to facilitate data submission to Codex JMPR, and a global recognized mechanism to accompany the process and set the technical parameters for accessing results as Codex instances. In order to ensure the validity of the work to be done and to be of benefit to national interests, the information should be collected by the entity responsible for the registration of pesticides, by local specialists trained for the process.

In support of this, Colombia has advanced the classification and regulation for minor uses, and in the grouping of tropical fruits, vegetables and herbs has established 13 fruit and vegetables groups and 4 herb groups, identifying representative crops as well as methods for expanding pesticide registration. This initiative, from the perspective of the needs of producing countries, is the first point to address, allowing the identification of minor uses in each country, or even region, and enabling extension of MRLs.

The benefits of grouping are:

- If the extension of use refers to the same plant pathogen that attacks other crops, the results of performance tests could be used to expand the use into a new culture.
- It militates against farmers improperly using unauthorized plant protection products against pests associated with these minor crops.
- It assists the objectives of reducing time and cost of registration, through extrapolation of efficacy trials and respective holding periods.

In connection with the financing of these initiatives, given the importance of the process for developing countries that require rapid progress in this field, it is proposing that regional projects be established, financed by international organizations or regional and local resources.

Regarding databases, the Codex EWG on Minor Uses and Specialty Crops promotes the use of the FAOSTAT database and the GEMS Food Cluster Diets, although they only contain detailed information for major crops. It is therefore recommended that the fruit and vegetable fields be unbundled, with interest focusing more on promoting work that could be made on a regional or geographical zones basis, starting with the prioritization of the list of minor crops and producing countries, with annual reporting.

Overview of Minor Use activities within Australia

Kevin Bodnaruk (AKC Consulting Pty Ltd), Janine Clark (Growcom Australia), Peter Dal Santo (AgAware Consulting Pty Ltd) and Alan Norden (Australian Pesticides and Veterinary Medicines Authority)

Introduction

The approval of safe and effective agricultural chemical products within all Australian agricultural sectors is a national issue, particularly for those minor users of agricultural chemicals whose use is not sufficiently economically attractive for a manufacturer to seek registration.

Before a chemical product can enter the Australian market, it must first be registered with the Australian Pesticides and Veterinary Medicines Authority (APVMA). Following registration, users of agricultural chemical products in Australia must comply with the control-of-use legislation that applies in their particular State. This legislation can vary between States, particularly with respect to what constitutes legal off-label use, but as a general rule only products registered by the APVMA can be used for labelled-use patterns. Product registration and new use patterns may only be submitted to the APVMA by the product registrant. To provide for 'minor uses' that do not attract commercial investment by registrants, users and affected industries may apply to the APVMA for consideration of a minor use permit to authorize an off-label use.

Five sectors represent the majority of minor use permit applications lodged, namely vegetables; fruit and tree nuts; non-crop situations; broad-acre crops; and forestry. Horticultural crops represent the vast majority of minor use permit applications at more than half of all applications. No central or single national minor use programme is established within Australia, although there is coordination of data generation and the making of regulatory submissions amongst a number of industries, most notably horticulture and grains via their respective research and development (R&D) arms.

There are approximately 900 current minor use permits issued by the APVMA. Copies of these permits may be obtained from the APVMA website at: <http://www.apvma.gov.au/permits/search.php>

User industry approaches to addressing needs

As noted above, users and affected industries may seek to have regulatory approvals granted for off-label uses that would otherwise be an offence, in the form of a minor use permit. Whilst no one central or single national minor use programme is established within Australia, the horticultural and grains industries through their respective R&D arms coordinate the necessary data generation and regulatory submissions for a large proportion of minor use permit applications lodged with APVMA.

Horticultural crops

Horticulture Australia Limited (HAL) operates the largest programme within Australia, and engages with its member industries to identify needs, prioritize projects, fund data generation (where necessary) and make regulatory submissions.

The HAL Minor Use Project regularly undertakes a Strategic Agrichemical Review Process (SARP). To date, fifty-four horticultural industries have conducted a SARP, with several more planned and some industries planning to update their SARP in 2012. The process aims to identify key minor use priorities by examining existing registrations and where a lack of suitable options exist to control key pests and diseases. The identification of new options for which industry would pursue minor use permits includes considerations of resistance management, their suitability for use in conjunction with Integrated Pest Management (IPM) and trade.

Since its inception in 1998, approximately AUS\$ 7.2 million has been invested by HAL through the minor use programme, with approximately AUS\$ 5.8 million of this by the vegetable industry. Annually, submissions to the APVMA from the HAL programme accounts for approximately half of all applications lodged by the horticulture sector, with other submissions lodged independently by individual growers or peak industry bodies at their own cost. In 2011 alone, the HAL minor use programme funded and commissioned AUS\$ 1.4 million of minor use projects, making 140 minor use permit applications and having 122 minor use permits issued by APVMA.

Broad-acre grains (including minor cereals, oilseeds and pulses)

In addition to activities in the horticulture sector administered by HAL, the Grains Research and Development Corporation (GRDC) has also, for a number of years, run a "Pesticides for Minor Uses in Grain" programme that seeks to address minor use issues facing Australia's grain, oilseed and pulse industries. The programme engages with industry bodies such as Pulse Australia Ltd and the Australian Oilseeds Federation, and provides regulatory assistance to those organizations in the development and submission of minor use permits. Over the period 1998/1999 to 2009/2010, AUS\$ 3.2 million (present value) has been invested in the grains minor use programme. Over half of the 25 grains crops covered by GRDC are classified as minor. Similar to horticulture above, a strategic review has been completed for 12 grain crops, examining existing pesticide options from the perspective of threats: resistance,

regulation, trade, etc. Minor grains, oilseeds and pulses comprise approximately 12 percent of all minor use submissions, and as with HAL, the programme does not administer all permits applied for by this sector.

Further details about the GRDC “Pesticides for Minor Uses in Grain” project may be found at: <http://www.grdc.com.au/director/events/grdcpublications/minoruses.cfm>

The legislative and regulatory landscape

‘Minor use’ is defined in legislation as

“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)”

Further details regarding minor use criteria are explained in the APVMA Guidelines for Determining Minor Uses, available at http://www.apvma.gov.au/publications/guidelines/docs/minor_uses_guide.pdf

As outlined above, there are two principle regulatory mechanisms utilized for the approval of new uses, namely (1) product registration (approved on-label uses); and (2) minor use permits (approved off-label uses). The product registrant or permit applicant (as the case requires) must provide appropriate supporting information to the APVMA to demonstrate that the proposed chemical product and its use(s) will be safe and effective. Generally this requires the provision of scientific data on the product and proposed use(s) covering key areas such as toxicology, residues for both local and overseas markets, occupational health and safety, environment, efficacy and crop safety.

The APVMA will usually require locally replicated trial data supporting the proposed use in Australia. However, the APVMA will consider overseas or other data provided it can be demonstrated that the data are scientifically relevant to the proposed use in Australia. This is particularly relevant to the consideration of efficacy, crop safety and residue data provided in support of permits for minor uses.

Generally, minor use permit applications seek to use existing registered products in a manner similar to the currently approved use patterns of major crops. Therefore issues such as worker safety and environmental impact remain essentially unchanged and the APVMA can often rely on the existing risk assessments. This is often also the case for efficacy and crop safety requirements, where similarities with currently registered use pattern(s) can be demonstrated. As a result, the APVMA rarely requires detailed data for permit applications seeking to use currently registered products for related minor uses. A principle consideration for the APVMA is whether a suitable Maximum Residue Limit (MRL) can be established for the proposed use.

In establishing MRLs, the APVMA considers all available data, including overseas data if available and determined relevant. The APVMA in the consideration of Permits for minor uses regularly extrapolates residue data between like commodities, provided that the data is sound and a similar use pattern is being proposed. This often allows the APVMA to establish Temporary MRLs to enable Permits to be issued for interim periods whilst additional local supporting data is generated, usually over 2 to 3 years. The level of data requested reflects the minimum required for sound

decision making, while keeping regulatory costs for minor uses to a minimum. The APVMA has published guidelines outlining residue data requirements for new uses; a copy of this document is available at http://www.apvma.gov.au/residues/docs/residues_and_minor_crops_info.pdf

Further details on the process and requirements for minor use permits are available at <http://www.apvma.gov.au/permits/agricultural/index.php>

Reference sources

Minor Use of Agricultural and Veterinary Chemicals in Australia. Report of the OECD Pesticide Risk Reduction Group Seminar on Minor Uses and Pesticide Risk Reduction (see pages 26–33). [http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono\(2005\)4&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf?cote=env/jm/mono(2005)4&doclanguage=en)

Submission on Reforms to Deliver Sustainable Minor Use Crop Protection Solutions for Australia’s Agricultural Industries. Dr Stephen Goodwin, Biocontrol Solutions (March 2011). http://www.daff.gov.au/__data/assets/pdf_file/0006/1906197/aus-minor-use-industries.pdf

Overview of Brazilian Minor Use activities

Luis Rangel (General Coordinator of Pesticides, Ministry of Agriculture) and

Juliano dos Santos Maly (Specialist in Regulation and Sanitary Monitoring, ANVISA)

Introduction

Brazil has a population nearly 200 million people, distributed in regions with different characteristics that provide particular challenges for food production. This is especially true for the supply of fresh food like fruits and vegetables that are environmentally safe and healthy, while providing economic security for growers. Part of the challenge is also competing in a globalized and demanding market.

The challenge of safe food production is closely related to the management of these crops, including the use of pesticides. However, Brazil has the same problems faced by other countries in terms of pesticides for crops of minor economic importance, and the solutions designed and implemented by the Brazilian government are not very different from solutions elsewhere, but nevertheless we need to consider local particular systems of crop production.

Although the methodology of pesticides registration in Brazil is clear, it involves the participation of the Federal Agencies of Agriculture, of Health and of Environment. It is therefore a complex procedure, with high costs for agrochemical companies. Since the governmental requirements are complex and the demand for registration of products comes solely from the pesticides companies, companies prefer not to spend time and money on Minor Crops. In addition, Brazilian rules require has request the residues studies at in a different level toas others countries, to the extent that considering that in some cases authorities do n’ot require studies to register some pesticides. It is an important issue to solve and make building a data bank for residues in Brazil more reliable.

In addition, our legislation to request the residues studies is different from others countries, considering, for example, that sometimes we don’t require these kind of studies to register some pesticides. This fact can make our residues studies database less strong. Therefore, since the early 1990s, this issue has been discussed in Brazil in order to find a solution to the problem. One result has been the strategy of grouping plant cultures, as recently included in the Brazilian legislation for pesticides, published in 2010, respecting the peculiarities of the Brazilian market. In developing this legislation, consultations were held with the staff of the IR-4 Program of the United States; the U.S. government through USDA; and the Canadian government, specifically Agriculture and Agri-Food Canada (AAFC) and Health Canada’s Pest Management Regulatory Agency (PMRA).

The legislation

The Brazilian Law for Minor Uses is based on the grouping of crops for the purpose of extrapolating data from “major” crops to “minor” crops. These groups are often defined according to the form of consumption (edable.g. peeled or unpeeled), broad botanical characteristics (consumed as tubers, leaves, fruit, nuts, etc.), and similar Good Agricultural Practice (GAP). There are two main cultures representing these groups: those not considered minor because there are a large number of active ingredients registered for use, for “minor Uses which the data from the crops with existing data will be used to provide MRLs and registrations for these minor uses; and those where some data extrapolation is also allowed among the crops considered minor, and where data can be generated on representative crops to cover other crops of the sub-group. The crops selected for data generation are those of greater economic interest, and hence chosen as the culture in which the residue studies are conducted.

Challenges

Some technical difficulties were observed after the Law came into force. Although some crops are similar botanically and have the same pests, good agricultural practices for a defined culture may not match another exactly, requiring the testing of efficacy and phytotoxicity for each culture, which requires time and expense for the agrochemical companies.

Moreover, some companies were concern about including specific cultures on product labels without a full investigation of potential phytotoxicity, efficacy and residues.

Currently the Brazilian government does not have a framework for public funding norto conducting Pesticide Residue Studies under Good Laboratory Practices (supervised studies).. For this reason, the Brazilian government is investing in the implementation of such a structure through the Brazilian Agricultural Research Corporation (Embrapa), and it is expected to be completed in 2012.

Another point of intense discussion is in relation to data protection. The Brazilian government decided that the duration for protection of data from Pesticide Residue Studies is one year, which, in principle, can be considered short.

Expectations

After the publication of the Law, the Brazilian government intends to:

- Increase the supply of pesticides for minor crops, offering products of low toxicity, such as modern chemicals, and considering the effect of the pesticides on the applicator and on IPM (beneficial natural enemies), with the goal of producing safe crops. In this way, some chemicals have been restricted in the review process for use in Minor Crops, because they have issues like high toxicity (most organophosphates, chlorinated hydrocarbons, etc.) or high occupational risk, especially considering the common agricultural practice asof backpack applications, which is widely used in Brazil, especially for crops grown on small areas.

- Increase knowledge on the subject for all involved, including producers, agrochemical companies and the government. To this end, the government organized the first annual workshop with the participation of all those sectors, on 26 October 2011.

After increasing our knowledge and production data for Pesticide Residue Studies, we hope to participate in projects and studies with other countries in the world, sharing not only data but also MRLs for Minor Crops.

Expectations for the Second Global Summit on Minor Uses

- Show the current status of Minor Crops in Brazil: difficulties, challenges and future strategy.
- Encourage the implementation of laws for Minor Crops in Latin America.
- Gain from other's experience with Minor Crops worldwide.
- Receiving criticism and suggestions on our performance and our legislation on Minor Crops.

Strategic actions for projects in Brazil

We currently have multiple demands from growers and industry. Considering that cost for all pesticide residue studies in the next two years will be borne solely by the pesticide industry, the Brazilian government's intention is to create priorities for the implementation of these studies, as follows:

- Priority I: Projects that simultaneously meet the demands of growers and industry.
- Priority II: Projects that exclusively meet the demands of the pesticide industry.
- Priority III: Projects that exclusively meet demand from farmers.

All projects will be analysed for the toxicological potential of each active ingredient. Projects with products that are not of interest to the government will be discouraged.

Canadian Minor Use pesticides programme

Manjeet Sethi and Shirley Archambault

Pest Management Centre, Agriculture and Agri-Food Canada

Introduction

Canadian farmers require safe and effective tools to manage weed, insect and disease problems that can threaten the quality, value and quantity of the crops they produce. Lack of access to pest management solutions can affect grower competitiveness, particularly in a country like Canada.

The Minor Use Pesticides Programme

The Minor Use Pesticides Programme was launched in June 2002 as a joint initiative between Agriculture and Agri-Food Canada (AAFC) and the federal regulator, Health Canada's Pest Management Regulatory Agency (PMRA), to increase access to new and effective crop protection tools and technologies. The Programme, which has been fortified under the federal Agricultural Regulatory Action Plan of the Growing Forward policy initiative, aims to increase grower competitiveness by improving access to new and effective crop protection tools and technologies.

The Minor Use Pesticides Programme works with growers, the provinces, manufacturers and the United States IR-4 Specialty Crops programme to establish grower-selected crop and pest needs, and match them with potential solutions, particularly reduced-risk products. As the front line guardians against pest issues, growers know from experience the types of persistent and emerging pest problems that can have serious effects on their operations. It is for that reason that growers select priorities at an annual priority-setting workshop.

AAFC then conducts field and greenhouse trials and commissions laboratory analyses to collect the required data, including efficacy and residue information, before drafting regulatory submissions to PMRA for the registration of new minor uses. Many of these new uses replace older chemistries and formulations which have been taken off the market.

These efforts assist in moving new products through the regulatory system, thus helping Canada's producers to compete in global markets.

Objectives

The Minor Use Pesticides Programme will provide benefits to Canadian producers, the environment, and consumers by focusing on:

- making minor use pesticide products, with emphasis on reduced-risk products, more readily available; and
- providing Canadian producers with access to new pest-management technologies to improve their competitiveness domestically and internationally.

Programme delivery

For many years, Canadian producers, especially those involved in the horticultural and specialty crop industries, have not had access to the same range of pesticide products as producers in other countries. Because growing minor crops involves so many diverse products and involves small acreages, many manufacturers have been unwilling to invest the time and money required to pursue pesticide registrations, despite the importance of this part of agricultural industry.

Now, AAFC is conducting field trials to generate the data needed to support submissions to the PMRA for registering minor use pest control products. This activity complements the existing roles and responsibilities of pesticide manufacturers in submitting products to the PMRA for registration, and encourages manufacturers to register products in Canada.

As a result, newer, more environmentally friendly and more efficient products will be made available to Canadian producers, which should help to level the playing field and allow them to be more competitive in global markets.

AAFC has modelled its new programme after the successful United States minor use pesticide programme, called Interregional Research Project No. 4 (or simply IR-4). AAFC is working closely with IR-4 officials to share information, consult on programme content, and build strong relationships. This collaboration provides the opportunity to work together on field trials and improve ways to support registrations, so that more registered minor use pesticides are available to producers in both countries at approximately the same time and with the same MRLs and tolerances.

Under the Minor Use Pesticide Programme, AAFC works with provincial governments, industry representatives and producers to:

- match pest problems with minor use pesticide solutions;
- establish priorities and gain industry support;
- conduct field trials; and
- prepare submissions for new pesticide uses to the PMRA.

Matching pest problems and priorities

Producers and producer groups in each province meet annually with their provincial minor use coordinator to identify and prioritize the major pest problems in their regions.

These pest problems are then matched with potential pesticide solutions, using input from pesticide manufacturers, to produce provincial lists of pest priorities and

possible solutions in three categories: weed, disease and insect pest problems. Non-chemical solutions, such as biopesticides, are also considered.

Provincial lists are then combined to form one national list, which is used at the annual AAFC Minor Use Pesticide Priority-Setting Workshop, usually held in March, to develop national priorities. Representatives from a broad range of stakeholder groups attend the workshop: provincial minor use coordinators, producers, PMRA, the pesticide industry, crop specialists, as well as representatives from the IR-4 programme and provincial and federal governments.

Establishing priorities and gaining industry support

At the workshop, participants reach a consensus on the top national priorities in each pest category, and additional priorities are determined to address regional needs. The agreement of manufacturers is sought to include the new, approved use(s) on the product label.

Conducting field trials and laboratory analyses

Once the priorities are established, AAFC's Pest Management Centre (PMC), in consultation with industry and government partners, undertakes to:

- obtain formal manufacturer support;
- prepare documentation to determine any additional data requirements;
- conduct field trials and lab analyses;
- provide quality assurance for the data-generation process;
- integrate data generated in Canada with the IR-4 pesticide programme;
- prepare registration submissions to Health Canada's PMRA; and
- provide transparent tracking and reporting of results to stakeholders.

While the Centre's headquarters are located in Ottawa, it conducts field trials at sites across the country. Staff at the 10 AAFC sites have undergone training to meet the Standards Council of Canada Good Laboratory Practices (GLP) recognition standards for carrying out trials and generating data on minor use pesticides. In addition, private contractors are used.

Preparing submissions for PMRA review

PMC reviews the data resulting from field trials and laboratory analyses, and prepares a submission to the PMRA to support the registration of the minor use pesticide.

Once the Centre has finalized a regulatory submission, the PMRA reviews it and decides whether or not to accept the pesticide for use in Canada. The PMRA bases its decision on whether the product demonstrates merit and value, and whether the risks to human health and the environment are acceptable.

When the PMRA accepts a pesticide for registration, it posts a notice on the Pest Management Regulatory Agency Web site, with a link to the AAFC Pesticide Risk Reduction and PMC Web site.

In addition, grower groups and provincial governments may also submit minor use proposals through a provincial minor use coordinator to the PMRA to address local and regional pest management problems.

Collaboration between the United States and Canada

Collaboration between the PMC and the IR-4 programme has substantially increased. The appropriate data is jointly accumulated in the United States and Canada, with submissions made to respective pesticide regulatory agencies concurrently (in Canada, to Health Canada's PMRA, and in the United States to the Environmental Protection Agency (EPA)). This saves time by reducing duplication of data collection activities. Through these efforts, growers on both sides of the border with the same crop and pest problems can have new uses of crop protection products registered in both countries simultaneously. Since 2003, numerous joint Canada/USA minor use projects have been undertaken.

User-Requested Minor Use Programmes of the Health Canada – Pest Management Regulatory Agency

John Worgan

Health Canada

Health Canada's Pest Management Regulatory Agency (PMRA) is the federal regulator for pest control products in Canada. There are two user-requested programmes that have been created to address user needs: the User-Requested Minor Use Registration (URMUR) programme and the User Requested Minor Use Label Expansion (URMULE) programme. The two programmes differ in that the URMUR programme covers pesticides not yet registered in Canada, whereas the URMULE programme is intended for label expansions of registered pesticides. Minor uses are also often added under regular registrant submissions.

Under the URMULE programme, applications can be made to the PMRA by either Provincial or Forestry Minor Use Coordinators or by the Pest Management Centre (PMC) of Agriculture and Agri-Food Canada (AAFC). Registrant support must be provided with the application to the PMRA. The application is reviewed by the PMRA to ensure that the human health and environmental risks are acceptable and that the proposed use has value. Scientific reviews include dietary and occupational exposure assessments as well as environmental and value assessments. For agricultural food crops, crop field trial residue data as well as value data are typically required to support the addition of the crop to the product label. Additional data, such as dislodgeable foliar residue data may be required, on a case-by-case basis, to refine the exposure assessment. If the product is found to have value and the human health and environmental risks are considered acceptable, the registration can be supported and the registrant is notified of the registration decision through a regulatory decision letter. It is then the responsibility of the registrant to submit a different application to have the minor use added to their product label.

The URMULE programme has evolved significantly over the past few years, especially with the establishment in 2002 of the Pest Management Centre of Agriculture and Agri-Food Canada to address the data requirements for the registration of minor crops in Canada. Previously, grower groups and organizations were responsible for the generation of residue and efficacy data, and often adequate funding was not available. PMC conducts many projects jointly with the United States Interregional Research Program No. 4 (IR-4) minor use programme. These projects are submitted for joint

regulatory review to Canada and the United States. This results in the registration of the minor uses at the same time in both countries and also facilitates the alignment of Maximum Residue Limits (MRLs).

The PMRA works collaboratively with PMC/AAFC, the provincial and forestry minor use coordinators, registrants and other stakeholders to ensure that the URMULE programme continues to meet the needs of Canadian growers. For example, PMRA provides regulatory advice at AAFC's annual Minor Use Pesticide Priority-Setting Workshop, meets PMC regularly to discuss minor use issues, and also participates in a Federal/Provincial Territorial Working Group for continued improvements to the minor use programme.

There are a number of regulatory incentives in place to encourage the registration of minor crops in Canada, including fee reductions or waivers, the Protection of Proprietary Interests in Pesticide Data Programme, and the use of a liability statement by the registrant on their label for the minor use expansion.

PMRA is currently considering further regulatory flexibilities that would promote label use expansions for minor crops. These include a flexible approach to value through consideration of history of use in foreign jurisdictions; economic benefits; and crop and pest grouping. From a residue chemistry perspective, two projects have been initiated to explore increased flexibilities in acceptance of foreign residue trial data to support a domestic registration. The first project will explore the feasibility of the exchangeability of residue data between the United States and Canada, and the second project will explore the concept of the proportionality between the application rate and resulting residues on the food crop. In addition, streamlining of the processes related to the URMULE programme is also being examined.

EU Minor Use Programme – EU Expert Group on Minor Uses

Johan Roman (Co-ordinator, EU Expert Group on Minor Uses North) and
Jean-Claude Malet (Co-ordinator, EU Expert Group on Minor Uses South)

History

As it was recognized that minor uses and speciality crops are of great importance to the European Union, Member States expressed the need to improve harmonization and co-operation among the EU member states to pursue authorizations. By improving harmonization and co-operation, duplication of work is avoided in risk assessment, as well as in gaining data for residue studies.

On the initiative of the EU Standing Committee on Food Chain and Animal Health for Plant Protection Product Legislation, in 2002 the EU Expert Group on Minor Uses was established, consisting of

- a Steering Group;
- two Technical Working Groups, North and South, with their respective co-ordinators, and
- Expert Working Groups (established in 2010).

The Technical Working Group zones were established according to residue legislation.

Terms of reference of the Technical Groups

Upon establishment of the Technical Groups, their role was to

- co-ordinate residue trial programmes;
- provide input for 'priority lists';
- develop harmonization at the work level; and
- liaise with companies to encourage support for minor uses.

State of play

Expert Working Groups

Under the umbrella of the Technical Working Groups, specific expert working groups (commodity related) have been established. Currently there are expert working groups for:

- Small fruit and stone fruit.
- Processed vegetables.
- Fresh vegetables and herbs.
- Ornamentals.
- Tobacco

Other expert working groups can be established, should the need arise.

Each expert working group is required to develop priority lists, all aiming to improve harmonization, share data, share work and develop joint projects to produce data for authorizations. These working groups meet at least twice a year.

The working groups consist of national experts from competent authorities, representatives of grower associations and, if desired, representatives of the respective plant protection product industries.

Minor Use database

Under the umbrella of the Technical Groups, an EU Minor Use database has been developed, containing not only information on authorized minor uses, but also information on existing trial programmes and trial programmes under development. Through such a database, sharing of information will be improved significantly.

Regulation 1107/2009

On 14 June 2011, Regulation (EC) 1107/2009 Concerning the placing on the market of plant protection products, replacing EU Directive 91/414, became effective in the whole of the European Union.

Special attention is given to minor uses, in particular through Article 51, Extension of authorisations for minor uses. Further elaboration on impact is taking place at the Technical Group level.

European Minor Use Fund

According to Art. 51 (9) of Regulation (EC) No 1107/2009, the European Parliament and the Council the Commission shall present a report on the establishment of a European Fund for Minor Uses. Work and cooperation in the EU will be strongly influenced by such a fund. The report has not yet (January 2012) been presented.

Orphan Uses Committee

Jean-Claude Malet

Minor Uses Expert and Coordinator South Europe, Ministry of Agriculture, France

The French structure for minor uses connected to the situation developed in Europe

Crop protection, particularly for the agricultural sub-sectors representing limited crop areas, is an ongoing challenge for producers wishing to ensure the expected level of quality for consumers.

A new tool dedicated to the search for appropriate solutions

The new orientation of agriculture regarding environmental protection can be discerned in the context of complementary reforms. These are characterized by a long review programme for all active ingredients in plant protection products, a programme that started in 1993

Within this framework, three-quarters of the former active ingredients have disappeared from the market, either because of the cost of the review programme or for toxicological reasons.

In parallel, there are emerging phytosanitary risks associated with global warming and the intensification of movement of organisms in international trade, necessitating the maintenance of solutions for effective plant protection in order to secure European food production and reinforce national food security.

Faced with this collective challenge, the Ministry of Agriculture proposes an action plan with all the stakeholders concerned by this problem.

The 'Orphan uses organization' is based on the principle of co-operation and mutual assistance among agricultural sectors. It focuses on research into sustainable solutions for plant protection and the coordinated mobilization of all stakeholders, including agricultural sectors, technical institutes, plant protection companies, the evaluation agency, and the Ministry of Agriculture.

The Orphan Uses Organization

The Orphan Uses Committee is composed of relevant professionals, and its role is to develop strategies for decision-making and to validate action plans validation.

It functions through thematic working groups organized by agricultural sectors, managed by the experts of the Plant Protection Service and technical institutes. These various working groups identify the needs of each sector concerned and propose possible innovative solutions.

An Operational Technical Committee is responsible for elaborating a synthesis of the specific working group proposals and for putting into place a common action plan. The committee is composed of technical experts from the Plant Protection Service, technical institutes, plant protection companies and the Evaluation Agency. The Operational Technical Committee is supported by a technical secretary in charge of coordination and follow-up of the action plan.

Expert Centre for Speciality Crops

Johan Roman

Senior Officer Plant Health, Netherlands Plant Protection Service,
Ministry of Economic Affairs, Agriculture and Innovation

Introduction

Authorizations for minor uses and speciality crops are a problem in the Netherlands, as the Netherlands' agriculture and horticulture are strong in high-value, specialized crops and these crops are of importance for the Dutch economy. To support the growers of these speciality crops, a wide range of research facilities and knowledge organizations, together with a well organized industry, is available to growers. In addition, various government bodies provide facilities and the Netherlands is taking up a leading position in Europe as regards cultivation techniques and sustainability. To make optimal use of activities of individual entities involved in speciality crops, the Netherlands Expert Centre for Speciality Crops was established in 2010.

What is this Expert Centre for Speciality Crops

The Expert Centre for Speciality Crops is a (virtual) network to facilitate minor crops and their inputs which are of importance to keep these high-quality crops viable, not only in the Netherlands but for Europe as well. The Expert Centre is an open, virtual knowledge centre, and not a new legal body.

Partners

The Expert Centre for Speciality Crops is an initiative bringing together both private and public organizations, namely:

- grower associations;
- the Board for the Authorization of Plant Protection Products and Biocides;
- the Ministry of Economic Affairs, Agriculture and Innovation; and
- Wageningen University and Research.

Each organization participating in the Expert Centre for Speciality Crops operates on its own responsibility and organization. More information can be found at www.specialtycrops.eu

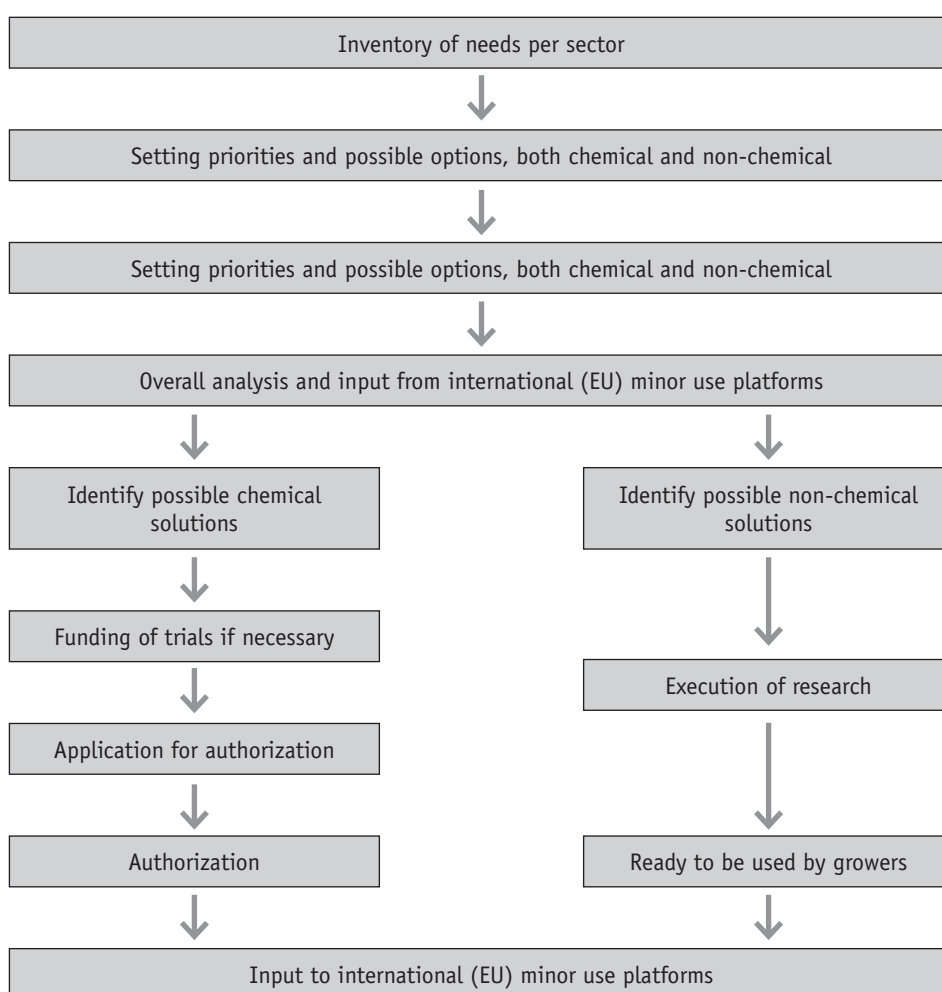
Aim

Its ambition is to reduce the number of minor use gaps in the Netherlands through efficient and effective national and international cooperation, and to be the knowledge centre for Europe.

Activity

As its ambition is to achieve a considerable reduction in minor use gaps, an effective and coherent procedures is essential, supporting faster and easier coordination between research, advice, financing and authorizations, so that innovations that are based on Dutch experience reach the market (more) rapidly. Collaboration with other EU Member States is in this process essential as well. The procedure followed to achieve this is outlines in Figure 1.

Figure 1. **OUTLINE OF PROCEDURE FOR INTRODUCING MINOR USE RESOURCES**



The United States IR-4 Project

Overview

Dan Kunkel and Jerry Baron

IR-4 Project

Since 1963, the publicly-funded IR-4 Project [USDA Interregional Research Project No. 4, A National Agricultural Program to Clear Pest Control Agents for Minor Uses] has been the primary resource in the United States for facilitating registrations of conventional pesticides and biopesticides for food (fruits, vegetables, nuts, herbs, spices, etc.) and non-food ornamental crops (nursery, landscape plants, Christmas trees, flowers, etc.). The IR-4 Project also facilitates registrations of pest management tools for minor and low volume uses on major crops. IR-4 is needed because the return on investment in the small markets associated with specialty crops and minor uses is not a priority business objective for companies involved in developing, registering and marketing pesticides. The US Department of Agriculture (USDA) recognized the need for specialty crop growers to have legal access to safe and effective pest management tools and established the IR-4 Project, which develops research data to support US Environmental Protection Agency (EPA) registrations. IR-4 concentrates its research on lower risk technology that respects human health and the environment.

More recently, IR-4 has played an active role in working with international agencies in harmonizing Maximum Residue Levels (MRLs) in order to help specialty crop growers avoid trade barriers caused by pesticide residues.

The mission of the IR-4 Project is to facilitate registration of sustainable pest management technology for specialty crops and minor uses.

The core objectives of the programme are:

- Reduced Risk Pesticide Research on Food Crops
- Conducting magnitude of residue studies
- Collecting efficacy and crop safety data
- Updating EPA and Codex Crop Groups
- Participating in international activities focusing on MRL establishment and data sharing
- Biopesticide and Organic Support Program
- Providing regulatory support and conducting efficacy studies
- Ornamental Horticulture Program
- Generating efficacy and crop safety data
- Public Health Pesticides
- Providing regulatory support and generating and sharing data

The IR-4 Project is a cooperative programme funded through the USDA and the State Agriculture Experiment Stations (SAES) at approximately US\$ 15 million annually. This direct support is supplemented by in-kind and infrastructure support from SAES, which is conservatively estimated to be equal to the amount of direct federal support.

IR-4 employs approximately 125 full-time-equivalent staff. The Headquarters unit performs administrative and study management functions, and IR-4 research is conducted at 30 field centres and 5 analytical laboratories across the United States. See the IR4 Project website (www.IR4.rutgers.edu) for a detailed overview of the IR-4 Project.

Annually, at priority-setting workshops, IR-4 stakeholders—comprising public institutions, USDA, commodity groups and growers—identify critical pest management voids for food crops that have limited weed, insect or plant disease management options. Once a sustainable pest management “Solution” is identified, IR-4 develops data (mostly pesticide residues) from field trials and sample analyses. In most studies, the chemical is applied in a field trial that simulates the proposed grower use. When the targeted crop has grown to the appropriate stage, samples of the crop are collected and shipped to the analytical laboratory where the amount of chemical remaining in or on the crop is determined. Yearly, IR-4 conducts nearly 600 field trials for approximately 85 residue studies (each pesticide or chemical and crop combination). Field and laboratory data from this research are compiled into a “regulatory package” and is submitted to the EPA requesting a pesticide tolerance or MRL.

In addition to submitting data to the EPA, IR-4 actively participates in the effort of reducing or eliminating potential trade barriers caused by pesticide residue levels. IR-4 does this by working with the crop protection industry and foreign governments in harmonizing international MRLs, and identifying crop group classifications. IR-4 also takes the lead in sharing data in an effort to internationally harmonize MRLs. IR-4 gathers and reformats data packages, supplements them with additional data and information, and submits them to foreign regulatory bodies for establishing an MRL. IR-4 also works on international capacity building by working with minor use programmes throughout the world. IR-4 conducts cooperative studies with Canada on a regular basis, as well as with other programmes around the world, and generates data to obtain international registrations for new specialty crop uses and minor uses on major crops.

The IR-4 Biopesticide and Organic Support Program funds research and provides regulatory support that enhances the development, registration and use of biopesticides in conventional specialty crop production systems, and facilitates the approval of pest management technology for use in certified organic production systems.

The IR-4 Ornamental Horticulture Program identifies and develops efficacy and phytotoxicity data to support reduced-risk pest management solutions for ornamental horticulture crops, with an emphasis on effective biological and chemical solutions compatible with Integrated Pest Management (IPM) and resistance management programmes. Data developed through this programme establishes or expands the number of ornamental horticulture crops or pests on pesticide labels. This programme helps growers understand which are the most effective tools that have a positive impact on beneficial organisms and can be best used within resistance management programmes.

Recently, IR-4 established a new programme in cooperation with USDA and the US Department of Defense to facilitate the registration of pest management products that control arthropod pests responsible for transmitting vector-borne diseases and that threaten human health.

In 2010, the IR-4 Program established over 200 new MRLs to support numerous new domestic registrations for specialty crops and minor uses. With assistance from IR-4, EPA also established several new crop groups and enhanced the existing Fruiting Vegetable, Citrus and Pome Fruit Crop groups. The IR-4 Biopesticide and Organic support Program facilitated three new registrations in 2010, which included using acetic acid for weed control in organically grown food and ornamental crops; registered HoneySweet Plum, a USDA plant-incorporated protectant technology to control Plum Pox Virus in stone fruit and almond; and funded research on *Trichoderma hamatum* isolate 382 for disease control uses.

The IR-4 Project continues as a productive programme with considerable results to support healthy, bountiful crops for United States growers, and is a model programme that is respected throughout the world.

The IR-4 Database for Food Crops

Diane Infante and Dan Kunkel

IR-4 Project

The mission of this database is to provide information regarding all the specialty crop need requests that were submitted to IR-4 HQ by US stakeholders (public institutions, USDA, commodity groups and growers). The IR-4 Food Crops database is located at www.IR4.rutgers.edu/food.html.

All projects start with a request from a US stakeholder and initiate a new entry in the IR-4 database. The Web site allows users to go to one place to find, search, track or submit their needs for crop protection products. There are various search topic options:

IR-4 Food Crops Database

- **Full Search.** Here you can search all entries in the database and can search the database on various topics, such as chemical, crop, pest and many others.
- **Available Study Protocol and Change Forms.** This allows a search by a specific study or a group of studies to see the Study Protocol and any Changes associated with the residue study.
- **EPA Timeline and Submission Status Report.** This allows viewing of the entire report, or to see where a study is in the study conduct phase. The estimated date a study will be submitted to EPA is also provided.
- **Master Study Schedule.** This gives access to all Good Laboratory Practices (GLP) studies from 1989 to the present, or one can do a specific search. This search provides chemical, crop, field trials, lab ID and other required fields associated with GLP research.
- **Performance/Crop Safety Data.** Allows one to view the data submitted to IR-4 to support a specialty crop.
- **Submit Project Clearance Request.** Allows the user to submit their request for a specialty crop need.

Selective inquires

These searches are restricted to:

- Future Researchable/Potential Projects
- Probable Future Registrations
- Studies in Registration Process
- IR-4 Registered (Labelled) Uses
- Efficacy/Crop Safety (E/CS) Needs

Current Year

Searches only on studies for the current year's research.

- Draft Protocol
- Tentative Project List

Support for the IR-4 Annual Workshop and selection of research projects

Each year, growers and other public stakeholders are asked to identify their needs by going on-line to nominate. The nomination process is to rank each need by an A, B or C, with A being the greatest need.

At the end of nomination process a Workshop is held to select from among all the A nominations the list of projects that will be researched in the following year. Funding allocations dictate how many projects are possible in a year.

Challenges related to specialty crops and minor uses of pesticides in Africa

An east African perspective

Lucy Namu

Kenya Plant Health Inspectorate Service

The sustainable production of food crops, including those of high value grown on limited production areas, is vital for human health and for national economies worldwide. Food crop production contributes to agricultural productivity, a varied and nutritional food supply and global food security. Sustainable production can only be realized through use of high quality agro-inputs, including the availability of crop protection solutions for pest management with appropriate measures to ensure food safety for consumers.

Africa is a net importer of food. Several African countries have gone into the production of non-traditional fruits and vegetables of temperate origin in order to diversify their agricultural exports and increase foreign exchange earnings. Crops can be grown throughout the year in most of Africa as the continent is endowed with a tropical climate. To increase income the farmer needs a higher value product, which can be obtained by adding value to primary or secondary products.

With increased production comes an equally rising pest burden that has presented challenges, summarized in the term now commonly used: minor uses of pesticides. Pesticide use in Africa, however, is certainly far lower than the rest of the world, but it is gaining significance, particularly with the diversification of crop production systems to include high value and non-traditional food crops. The production acreage or tonnage of production of these non-traditional and high value crops is still too insignificant to warrant sufficient return for manufacturers from developing and registering pesticides for them. The goal for all stakeholders in agricultural production should be to maintain availability, in the light of economic, regulatory and market challenges.

To address the issues of specialty crops and minor use of pesticides, the first Global Minor Use Summit was held. Several recommendations were proposed, including the development of capacity building initiatives directed to developing countries, the establishment of a Codex Working group on specialty crops and minor uses, and to develop communication channels to improve information sharing. From the first Global Minor Use Summit recommendations, several follow-up activities involving African participant countries were undertaken. Some are listed below.

- Regional workshops were organized involving countries from the Western and Eastern Africa regions. These workshops aimed at building capacity within these African countries to provide safer placement of plant protection products such as bio-pesticides and their use in agriculture.

- Some countries in the African region participated in a pilot study organized by the United States Department of Agriculture (USDA) and the Interregional-4 (IR-4) Project that examined the pesticide residues from different regions to support global zoning.
- Information sharing on the registration and authorization of plant protection products, under the auspices of the East African Community (EAC) region, that included Burundi, Kenya, Rwanda, Tanzania and Uganda.
- Increased cooperation among countries in data sharing for the promotion of regulatory efficiencies, as steps towards increased harmonization among African countries. This work has been ongoing in the EAC region.

While there has been progress made in capacity building efforts, there still remains significant work to be done.

For instance within the regulatory environment, efforts in the harmonization of plant protection registration requirements are ongoing in the African region. There is need to step-up this work in order to promote regulatory efficiencies in achieving outcomes and avoid duplication of work. Support could be provided to facilitate information sharing mechanisms and discussion on issues such as sharing of data, and registration procedures for authorization, which should include the reduced-risk pesticides and bio-pesticides. Registration of pesticides for minor uses (which in the African region could be a significant number of crop-pest combinations) cannot be underestimated. For example, Kenya, being a lead exporter of specialty crops to the European Union (EU), has had a myriad of challenges that include limited plant protection options for these crops, emerging pests that necessitate various pesticide options, and the more obvious challenge of the few agrochemical companies showing little interest in registration for these minor uses. To this end, there is need to develop capacity in the harmonization of crop grouping to facilitate the extrapolation of data from major crops to minor crops, and to increase collaborative stakeholder exchanges to prioritize minor use needs within the region.

An associated problem is the lack of sufficient pesticide residue data and clear policy on minor uses necessary for the establishment of Maximum Residue Limits (MRLs). Differences in the policy for MRL setting has resulted in trade constraints. Efforts should be made to provide for greater transparency in the process of setting MRLs. Capacity in the generation of internationally acceptable data for MRL setting is necessary to increase participation of African countries in this process, particularly through work sharing initiatives, which should be encouraged. This would be based on priorities established between growers and the agrochemical industry in the countries, for provision of effective plant protection products that do not affect trade. Resultant data could be incorporated into regional databases that would benefit comparable countries.

It is hoped therefore that this second Summit will discuss proposed strategies to implement mitigation measures for some of these challenges identified, and identify action areas to address the challenges currently experienced in African countries with respect to minor uses of pesticides, particularly on specialty crops.

Minor use incentive schemes globally industry perspective of success

Vassilia Sgouri and Sandra Keller
CropLife International

About CropLife International

CropLife International is a global federation representing the plant science industry. It is a network of regional and national associations in 91 countries. The member companies are committed to supporting sustainable agriculture through innovation in crop protection, plant biotechnology and seed production. Committees and working groups are served by the CropLife Secretariat, located in Brussels, Belgium. CropLife issues documents such as guidelines, manuals and training material, which are available free-of-charge on the CropLife website (www.croplife.org).

Introduction

This document reports on a survey carried out in 2011 by the CropLife International Minor Use group, a sub-group of the Regulatory Steering Committee, on “Successful use of Regulatory Incentives for the Registration of Pesticide Minor Uses”. The aim of the survey was to gain insight into the views of global plant science companies on existing incentive schemes, and to quantify which schemes are used successfully and enhance the registration of pesticide minor uses. This could be used for cross-fertilization between country schemes to improve solution finding.

The questionnaire for the CropLife survey was based on the report of the OECD survey on “Regulatory Incentives for the Registration of Pesticide Minor Uses”, which collates regulatory incentives adopted by OECD member countries for the registration of minor uses. The questionnaire was, however, designed to not limit the survey scope to OECD member countries.

This paper also contains suggestions made by respondents that could be considered for the future in developing new incentives for the benefit of enhancing minor use registrations.

Methods

Questionnaire

The CropLife secretariat, with input from the CropLife minor use group, designed the survey and also collected and compiled the responses. In order to reach a broader base within industry, the questionnaire was disseminated to all member companies

of CropLife International and regional CropLife associations, through which also manufacturers that are not individual members of CropLife International were invited to participate.

The questionnaire was designed to cover a list of regulatory incentive schemes for minor uses globally, and to differentiate between awareness of the existence of such schemes and their practical use in support of registrations.

The questionnaire was a mixture of multiple choice and open questions.

Participants

Responses were received from member companies of CropLife International as well as from two associated members. Some completed questionnaires were in themselves a compilation from several regional representatives of the companies responding. In total, 16 completed questionnaires were received and analyzed for this survey.

The participation is considered very good, as only one member-company (of the 8 member companies) did not participate, and responses had been collected from various national and international businesses around the globe.

Definition of success

The objective of introducing incentives in regulatory schemes is primarily to enhance minor use registrations for the benefit of safe food production in sustainable agriculture. Therefore, the number of minor use registrations achieved is an easy measure for success, albeit falling short of considering the value of an individual minor use registration or to define the percentage of registrations versus the minor uses listed as “still requiring a solution” in a country. “The more minor use registrations, the better!” is the underlying principle, chosen for its simplicity, that allowed the survey to be conducted in the given timeframe and with a moderate effort by respondents. Other factors that were not measured but would be “nice to have” if more time and resources were available, would include:

- Relevance of registrations? (How many uses really addressed production needs?).
- Economic value? (Economic impact on farmers, food processors, retailers, international commerce or producing country economy.)
- Addressing public interest? (Social impact.)
- Effect on trade facilitation or trade hindrances?
- Were there any registration failures? Or percentage of unsuccessful submission (not enough data, no recognition of other countries’ data, etc.)

Results

All respondents submit for minor use registrations, albeit not in all countries. The question: “Does your company take the existence of a minor use scheme into account for registration decisions?” was for most respondents (11/15) a positive factor. Regulatory incentives are the main factor in making decisions on minor use label extensions. Some of the national respondents answered that they do not take the regulatory scheme in their country into account (mainly in Mexico and Australia).

Existing schemes

By far the most well known and the most used is the USA minor use scheme, closely followed by the Canadian scheme. The influence of IR-4 in improving levels of awareness and the attractiveness and size of the market could have resulted in this significant difference. Known, but used only by some companies, are the minor use schemes in Japan, EU, Australia and Brazil. Different options for a minor use programme are discussed in the EU. With some respondents there appears to be confusion, whether to respond to the schemes existing in EU member states or to the initiative of supporting EU import tolerances through the Pesticide Initiative Programme (PIP). For Brazil, the use relates to planned or completed submissions rather than achieved registrations. Schemes less well known and even less used are those in New Zealand and South Africa.

Seven respondents said that they know about Global Joint Reviews (GJR), but no answers were received with respect to how many minor uses have been registered according to the decisions made through GJR. This will however be addressed by OECD with a survey planned by their Expert Group on Minor Uses (EGMU).

Successful existing schemes in terms of awareness and use

The number of the respondents knowing and using the EU scheme appears to be too low. This may be due to the fact that it may not have been clear which scheme was being referred to (UK, Germany, France, Netherlands, Belgium, etc.). At least four companies are involved in technical expert teams and have launched projects in the EU.

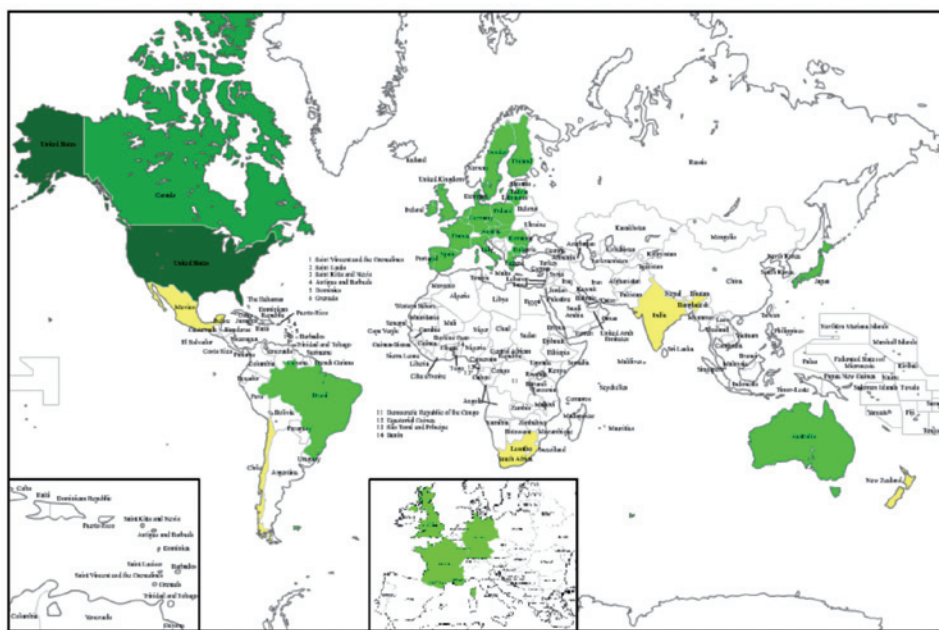
Table 1. SUMMARY OF AWARENESS AND USE OF MINOR USE SCHEMES

SCHEME	PROMPTED	AWARE**	PROMPTED	USE**
USA minor use scheme (not IR-4; operational since 2004)	yes	9	yes	9
Canadian minor use scheme (operational since 2010)	yes	8	yes	8
EU minor use scheme (under development)	yes	5	yes	1
Japan minor use scheme (operational since 2003)	yes	5	yes	2
Australian minor use scheme (under review)	yes	4	yes	2
New Zealand minor use scheme	yes	2	yes	0
South Africa minor use registration (amended in 2009)	yes	1	yes	0
Brazil minor use scheme (introduced 2010/11)	yes	5	yes	2 (1*)
Global Joint Reviews	yes	7	no	
Germany	no	1	yes	2
UK	no	1	yes	2
Chile	no	1	no	
France	no		yes	1
China	no		yes	0
Thailand	no		yes	0
Middle East	no		yes	0
Mexico	no		yes	2
ASEAN	no		yes	1*
SAHEL	no		yes	0
India	no		no	1

Notes: * = in planning or submitted, but no registration achieved yet.

** = measured in number of respondents (not number of minor use registrations).

Figure 1. MINOR USE SCHEMES WORLDWIDE



Key: Dark and medium green = Countries with well-known minor use incentive schemes that are used;
 Light green = Countries with known minor use incentive schemes that are little used;
 Yellow = Countries with little-known minor use incentive schemes that are not (yet) used; and
 White = Countries without a known minor use incentive scheme.

Number of minor use registrations per scheme

With the intention of quantifying the effect of minor use registration schemes on registrant’s decisions to register for minor uses, the survey included questions around the number of registrations made per country or region.

Most respondents referred to the fact that they had participated in IR-4 work and subsequently registered minor uses in the USA and some also in Canada. A more accurate source for exact numbers in the USA would be the IR-4 list of projects.

As not all respondents included comprehensive accounts of their minor use registrations, it would not be sensible to simply add up the figures reported. In most cases, examples were given rather than comprehensive lists. From the examples and figures submitted it would seem that the number of minor uses per compound varies widely between 1 and over 20. In addition to the USA and Canada, successful minor use registrations have been reported in Japan, Mexico and India.

The reasons for the limited information on the number of minor use registrations are likely to be due to a number of challenges, which are listed below. To consider those might be valuable for anyone wishing to quantify minor use registration success in future.

- Quantification is partly hampered due to unclear differentiation between minor crops and minor uses.
- Companies are hesitant to disclose exact figures.
- Some crops represent crop groups, which increases the total number of minor crops that effectively benefit from such a registration.
- A number of minor uses were included in (regular) registrations for countries, where no minor use scheme exists or where the company is unaware of the existing scheme.

- Registrations for minor uses also exist as part of (regular) registrations in countries that have operational minor use programmes.
- Some minor use schemes are unknown to registrants or introduced recently (submissions not yet processed).
- Import tolerances for minor crops are equally important for trade and should also be considered in such quantification.
- Quantification is challenging, if re-registrations for minor uses are also considered.

Given the challenges implicit in the above list, the survey did not attempt to assess the size of the minor use registrations required, albeit this would be of interest and would allow putting the number of successful minor use registrations into perspective. The identification of the number of minor uses that remain without response (those that still need a solution) remains unknown. The ratio changes over time as additional minor use solutions required arise from new restrictions in the existing registrations or from registration loss (which can be triggered by new market needs, expansion of use of spices or from changes in diets) or from an increase in pest pressure (e.g. new hosts for a pest or disease, the area affected by a pest, or even needs created from the resistance strategy and the cultivation techniques).

Attractive incentives for industry

The survey also looked at different types of regulatory incentives to identify what incentives are most likely to attract companies to decide in favour of registering for minor uses. The two most frequently mentioned incentives are extension of the period of protection of regulatory data, and lower fees; followed by fast authorization or shorter review time, and reduced data requirements or support for data generation. Top priority quite clearly is extension of the data protection period, during which secondary applicants will have to provide their own registration data for market entry. The other key priority identified was lower registration fees or altogether waiving registration fees for label extensions. Table 2 reflects a wish list of incentives that make a decision to register a minor use more attractive.

Table 2. FACTORS MAKING A DECISION TO REGISTER A MINOR USE MORE ATTRACTIVE

INCENTIVE	TOTAL **
Data protection extensions	7
Lower fees or no-cost label extensions	7
Attractive market or market share	5
Funding available for data generation	5
Simplicity of scheme, reduced data requirements or accept foreign data and crop groups	5
Time or priority review	5
Enforce legal use or cut down on CF* products	4
MRLs set in keeping with regional or global standards	4
Dedicated contact person for minor uses, or facilitation to manage stakeholders	3
Harmonized schemes across countries	2
Protection against or no liability	2
Minor use definition	1

Notes: * = Counterfeit products (CF) are any products sold illegally for crop protection.

** = measured in number of respondents (not number of minor use registrations).

It is not within the scope of this paper to analyse existing regulatory incentive schemes against the wish list in Table 2. However, the USA/IR-4 (8 times) and Canada (6 times) were mentioned most frequently as positive examples, and the new scheme in Brazil was referred to twice in acknowledgement of the provisions for extrapolations to register for minor uses. Other schemes that were suggested to serve as models were GJR (1) and PIP (1).

Conclusions and way forward

As a next step, CropLife will try to identify an existing minor use scheme that matches the incentives rated most attractive. Such a scheme, or a model scheme, should be advocated. If more regulatory incentive schemes or a combination of incentives were used more frequently, this would result in more solutions being available for producers and would reduce the use of unregistered products on minor crops. The biggest success factors of existing schemes have been identified to be extension of periods of data protection, and waiver of fees. Participants in the survey have mainly recognized the USA and Canada for adopting that kind of incentives.

The analysis of the survey answers also revealed the potential for more minor use registrations if:

- mutual recognition were applied (EU). Attractiveness increases if mutual acceptance is added to data protection (see the USA and Canada);
- waivers were applied to tackle specific national data requests;
- registration were made easier, i.e. by harmonized regulatory requests like extended extrapolation schemes and crop grouping; or
- registration timelines were shortened.
- Beyond the control of regulators, but relevant for decisions to register for minor uses, were:
 - the general market of that country;
 - international trade in that (minor) crop;
 - market share of manufacturer;
 - infrastructure to market or deliver product to minor use growers;
 - cultivation techniques and likelihood of farmers implementing new cultivation techniques; or
 - individual company strategy.

The survey also showed that raising awareness about existing minor use schemes is important. The Global Minor Use Summit is an event that provides an opportunity for raising such awareness among partners working towards finding minor use solutions.

INTEGRATED PEST MANAGEMENT
FAO PREFERRED APPROACH TO CROP PROTECTION

Francesca Mancini and Mark Davis

PEST MANAGEMENT CHALLENGES IN
THE CANADIAN ORNAMENTALS INDUSTRY

Cary Gates and Peter Isaacson

Integrated Pest Management FAO preferred approach to crop protection

Francesca Mancini and Mark Davis
AGPP, FAO, Rome

Introduction

Countries are facing the challenge of needing to intensify agricultural production to meet increasing demand for food, feed and fibre generated by a growing populations and changes in dietary patterns. However, countries are also facing growing concerns about environmental and social impacts associated with intensive cultivation, including pesticide use and the pressure to meet the quality standards demanded in international trade. Changes in pest management practices to more sustainable approaches with reduced reliance on pesticides are required with particular urgency in countries lacking the capacity to mitigate risks to farmers, workers and consumers as well as to the environment.

Approving pesticides for minor uses and approving maximum residue limits (MRLs) for these so-called minor pesticide-crop combinations has two drawbacks. First, it fails to recognize the very limited capacity for pesticide evaluation and registration in most developing countries, and second, it has the potential to undermine integrated pest management (IPM) and other sustainable crop production and protection approaches by increasing the availability and the acceptance of widespread pesticide use.

FAO promotes IPM as the preferred approach to crop protection and regards it as a pillar of both sustainable intensification of crop production and pesticide risk reduction. In this paper, we briefly describe the organization's new paradigm for crop production, which includes IPM principles and the strategies to reduce overall pesticide risks.

Sustainable crop intensification

The intensification of agriculture achieved to date has been primarily based on the use of synthetic inputs, including pesticides, to complement or replace natural processes, and on crop engineering to increase the genetic production potential. This model of modern agriculture has allowed for a significant increase in crop production in some parts of the world. It has, however, also had negative impacts on the natural capital, including soil and water contamination from chemical agents, which are compromising the ability of agro-ecosystems to sustain and eventually increase the current production levels.

FAO urges governments of developing countries to pursue further intensification of agricultural production with a more systematic approach to managing natural resources that protects and enhances the biological processes underpinning production. Sustainable intensification of agriculture means producing more from the same area of land, with less use of non-renewable inputs. It builds and complements the natural processes that support plant growth, including pollination, natural predation for pest control, nutrient cycling, soil regeneration and water conservation. It is largely based on farmers' knowledge and skills, and local solutions within the reach of small-scale farmers' capacity. The principles of sustainable intensification are described in FAO's latest guidelines for policy-makers, *Save and Grow* (FAO, 2011; <http://www.fao.org/ag/save-and-grow/>).

Integrated Pest Management

The irrational use of pesticide compromises the pest regulating services inherent to the agro-ecosystem. Prolonged over-reliance on pesticides has been shown in different regions and cropping systems to have destructive effects on natural control mechanisms, and to lead to development of pesticide resistance, resulting in an increase in pest outbreaks and insurgence of new pests.

Recognizing that inappropriate use of pesticides has exacerbated pest problems and that in many crops there is often considerable scope for reduced pesticide use through prevention of pest development and use of non-chemical pest management techniques, has brought about a renewed interest in IPM.

Agenda 21 from 1992 includes IPM as an 'optimal solution' to plant protection problems. IPM principles and practices vary considerably across implementing agencies. However, there is a growing international consensus on the need to adopt an agro-ecosystem-based approach. This is being reiterated in discussions and documentation being prepared for Rio+20.

FAO defines IPM as

"the careful consideration of all available pest control techniques and subsequent integration of appropriate measures that discourage the development of pest populations and keep pesticides and other interventions to levels that are economically justified and reduce or minimize risks to human health and the environment. IPM emphasizes the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms."

The FAO definition is widely accepted among development organizations, including the UN system, the World Bank and Pesticides Action Network (PAN).

An Integrated Pest Management Programme includes the following elements:

- i) growing a healthy crop;
- ii) preventing build-up of pest populations;
- iii) preserving and enhancing populations of beneficial insects;
- iv) regular field observations of the crop's health and key pest and beneficial insects; and
- v) managing resistance.

IPM systems focus on building an agro-ecosystem's capacity to stay productive over time. Pesticides that are used in an IPM programme should have no adverse effects on beneficial insects or on the stability of the agro-ecosystem.

Worldwide, IPM research started on field crops where the largest volume of pesticides were being used, such as cotton and rice. Several low-chemical IPM approaches have also been traditionally practiced on indigenous crops by small-scale farmers around the world.

IPM is particularly relevant in the context of specific requirements regarding pesticide selection and use, and the reduction of pesticide residues. It has therefore become especially important to reduce pesticide residues in export food crops, like fruits and vegetables. New Zealand, for example, adopted widespread IPM programmes in top fruit production in response to tougher MRL requirements by importing countries.

A key element for IPM programmes is farmer education on alternative, less pesticide dependent and more sustainable production practices. New pests occur regularly and existing pests may develop resistance to labelled pesticides. Education of farmers is therefore essential to achieving an effective pest management system that is able to respond to a changing farming environment.

FAO guidance on pest and pesticide management

FAO has further developed guidance on Pest and Pesticide Management for policy development in a multi-stakeholder exercise, which involved several governmental, non-governmental and some private sector organizations. The following three steps are identified as critical to reducing pesticide risks.

1. **Reduce reliance (Integrated Pest Management).** This entails preventing the build-up of pest populations and pest and disease outbreaks, and simultaneously strengthening plant health to withstand pest damage. This requires the comprehensive management and monitoring of the crop ecosystem, thereby reducing the need for chemical intervention.
2. **Select pesticides with the lowest risk.** Where the use of pesticides is deemed necessary, select products with the lowest risk to human health and the environment from the available registered products that are effective against the pest or disease. Clear instructions and training in the proper use of pesticides are required. Training is not, however, a substitute for the first step, in particular in developing countries where large numbers of poor small-scale farmers generally fail to adopt the minimum required safety measures. In these countries, FAO recommends the identification and phasing out of pesticides that pose unacceptable risks in the local condition of use (Highly Hazardous Pesticides).
3. **Ensure proper use** of the selected products: for approved applications and in compliance with international standards.

The first step focuses on reducing the need for chemical pesticide use through the adoption of IPM, the second and the third steps aim to reduce the risks associated with the use of products that pose hazards to human health and the environment.

Selection of pesticides and proper use should not be the primary point of attention in cases where current levels of pesticides use are unjustifiably high and can be reduced.

FAO encourages the use of policy and field tools to reduce the use of pesticides.
Examples are:

- Pesticide use reduction targets
- Promotion of IPM
- Promotion of Good Agricultural Practices (GAP)
- Enhancing access to non-chemical alternatives
- Farmer education
- Financial instruments
- Identification and phasing out of highly hazardous pesticides

The FAO Guidance document (International Code of Conduct on the Distribution and Use of Pesticides Guidance on Pest and Pesticide Management Policy Development) is available at: http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/Code/Policy_2010.pdf)

Pest management challenges in the Canadian ornamentals industry

Cary Gates (Flowers Canada, Ontario) and
Peter Isaacson (Canadian Nursery Landscape Association)

Greenhouse ornamentals

Floriculture farmers are among the most hard-working, entrepreneurial and creative farmers in Canada, and are justifiably proud of their leading-edge achievements in producing crops whose quality is renowned throughout the world. The following concerns in the pest management area outline some of the difficulties under which they work. Statistics Canada's 2009 report on the Greenhouse, Sod and Nursery Industries has indicated that there are 1100 ha of greenhouse ornamental production in Canada, with gross farmgate receipts valued over \$CDN 1.5 billion. Ontario represents approximately 55% of this production and is by far the largest ornamentals producing region in Canada.

Ornamentals nurseries

Commercial ornamentals nurseries in Canada comprise 19 892 ha of growing area and account for \$CDN 644 million in sales (Statistics Canada, 2010). Ornamental nursery stock covers a diverse range of plant material grown in containers or in the field, and includes annual and perennial plants ranging from woody (e.g. trees, shrubs and rose bushes) to herbaceous. The end purpose of the plants may be ornamental (e.g. urban landscape) or functional (e.g. fruit trees, grape vines or forestry seedlings). As with any type of horticultural business, nursery growers deal with pests on a daily basis, which must be prevented or controlled in order to avoid damage to crops.

Ornamental crops are the third largest Canadian-produced agricultural crop by farmgate value. IPM needs in ornamental horticulture are significantly different from those in the food plant, horticulture or livestock industries. Several characteristics that strongly influence the priorities for IPM and minor use in the ornamental sector are:

- **Pest Tolerances** – tolerances for pests, even low-risk pests, are low because marketability of ornamental products depends on the high quality cosmetic appearance of whole plants.
- **Product Consumption** – growers produce plants that are not “consumed” in the traditional sense, in that they are not eaten by the end consumer and are not subject to crop residue requirements.

- Regulatory Requirement – International tolerance for the presence of quarantine pests in traded ornamental products is essentially zero, and quality pests very low, so the successful implementation of an IPM protocol must identify alternative strategies for meeting quarantine and certification requirements.
- Crop Complexity – individual farms usually grow a large number of crops simultaneously, each of which may have different pests, requiring management under different tolerances.
- Crop Intensity – intensive operations may have several species of plants in close proximity to each other especially in container production.

Challenges

1. The Canadian technology gap prevents flower and nursery growers from competing on a level playing field with global counterparts.
2. Dissimilarities in occupational exposure risk assessment default values can necessitate unique data requirements for greenhouse pesticide registrations in Canada.
3. New IPM tools and biological controls are highly favoured by farmers but can face delays in approval.
4. Pesticide registrants could be encouraged to bring innovative and sustainable products to Canada.
5. Insufficient applied pesticide research.
6. Growers are left with few options to deal with invasive alien and quarantinable pests.
7. Pesticide crop labelling can be limited on Canadian ornamental pesticides.

Recommendations

1. The technology gap needs to be addressed through increased data sharing, acceptance of data packages from other jurisdictions (e.g. US-EPA), increased harmonization and global pesticide submissions to ensure new pest control products are available in Canada and other countries at the same time.
2. International data sharing and building of databases could help satisfy regulatory bodies concerning the safety of various chemistries. The Canadian industry is working with the Canadian government to address this.
3. To improve and encourage the use of biocontrols and reduced risk products simplified regulatory and registration processes are encouraged.
4. Financial and time-saving incentives for registrants are encouraged.
5. Increased funding toward research initiatives both provincially and federally is recommended.
6. Improving the ability to expand pesticide labels quickly for new pests through rationale documents would help to reduce the burden to growers and the need for emergency use registrations.
7. Ornamental horticulture industries do not suit the one crop-one pest solution that is common for edible horticulture crops. A logical, OECD crop grouping approach could help address this issue.

**REGULATORY PROPOSAL, VALUE GUIDANCE
BENEFIT INFORMATION AND USE HISTORY**

Health Canada Pest Management Regulatory Agency

**EFFICACY EVALUATION OF
PLANT PROTECTION PRODUCTS:
PRINCIPLES OF EFFICACY
EVALUATION FOR MINOR USES**

EPPO/OEPP

**EFFICACY EVALUATION OF
PLANT PROTECTION PRODUCTS:
EFFICACY AND CROP SAFETY
EXTRAPOLATIONS FOR MINOR USES**

EPPO/OEPP

Regulatory Proposal, Value Guidance Benefit Information and Use History

Health Canada Pest Management Regulatory Agency

The attached document was provided by Health Canada Pest Management Regulatory Agency (PMRA) as input to the Summit.

The original file is available at:

http://www.hc-sc.gc.ca/cps-spc/alt_formats/pdf/pest/part/consultations/pro2010-07/pro2010-07-eng.pdf

Regulatory Proposal PRO2010-07
Regulatory Proposal, Value Guidance –
Benefit Information and Use History
(publié aussi en français)
17 November 2010

This document is published by the Health Canada Pest Management Regulatory Agency.

For further information, please contact:

Publications, Pest Management Regulatory Agency
Health Canada - 2720 Riverside Drive - A.L. 6604-E2
Ottawa, Ontario - K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service: 1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

ISSN: 1197-740X (print)
1925-122X (online)

Catalogue number: H113-8/2010-7E (print)
H113-8/2010-7E-PDF (PDF version)

© **Her Majesty the Queen in Right of Canada,
represented by the Minister of Health Canada, 2010**

All rights reserved. No part of this information (publication or product) may be reproduced or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, or stored in a retrieval system, without prior written permission of the Minister of Public Works and Government Services Canada, Ottawa, Ontario K1A 0S5.

Preface

The objective of this Regulatory Proposal is to reduce the regulatory burden on stakeholders by providing a more flexible approach to fulfill the value requirements for registration of pest control products. This new approach aims to facilitate access to new and effective crop protection tools and technologies and supports the objectives of the federal Agricultural Regulatory Action Plan and the Growing Forward Agricultural Policy Framework.

Introduction

In accordance with paragraph 4.(2)(d) of the *Pest Control Products Act* (PCPA), only pest control products that are determined to be of acceptable value are approved for use in Canada. Value in respect of a pest control product is defined in subsection 2.(1) as:

the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration and includes the product's:

- a) efficacy;
- b) effect on host organisms in connection with which it is intended to be used [e.g. crop tolerance]; and
- c) health, safety and environmental benefits and social and economic impact.

Approaches to value assessment

The Pest Management Regulatory Agency (PMRA) of Health Canada requires applicants to submit data and/or a scientific rationale (extrapolated from data) to identify the level of control, crop safety and other non-safety adverse effects¹ associated with the proposed registration. This data is assessed based on PMRA's understanding of the appropriate level of control and crop safety, other non-safety adverse effects and in context with other available information (e.g. resistance management, Integrated Pest Management (IPM), registered alternatives, user identified needs), in order to determine whether the proposed registration is of acceptable value.

This document describes how and when information other than the efficacy, crop safety and other non-safety adverse effects that PMRA normally expects applicants to provide, may be used to determine acceptable value for the purpose of the registration of a pest control product. This information may include evidence of a product's use history in another country as well as analysis of the potential benefits of a product.

Submitting use history information can provide evidence to determine that the proposed use of a product has acceptable value in situations where efficacy and crop safety data are insufficient, or on occasion unavailable. Furthermore, insight into the potential benefits of a product to users would be relevant in order to determine whether the product is of acceptable value, i.e. where data or use history information

¹ Non-safety adverse effects encompass not only crop safety but also adverse effects related to industrial uses (e.g. corrosion, impact on industrial process, staining) and other non-crop use sites (e.g. domestic animal injury, corrosion and plugging of equipment).

are not fully conclusive; or where there is uncertainty on the appropriate performance level against which data and other information should be assessed.

Experimental data (efficacy and crop safety) are still an important part of the value assessment, however, for minor uses, accurate benefit and use history information may be sufficient to establish acceptable value without the need for supporting trial data. This new approach is expected to facilitate earlier registration of minor uses in Canada by leveraging the experience gained in other countries and increasing our understanding of the benefits associated with minor uses. For applications involving major uses which have a history of use in other countries, acceptable benefit and use history information could, depending on the level of detail provided, supplement, reduce or in certain cases replace the data that would otherwise be expected to be submitted.

Scope

Benefit analysis and use history can be used to support the registration of most pesticide uses except for those uses that relate directly to public health for example, swimming pool and spa products, disease vector control products and personal insect repellents. For these types of uses, trial data are required given the potential human health implications.

Description of Use History and Benefit Analysis

1) Use History

a) Relevant use pattern

Details on use history in another country should be provided by experts who are familiar with the product, its performance under commercial conditions, and the factors that can affect its performance. To be eligible for consideration, the product or use must have been fully registered in a country with a pesticide regulatory system broadly comparable to Canada (e.g. OECD countries) and used under commercial conditions such that product use and level of performance can be reliably documented.

The use that is documented should be comparable to the use proposed for registration in Canada in terms of product formulation, rate(s), number of application(s) and timing. When non-safety adverse effects are the only concern, use histories with higher rate(s) and number of application(s) are acceptable. The application should document the use history, whenever possible, under comparable use conditions for non-crop uses and for crop uses. Such information *may* include (on a crop or site specific basis): how often the product is recommended; estimates of percent crop or site treated for the specific area (level of user adoption); estimates of crop injury or product failure; and performance level.

b) Use history analysis

Technical experts knowledgeable about commercial production practices, such as extension personnel, university researchers or agricultural department officials should provide use history analysis or validate use history supplied by the registrants. It is the responsibility of applicants to solicit, coordinate, and submit any use history analysis to PMRA.

- Use history information provided by field technical experts should include:
- an explanation of the technical expertise and scope of experience with the use of the product, familiarity with the level of pest infestation that the product is intended to control and knowledge of the applicable production system(s) in which the product is used;
 - a description of the relevant use pattern of the product, how the product is used under commercial conditions (formulation, rate(s), timing and number of application(s), changes in the use directions over time) and level of adoption of the product by the users in production practices;
 - insight into the observed performance of the relevant use of the product on its own, relative to no control and/or relative to alternative methods of control, and how it meets commercial expectations, as well as the factors that may affect performance; and
 - a discussion of the product's contribution to pest management, including any additional benefits to users, contribution to resistance management, and link to IPM.

The field technical experts contact information must also be provided in the event that clarification is required.

c) Additional use history information and rationales

Registrants should provide information on any incident or product failure reports, and any remedial actions/changes to use directions made in response to such reports. Market information (e.g. product adoption and sales) may also be provided. This information can be submitted separately to PMRA by the registrant if the applicant is a third party.

When the use pattern documented in the expert analysis is different from the use proposed in Canada, the applicant must provide a rationale to explain why it is applicable to support the proposed Canadian use.²

2) Benefits analysis

Insight into the potential benefits associated with the availability of new use(s) or new product(s) allows increased flexibility in the regulatory decision. For example, knowing the level of control and crop safety needed by users under commercial conditions instead of relying exclusively on data which sometimes do not reflect the proposed use(s) can have a significant impact on the registered rate of application.

The type of "benefits" information and level of detail that applicants should provide will vary from situation to situation. However, the objective is to show why the proposed product is needed, and to emphasize how and to what extent its registration would benefit Canadian users.

Applicants should explain the pest control need that the proposed use(s) would address. This could relate to a combination of the following factors (this is not

² Additional data may be required, depending on the extent of the difference.

an exhaustive list; other considerations may also be relevant depending on the circumstances):

- uncontrolled or sub-optimal control of pests causing widespread or sporadic crop damage;
- limitations in existing methods of control such as narrower pest spectrum, duration of control, conditions of use (e.g. long re-entry intervals, large buffer zones), application methods (e.g. aerial vs. ground);
- economic benefit and performance level considerations from the users perspective;
- the need for additional pest control tools to support resistance management, IPM, and risk reduction strategies;
- acceptability of use in certain countries or sectors with specific requirements (e.g. organic production)
- the phase-out of a product(s) following re-evaluation, giving rise to the need for alternative tools of control;
- an emerging pest problem or one that is expected to arise in the short to mid-term (e.g. invasive alien species); and
- export trade impediments (e.g. domestic producers lack access to an important product either used by foreign competitors or required by another country as a condition of importation).

Projected benefits of the proposed use should be described in relation to the pest problem. Quantitative estimates (e.g. incremental benefit based on assumptions around increased yield/quality or reduced costs of production) are preferable, although qualitative information may be acceptable.

When to Submit Use History and Benefit Analysis

Consideration of use history and analysis of the potential user benefits for product registration forms part of the value assessment process. The submission of this new value information provides a method to replace some or all the efficacy and non-safety adverse data required for registration or to overcome data limitations. It can also provide a response to uncertainties with respect to a product's acceptable value that might otherwise necessitate the modification, withdrawal, or rejection of an application for registration. Where trial data submitted by applicants in support of a registration are sufficient for PMRA to make a determination of value for the purposes of registration, submission of benefit and use history information is not necessary.

Nevertheless, benefit information is always useful to help provide context with regard to the regulatory decision, even when a complete data package is submitted. Communication between applicants and PMRA through presubmission meetings and/or during the submission review process affords opportunities to discuss the availability or generation of value information to support registration.

Submission Process

Applicants should incorporate the use history and benefit information into the data code (DACO)

10.1 Value summary with subheadings. This document could be associated in the e-index builder with as many or as few DACO as apply. The document should contain an executive summary that highlights the overall value of the product (10.1), and as appropriate a discussion of efficacy

(10.2), non-safety adverse effects

(10.3), economics

(10.4), sustainability

(10.5) or

other (10.6).

Supporting Documents:

Separate documents are being developed and will be made available separately on the Pesticides and Pest Management portion of Health Canada's website and through e-mail distribution to provide more details on how to generate the use history and benefit information package.

Efficacy evaluation of plant protection products: Principles of efficacy evaluation for minor uses

European and Mediterranean Plant Protection Organization (EPPO)
Organisation Européenne et Méditerranéenne pour la Protection des Plantes (OEPP)

Specific scope

This standard describes the principles for determining requirements for efficacy evaluation for minor uses of plant protection products in a registration procedure.

Specific approval and amendment: First approved in September 2003.

Introduction

Minor uses are those uses of plant protection products (defined in relation to crops and pests) in which either the crop is considered to be of low economic importance at national level (minor crop), or the pest (minor pest) is not important on a major crop¹. It should be noted that a minor use in one country may be a major use in another country, and it is for each country to define what are its minor uses. Lists of major or minor crops are available in many countries, including those based only on criteria to establish maximum residue limits (MRLs) (where consumption of plants and plant products as food is the key issue).

For the purposes of this standard, the minor uses that are of interest are those for which the volume of plant protection products that would be used at a national level is insufficient for an applicant to wish to seek registration. Registration of plant protection products is a complex system needing the generation of a considerable amount of data. The financial cost of producing the data is so high that the crop protection industry increasingly gives priority to seeking registration for products to be used on the main crops and against the main pests, with the consequence that fewer plant protection products are being proposed for registration for minor uses. Furthermore, the process of re-evaluation of old active substances is removing more and more useful products from the market. As a consequence, for many minor uses, there are few or no products available, or else the products registered are not satisfactory (because of insufficient efficacy, development of resistance, etc.). Other

¹ The concept of minor use applies in an equivalent manner to plant growth regulators.

methods to protect the crops often do not exist or are not sufficiently effective. Growers urgently need products to protect crops—often high value—grown on small areas, or to control pests that are only incidentally of economic significance. There is widespread interest in EPP0 countries in designing a simpler process to provide products for minor uses. The most widely accepted solution is to facilitate the extension of an existing registration to include a minor use.

EU legislation sets a framework to achieve that objective but, in general terms, leaves to each Member State the definition of the minor-use concept and its practical application. Under EU Directive 91/414 (EU, 1991), it may be requested that “the field of application of a plant protection product already registered in the Member State in question be extended to purposes other than those covered by this authorization”. Thus, an extension of the field of application of an already registered product can be granted, provided that “the documentation and information to support an extension of the field of application has been submitted by the applicant” and “the intended use is minor in nature”. By this procedure, products for minor uses can be registered at national level provided that the applicant requests it. But the Directive does not specifically refer to efficacy evaluation.

EPP0 recommends that a pre-requisite to register and use a product is that it should have an acceptable level of efficacy (EPP0 Standard PP 1/214), in order to ensure that products with little benefit in plant protection do not cause an unnecessary burden to the environment. The level of efficacy should be demonstrated by the submission of trial data covering the crops to be protected and the pests to be controlled, or by suitable extrapolation. In principle, an equivalent amount of efficacy data should be provided when a registration is extended to a new use. However, for the reasons given above, it is preferable to develop a special procedure for minor use registration, with different requirements for efficacy data. The present document is intended to provide general principles on efficacy evaluation for minor uses. It does not cover other minor-use requirements, such as residue and ecotoxicological studies, which have to be addressed by the applicant and considered by the appropriate authority.

Efficacy requirements

Efficacy is defined as the direct effect (effectiveness) on the pest or on the modification of plant growth (growth regulators), together with other indirect effects, such as those on the crop being protected, on succeeding or adjacent crops, on natural enemies, or on the development of resistance (see EPP0 Standard PP 1/214 – Principles of acceptable efficacy²). The method of assessment of efficacy for minor uses should, in principle, follow the layout of specific EPP0 Standards relating directly to a particular crop and pest combination, and also some general standards (e.g. phytotoxicity). In extending an existing registration to a minor use, the two most important aspects of efficacy evaluation are the demonstration of direct efficacy against the target pest, and the absence of phytotoxicity on the

2 See: <http://pp1.eppo.org/getnorme.php?n=214>

minor crop. The other elements of efficacy are generally adequately covered by the existing registration dossier.

Demonstration of effectiveness

For major uses, efficacy data is mainly obtained in trials correctly set up according to the principles of good experimental practice and performed by official or officially recognized organizations. Data from other sources may be used to supplement that data. For minor uses, however, the objective is to reduce the burden of efficacy trials, by using information from other sources as far as possible, to simplify and speed up the process, including:

- comparison and extrapolation from the original registered uses;
- data from efficacy trials; and
- data from other sources.

Comparison and extrapolation from the original registered uses

Data available from registered uses can be studied to assess the likely direct efficacy of minor uses. This assessment can be aided by extrapolation: certain groups of pests or crops are considered to be more or less equivalent in relation to the efficacy of plant protection products. Some countries have prepared lists of crops and pests for use in extrapolation which can be the basis for the registration of products for minor uses.

The elaboration of such lists can be difficult, since it should be based on present scientific knowledge and, as far as possible, practical experience. Considerable expertise is needed, and this seems to vary from country to country. In some countries, for instance, only a few examples of already accepted extrapolations are provided as guidance to the applicant. Numerous factors may have to be taken into consideration, for example, whether and how the climate, edaphic factors and agronomic conditions, which may be different between the registered use and the proposed extension to a minor use, will influence efficacy. Similarly, the differences between protected crops and outdoor crops, and between autumn and winter versus spring sown or planted crops, may need to be considered. A convincing case has to be made for a valid extrapolation from one to another of those situations.

For fungicides, if a product can control a pathogen in a variety of situations, it may control a related pathogen in a comparable situation. If a product can be used against a pathogen on one crop, it may perhaps be used against it on other crops. In some cases it may be possible to extrapolate in this way without supporting data. Nevertheless, it should be stressed that the epidemiology of a pathogen can be different on different host plants.

For insecticides and acaricides, it is sometimes possible to generalize the use of a product to a whole group (e.g. aphids or mites), within which several species can be controlled, without supporting data for each species. Similarly, there are pest species that can attack several host plants and it can be argued, in these cases, that efficacy on other hosts should be considered equivalent. Data showing that a product can control many insects or mites feeding in the same situation on the plant may also justify extrapolation for the same timing for treatment.

For herbicides, the composition and characteristics of the weeds present in a crop are the key factors influencing efficacy, but the crop also plays an important role. The required level of weed control varies according to the crop, the cropping system, the timing of treatment and its relation with sowing or planting time.

Efficacy trials

Data from efficacy trials may be needed when extrapolation cannot be used to support the registration of a product for a minor use. The trials should be performed according to the appropriate EPPO Standard, by official or officially recognized organizations and following good experimental practice. The number of trials needed should be reduced to a minimum. In general, 2 or 3 trials could be acceptable, but each case should be considered individually. Trials in different locations and years may be useful, according to the relative importance of the problem, subject to the total number of trials allowed. See also EPPO Standard PP 1/226 – Numbers of efficacy trials³. In general, trials set up in other countries should be accepted, provided that a case for comparability is presented and agreed.

Under certain circumstances, trials may also be performed, under official supervision, by farmers and other commercial users (“user-derived evidence”)⁴. Data obtained in this way may be used to support an application for registration of a minor use, but this option is only appropriate for some situations where very good control and supervision of the trials can be assured. Data from this type of trial, properly conducted, may, however, be preferable to data supported only by the type of information described below under “Other sources”.

Other sources

The comparison between registered uses and minor uses can, in certain cases, be supported by data obtained from bibliographic references, provided that comparability can be demonstrated. Comparability should be based on dose rates and on number and timing of treatments. The comparison should also consider the pest complex and crop practices in the country, the behaviour of the pest (specific or polyphagous) and the relative abundance of pest populations. Efficacy data obtained in growth-room or laboratory trials can also be used to give some indication of likely effectiveness in the field. The registration of a given minor use in another country may support an application for registration, provided that comparability between national conditions can be demonstrated.

Phytotoxicity (crop safety)

Phytotoxicity can be a very important aspect of overall efficacy when dealing with minor crops. It is particularly relevant with certain products, such as herbicides, and some types of application, such as soil or seed and plant treatments. Factors to consider with respect to phytotoxicity are the plant species and, in some cases, cultivar, together with the type of plant protection product and its mode

³ See: <http://pp1.eppo.org/getnorme.php?n=226>

⁴ There is good experience of such user-derived evidence in certain EPPO countries.

of application (e.g. dose rate, water volume, timing). Extrapolation is possible in some situations, but should be well reasoned in order to ensure crop safety. It may be based on comparison between the minor crop and crops on which the product is already approved. Other data, such as that obtained from the database of the product, can help. Information on phytotoxicity can also be obtained from trials other than efficacy trials, such as those set up for obtaining residue data, where crop safety assessments can be made. The occurrence of damage by the product on other crops (including succeeding crops), particularly on sensitive crops or plants, or in favourable conditions (e.g. plant growth stage, climatic conditions), could require the setting up of specific trials on phytotoxicity. In this case, conditions to prevent phytotoxicity on the crop should be taken into account in considering extension of the registration.

Obligations of the applicants

As with other types of uses, applicants should make the necessary application for the registration of a named plant protection product (already registered for other uses) for a defined minor use. Thus, they have to prepare a dossier of information. In submitting the dossier on efficacy, the applicant should establish that the use is really a minor one. The applicant should then adequately demonstrate that the product has satisfactory efficacy for the proposed minor use. This should be done by the methods described in this standard.

Obligations of the registration authorities

The registration authorities should recognize the importance of facilitating registration for minor uses in order to provide farmers with as wide a range of products as possible to protect their production. They should prepare guidance on extrapolation, or reference lists which could be an effective basis for extrapolation. The procedures for registration of plant protection products for minor uses in relation to efficacy should be established by each registration authority and they should be made easily available to applicants or other authorities. It would be useful to maintain a database of minor uses for which registration has been obtained. With regard to these efficacy requirements, registration authorities should adopt a more flexible approach for minor uses than for other applications, and should be prepared to consider efficacy data whose form and content may not correspond with the normal dossier for registration. They should, however, be convinced by the application that the use of any product will represent an overall benefit, and that any risks, especially concerning crop safety, will be minimal.

References

- EU [European Union].** 1991. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. *Official Journal of the European Communities*, No. L230: 1–32. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1991L0414:20070201:EN:PDF>

Efficacy evaluation of plant protection products: Efficacy and crop safety extrapolations for minor uses

European and Mediterranean Plant Protection Organization (EPPO)

Organisation Européenne et Méditerranéenne pour la Protection des Plantes (OEPP)

Specific scope

This standard describes the principles of extrapolation regarding the efficacy and crop safety of plant protection products intended for minor uses. It provides guidance for regulatory authorities and applicants in the context of the registration of plant protection products for minor uses. It also provides detailed lists of acceptable extrapolations organized by crop groups, and these will be added as they are developed.

Specific approval and amendment: First approved in September 2007.

Introduction

The aim of this standard is to provide guidance on principles of extrapolation regarding the efficacy and crop safety of plant protection products intended for minor uses. The text includes extrapolation tables which provide guidance for applicants and regulatory authorities to seek and grant authorizations in the absence of specific data (or with reduced data), whilst ensuring efficacy and crop safety of the extrapolated use. At the time of publishing, the extrapolation tables are in preparation. Once agreed, they will be maintained and updated separately from this standard by the EPPO Panels on Efficacy Evaluation and will be published as 'Extrapolation tables for efficacy/crop safety of plant protection products (insecticides/fungicides/herbicides) to accompany EPPO Standard PP 1/257'.

These principles and examples of extrapolations (given in the extrapolation tables) provide a harmonized framework to support regulators, but it is important to ensure that expert judgement and regulatory experience are employed when using this document.

Background

Minor uses are those uses of plant protection products (defined in relation to crops and pests) in which either the crop is considered to be of low economic importance at a national level (minor crop), or the pest is of limited importance on a major crop

(minor pest). It should be noted that a minor use in one country may be a major use in another country, and it is for each country to define what are its minor uses.

The availability of plant protection products to growers of minor crops is becoming increasingly limited. Given the small quantity of a plant protection product that would be used for a certain minor crop, agrochemical companies find it difficult to justify the registration costs. The requirement to generate a considerable amount of data makes the authorization process very expensive. However, minor crops are of substantial economic importance in many countries. For minor use authorization, it is therefore preferable to explore other possibilities for determining the efficacy and crop safety of a plant protection product than those based on the amount of data normally required.

Under EU directive 91/414¹, it may be requested that “the field of application of a plant protection product already registered in the Member States in question be extended to purposes other than those covered by this authorization”. An extension can be granted, provided that “the documentation and information to support an extension of the field of application has been submitted by the applicant” and “the intended use is minor in nature”. By this procedure, plant protection products for minor uses can be authorized at national level provided that the applicant requests it. The Directive does not specifically refer to efficacy evaluation, but EPPO Standard PP 1/224 Principles of efficacy evaluation for minor uses² recommends registering and using a product which has an acceptable level of efficacy.

Efficacy requirements

Efficacy is defined as the direct effect (effectiveness) on the pest or on the modification of plant growth (growth regulators), together with other indirect effects, such as those on the crop being protected, on succeeding or adjacent crops, on natural enemies, or on the development of resistance (see EPPO Standard PP1/214 – Principles of acceptable efficacy³).

In extending an existing registration to a minor use, the two most important aspects of efficacy evaluation are the demonstration of direct efficacy against the target pest, and demonstration of safety to the crop.

For major uses, efficacy data are mainly obtained in trials set up according to the principles of good experimental practice and performed by official or officially recognized organizations. Data from other sources may be used to supplement this data. For minor uses, however, it is important to minimize the burden of efficacy trials. Therefore, in order to simplify and speed up the process the following information may be used, as far as possible:

- comparison and extrapolation from the original registered uses;
- use of data from a limited number of efficacy trials; and
- use of data from other sources.

1 EU [European Union]. 1991. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. Official Journal of the European Communities, No. L230: 1–32. Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1991L0414:20070201:EN:PDF>

2 See: <http://pp1.eppo.org/getnorme.php?n=224>

3 See: <http://pp1.eppo.org/getnorme.php?n=214>

This present standard deals specifically with comparison and extrapolation from original registered uses.

For minor uses, additional data for minimum effective dose is not usually needed because determining the minimum effective dose is less important than for non-minor uses.

Data available from the original registered uses can be studied to assess the likely direct efficacy of minor uses. This assessment can be aided by extrapolation: certain groups of pests or crops are considered to be more or less equivalent in relation to the efficacy of plant protection products.

Principles of extrapolation

EPPO Standard PP 1/224 – Principles of efficacy evaluation for minor uses – describes the principles for determining requirements for efficacy evaluation regarding authorizations of plant protection products for minor uses and should be considered in connection with this standard. It refers to extrapolation as one of the possibilities for demonstrating efficacy.

Many extrapolations will be applicable across Europe. However, differences may exist between different regions, e.g. the northern and the southern parts of Europe. This has been considered for the extrapolations that are included in the extrapolation tables for effectiveness and crop safety of plant protection products. However, 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 plant protection products. This standard supports national experts in their review.

Extrapolations may be used to allow an existing authorization to be extended to include additional crops or pests in the absence of specific data. Extrapolation may also allow a more reduced data package than normally would be required to support another use, as specified in EPPO Standards PP 1/224 – Principles of efficacy evaluation for minor uses – and PP 1/226 – Numbers of efficacy trials⁴. However, the present standard does not address reduced data for an authorization of a plant protection product for a major use, but only for minor use authorizations.

The extrapolations included in the extrapolation tables of this standard are based on an examination of biological and chemical evidence that justifies assumptions of efficacy without a full set of supportive data. The extrapolation tables are not exhaustive. When an extrapolation is not listed, it does not mean that it may not be acceptable.

For purposes of acceptance of trial data for the registration of plant protection products, the EPPO region has been divided into four agro-climatic zones (see EPPO Standard PP 1/241 – Guidance on comparable climates⁵). From this perspective, extrapolations are possible within the same agroclimatic zone. Between zones, extrapolation may also be appropriate if the conditions are deemed to be comparable to those in that country (or in special cases, regions of countries) where the product is already authorized. For crops grown in protected situations

⁴ <http://pp1.eppo.org/getnorme.php?n=226>

⁵ <http://pp1.eppo.org/getnorme.php?n=241>

there may be greater scope to extrapolate because the environmental conditions are controlled and less variable.

The effects of climate on pest-crop interrelationships should also be taken into account. However, climate is only one factor that may affect the effectiveness and crop safety of a product in addition to other factors (agronomic, edaphic, target-related) when establishing the relevance of data generated within different member states.

Extrapolations may only be accepted for the extension of use of a given plant protection product used at the same or in a similar dose, applied under similar conditions (e.g. timings, growth stages, application methods, soil conditions). Extrapolations cannot automatically be reversed, i.e. permission to extrapolate from situation A to situation B does not automatically permit extrapolation from situation B to A. Extrapolation is hampered by potential variability in pest-crop-product interactions. However, the scope for extrapolation may be extended as data and experience with a certain plant protection product increases. Extrapolation may be limited when a certain plant protection product is known to be effective for a rather specific set of conditions. The less specific this set, the greater the scope for extrapolation.

The accompanying extrapolation tables are based on the principle that certain crops can be considered equivalent in relation to effectiveness or crop safety and can be grouped together in crop groups. A crop group contains all crops for which an extrapolation can be performed from an indicator crop (for a particular plant protection product), regarding either:

- effectiveness against a particular pest; or
- safety for a particular crop.

Indicator crops are those crops that can be considered representative of effectiveness or crop safety for their crop group and for which a set of data is or should be available. Within a crop group there might be some crops for which certain pests are considered to be more difficult to control and therefore collecting some additional evidence is recommended while extrapolating from an indicator crop. It should be noted that it is commonly preferable to have data on several of the crops within the crop group, but data on the indicator crop should also be available.

If effectiveness of a plant protection product has been adequately demonstrated against a major pest or a range of related pests for a particular crop group, it may be possible to extrapolate to other related pests in other crop groups.

Efficacy extrapolations for fungicides and insecticides

A decision-support scheme for extrapolations regarding fungicides and insecticides (which includes bactericides, acaricides, molluscicides and nematicides) is given in Appendix 1.

Key factors that may be relevant for extrapolation

Crop

Crop morphology, botanical family, cropping system and growth pattern. It should be noted that closely related species may still differ significantly in growth pattern, leaf surface or the parts of plant that are harvested. Extrapolation may be relevant from a major economic crop, but in some circumstances a more challenging situation for control may be found in a minor crop.

Disease or Pest

Taxonomic relationship, biology, life cycle, behaviour, plant parts attacked, damage caused. Closely-related species may have significant differences. A given pest species may behave differently between crops. For example, different generations of a pest may cause different types of damage, so care is needed with extrapolation between crops, or similarities in feeding behaviour of insects may make extrapolation across a range of pest groups appropriate, but the biology of the individual pest is still important.

Product

Mode of action, timing, frequency, method of application, preventative or curative treatment, systemic or non-systemic, formulation, dose, extent of existing database, existence of regional differences in susceptibility to plant protection products.

Agronomic

Growing conditions (field or protected) and cultivation techniques, growing systems, soil type (particularly for soil treatments). Generally, protected situations are considered less challenging than field situations, particularly for foliar applications.

Seed treatment

Extrapolation between seed treatments of different crops is normally more acceptable when the seeding density and thousand-grain weight is similar. Furthermore, different sizes of seeds between different crops may lead to different dilution effects, which may mean that extrapolation is not possible.

Other factors of importance, for which similarity is necessary, are: sowing period, time of appearance of pest, application technique, seed skin (rough vs smooth surface). Substantial differences in growth rate can lead to different dilution effects for systemic plant protection products and extrapolation may not be possible if this is the case.

Efficacy extrapolations for herbicides

A decision-support scheme for extrapolations regarding herbicides is given in Appendix 2.

Specific principles which may be relevant for extrapolation between crops for the same target weed include:

- when considering the acceptability of an extrapolation, account should be taken of timing of weed control, time and method of sowing or planting, competitiveness of the crop, time and method of harvesting, and ease of separating crop and weed seeds;

- when effectiveness of a herbicide has been adequately demonstrated against a major weed species or a range of species from a particular plant family, it may be possible to extrapolate to a related weed species;
- extrapolation may be possible from the control of a particular weed outdoors to the same species under protected conditions, since conditions are less variable and weeds under protection tend to be more sensitive. However, effectiveness under protected conditions cannot be extrapolated to outdoor use, as weeds grown outdoors are usually hardened off and therefore less sensitive to herbicides; and
- the efficacy of soil-acting herbicides against weed species in the field cannot be extrapolated to use in container plants or plants in artificial substrate. This is due to the likelihood of differing effects of different growing media on efficacy.

Extrapolation from one weed species to other weed species is generally not possible, because of differences in the sensitivity of weed species to a herbicide. However, when trials are carried out with several weed species from the same group of weeds (e.g. annual dicotyledonous species or annual grasses), extrapolation is possible to the whole group. This does not mean that all weeds in this group are susceptible. The susceptible weeds should be mentioned on the label.

Critical factors that may be relevant for extrapolation

Crop

Crop morphology, competitiveness of the crop, growth habit, growth pattern. It should be noted that closely-related species may still differ significantly in growth habit. Time and method of sowing or planting, cropping system, time and method of harvesting, and ease of separating crop and weed seeds.

Weed

Taxonomic relationship, biology, life cycle, behaviour, growth stage. Closely-related species may have significant differences.

Product

Mode of action, time of application, frequency, method of application, aerial or soil treatment, formulation, dose, spray volume, extent of existing database, possible regional differences in susceptibility of weeds to plant protection products.

Agronomic

Growing conditions and cultivation techniques, growing systems, field or protected, soil type (particularly for soil treatments).

Efficacy extrapolations for plant growth regulators

No information is available at this time.

Crop safety

Phytotoxicity is particularly relevant with certain products, such as herbicides, some types of application, such as soil, seed or plant treatments, and for specific crops, like ornamentals. Phytotoxicity can vary considerably between different crop species, cultivars of the same crop and between different plant protection products.

Extrapolation is possible in some situations but should be well reasoned in order to ensure crop safety. It may be based on comparison between the minor crop and crops on which the product is already approved. If an extensive database on crop safety for the plant protection product is available, crop groups may be developed. At the same time, extrapolation may not be possible where use of the product has resulted in crop damage on some crops or cultivars, where the crops concerned are significantly different, or when a crop is known to be particularly sensitive.

In addition to or to assist extrapolation, it may be possible to assess crop safety while obtaining data for residues or effectiveness for a particular plant protection product.

The general principles for extrapolation in this standard apply also in cases of extrapolation for crop safety. In addition, the following specific principles are important:

- the method of application for the crops involved in the extrapolation should be similar; and
- Availability and interpretation of evidence of crop safety (or of phytotoxicity) from standard pre- and post-emergence pot tests and glasshouse varietal screens should be treated with care. Conditions in a glasshouse can affect the structure of plant surfaces, as well as pest biology, thereby changing the crop safety of a product.

In addition to these specific principles the following critical factors may be relevant for extrapolation for crop safety:

- taxonomic relation to the crop for which the product is already approved;
- similarity in morphology of the crops concerned; and
- availability of adequate crop safety data showing a good margin of safety for the crop(s) from which extrapolation is required and across a range of cultivars.

Crop safety extrapolations for fungicides and insecticides

As a general principle, insecticides (which includes bactericides, acaricides, molluscicides and nematicides) and fungicides would be expected to have low phytotoxic activity with limited adverse effects on the treated crop. The extent of extrapolation within or between crops is largely dependent on the use of the product, known sensitivity of the treated crop and/or growth stage, and the extent of existing knowledge.

Evidence may be available from standard pre- and post-emergence pot tests and glasshouse varietal screens. Such preliminary data provides a very useful baseline of inherent crop safety properties for a particular active substance. Following this, trials using the relevant formulation will provide assessments of phytotoxicity in both efficacy trials on the main target crops, and possibly data from specific crop safety trials. Where relevant for major crops, these should also include some evidence on yield effects. Using this combination of glasshouse and field data, information can be built up on a range of uses and also perhaps formulation types. As existing knowledge builds up, the scope for extrapolation to other crops in the absence of further crop safety data becomes greater.

Where there are significant differences between the current use and a proposed extrapolation, particularly regarding dose and formulation, additional data may be required. However, even in these circumstances there may be evidence of inherent

crop safety at high doses, or across a range of formulation types, which could be used as evidence in making a reasoned case. Other factors such as timing, application method, growing conditions and crop morphology will also need to be addressed, either by a reasoned case or further limited data. For insecticides and fungicides with a robust database indicating inherent crop safety across a range of conditions and crops, additional data may only be required in very specific circumstances, e.g. for a new crop of known particular sensitivity.

Given the above, the suitability of extrapolation from a crop safety perspective will need to be considered on a case-by-case basis for a particular product, making full use of existing knowledge. Nevertheless some general comments on crop safety for particular crop groups are provided in 'Extrapolation tables for crop safety of fungicides and insecticides' as well as, where known, information on the more sensitive crops and crop stages. These are particularly appropriate as test plants because they represent a 'worst case' and provide greater scope for extrapolation. They could be used as indicator plants in crop groups for crop safety extrapolations to be developed in the future, as experience in crop safety extrapolations develops.

Crop safety extrapolations for seed treatment

See Section *Seed treatment*

Crop safety extrapolations for herbicides

Crop safety is particularly an issue in the case of herbicides. Specific principles are not available and extrapolations have to be considered on a case-by-case basis.

If a herbicide is demonstrated as only effective against monocotyledonous species, it may be possible to extrapolate crop safety between dicotyledonous crops, and vice versa. However, this will depend on the information available on the active substance. In Extrapolation tables for crop safety of herbicides, a list of examples for crop safety extrapolations is given, based on existing experience. This list is not exhaustive and can be extended as experience develops.

The following tables are being developed:

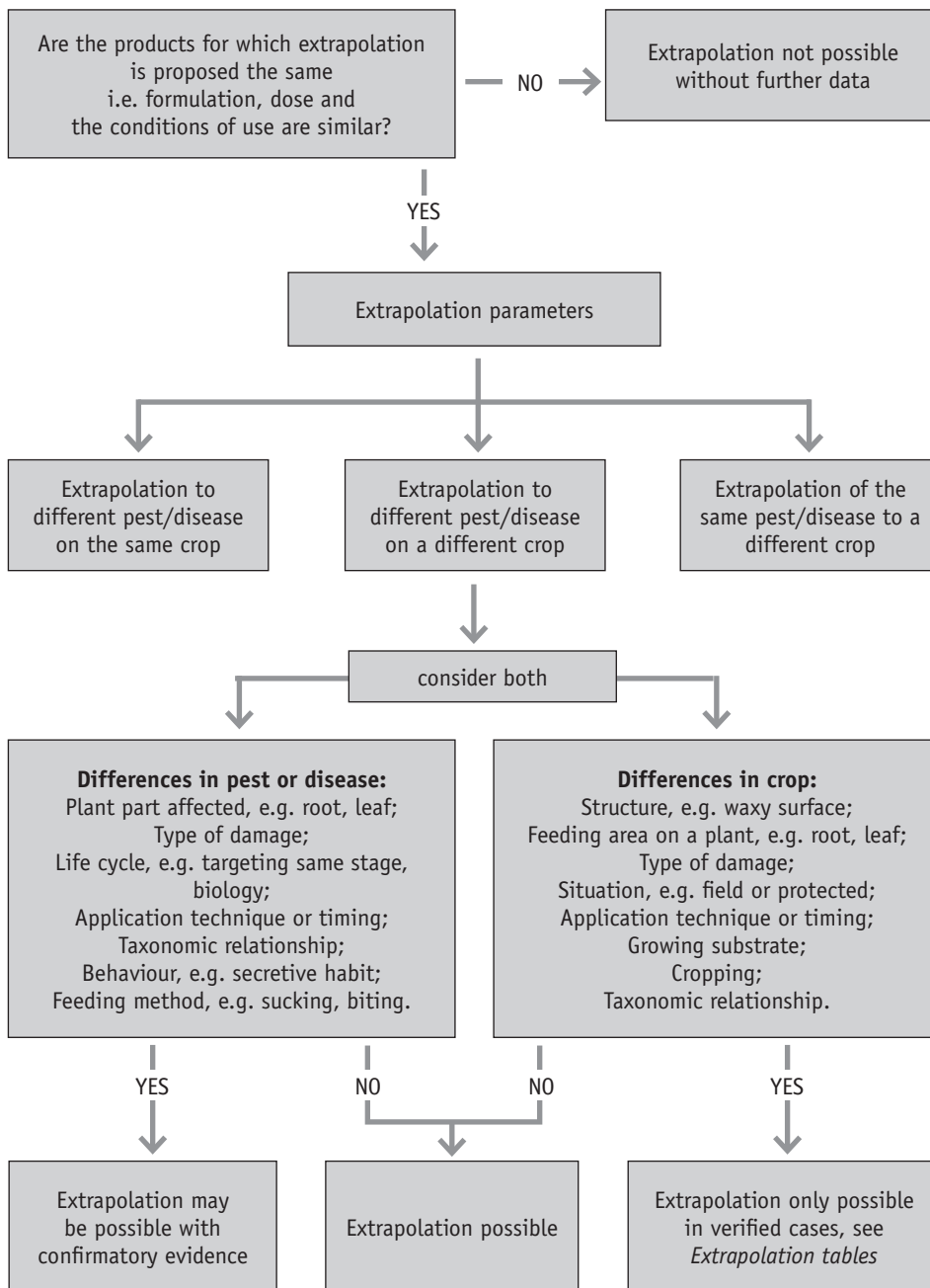
Extrapolation tables for effectiveness of plant protection products

- Extrapolation tables for effectiveness of fungicides
- Extrapolation tables for effectiveness of insecticides
- Extrapolation tables for effectiveness of herbicides
- Extrapolation tables for effectiveness of plant growth regulators.

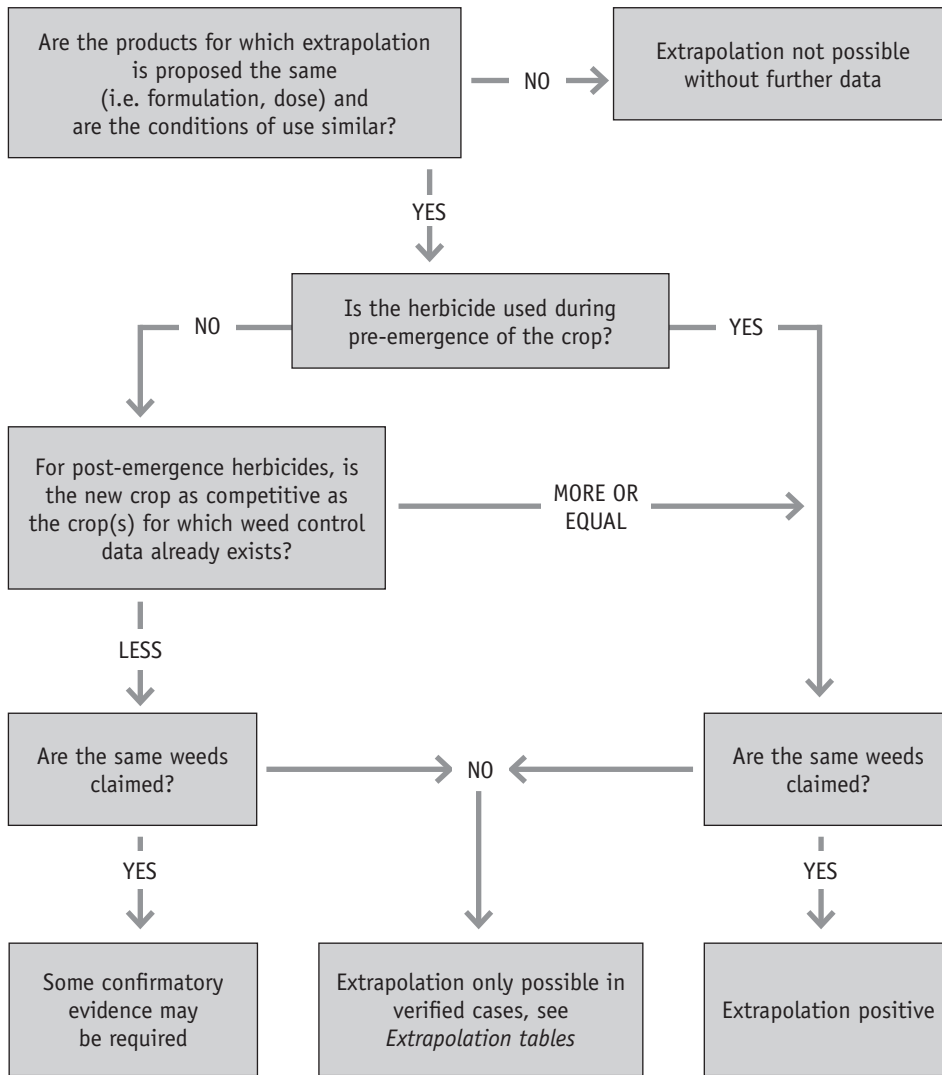
Extrapolation tables for crop safety of plant protection products

- Extrapolation tables for crop safety of fungicides and insecticides
- Extrapolation tables for crop safety of herbicides
- Extrapolation tables for crop safety of seed treatments.

Appendix 1. **DECISION-SUPPORT SCHEME FOR EXTRAPOLATIONS FOR FUNGICIDES AND INSECTICIDES**



Appendix 2. **DECISION-SUPPORT SCHEME FOR EXTRAPOLATIONS FOR HERBICIDES**



PESTICIDE STOCK MANAGEMENT SYSTEM

Richard Thompson

EU MINOR USE DATABASE

Mario Wick

UNITED STATES-CANADA GROWER PRIORITY DATABASE

Matt Lantz, Dan Botts and Craig Hunter

PEST INFORMATION MANAGEMENT SYSTEM OF THE EAST AFRICA PHYTOSANITARY INFORMATION COMMITTEE

Esther W. Muchiri

THE US DEPARTMENT OF AGRICULTURE US ENVIRONMENTAL PROTECTION AGENCY MRL DATABASE

GLOBAL NEEDS DATABASE

Miles R. Thomas and Fritz Schuster

PEST MANAGEMENT CENTRE'S MINOR USE PESTICIDES PROGRAMME DATABASE

Manjeet Sethi and Shirley Archambault

THE DATABASE REQUIRED FOR THE ESTABLISHMENT OF MRL GLOBAL HARMONIZATION FOR MINOR USES PESTICIDE-MINOR CROP COMBINATION

Sri Noegrohati

Pesticide Stock Management System

Richard Thompson

Introduction

FAO has developed the Pesticide Stock Management System (PSMS) as a database tool for countries to use for the management of their pesticides. PSMS has three main components for the management of pesticides throughout their life cycle, namely:

- Registration;
- Stock management; and
- Management of obsolete pesticide wastes.

System architecture

PSMS is based on a database held at FAO, Rome, that can be accessed through a Web application (<http://psms.fao.org/psms>). Access to the system is limited to users nominated by their country or region. The system has various levels of secure access that are controlled by user names and passwords that determine the role, authority and country of each user. Each user can only view and modify data to which they are authorized.

In addition to the Web system, there are electronic templates and paper forms that can be used to capture information for the system. In countries where the internet connectivity is poor, it is possible to install the system on to a local area network (LAN), but this limits its availability only to the users of that LAN.

Registration component

The registration component aims to support the maintenance and communication of national and regional pesticide registries (e.g. the pesticides registered by the Comité Sahélien des Pesticides in CILSS countries). A registrar can use the system to record all the pesticides registered for use in their country. This includes pesticides for use in agriculture, forestry, aquaculture, animal health and public health. The system holds information on:

- commercial name;
- active ingredient and formulation;
- validity of registration;
- allowed uses (including pests and where appropriate, crops, MRLs and GAP); and
- allowed packages (including size, type and material of construction).

The pesticide registry can be entered directly or imported by means of an MS Excel™ template. The system also allows the registrar to manage de-registration, restricted uses and banned pesticides.

PSMS also aims to assist registrars in their decisions as to whether or not to grant requests for registration. Countries can elect to share their registry information with other countries. Users are able to search the registers of other countries for pesticides that have been registered for particular uses, e.g. on specific crops or against specific pests. PSMS will provide a list of pesticides in the database that match the search criteria. In this way, national registrars can identify other pesticides that are effective whilst representing the least risk to users, public health and the environment.

Future developments of PSMS will link it to other databases relevant to pesticide registration, including MRLs from Codex Alimentarius and Homologa.

Stock management

PSMS supports the management of pesticide stock throughout its life cycle: authorization of imports; customs clearance; release from national manufacturers and formulators; through the distribution chain to pesticide stores; and, ultimately, to users. It also covers the return of empty containers and unwanted pesticides.

The system was first developed in 2005 to support the management of pesticide stocks used in the control of desert locusts following the major outbreak in West Africa in 2004. It is still being used for this purpose and whenever there is an outbreak of a migratory pest, the system is used to identify whether there are suitable existing stocks in the region before new stocks are procured. In this way, the subsequent outbreaks in Tanzania and Yemen have been addressed by donations of existing stocks from Mali and Senegal, saving both the cost of new pesticides and the cost of disposal of pesticides that could otherwise have become obsolete.

The system functions by giving each individual pesticide container a unique identification number in the form of a bar code. As the container is moved along the distribution chain, the barcode is scanned, and PSMS updated with its new location.

The system enables national users to identify location and condition of pesticide stocks, informing decisions on procurement and usage requirements.

Currently the stock management component of PSMS is primarily being used to manage stocks that are under the control of governments or bodies such as the Desert Locust Control Organization. A number of countries have requested that the system be extended to manage pesticide stocks within the commercial sector. The system is being piloted for this purpose in Mali and Lebanon.

Management of obsolete pesticides

PSMS also includes a component that assists countries to develop safeguarding and disposal strategies for their obsolete pesticides.

The process initiates with an inventory and environmental assessment of the pesticide stocks and other pesticide wastes (e.g. empty containers and other contaminated materials). The data is collected on standardized paper forms that are then entered into the system. PSMS uses the methodologies outlined in FAO's Environmental Management Tool Kit to develop the safeguarding strategy by prioritizing the stores that represent the highest risk to public health and the environment, and by selecting low-risk stores to be used as collection centres.

Many countries also have locations with buried pesticides, spilled pesticides or areas with high contamination through excessive use. These sites represent a particular problem and require extensive and expensive investigations to identify a risk mitigation strategy. It has been the case in other projects that funds are consumed entirely by these investigations without any risk mitigation activities being undertaken. The PSMS system is being developed to include a rapid environmental assessment (REA) of these sites. The REA is an initial low cost and objective assessment that facilitates the prioritization of the high-risk sites. Only the high-risk sites then require intrusive investigations and the development of risk mitigation strategies.

EU Minor Use Database

Mario Wick

Julius Kühn-Institute (JKI), Kleinmachnow, Germany

The sharing of information about joint databases and national activities aimed at closing minor use gaps is essential for effective international cooperation in the field of minor uses. Consequently, the crucial importance of database accessibility has been and will continue to be stressed at all meetings on the topic of minor uses. Many EU Member States have already published a list of their national pesticide approvals on the Internet. The European Commission is also working on an approvals database of plant protection products approved in the Member States. In terms of content, only partial solutions are currently available, and these are spread out over different sites on the Internet.

The aim of the current database project is to collate all essential information on cooperation in the field of minor uses into a single database located at a single site on the Internet, and accessible to all interested parties free of charge. The database will serve as a working basis for the EU's Expert Working Groups (EWGs) on Minor Uses and will enable the effective cooperation needed for closing minor use gaps. Furthermore, it will facilitate work- and cost-sharing in the implementation of research projects and testing, and will promote improvements in harmonization in the field of minor uses.

In the initial phase, data for the following lists will be entered into the database for the entire European Union (Members States whose data are already contained in the respective lists are shown in parentheses):

- List of national authorizations (DE).
- List of national crop acreages (AT, BE, BG, CZ, DK, EE, FI, DE, GB, GR, HU, IE, LT, LV, NL, NO, SK, SE).
- List of national minor uses according to EU regulation 1107/2009, Article 51 (8) (DE).
- List of available national studies on efficacy, plant tolerance and pesticide residues (DE).

Work programmes and project lists of the EU EWGs on Minor Uses for Small and Stone Fruits, and for Fresh Vegetables.

In parallel, all Member States (authorities, companies, etc.) will be offered free use of the database to promote the accessibility of their data on minor uses.

A form (Excel™ spreadsheet) has been developed to facilitate the transmission of data to the EU Minor Use Database. The data can be read into the central database in this format. Each Member State is responsible for providing and regularly updating their own data. The Database Administrator assimilates Excel spreadsheet data

from various databases. The editing function available on the Internet can be used for smaller volumes of data. The goal is to have the list of approvals updated at monthly intervals, depending on the capacity of the EU Member States. The lists from the EWGs can be updated continuously. However, they should be updated at least semi-annually, after the EWG meetings. Annual updates are sufficient for the other information lists.

United States-Canada Grower Priority Database

Matt Lantz (Bryan Christie, Inc), *Dan Botts* (Minor Crop Farmers Alliance - MCFA) and *Craig Hunter* (Canadian Horticultural Council - CHC)

The United States-Canada Grower Priority Database is located at www.uscanadagrowerprioritydatabase.com; a bilingual version of the Canadian portion of the database is available at: www.canadiangrowerprioritydatabase.ca

The mission of the database is to capture grower-identified priorities for resolving differences in available crop protection tools and MRLs in the United States and Canada. The database allows users to go to one place to identify:

- potential trade barriers – situations where an active ingredient or use is available in one country but not the other;
- potential trade irritants – situations where the two countries have different MRLs (or no MRL) for corresponding uses; and growers' priorities for addressing these discrepancies.

The database, while not directly regulatory in nature, is designed to provide support for the orderly and expedited consideration and removal of potential trade issues that might exist in the NAFTA region. Each of the stakeholders involved in the development, generation, and verification of data for the database has the opportunity to extract value from the information contained in the database. The database also serves to monitor progress in removal of potential trade impediments.

United States priorities are oriented towards the harmonization of MRLs and are identified by commodity, active ingredient, brand name and registrant combinations. Each priority has been ranked by growers as being very high, high, intermediate or low. This information is included in a password-protected section of the database (passwords can be obtained from the database administrator via e-mail).

The Canadian portion of the database focuses primarily on the registration of uses not currently registered in Canada but available elsewhere (particularly in the United States, but also in other OECD countries). It contains priority pest information and the regulatory status for each grower-identified priority. In 2011, priorities identified at the Canadian Annual Minor Use Priority Setting Workshop were integrated into the database.

Each year, United States and Canadian growers are asked to update their priorities. Registrants are given the opportunity to review and provide comments such as “MRL data application submitted in 2011”, “Efficacy data available” or “Support for registration”.

The database helps in reducing the Technology Gap as we get registration of actives currently on the list, and new registrations through the NAFTA Joint Review and the Global Joint Review. Joint work between the Canadian Minor Use Programme and the IR-4 Program has created common registrations and MRLs which prevented an increase of needs on the list.

The database has been a success from both United States and Canadian grower perspectives. Out of the 887 United States grower-identified priorities, 254 priorities (29%) now have new Canadian MRLs established at acceptable levels. To date, over 400 Canadian grower-identified priorities have been addressed through product registrations in Canada.

The United States is considering whether to expand this model to include priorities for additional markets beyond Canada.

For additional information on the United States-Canada Grower Priority Database, please contact Kimberly Berry at Bryant Christie Inc. in Seattle, Washington, USA (kimb@bryantchristie.com).

For additional information on the Canadian portion of the database, please contact Debby LeBlanc at the Pest Management Regulatory Agency in Ottawa, Canada (Debby.LebLANC@hc-sc.gc.ca).

Pest Information Management System of the East Africa Phytosanitary Information Committee

Esther W. Muchiri
EAPIC, Nairobi, Kenya

About EAPIC

The East Africa Phytosanitary Information Committee (EAPIC) was formed in Nairobi in April 2006 during a Pest Risk Assessment (PRA) meeting of regulatory officials from Kenya, Tanzania, and Uganda. Zambia, Rwanda and Burundi joined later. The Mission of EAPIC is to serve as a secure electronic repository of national plant pest lists and for sharing official pest information among member countries and international and affiliated entities, thereby increasing food security and international trade. The overall goal is to have a functional and dynamic Pest Information Management System (PIMS) that should facilitate the creation of PRAs, leading to increased trade and food security in the region by 2015.

Objectives of EAPIC

Pest lists development

- Build national capacity to develop pest lists through training, workshops, etc.
- Input national pest lists into the EAPIC PIMS database for five priority crops (maize, cassava, banana, rice and beans).

Pest surveillance

- Build national capacity to conduct surveillance through training, workshops and seminars.
- Develop surveillance protocols (adopt existing protocols, e.g. IPDN).
- Conduct country-specific surveillance for priority crops and others selected crops.
- Develop national surveillance teams of recognized specialists.
- Develop maps for pest-free areas in the region.

Linkages with stakeholders

- Develop materials to create awareness on plant pest information.
- Identify relevant linkages with partners and stakeholders, and their roles or mandates.
- Establish collaboration mechanisms and joint activities with relevant partners and stakeholders.

Pest Information Management System

The Pest Information Management System (PIMS) is a regional database for storing plant pest lists and surveillance data. The system was first developed by NCSU with support from USDA, and later upgraded through funding by FAO.

PIMS will complement other trade initiatives in the region and help to prioritize specific needs for pest survey, detection, inspection and diagnosis. Through officially sanctioned, Web enabled pest databases, EAPIC member countries will be able to access reliable information locally for domestic programmes, as well as share critical information to satisfy international obligations (e.g. the International Phytosanitary Portal of the IPPC).

On a regional basis, national plant protection organizations will now be able to combine resources and strategies for agricultural pest management and exclusion.

PIMS is hosted at the regional centre of excellence housed at the Kenyan Plant Health Inspection Service (KEPHIS), and can be accessed at www.eapic.org

Achievements to date include:

- Developing priority pest lists for surveillance by all member countries.
- Reports on each member country with preliminary findings on in-country surveillance capacity and ongoing surveillance initiatives
- Developing the Pest Information Management System (PIMS).
- Acquisition of servers for EAPIC member countries (Uganda, Tanzania and Zambia).
- Improving the EAPIC Web site into an information portal.
- Upgrading the PIMS database with improved search functionalities.
- Developing a regional phytosanitary-related Expert Database.

Funding to date

2006–2007	USDA-funded EAPIC activities in collaboration with USAID/EA
2008–2009	FAO started providing stability to EAPIC by collaborating in the development of pest databases through its funding of an EAPIC Coordinator. FAO also funded improvement of PIMS in response to requests by users.
2010	USDA and USAID/EA funded the EAPIC regional meeting.
2011	USAID/COMPETE provided funding to oversee the activities of EAPIC including: (1) developing a dynamic EAPIC Web portal; (2) improvement of PIMS; (3) rice pest surveillance; and (4) labour fee for EAPIC coordinator.

Partners

EAPIC works closely with and receives support from United States Agency for International Development (USAID); United States Department of Agriculture (USDA); Animal and Plant Health Inspections Service (APHIS); Food and Agriculture Organization of the United Nations (FAO); Kenya Plant Health Inspectorate Service (KEPHIS); Centre of Phytosanitary Excellence (COPE); Common Market for Eastern and Southern Africa (COMESA); Kenya Agricultural Research Institute (KARI); and International Plant Protection Convention (IPPC).

The US Department of Agriculture US Environmental Protection Agency MRL Database

The USDA-EPA MRL Database is located at www.mrldatabase.com. The mission of the Web site is to provide the most accurate international MRL information possible for US exporters. The database is currently a free site to users. It is supported by a combination of USDA and US-EPA funding.

The MRL Database includes MRLs for 343 active ingredients for 351 commodities in 86 markets. The information displayed in the MRL database draws from a database that includes 5.2 million MRLs. The database includes MRLs currently in effect for EPA-registered active ingredients and their corresponding foreign MRLs.

The database is unique in that it includes deferral paths for MRLs. For example, the database indicates whether the displayed MRL comes from the country's national list, from another market which the country uses to supplement its national list, or from Codex MRLs.

The database also includes notes on commodity and crop groups, so users know if the MRL displayed is established on the individual commodity, such as "apple", or for a broader crop group, such as "pome".

Market information pages are available describing each market's MRL policies and testing regimes.

The MRL database is updated on a daily basis with the latest MRLs around the world, and undergoes extensive and regular auditing to ensure accuracy.

The MRL Database is widely used, with over 100 000 unique visitors last year.

For additional information on the USDA-EPA MRL database, please contact Kimberly Berry at Bryant Christie Inc. in Seattle, Washington, USA (kimb@bryantchristie.com).

Global Needs Database

Miles R. Thomas (Head of Knowledge Management, Food and Environment Research Agency - FERA, York, UK)
and *Fritz Schuster* (Agrobase-Logigram SARL)

The Global Needs Database is programmed to offer international information on (1) registered uses, (2) required uses, including agricultural statistics, (3) ongoing projects and (4) index of contacts.

Part 1, on Registered Uses (Homologa database), already includes information from over 60 countries listing crops, pests, products, active ingredients, manufacturers and use patterns. The data are collected from a variety of sources, depending on national information availability, but mainly, and wherever possible, from the official sources in the different countries. The bigger countries are updated every month; the smaller countries at least once a year; but in general 3–4 times a year. All information is translated into English and standardized through a common coding system for crops, active substances, etc. The database also includes almost all relevant countries for MRL information (about 27, including Codex). The reporting options allow analysing crop and pest data at an international level, and combining registration data with MRLs. The system is also able to send alert messages for any changes, updates, etc., via e-mail. Users will be informed automatically of changes in the product registration and MRLs depending on what they have chosen as a request profile.

A new version of Homologa is expected to be released in the first semester of 2012, and will contain the option to work with an open number of languages. The database is accessible via the Internet.

Part 2, on Required Uses, is programmed to accept the lists of required uses of crop–pest–product combinations from countries or regions, including a description to reflect if the requirement is to establish an MRL or to register the use. There are also fields to allow an evaluation of the importance of the need, such as crop statistics, potential infested areas, potential loss and other significant reasons, like health issues, avoidance or combating pesticide resistance.

Part 3, on Ongoing Projects, allows database users to list national and regional projects that are being planned or conducted. It includes:

- description of project;
- status quo of need or project in progress;
- description of GAP, use details; and
- documentation of data requirements.

Part 4 is an Index of Contacts, with profiles to allow interested parties to contact each other.

The Global Needs Database has been developed by Agrobase Logigram, in association with the UK governmental Food and Environment Research Agency (FERA), based on its existing Homologa database and its registration- and MRL-data transfer services for other databases. It is currently populated and searchable for Part 1, and ready to be populated for Parts 2, 3 and 4. The partnership is therefore offering itself as a complete service provider and, whilst also a software developer, is not positioning itself as such in this instance.

Pest Management Centre's Minor Use Pesticides Programme Database

Manjeet Sethi and Shirley Archambault

Pest Management Centre, AAFC

The database of the Pest Management Centre (PMC) of Agriculture and Agri-Food Canada (AAFC) is known as the Minor Use Pesticides Programme System (MUPPS).

The Minor Use Pesticides Program (MUPP) initiates projects to test products on crops based on priorities from the March Priority Setting Workshop, with approximately 65 projects selected each year. A project consists of studies and a collection of field, processing or lab trials, or a combination, which are used to demonstrate the tolerance, efficacy or residue of a product. In order to track the details of this work and provide the growers with project progress updates and submission timeframes, PMC required a tracking system, and the MUPPS database was created.

The bilingual (English/French) database, originally designed in ACCESS in 2004, was converted to an ORACLE system in 2007. Its main function is to assist in the administration and tracking of projects, studies, trials and submissions (product registrations) to Health Canada's Pest Management Regulatory Agency (PMRA). It is a data capture application, which uses the data provided to automatically update the status of submissions, projects, studies and trials, and to notify users of significant events, especially those requiring action.

MUPPS is an internal database with access limited to personnel working on PMC projects. This includes PMC staff located in Ottawa and at 7 regional offices, as well as AAFC research employees located at nine minor-use research sites across the country. The database is Web-enabled to allow the regional test sites access to the application in order to enter trial data directly into the database. MUPPS also allows AAFC researchers to sign up for trials and order test items required for their trials.

Within the database, each project captures general information such as the crop, pest, product and active ingredient. It also includes the application use pattern, the data requirements necessary for submission, and information related to the actual submission of the project to the PMRA. At the trial level, items such as the crop zone, test site, application and harvest dates, and pest pressure are collected.

To monitor the progress of projects and allow for these to be reported, a series of statuses has been included in MUPPS. A status is a short description of the current state of the project, study or trial that changes as data is input. For example, as application and harvest dates for a trial are inputted, its status changes from initiated, to application phase, to harvest phase and finally to complete. The statuses

roll up from the trial level to the study and then the project level, until all levels are completed. Typical project statuses include Project Initiated, Planning Phase, Data Generation, Reporting Phase, and Project Complete.

MUPPS is a complex system, with approximately 47 code tables (behind-the-scenes elements that ensures users enter information in a consistent, bilingual manner) to assist in its operation. Examples of code tables are pests, crops, products, organizations, etc.

In addition to the tracking element of MUPPS, the system also contains approximately 45 report templates to allow for the communication of information. Data for the public is generated by the report function and sent via the PMC list server, to be posted on the AAFC Web site. The reports range from management tracking (Submissions and Registrations by Fiscal Year), to quality assurance (Trial Inspection Status, Study Audits), communication (Project Status by Crop, Registrations by Fiscal Year), and requests for proposals (RFPs), as well as project-, study- and trial-level information. They also incorporate RFP templates (posted for bidding by the public) to aid in the contracting of trials that are not selected by AAFC staff.

The database required for the establishment of MRL global harmonization for minor uses pesticide-minor crop combination

Sri Noegrohati

Faculty of Pharmacy, Gadjah Mada University, Yogyakarta, Indonesia, and
Technical Consultant on MRLs for Ministry of Agriculture, Indonesia

Globalization not only affects the mobility of people around the world, but also cultural exchange and food habits. Therefore the consumer demands for specialty crops and minor crops are continuing to increase. Many of the minor crops listed in Annex I of CX/PR 11/43/9 and Appendix D SANCO 7525/VI/95 - rev. 9, are from tropical and sub tropical region, such as Indonesia and other ASEAN countries. However, the global movement of ASEAN crops is sometimes hindered by the MRL differences between countries and whether or not a certain pesticide is registered in the importing country. To overcome these problems, harmonization of MRLs and pesticide regulations would be the best solution. Therefore we agree that developing a database to be shared, is a priority for this coming meeting. Since 1996, ASEAN harmonized and endorsed ASEAN MRLs for certain combinations of pesticides and crops that are moving regionally among ASEAN countries. National pesticide residue exposure data were generated through national Supervised Pesticide Residue Trials (SPRTs), following criteria presented in the FAO manual.

Evaluation of these data and dietary intake based on national or regional diet, both long term and short term, were performed annually by the ASEAN expert working group on the Harmonization of MRLs (ASEAN EWG-MRLs) of pesticides, and then harmonized ASEAN MRLs were proposed. The confidentiality of the data is kept within the National Ministries of Agriculture and ASEAN EWG-MRLs. The accepted proposed harmonized MRLs will be discussed in the Senior Officials Meeting of the ASEAN Ministers of Agriculture and Forestry (SOM-AMAF) to be endorsed by AMAF. Some of these data are also submitted to the FAO/WHO JMPR to be evaluated as Codex MRLs.

Based on the above experiences, to support a database on residues trials for minor uses, we propose to collate decline study data obtained from SPRTs of minor use pesticide on representative crops of specialty and minor crop group combination, carried out in the tropical zone. Tropical pesticide residue exposure data, as well as decline study data, are scarce. Since certain pesticide behave similarly in some zones of the four zones in the global zoning study, but some other pesticide behave

differently, the dissipation rates obtained from decline studies in tropical zones should be compared with the existing data from temperate and cold zones. If they are not significantly different, then they can be harmonized globally. If they are significantly different, to be able to harmonize globally, the pre-harvest interval could be adjusted according to the efficiency-safety balance. The data obtained could be submitted to JMPR to be evaluated and harmonized globally. It is expected that with this mechanism, global harmonization of minor use pesticide on minor crops can be done efficiently based on minimum exposure data whilst remaining scientifically sound.