



A word of thanks to the Global Minor Use Summit 2 Delegates.....

From February 21 to 23, 2012, the Second Global Minor Use Summit took place at FAO Headquarters in Rome Italy. The Summit was attended by approximately 230 delegates representing over 50 countries, which included developed, developing and countries with economies in transition. The delegates were there to continue the work from the first Global Minor Use Summit by addressing many of the issues relating to minor uses. These include pest control, availability and use of pesticides, and the impact of pesticide MRLs on specialty crops and minor uses in trade. The Organizing Committee was pleased to see the great interest and enthusiasm of the delegates and their support in identifying possible solutions to resolve minor use issues. The next steps will be to advance the recommendations from the Summit, starting with the establishment of a Steering Committee to centralize communication, coordination, and establishment of a global needs database. There is much work to accomplish under the 5-year work plan developed by the delegates, and we will be looking to you to assist in accomplishing many of these endeavors. Hopefully we can return in five years for another summit to review our many accomplishments and make plans to further address minor use issues.

Daniel Kunkel, Program Chair, Global Minor Use Summit 2, August 2012.

GLOBAL MINOR USE SUMMIT 2

**Report of the Second Global Minor Use Summit
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS, Rome, Italy
February 21-23, 2012**

**Sponsored by:
Food and Agriculture Organization (FAO), the US Department of Agriculture Foreign
Agricultural Service (USDA-FAS), the US Environmental Protection Agency (EPA) and the
USDA/Interregional Research Project Number 4 (IR-4).**

Report of the Second Global Minor Use Summit (GMUS 2)

Introduction and Background

Minor use pesticides are products that growers deem to be necessary to deal with pest problems in low acreage crops or represent minor uses on large acreage crops. There are both pest and pesticide management aspects to the issue of minor uses. On the one hand, growers need cost effective solutions for managing pests and diseases on crops, whether they be major or minor. The pest management solutions may be cultural, mechanical, biological or chemical. On the other hand, chemical and biological pesticides need to be effectively regulated to ensure health and environmental safety and, in most cases, efficacy of products. Provision of pest and pesticide management needs, depends on legislative, institutional and technical capacity being available to countries. The specific issue of minor uses challenges many developed countries. In developing countries, the capacity for effective basic pest and pesticide management is generally severely limited, and addressing minor uses is a refinement that is beyond the capacity of most.

At the same time, trading food products requires adherence to safety standards that include pesticide maximum Residue Limits (MRLs). If a pesticide is not registered for use on a given crop, then no MRL will be established, and consequently that crop cannot be traded with detectable residues of that pesticide. It is also important to note that it is the importing country that must establish or accept an MRL, and the exporting country that must comply with it.

The crop protection industry is reluctant to conduct the research that is required to register products for minor uses. The low acreage of minor crops results in an insufficient return on investment of the expenditures that are required to attain regulatory approval. Additionally there are resources required to maintain minor crop registrations and liability issues from possible crop damage that the crop protection industry is often unwilling to assume. On a global basis, this presents problems for producers because of a lack of authorized options to control pests and diseases. This also affects producers seeking market access as well as exporters and traders of those commodities. Trade barriers often occur due to a lack of, or differences in, acceptable Maximum Residue Levels (MRLs) on produce.

In order to address some of these issues, the first Global Minor Use Summit (GMUS) was held in December of 2007, at the Food and Agriculture Organizing (FAO) Headquarters in Rome, Italy. The GMUS was co-organized by FAO, US Department of Agriculture (USDA), US Environmental Protection Agency (EPA) and the Interregional Research Project number 4 (IR-4). Participants of the first Summit developed the following action items:

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.

A strong foundation of cooperation and collaboration has been built among countries as a result of the 2007 GMUS action items and there has been a great deal of advancement in addressing minor use needs. However, there are still issues facing growers and producers throughout the world.

In 2011, an Organizing Committee (see [Attachment 1](#)) was established to oversee the planning for a second Global Minor Use Summit (GMUS-2). The Organizing Committee sought input on the planning for GMUS-2 from an Advisory Committee made up of specialists who were nominated and selected from global regions and different affiliations. The focus of both committees was to ensure that the GMUS-2 agenda covered topics relevant to minor uses issues and built upon the first Summit to elicit discussion and for identification of new areas and/or existing areas that require further development and action. A key objective of the second summit was reviewing the progress of the 2007 summit action items, specifically focusing on international and regional progress, ongoing cooperation and collaborations, and capacity development. Participants were also challenged to develop a 5-year plan to move this progress further.

Structure and Overview of the Summit

GMUS-2 was held in February 2012 and again hosted by FAO at their headquarters in Rome, Italy. The Second Summit was also co-organized by FAO, USDA, USEPA and IR-4. The Summit was attended by approximately 230 delegates representing over 50 countries, which included developed, developing and countries with economies in transition.

GMUS-2 focused on global agreements for pesticide regulatory policy, procedures and methodology, and other technical areas to help deal with minor use issues. Solutions to minor uses (including MRLs) provide growers with greater access to safe tools to grow their crops and are essential for free and fair trade among nations. The Summit provided significant opportunities for input and discussion over three days.

Day 1 provided updates on current activities and challenges from global regions, grower and chemical industry perspectives and existing collaborations and cooperation activities developed since 2007.

Day 2 focused delegate participation in breakout groups covering four topics:

1. Concrete planning for dealing with minor use issues with regard to registrations and MRLs for trade;
2. Capacity Development and Data Generation;
3. Data sharing, data needs and databases; and
4. Regulatory incentives and policy considerations to promote the registration of minor use registrations.

Day 3 and final day of the Summit reported on key findings and recommendations from each of the four breakout groups, and attendee input provided recommendations for a five year plan of progress.

Summary of Discussions and Findings by the Four Breakout Groups

1. *Concrete planning for dealing with minor use issues with regard to registrations and MRLs for trade.*

There were 10 central challenges identified that ranged from harmonized MRLs and implementation of crop groups (both for residue data extrapolation as well as performance or value data extrapolation) to greater communication and transparency of risk analysis and the benefits that pesticides provide to consumers, growers, and industry (see [Attachment 2](#)). These communications may also serve to remove the need for private standards (private sector mandated “secondary standards”), which are often set with no health or safety basis. It is evident that continued increase in resources and confidence in JMPR and Codex are needed, so Codex can be recognized as the global standard regulating pesticide limits on commodities in trade. In many cases the lack of import MRLs is just as large of an issue as the lack of domestic MRLs and further highlights the importance of greater recognition of Codex MRLs in order to alleviate these issues. The value of developing and providing international guidelines for data requirements and evaluations would further encourage regional and international generation of data that would provide consistent MRL values.

2. *Capacity development and data generation.*

The discussion began by identifying the wide range of capacity needs that countries require for effective pest and pesticide management, of which minor use pesticide registration is one that is not easily isolated from others. For example, without adequate laboratory services to determine pesticide residues in food, monitoring newly registered minor use pesticides for compliance with standards cannot be carried out. Many developing countries lack the necessary capacity to regulate and manage pesticides effectively throughout their life cycle. Similarly, insufficient extension services in many countries do not provide consistent quality pest management advice to growers.

It was also noted in this group in particular, that providing highly effective integrated pest management solutions to growers is often more important, than relying solely on chemical pest control solutions. Such solutions should be based on Integrated Pest Management (IPM) approaches built on 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.

Five action areas were captured that would enhance technical capacity and policy considerations to better inform and engage governments and other stakeholders (see [Attachment 3](#)). It was noted that capacity development is needed throughout the system as a “value chain”, linking growers, technical personnel, regulators and policy makers. In order to increase minor use capacities, the five areas identified were:

- Support commodity group classifications within Codex, and adopt this classification system as the foundation for national grouping systems. In order to achieve this it will be necessary to develop capacity at the national level in order to better participate in the establishment of Codex crop grouping, and thereby help countries ensure their minor crops are included and assist countries in modifying the Codex groups (when deviations are necessary) to fit national needs;
- Enhance country capacity to apply tools for better utilizing existing data, generating new data, and implementing alternative pest control options. Harmonized regional approach with resource allocation focused on IPM programs including biopesticides and reduced risk ai's. This will be enhanced by encouraging use of available IPM tools, and providing capacity to better understand and utilize tools such as proportionality and decline curves
- Increase regional access to laboratories/fields/processing facilities capable of generating high quality data needed for conducting residue studies and Good Efficacy Practice (GEP) compliant efficacy studies. This will be advanced by identifying, strengthening and better utilizing regional reference laboratories, and providing training and opportunities to participate in international data generation activities. Hardware *and* training will need to be provided to countries and regional facilities where capacity building efforts focused on working toward GLP
- Increase the number of countries (regions) having an effective and transparent system for evaluation and registration of all pest control products, including a uniform/harmonized standard for providing support, considerations, and incentives for minor uses. This will be achieved by identifying and strengthening existing minor use systems, and providing capacity to strengthen all national government regulatory systems in order to enhance regulatory management of all pesticides, and to be able to adopt and implement minor use models/strategies.
- Improve coordination and collaboration between all organizations working to address minor use/pest control issues (from local, national, regional, and global levels; and capacity providers). Achieving this will require 1) Support for the establishment of more regional expert working groups (regulatory and technical) that can be utilized to support minor crops/uses/pest control options; 2) Establish procedures for mutual recognition of data; 3) Identify and utilize existing programs as models such as working groups on biopesticides, reduced risk pesticides, IPM, mutual recognition of data, etc.; 4) Encourage the development of and participation in regional/global projects; 5) Establish a proactive global coordination body/group to help identify and exchange data, coordinate field studies, etc. and to identify and obtain funding resources

3. *Data sharing, data needs and databases.*

Data and information sharing are critical to address many of the minor use issues. Generating data is costly, while data-sharing promotes optimization of scarce resources needed for data generation. Available data can often be used to support registration processes in other countries or for similar crops. Shared information about priority “minor use data gaps” can also

facilitate partnerships for data generation that reduce overall costs to each of the partners and also strengthen understanding and trust between trading partners and between other stakeholder groups in the process. There are many examples of data sharing between countries however, such collaboration is not systematic: it tends to be limited to a few groups of workers in a limited number of countries who have developed relationships over the years. Enhancing this process and promoting more successful partnerships requires an improvement in the way that relevant information is shared globally, especially taking into consideration the specific needs and constraints facing developing countries. The types of information to be shared include data required for regulatory decision-making at national level; prioritized needs in various countries developed on the basis of growers' concerns; information on on-going or planned data generation projects; information on pesticide registrations, nationally recognized GAPs and pesticide MRLs.

There are a number of **opportunities** and **challenges** that need to be recognized in planning the way to more efficient and effective data sharing, which optimizes the use of data and promotes equitable distribution of benefits among various stakeholder groups. Those identified by this group include:

- A number of databases exist which are successfully addressing data needs of particular groups of stakeholders. Information on some can be found in the background documentation compiled for the GMUS-2 ([http://www.gmup.org/GMUS2_webversion%20\(2\).pdf](http://www.gmup.org/GMUS2_webversion%20(2).pdf))
- Issues of data ownership and costs of accessing data limit the utility / accessibility of some of the existing databases.
- There are differences in the scope, structure, language of existing databases. These databases have been designed to meet the needs of specific stakeholder groups (mostly at the national level) and to a large extent are successfully meeting these needs but may not meet the needs of others.
- There is ongoing work within the Codex Committee on Pesticide Residues (CCPR) that will facilitate international harmonization of crop grouping systems (data extrapolation from a small number of commodities to other related commodities) and setting criteria that may reduce data requirements for minor uses. The work of the CCPR electronic working group on minor uses is a means of global priority setting for the establishment of MRLs for minor crops.
- Recent and ongoing "Global" data generation projects will improve understanding about sources of variability in field trials and strengthen evidence-based decisions on data pooling and data requirements for specific minor uses.

Please see [Attachment 4](#) for further details.

4. *Regulatory incentives and policy considerations to promote the registration of minor uses.*

Certainly one of the options to obtain minor use solutions is to make registration of minor uses more attractive for the manufacturer. One of the key considerations in registration submissions is the economic return to an applicant from registration of those uses, in particular the associated costs of generating the data required for obtaining and maintaining regulatory approval. Another key consideration is the potential liability from those uses once approved. Typically minor uses involve crops grown on a small scale (minor crops) and often are high value specialty crops. Minor uses can also involve uses on major crops where there is a need of controlling minor pests and diseases. This results in a situation where specialty crop growers are either without or are lacking sufficient access to pest control products to adequately protect those crops. The major factor hindering the regulatory approval of minor uses is a lack of data and is attributable to the lack of funding required to generate such data and the low interest of manufacturers in generating data for those minor crops. This lack of generation and funding has resulted in fewer MRLs for specialty crops and minor uses and this is especially true at the international level.

The implementations of regulatory incentives have demonstrated, in a number of countries, that it is a useful mechanism to facilitate the registration of minor uses. In many cases, economic incentives creates a sharing of the responsibility by adding “value” to minor uses, and encourages registrants to add minor uses to their product labels. Possible incentives such as data protection, expedited reviews, and fee waivers for minor uses were reviewed at the Summit. The technical and research areas such as data extrapolation and data sharing incentives were also discussed. The break out group identified four key themes with fifteen underlying recommendations (see [Attachment 5](#)). These included:

- *Structures and Communications*, with a view of identifying an advocate or global minor use structure to coordinate, centralize needs and communication with a view to possibly undertaking a global priority setting process (possible workshop) to enhance collaboration.
- *MRLs and import tolerances*, recommendations included harmonizing MRLs for minor crops in line with Codex MRLs and developing standardized procedures for application of import tolerances, develop formal processes for the consideration and acceptance of data and assessments conducted elsewhere and procedures for expediting MRL setting.
- *Registration Activities*, recommendations focused on simplified procedures for authorizing minor uses, maximizing opportunities during other regulatory action, expedited regulatory assessments, issues associated with liability and acceptance of data and assessments conducted globally.
- *Economic incentives*, recommendations included, developing funding for structures and data generation, examining procedures and initiatives to waive or reduce regulatory assessment fees and enhancing attractiveness in registering minor uses through data protection incentives.

Overall conclusions and recommendations and next steps

Minor uses of pesticides are a specific element of a broad spectrum of pest and pesticide management issues that all stakeholders represented at the Summit gathered to address. The stakeholders at the Summit focused their attention on issues concerning minor use pesticides and identified five main themes that cut across many of the areas discussed to address this issue and are included below (also see [Table 1](#)):

1. Coordination & Collaboration

In order to support greater coordination and collaboration, a Global Minor Use Steering committee needs to be established as soon as possible. Initially this committee will be represented by members of the GMUS Organizing Committee and eventually include members from the grower and industry sectors. Among other tasks, this committee will lend support by creating a terms of reference to develop a new single global needs database including financial feasibility and long term sustainability. In the short term (to address this need), existing databases can be expanded to include critical information to the global community and be provided in a central location at the www.gmup.org. These databases would include: contact information, a description of each database and specific use instructions as well as a “comment section” where countries could indicate their needs and concerns. Eventually, it is expected that the databases will be combined into a single entity as noted above and be provided to stakeholders at a centralized public location. Such a global database should use the standards/common codes already agreed at international level e.g. crop, pest and pest grouping, and pesticides and should accommodate different languages. There was also broad support among the delegates to have the steering group undertake a global priority setting process (possible workshop) to enhance collaboration.

2. Communication

Communication efforts will largely rely on the GMUP.org website to include database information, sharing risk and benefit communications of pesticides, and to further link those interested in working toward solutions for minor use issues.

3. Incentives

The incentives identified by the Summit are meant to encourage the implementation and promotion of minor uses. Since many of the incentives are related to the other activities, such as data generation and sharing, standardized report format and applications, and MRL levels, close communication and co-ordination throughout the network (local, regional and international) is required. The implementation of regulatory incentives will rely on documentation and communication of existing funding structures and programs, collecting and reviewing import tolerance setting procedures, documenting existing authorization procedures, economic incentives and programs or approaches addressing liability. It was also recommended to explore a possible meeting of legal experts between government and industry to provide advice on liability issues.

4. Capacity Development

For continued efforts in capacity development, it is important that information on existing pesticide and other pest management tools be disseminated as rapidly as possible to support long term sustainability of these programs. Expert groups at the regional level can be used to support a global infrastructure. Programs that are established need to be maintained or expanded and where programs don't exist, they need to be supported and established as soon as possible. These programs will require equipment and training that should be based on global guidance through Codex (FAO) and OECD guidance documents. These regional (or national) programs would work in a collaborative manner to address stakeholder needs.

There are specific barriers and difficulties associated with minor use pesticides that need to be addressed within the context of effective and sustainable mechanisms for the provision of pest management solutions and for the life cycle management of pesticides. In the first instance, it was agreed that effective and sustainable crop protection does not depend solely on chemical pesticides but should be built on ecologically based IPM where pesticide use and other interventions are kept to levels that are economically justified and reduce or minimize risks to human health and the environment. It is therefore important to build capacity at all levels to ensure that growers are provided with timely and effective advice on sustainable crop protection.

Noting that legislative, institutional and technical capacity for life cycle management of pesticides is lacking in many developing countries, it was agreed that in addressing minor uses, the overall capacity needs to these countries also needs to be addressed. Addressing broader needs will ultimately benefit the minor use issue, but addressing minor uses in isolation to other needs would be unsustainable.

5. Registration of Minor Uses and MRL setting

Registration of Minor Uses and MRL setting processes on global bases rely heavily on Codex. Therefore, it is critically important to continue supporting the JMPR process. GMUS-2 delegates recognize that the JMPR requires more resources and a broader expert panel to accomplish its increasing task of reviewing data for Codex. Also in this regard, the Codex MRLs must be utilized to a greater extent and be recognized as a legitimate standard by all countries in order to reduce the burden placed on commodities in trade. In order to address these issues additional meetings will be planned, both within the Codex Committee on Pesticide Residues (CCPR) and as informal meetings aside from CCPR to explore greater support for JMPR through funding and capacity development, as well as continued support for crop group extrapolations for broader use of residue and efficacy evaluations. It is anticipated that the Electronic Working Group on Minor Uses will lead or participate in many of these action items.

Conclusion

In closing, the Summit delegates showed great interest and enthusiasm to provide support in efforts to resolve minor use issues. They recognized the importance of establishing a governing body, identified as a Steering Committee, to coordinate these activities. Implementing this body is paramount to maintain and increase progress being made to address matters around minor uses. The Steering Committee would centralize communication, coordination, and will be charged with developing the terms of reference for funding and establish a global needs database. The committee would ensure that the 5-year work plan be implemented and would organize a global needs workshop for minor uses. Finally, it will be critically important for delegates to contribute to advancing the five year work plan and to communicate the importance of addressing minor uses to their colleagues, particularly to those in government, and with regional and international representatives in order to garner support to address minor use needs. The GMUS-2 was a great success due to the diligence of its participants in developing a five-year plan with action items that could be accomplished in short, medium and long term time frames. Please see www.gmup.org for additional information and updates.

Table 1. Work plan: Themes and tasks resulting from the breakout groups and participants.

Theme 1 Coordination & Collaboration	Theme 2 Communication	Theme 3 Incentives
<p>1.1 Global priority setting process for minor uses</p> <ul style="list-style-type: none"> • Establish group to explore feasibility of having global priority setting process/meeting <p>1.2 Databases</p> <ul style="list-style-type: none"> • Expand existing databases to capture global minor use grower needs/priorities • Expand existing databases to document available minor use data for registration • Investigate the feasibility of having a new single global needs database <p>1.3 Participation in joint initiatives</p> <p>1.4 GMU Steering Committee</p> <ul style="list-style-type: none"> • Establish membership • Identify experts to do feasibility study on database with TOR 	<p>2.1 Enhancement of the GMU Portal</p> <ul style="list-style-type: none"> • Expand GMU portal to include links to various databases currently available from various sources <p>2.2 Risk communication</p> <ul style="list-style-type: none"> • Identify and review existing risk communication tools by national authorities, FAO and other organizations • Provide available material on the GMU Portal for dissemination <p>2.3 Benefit communication</p> <ul style="list-style-type: none"> • Identify available materials <p>2.4 Establish list of (and networks of) existing working groups</p> <ul style="list-style-type: none"> • List will be added to GMU Portal 	<ul style="list-style-type: none"> • Monitor implementation and uptake of regulatory incentives • Promote and implement new incentives as they are developed <p>3.1 Funding structures and programs</p> <ul style="list-style-type: none"> • Document existing structures and programs • Develop and release guidance on the establishment of national and regional programs <p>3.2 Import MRLs</p> <ul style="list-style-type: none"> • Collect and review existing import tolerance setting procedures • Develop and release guidance on the process for seeking import MRLs <p>3.3 Authorization procedures and requirements</p> <ul style="list-style-type: none"> • Document existing authorization procedures and requirements • Monitor new procedures that add value to minor uses <p>3.4 Economic</p> <ul style="list-style-type: none"> • Document existing economic incentives <p>3.5 Liability</p> <ul style="list-style-type: none"> • Document and assess existing programs addressing liability wavers • Explore possibility of having a meeting of legal experts of government and industry to advise on issues related to liability
<p>Red = short term items (12 months), Green medium term items (24-36 months), Blue long term items (5 years)</p>		

Table 1. Work plan: Themes and tasks resulting from the breakout groups and participants (cont.).

Theme 4 Capacity Development	Theme 5 Registration of Minor Uses and MRL setting
<p>Tasks:</p> <p>4.1 National and regional capacity</p> <ul style="list-style-type: none"> • Disseminate information on existing pesticide and pest management tools (e.g., extrapolation methods, crop grouping, IPM) • Facilitate the strengthening or establishment of new regional expert working groups that support minor use issues • Develop and implementation new tools and guidance • Establish sustainably operating regional expert working groups for minor uses <p>4.2 Engage policy makers to implement regulatory initiatives</p> <ul style="list-style-type: none"> • Include decision makers at technical meetings or workshops to demonstrate importance of implementation of technical inputs <p>4.3 Establish national minor use programs</p> <ul style="list-style-type: none"> • Provide guidance to national authorities on design and implementation of minor use programs <p>4.4 Encourage greater participation in data generation</p> <ul style="list-style-type: none"> • Initiate collaborative projects to better participate in Codex processes (e.g., crop grouping, data submissions, MRL setting process) • Implementation of collaborative projects • Stakeholder engagement in data generation and other areas to support minor uses <p>4.5 Provide guidance on Codex processes</p>	<p>Tasks:</p> <p>5.1 Harmonized data requirement and submission documents</p> <p>5.2 Crop Grouping (residue and efficacy)</p> <ul style="list-style-type: none"> • Explore possibility of establishing a working group to develop a guidance document on efficacy data under CCPR • Hold meeting to explore efficacy crop grouping -Consult existing schemes such as EPPO <p>5.3 JMPR capacity building</p> <ul style="list-style-type: none"> • JMPR capacity building as an agenda item at CCPR • Explore possible funding sources for JMPR • Expanding JMPR expert panel to include broader representation <p>5.4 Transparency in registration decisions</p> <p>5.5 Working towards common MRLs</p> <ul style="list-style-type: none"> • Side meeting at April 2012 CCPR to discuss barriers to harmonization • Support and involvement for Crop grouping at CCPR and representative crops • Develop questionnaire through the electronic Working Group on Minor Uses/CCPR on import MRL setting by national authorities • Urge regulatory bodies to utilize Codex standards
<p>Red = short term items (12 months), Green medium term items (24-36 months), Blue long term items (5 years)</p> <p>CCPR = Codex Committee on Pesticide Residues JMPR=Joint WHO/FAO Meeting on Pesticide Residues</p>	

Attachment 1.

Global Minor Use II – Organizing Committee

Country	Name	Organization/Comments
Australia	Alan Norton	Australian Pesticide and Veterinary Medicines Authority APVMA and Chair OECD Expert group on Minor Uses
Brazil	Luis Rangel	Ministry of Agriculture, Pesticide Coordinator
Canada	Manjeet Sethi	Executive Director Pest Management Centre, AAFC
China	Mr Shan Wei Li	Director of Residues Division, ICAMA
FAO	Renata Clarke YongZhen Yang	FAO - Food and Nutrition Division FAO - Plant Protection and JMPR Secretary
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
US	Dan Kunkel Jerry Baron Lois Rossi Jason Sandahl Sherrilynn Novack	IR-4, Associate Director (Chair) IR-4, Executive Director US EPA, Registration Division Director USDA-FAS, Senior Program Manager IR-4, Communications Manager

Attachment 2.

Breakout Group 1 – Concrete Planning for Dealing with Minor Use Issues (Registration and MRLs for Trade)

Challenges	Issues	Recommendations	Next Steps/Implementation
<p>1-Lack of <u>timely</u> issuance of MRLs in a globalized harmonized fashion.</p>	<p>Lack of resources for JMPR One JMPR meeting per year is not enough</p>	<p>-Continue the JMPR/CCPR pilot process and make it a standard approach -Seek efficiencies and resources for JMPR -Explore the concept of getting an unbiased provisional MRL while going through the JMPR review process -Streamline of submissions to JMPR</p>	<p>-Ensure delegates are aware of JMPR capacity building paper -Continue efforts on JMPR capacity building -Greater reliance on regional assessments using peer review during JMPR meeting (explore possibility of bringing in the Risk Analysis Principles of the Electronic Working Group) -Explore who is allowed to contribute to JMPR -Capacity building agenda item at upcoming CCPR meeting provides opportunity to raise issues</p>
<p>2-Lack of harmonized data requirements and evaluations</p>	<p>Lack of a common MRLs Lack of common data requirements and interpretation of data for establishing MRLs, e.g. residue trials, crop grouping, GLP requirements. Conflicting standards and erosion of Codex MRLs, selective MRL markets Cooperation and implementation on zones for establishing international standards, and after change national (rules) standards. Transparency of the establishment of national MRLs Identifying/understanding barriers to harmonization Lack of processes or regulatory mechanism to apply for an import</p>	<p>-Flexibility in data requirements for minor crops -National authority harmonized with Codex requirements -ACP countries to regroup themselves in regional structures that would then have the same requirements by region. -Efficiencies to maximize resources including more involvement in global work shares/reviews</p>	<p>-Delegates of CCPR to support crop grouping, representative commodities and the electronic working criteria for minor crops -Explore possibility of holding a side meeting at the next CCPR meeting to discuss harmonization issues -Stakeholders to continue supporting the setting of regional harmonization registration systems in ACP (once set as recognized regulatory entities, they can set acceptable common residue data requirements for the region)</p>

	tolerance.		
3-Capacity Building		-Capacity building and non-OECD countries participating in a global joint review	-Refer the recommendation to Group 2
4-Crop Grouping	Lack of consistency between efficacy crop grouping and residue crop grouping Crop grouping extending to efficacy / efficacy extrapolation	-Explore possibilities to implement a global efficacy data extrapolation system (e.g., EPPO system). -Completion of the ongoing residues crop grouping	-Hold a meeting where this concept can be explored -Crop grouping is an agenda item at upcoming CCPR meeting and support the initiative -Explore possibility of establishing a working group to develop guidance document on crop efficacy data extrapolation under CCPR
5-Risk communication	Risk communication Interference of Secondary standards with MRLs	- Capacity building in risk communications - FAO/WHO Communications - Aim communication tools to the whole value chain including NGOs and retailers.	-Review existing communication tools (eg. Crop Life , EFSA, national & international agencies) for consideration as common communication to the public.
6-Benefit communication	Benefit communication	-Healthy and nutritional foods - Share communication tools about food safety between organizations (e.g., consult with Crop Life re: available resources & communication experiences) - Communication tools/programs funded by agencies (e.g., EU communication program for schools)	
7-Economic Costs and Risks, Liabilities	Economic Costs and Risks, Liabilities		-Industry position paper to be peer-reviewed and distributed to stakeholders. -Link to Group 4 -Explore possibility of having a meeting of legal experts of government and industry to advise on resolving issues related to

			liability.
8-Regulatory	Need for consistent regulatory incentives (e.g., data protection, additional years, etc.) Need for further collaboration / cooperation among growers, industry and governments	(See Group 4 and results from the Crop Life incentives survey) - Global priority setting process/database (ties into Group 3) - Governments to encourage stake holders to collaborate, through facilitating such activities such as meetings to discuss the grower needs and company projects for minor crops	- Delegation to attend existing national priority setting meeting as observers -Set up a group to explore the feasibility of having a Global Priority setting meeting
9-Imports MRLs	Import MRLs/tropical fruits and vegetables are mostly grown in tropical fruit producing countries and exported to non-tropical fruit producing countries .	- Capacity building for preparing import MRL dossiers -Explore among national authorities acceptance of Codex MRLs for import MRLs for crops not grown in that country and compounds not registered	-Refer to Group 2 for Capacity Building -Develop questionnaire through the Codex electronic working group on minor uses
10-Codex/JMPR	Confidence in Codex process as a appropriate standard by all countries. Lack of Codex MRLs for new chemicals leads to continued use of older chemicals with Codex MRLs Conflict between national and Codex MRLs	-Explore (quantify) why countries are moving away from accepting Codex MRLs -Have more than one JMPR meeting	-Include in questionnaire above - Continue efforts of JMPR capacity building efforts

IN SUMMARY:

Main issues are:

- 1- **Timely issuance** of Codex MRLs (confidence, efficiency, resources at JMPR level, acceptance, secondary standards...)
- 2- **Harmonized residues data set requirements**
- 3- **Crop grouping for residues (finalization of existing initiatives)**
- 4- **Risk Communication (to consumers, growers, industry) - KEY**
- 5- **Regulatory incentives**

Efforts to be done in:

- 1- **Capacity building (JMPR, delegates, authorities...)**
- 2- **Increasing efficiency in Codex MRLs setting process**
- 3- **Continue building confidence and trust of Codex/JMPR.**
- 4- **Global harmonization (data set, crop grouping, global prioritization of minor crops issues, involvement of countries)**

Attachment 3.

Breakout Group 2: Capacity Development and Data Generation.

The discussion began by identifying the wide range of capacity needs that countries require for effective pest and pesticide management, of which minor use pesticide registration is one that is not easily isolated from others. For example, without adequate laboratory services to determine pesticide residues in food, minor use pesticide registration is a somewhat academic exercise. Most developing countries lack the necessary capacity to regulate and manage pesticides effectively throughout their life cycle.

Overarching Recommendations:

- Better engage decision makers to implement technical capacity development into policy
- Capacity development needs “value chain” approach (not piecemeal actions), engaging all stakeholders from farmers, to technicians, to regulators, and to policy (decision) makers

Areas for capacity development:

1. Crop Grouping/Extrapolation:

Goal: Have *Codex Classification of Foods and Feeds, and Principles and Guidance for the Selection of Representative Commodities for the Extrapolation on MRLs*, completed by Codex within five years.

Strategy: Countries are encouraged to adopt and implement Codex Crop Grouping Classification and extrapolation procedures as groupings are completed by Codex: encourage all countries to follow the Codex groupings as closely as possible in order to facilitate trade. This will be accomplished by 1) Develop capacity at the national level in order to better participate in the establishment of Codex crop grouping, and thereby help countries ensure their minor crops are included and assist countries in modifying the Codex groups (when deviations are necessary) to fit national needs; 2) OECD will insert Codex Crop Grouping document into their Field Study Guidelines once adopted by CAC.

2. Tools

Goals: Enhance country capacity to apply tools for better utilizing existing data, generating new data, and implementing alternative pest control options. Harmonized regional approach with resource allocation focused on IPM programs including biopesticides and reduced risk active ingredients.

Strategy: Encourage use of available IPM tools, provide capacity to better understand and utilize tools such as proportionality, decline curves, etc....

3. Laboratory and Field Research

Goal: Increase number of countries with (or regional access to) GLP (or near-GLP) compliant laboratory/field/processing capabilities needed for conducting residue studies and GEP compliant efficacy studies.

Strategy: 1) Identify, strengthen and better utilize regional reference laboratories within capacity building programs; 2) Provide training and opportunities to participate in international data generation activities, with capacity building efforts focused on working toward GLP compliant operations.

4. Regulatory Infrastructure

Goal: Increase the number of countries (regions) having an effective and transparent system for evaluation and registration of all pest control products, including a uniform/harmonized standard for providing special support, considerations, and incentives for minor uses (refer to recommendations of break out group 4).

Strategy: Identify and strengthen existing minor use systems, and provide capacity to strengthen all national government regulatory systems in order to enhance regulatory management of all pest control products, and to be able to adopt and implement minor use models/strategies.

5. Coordination and Collaboration

Goals: Improved coordination and collaboration between all organizations working to address minor use/pest control issues (from local, national, regional, and global levels; and capacity providers)

Strategies: 1) Support the establishment of more regional expert working groups (regulatory and technical) that can be utilized to support minor crops/uses/pest control options; 2) Establish procedures for mutual recognition of data; 3) Identify and utilize existing programs as models such as working groups on biopesticides, reduced risk pesticides, IPM, mutual recognition of data, etc.; 4) Encourage the development of and participation in regional/global projects; 5) Establish a proactive global coordination body/group to help identify and exchange data, coordinate field studies, etc. and to identify and obtain funding resources.

Attachment 4.

Breakout Group 3: Data sharing, Data needs and Databases BOG discussions

This BOG had 50 delegates representing every continent. We had input from every point of view and lively discussions. Much discussions occurred on what would need to be included in a database such as:

Crop, pest, active, number of trials, GAP, Registration decision, MRL, data holder, occupational exposure data, etc.

The group identified 2 main components that would need to be included in the database:

- 1) Regulatory decision making data and
- 2) Grower needs / wish list / project status.

Communication is an important component for both.

Noted the need to consider the capacity of each region, including developing countries that have different challenges such as a need for a proper infrastructure to get access to internet, basic capacity building, training, and data generation. These considerations can be addressed using the information from the above components of the database.

The recommendations are of 3 steps:

- 1) Expand the GMUS portal to include links to various databases currently available from various countries (e.g. IR-4, UK, EU, etc. and any private databases who wish to be included) and include contact information, a description of each database and specific use instructions as well as a comment section where countries could indicate their needs / concerns. Email notifications could be sent when a database will be added to the portal. It will be important to also make the GMUS portal a communication and interactive tool. This is a first step in providing developing countries access to available data. Each contributor should be responsible for having updated and relevant data sources on their website.
- 2) Expand the GMUS portal to include a link to an existing publicly available database system to collect and document global minor use needs.
- 3) Create a working group / committee that would explore the feasibility of having a new single global need database and find financial resources to develop such database as well as long term sustainability. It was also recommended to use the standards / common codes already developed e.g. Crop, pest / pest grouping, and pesticides. It should also accommodate different languages. The committee should provide timeframes for the various activities.

It would be expected that countries around the globe would then be able to share data, avoid duplications and use extrapolation when it is feasible. For instance where new projects are being proposed under the grower needs category, any other country could consider asking to be a partner in the project. This could give them access to the use as a much lower cost and much sooner. This could also facilitate registrant cooperation for a registration on a global basis when the market size in one country may not have made it possible. This in turn could lead to a global MRL to facilitate trade.

Discussions also included the use of extrapolation tables to facilitate broader registrations. This would be associated with capacity building.

The group proposed that the whole GMUS 2 support the establishment of the database working group so that ongoing developments and sharing continue over the years until the next conference.

For this working group, it was proposed that one representative from each continent plus one from FAO and one from CropLife make up the committee. If the group agrees then they could move ahead to implement this.

Attachment 5.

Breakout Group 4: Regulatory incentives and policy considerations to promote the registration of minor uses.

<u>Regulatory Incentives / Initiatives / Policies considerations</u>			
Structures / Communications	MRLs	Registration Activities	Economic incentives
<p>Identifying advocate / platform / Global MU structure governance</p> <p><i>Action:</i> Development of a Global MU structure governance</p> <p><i>Responsibility:</i> GMUSII – OC (guidance needed - taking into account existing structures)</p> <p><i>Timeframe:</i> ASAP</p> <p><i>Requirements:</i> Building between whole of chain Co-ordination structure required Centralised information exchange Communication and Co-ordination (advocate bridge)</p> <p>National / Regional / Global – communication</p>	<p><u>Import tolerance application process standardised/expedited</u></p> <p><i>Action:</i> Develop standardised procedures for the application for import tolerances</p> <p><i>Responsibility:</i></p> <p><i>Timeframe:</i></p> <p><i>Requirements:</i> Harmonisation of MRL Establishment of MRLs (global trade procedures) Acceptance of CODEX MRLs around world</p> <p>Mutual acceptance of data & assessments</p> <p><i>Action:</i> To expedite standard setting procedures develop formal process for the consideration for the acceptance of data & assessments conducted elsewhere</p> <p><i>Responsibility:</i></p> <p><i>Timeframe:</i></p> <p><i>Requirements:</i></p>	<p><u>Procedures</u></p> <p><i>Action:</i></p> <ol style="list-style-type: none"> 1. Develop simplified and efficient procedures for the authorisation process 2. Develop provisions for temporary approvals 3. Maximise <ul style="list-style-type: none"> - participation in the GJR process - minor use outcomes through the GJR process <p><i>Responsibility:</i></p> <p><i>Timeframe:</i></p> <p><i>Requirements:</i> Authorisation procedures Global Joint Reviews – harmonisation of evaluation systems Temporary approvals</p> <p><u>Bundling opportunities</u></p> <p><i>Action:</i> Evaluation - establish mechanisms to allow minor use considerations during other reviews</p>	<p>Funding for structures & data generation</p> <p><i>Action:</i></p> <ol style="list-style-type: none"> 1. Structure - encourage the establishment of dedicated funding for structures/programs to support minor uses 2. Data generation - encourage provisions for data generation 3. Research - encourage research on both chemical & non-chemical means (IPM / Resistance Mgt.) <p><i>Responsibility:</i></p> <p><i>Timeframe:</i></p> <p><i>Requirements:</i> Registration fees - waive/reduce</p> <p><i>Action:</i> Explore procedures and initiatives to reduce /waive registration fees for minor uses</p> <p><i>Responsibility:</i></p> <p><i>Timeframe:</i></p> <p><i>Requirements:</i></p>

<p>Priority setting process <i>Action:</i> Global, regional and national priority setting processes <i>Responsibility:</i></p> <p><i>Timeframe:</i> Medium <i>Requirements:</i> Collaborative involvement growers, registrants, regulators (others)</p> <p>Need clear plans e.g. 3 years, 5 years</p> <p>Share success of existing <i>Action:</i> Document existing schemes, principles, procedures <i>Responsibility:</i> <i>Timeframe:</i> ASAP <i>Requirements:</i> programs/knowledge exchange</p>	<p>Global Joint Reviews <u>DATA EXTRAPOLATION</u> Data sharing Crop grouping & representative crops – acceptance globally (MRLs) MRL setting and extrapolation Temporary registration – links MRLs, Codex Accept reviews of MRLs from other countries</p> <p><u>Expedited MRL setting process</u> <i>Action:</i> Develop procedures to reduce timeframes for the establishment of MRLs (<i>Responsibility:</i> <i>Timeframe:</i> <i>Requirements:</i></p>	<p>Re-evaluation - include within the re-evaluation processes procedures to allow minor uses</p> <p><u>Re-evaluation</u> Encourage regulatory agencies to utilise other agencies re-evaluations</p> <p><i>Responsibility:</i> <i>Timeframe:</i> <i>Requirements:</i></p> <p><u>Timeframes / Expedited registration process</u> <i>Action:</i> Develop procedures and initiatives to reduce timeframes for the assessment of minor uses <i>Responsibility:</i> <i>Timeframe:</i> <i>Requirements:</i> Incentive of expedited reviews where minor uses are included alongside major use submissions</p> <p><u>Liability</u> <i>Action:</i> Develop framework and/or common policy to address liability concerns inhibiting minor use authorisations <i>Responsibility:</i> <i>Timeframe:</i> <i>Requirements:</i> Liability of MUs for registration</p>	<p>Data protection <i>Action:</i> Explore and implement provisions for data protection incentives for minor uses <i>Responsibility:</i> <i>Timeframe:</i> <i>Requirements:</i> Extensions New concepts</p> <p>Data sharing</p>
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Capacity building development
Awareness communication & training
Getting other countries involved in process (e.g. Ethiopia)