Global Minor Use Summit

3-7 December, 2007
Rome, Italy
Global Minor Use Summit

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Technical Initiatives and Challenges: Crop Grouping Initiatives

Importance of Crop Grouping and Residue Extrapolation; Existing Crop Grouping/Classification Systems

EU, Codex, Japan, US — Dave Lunn, New Zealand, Food Safety Authority

Crop Grouping Harmonization

Effort Bernie Schneider, US Environmental Protection Agency

Hong Chen, International Crop Grouping Consulting Committee

Cooperation & Policy Considerations: Presentations by Sectors: Government, Industry, Growers

Global Zoning & Residue Programs — Jeff Herndon, US Environmental Protection Agency

FAO Initiative on Residue Data Sharing and Networking — Gero Vaagt, FAO

Steps Towards a Harmonised Minor Use Authorisation Procedure in the EU

Peter Watson, European Crop Protection Agency

Global Regulatory Initiative— Lois Rossi, US Environmental Protection Agency

Registrant Considerations in Proposing Global Joint Review/Workshare —

Bernhard Johnen, CropLife International

Training Sessions

U.S./Canada/ IR-4 Model GLP Studies

IR-4 Program Overview: History, Collaborations, Future Direction, Jerry Baron, IR-4 Project Executive Director

Residue Programs, Databases, Tolerance Petitions, Dan Kunkel, IR-4 Project Associate Director

GLP Field Trials and Field Data Books, Robin Bellinder, IR-4 Field Research Director

GLP Analytical Laboratory Procedures and Report, Pim Larsson-Kovach, IR-4 Analytical Laboratory Director

Quality Assurance Audit Procedures, Tammy White, IR-4 QA Manager

Discussion on Canadian requirement Ken Campbell, Agriculture and AgFood Canada

Involvement of States in US Minor Crop Registrations, Mary-Ann Warmerdam, California Dept. of Pesticide Regulation

JMPR and CCPR Data Review Procedures

Manufacturer Data Dossiers to JMPR, Caroline A Harris, Exponent

JMPR Review and MRL Recommendations, Arpad Ambrus, JMPR

CCPR Procedures, Jeronimas Maskeliunas, Codex

National and Regional Data Review Procedures

EU MRL Procedures, Francesca Arena, European Commission

Japan MRL Procedures, Tsuyoshi Sakamoto, Yasuo Kitamura, Food and Agricultural Materials Inspection Center

U.S. MRL Procedures, Jeff Herndon, US Environmental Protection Agency
Global Minor Use Summit
Agenda for Monday, 3 December, 2007

Background
The increasing consumption and global trade of specialty / minor crops demand efficient crop protection measures that facilitate international trade, suit the needs of farmers, ensure efficacy, ensure food and environmental safety, and benefit consumers. Obstacles, such as disincentives for pesticide development and registration, financial and technical constraints for residue data generation and discrepancies in regulatory standards among countries, limit access to newer and less hazardous pest control methods for growers, raise trade issues and increase food safety concerns.

While various countries have worked to develop specific strategies focused on specialty crops and minor uses there is still much work to be done from a global perspective. The Food and Agriculture Organization of the United Nations (FAO), the US Department of Agriculture (USDA: the Foreign Agricultural Service and The Cooperative State Research, Education, and Extension Service's IR-4 Project) and the US Environmental Protection Agency (US EPA) have jointly initiated the Global Minor Use Summit. The special issues of crop protection for specialty crops will be specifically addressed over the five days of the conference.

Day 1 is designed to set the stage by providing information on what’s going on where you are, how it is working-- what is going well, what are the challenges, what needs to change, and what are the “unidentified” issues from a global perspective. This will be described from the point of view of geographic regions; growers; the crop protection industry; the import/export business; and food retailers, producers and consumers.

Day 2 continues to set the stage by providing information on what is currently being done to address minor use issues around the globe including OECD and EPPO efforts; looking at efficacy and crop safety data development issues; reviewing in detail current data generation efforts from the point of view of geographic regions; crop grouping harmonization efforts; and on-going cooperation in the area of data development, data-sharing, global registrations, MRL harmonization, and developing country initiatives.

Day 3 and the morning of Day 4 provide an opportunity to synthesize the information provided in the first two days and propose “global” solutions to specific issues. This will be done through break-out groups focusing on specific issues and then in a plenary session where future plans will be developed.

Day 4 afternoon and Day 5 provide in-depth training on various topics.

The Summit Organizing Committee
IR-4 Project
Jerry Baron Chairperson,

USDA FAS
Jason Sandahl,
Julie Callahan

US EPA
Lois Rossi

FAO
Gero Vaagt
# Global Minor Use Summit

**Monday, 3 December, 2007**

## Current Minor Use Status and Challenges

**Moderator:** Gero Vaagt

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<tr>
<td>09:00</td>
<td>Opening Remarks — Shivaji Pandey, FAO</td>
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<tr>
<td>09:15</td>
<td>USDA — Gale Buchanan, Under Secretary</td>
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<tr>
<td>09:30</td>
<td>U.S. EPA — James Gulliford, Assistant Administrator</td>
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<tr>
<td>09:45</td>
<td>Goals and Objectives of the Summit — Jerry Baron, Summit Organizing Committee</td>
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<tr>
<td>10:00</td>
<td>Coffee Break</td>
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<tr>
<td>10:20</td>
<td>Global Minor Use Panel — Current State of Specialty Crop Programs, Initiatives, &amp; Challenges</td>
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<tr>
<td>10:00</td>
<td>Coffee Break</td>
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<tr>
<td>10:20</td>
<td>Q &amp; A Session for Regional Panels</td>
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<td>12:15</td>
<td>Lunch Break</td>
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<tr>
<td>13:30</td>
<td>Presentation on MRL Database, Matthew Lantz</td>
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<tr>
<td>14:15</td>
<td>Continued Global Minor Use — Current State of Specialty Crop Programs, Initiatives, &amp; Challenges</td>
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<tr>
<td>15:30</td>
<td>Q &amp; A Session for Growers</td>
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<td>16:00</td>
<td>Coffee Break</td>
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<tr>
<td>16:15</td>
<td>Crop Protection Industry — Angel Saavedra, CropLife Latin America</td>
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<tr>
<td>16:15</td>
<td>Q &amp; A Sessions for Crop Protection Industry</td>
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<tr>
<td>17:15</td>
<td>Q &amp; A Session for Import/Export Business, Food Retailers, Producers, Consumers</td>
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<tr>
<td>17:30</td>
<td>Wrap-up Day 1, Review Day 2 Schedule — Jerry Baron</td>
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<tr>
<td>18:00</td>
<td>Reception — Provided by the Australian Government</td>
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**Panel by Regions:**

- **Africa** — Sandra Keller, South Africa
- **Asia** — Nuansri Tayaputch, Thailand
- **Australia/Oceania** — Peter Dal Santo, Australia
- **Europe** — Susanne Sütterlin, The Netherlands
- **North America** — Dan Kunkel, USA
- **Latin America** — Adriana Velez, Colombia

**Panel by Sectors:**

- **Growers**
  - Wally Ewart, California Citrus Quality Council
  - Houbin Chen, China, Litchi Growers Association
  - Richard Harnden, Berry Garden, Ltd., UK
  - Bernd Holtschulte, International Seed Federation
  - Enrique Negrete, Mexican Avocado Growers Association
- **Crop Protection Industry**
  - Doug Nelson, CropLife America
  - David van Hoogstraten, European Crop Care Association
- **Import/Export Business, Food Retailers, Producers, Consumers**
  - Caroline Harris, Exponent;
  - Kristian Möller, EUREPGAP;
- **18:15 – 18:30** Q & A Session for Import/Export Business, Food Retailers, Producers, Consumers
## Technical Initiatives & Challenges, Cooperation, and Policy Considerations

**Morning Moderator: Constance Jackson**

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<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>09:00 – 09:10</td>
<td>Overview of the Day - Jerry Baron</td>
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<tr>
<td>09:10 – 09:40</td>
<td>Thought Starter: Work by the OECD Expert Group on Minor Uses (EGMU) Sylvie Poret, OECD and Alan Norden, Australian Pesticides and Veterinary Medicines Authority (APVMA)</td>
</tr>
<tr>
<td>09:40 – 10:00</td>
<td>Report From the EPPO Workshop on Mutual Recognition of Minor Uses Berlin, Germany October 2006 Vlasta Zlof, European and Mediterranean Plant Protection Organization (EPPO)</td>
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<tr>
<td>10:00 – 10:20</td>
<td>Report on OECD Residue Chemistry Expert Working Group — Raj Bhula</td>
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<td>10:20 – 10:40</td>
<td>Efficacy and Crop Safety Data Development Issues, David Richardson, Pesticide Safety Directorate</td>
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<td>10:40 – 11:00</td>
<td>Coffee Break</td>
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<tr>
<td>11:00 – 13:00</td>
<td>Technical Initiatives and Challenges: Data Generation - Panel Discussion</td>
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<td>› Africa — Lucy Namu, Kenya</td>
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<td>› Asia — Yibing He, China</td>
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<td>› Latin America— Roberto Gonzalez, Chile</td>
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<td>› Europe— Sonia Barker, EU; Karsten Hohgardt, Germany</td>
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<td>› Oceania — Kevin Bodnaruk</td>
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<td>› North America— Ken Campbell, Canada</td>
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<td>› Crop Protection Industry — Michael Kaethner, CropLife International</td>
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<td>13:00 – 14:30</td>
<td>Lunch Break</td>
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**Afternoon Moderator: Mark Robson**

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<tr>
<td>14:30 – 15:00</td>
<td>Q &amp; A Session for Data Generation</td>
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<tr>
<td>15:00 – 15:40</td>
<td>Technical Initiatives and Challenges: Crop Grouping Initiatives</td>
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<td>› Importance of Crop Grouping and Residue Extrapolation; Existing Crop Grouping/Classification Systems – EU, Codex, Japan, US — Dave Lunn, New Zealand, Food Safety Authority</td>
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<td>› Crop Grouping Harmonization Effort Bernie Schneider, US Environmental Protection Agency, Hong Chen, International Crop Grouping Consulting Committee</td>
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<td>15:40 – 16:00</td>
<td>Q &amp; A Session for Crop Grouping Initiatives</td>
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<td>16:00 – 16:20</td>
<td>Coffee Break</td>
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<td>› Global Zoning &amp; Residue Programs — Jeff Herndon, US Environmental Protection Agency</td>
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<td>› FAO Initiative on Residue Data Sharing and Networking — Gero Vaagt, FAO</td>
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<td>› Steps Towards a Harmonised Minor Use Authorisation Procedure in the EU</td>
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<td>› Global Regulatory Initiative— Lois Rossi, US Environmental Protection Agency</td>
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<td>› Registrant Considerations in Proposing Global Joint Review/Workshare — Bernhard Johnen, CropLife International</td>
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<tr>
<td>18:20 – 18:45</td>
<td>Q &amp; A Session for Cooperation and Policy Considerations</td>
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<td>18:45 – 19:00</td>
<td>Wrap-up Day 2; Instructions for Day 3</td>
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Global Minor Use Summit
Wednesday, 5 December, 2007

Seeking Solutions

09:00 – 10:40  Break-out Sessions
10:40 – 11:00  Coffee Break
11:00 – 13:00  Continue Break-out Sessions
13:00 – 14:30  Lunch Break
14:30 – 15:30  Break-out Groups Meet
               Finalize Reports & Recommendations
15:30 – 17:50  Reports & Recommendations From
               Break-Out Groups — Panel with
               break-out group leaders
16:30 – 16:50  Coffee Break Included
17:50 – 18:00  Wrap-up Day 3; Review Day 4 & Day 5
               Schedules

Break-out Group Leaders
Residue Trials/Data Generation
Dan Kunkel
Roberto Gonzales

Mechanisms and Platform for Data Sharing/
Information Sharing; Network; Long-term Training
Bill Bryant
Mario Wick
Yongzhen Yang

MRL Harmonization
Peter Chan
Raj Bhula

Commodity Groups/Growers
Dan Botts
Houbin Chen

Regulatory Issues and Initiatives with Focus on
Industry Issues
Kathy Monk
Peter Watson

Efficacy and Crop Safety Data Development
Alan Norden
Susanne Sütterlin
Group A: Residue Trials/Data Generation  
**Moderators:** Dan Kunkel, IR-4 Project; Roberto Gonzales, University of Chile  
Strategies for identifying and collecting information on existing national/regional residue data generation programs; identify differences in national requirements for conducting residue trials and opportunities to harmonize requirements; identify mechanisms for storing and sharing available residue data for minor uses; identify opportunities for collaborative data generation to support minor uses; critique effectiveness of current crop grouping harmonization efforts.

Group B: Mechanisms and Platform for Data Sharing/Information Sharing; Network; Long-term Training  
**Moderators:** Bill Bryant, Bryant Christie, Inc; Mario Wick, Federal Biological Research Center for Agriculture and Forestry; Yongzhen Yang, FAO  
Strategies for identifying and collecting information on existing data sharing programs; identify mechanisms for sharing available data on, for example, minor use assessments, recent minor use approvals, current & proposed projects; joint reviews; and contact information; strategies for facilitating networking; strategies and priorities for long-term training programs.

Group C: MRL Harmonization  
**Moderators:** Peter Chan, Pest Management Regulatory Agency, Canada; Raj Bhul, Australian Pesticide and Veterinary Medicine Authority  
Identify existing national/regional/ international MRL setting programs; importance of harmonized MRLs with focus on minor uses; mechanisms to identify minor uses with MRL harmonization issues; opportunities and strategies to achieve MRL harmonization.

Group D: Commodity Groups/Growers  
**Moderators:** Dan Botts, Florida Fruit and Vegetable Association; Houbin Chen, Litchi Grower Association  
Identify issues growers have in producing minor crops; identify most effective types of assistance from governments and the crop protection industry to facilitate minor crop production; identify possible collaborative efforts to address grower minor use issues; discuss existing minor use programs, common elements of effective programs, mechanisms for expansion or setting up new programs; importance of harmonization issues from grower viewpoint; include consideration of very minor uses.

Group E: Regulatory Issues and Initiatives with Focus on Industry Issues  
**Moderators:** Kathy Monk, US Environmental Protection Agency; Peter Watson, CropLife International  
Identify issues the industry faces in developing crop protection products for minor uses; propose mechanisms/collaborative efforts to address these issues; discussion of existing minor use programs, common elements of effective programs, mechanisms for expansion or setting up new programs; identify incentives, include consideration of very minor uses.

Group F: Efficacy and Crop Safety Data Development  
**Moderators:** Alan Norden, Australian Pesticide and Veterinary Medicine Authority; Susanne Sütterlin  
Strategies for identifying and collecting information on existing national/regional efficacy and crop safety data generation programs; identify differences in national requirements for conducting efficacy and crop safety trials and opportunities to harmonize requirements; identify mechanisms for storing and sharing available efficacy and crop safety data for minor uses; identify opportunities for collaborative efficacy/crop safety data generation to support minor uses.
Global Minor Use Summit
Thursday, 6 & Friday, 7 December, 2007

Solutions & Future Plans
Moderator: Lois Rossi
09:00 – 09:30 Overview of Morning & Summary of Recommendations — Lois Rossi, US Environmental Protection Agency
09:30 – 10:15 Coffee Break/Informal Discussions
10:15 – 12:00 Develop Plans for Solutions — Panel with Break-out Group Leaders
12:00 – 12:30 Closing Remarks — Summit Organizing Committee

Training Session
Friday
09:00 – 12:00 Session B. JMPR and CCPR Data Review Procedures
Coffee Break 9:50 – 10:20 included
• Manufacturer Data Dossiers to JMPR
  Caroline A Harris, Exponent
• JMPR Review and MRL Recommendations — Arpad Ambrus, JMPR
  • CCPR Procedures — Jeronimas Maskeliunas, Codex
12:00 – 13:30 Lunch break
13:30 – 15:30 Session C. National and Regional Data Review Procedures
  • EU MRL Procedures — Francesca Arena, European Commission
  • Japan MRL Procedures — Tsuyoshi Sakamoto, Yasuo Kitamura, Food and Agricultural Materials Inspection Center
  • U.S. MRL Procedures — Jeff Herndon, US Environmental Protection Agency
15:30 – 15:45 Closing of Training Session
  Jerry Baron, IR-4 Executive Director
15:45 – 16:00 Coffee Break
16:00 – 17:45 Session D. Detailed Q & A Workshop Between Trainers and Trainees
Break-out Workshops
  • Field Residue Trials — Robin Bellinder, IR-4 Field Research Director
  • Analytical Research — Pim Larsson-Kovach, IR-4 Analytical Laboratory Director
  • Quality Assurance Audit Procedures
    Tammy White, IR-4 QA Manager
  • Discussion on Canadian requirement
    Ken Campbell, Agriculture and AgFood Canada
  • Involvement of States in US Minor Crop Registrations, Mary-Ann Warmerdam, California Dept. of Pesticide Regulation

IR-4 Project
Providing Solutions for Pesticide Registration
Training Session
09:00 – 12:00 Session A. U.S./Canada/IR-4 Model GLP Studies
• Program Overview: History, Collaborations, Future Direction
  Jerry Baron, IR-4 Project Executive Director
• Residue Programs, Databases, Tolerance Petitions
  Dan Kunkel, IR-4 Project Associate Director
  • GLP Field Trials and Field Data Books
    Robin Bellinder, IR-4 Field Research Director
  • GLP Analytical Laboratory Procedures and Report — Pim Larsson-Kovach, IR-4 Analytical Laboratory Director
  • Quality Assurance Audit Procedures
    Tammy White, IR-4 QA Manager
  • Discussion on Canadian requirement
    Ken Campbell, Agriculture and AgFood Canada
  • Involvement of States in US Minor Crop Registrations, Mary-Ann Warmerdam, California Dept. of Pesticide Regulation

FAO/WHO Joint Meeting of the Experts on Pesticide Residues (JMPR)
FAO/WHO Consultative Committee on Pesticide Residues (CCPR)
Joint Meetings
09:00 – 12:00
Coffee Break 9:50 – 10:20 included
• Manufacturer Data Dossiers to JMPR
  Caroline A Harris, Exponent
• JMPR Review and MRL Recommendations — Arpad Ambrus, JMPR
  • CCPR Procedures — Jeronimas Maskeliunas, Codex
12:00 – 13:30 Lunch break
13:30 – 15:30
• EU MRL Procedures — Francesca Arena, European Commission
• Japan MRL Procedures — Tsuyoshi Sakamoto, Yasuo Kitamura, Food and Agricultural Materials Inspection Center
• U.S. MRL Procedures — Jeff Herndon, US Environmental Protection Agency
15:30 – 15:45 Closing of Training Session
  Jerry Baron, IR-4 Executive Director
15:45 – 16:00 Coffee Break
16:00 – 17:45
• Field Residue Trials — Robin Bellinder, IR-4 Field Research Director
• Analytical Research — Pim Larsson-Kovach, IR-4 Analytical Laboratory Director
• MRL Data Dossiers — Jay Vroom, CropLife America
• Risk Assessment and MRL Recommendation — Raj Bhula, Australian Pesticide and Veterinary Medicine Authority
The Summit Organizing Committee wishes to thank all those who participated in this first Global Minor Use Summit and the Australian Government for providing valuable funding!