



**Global Minor Use Summit  
Rome**

**December 3-7, 2007**

## ***Challenges and Reforms in Support of Minor Uses: The Registrant's Perspective***

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## Points Will Cover in Presentation

- Minor crops are important to CropLife America and to global farm and consumer economy
- Costs of registering and defending new actives continues to rise
- Minor crops can bring major liabilities
- Suggested reforms to assist minor crop protection products



# Minor Crop Defined

- In the U.S.:
  - *technical* definition:
    - total production for the crop is fewer than 300,000 acres,
    - OR
  - *practical* definition:
    - any pesticide use which does not provide sufficient economic incentive for a registrant to support initial or continuing registration



# Minor Crops

(Acres)

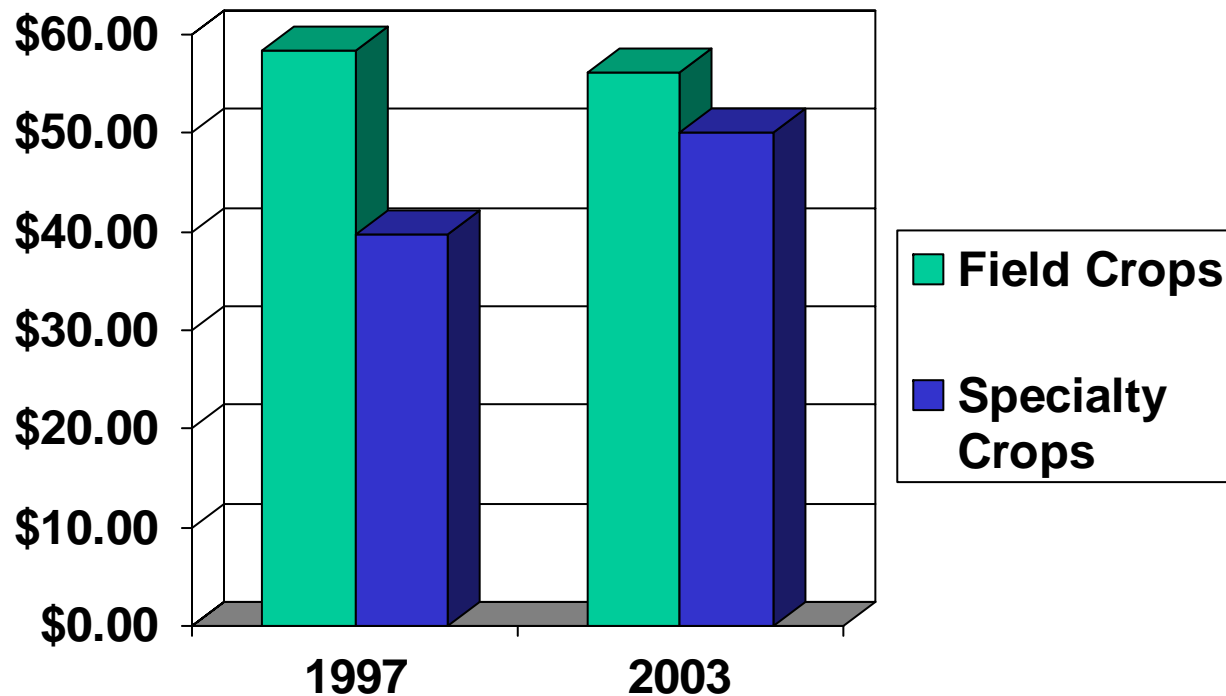
Value of production per acre in dollars

|                  |       |  |   |
|------------------|-------|--|---|
| Potential Market | Large | <ul style="list-style-type: none"> <li>• Barley (2.95 million) (\$166)</li> <li>• Oats (1.5 million) (\$109)</li> <li>• Sorghum (4.9 million) (\$176)</li> </ul> | <ul style="list-style-type: none"> <li>• Oranges (732,000) (\$2,400)</li> <li>• Apples (381,000) (\$5,500)</li> </ul>   |
|                  | Small | <ul style="list-style-type: none"> <li>• Chickpeas (133,000) (\$286)</li> <li>• Rye (274,000) (\$86)</li> </ul>  | <ul style="list-style-type: none"> <li>• Artichoke (7,000) (\$4,000)</li> <li>• Carrots (82,000) (\$6,500)</li> <li>• Strawberries (56,000) (\$25,000)</li> </ul> |
|                  |       | Low  | High  |
|                  |       | Value of crop per acre   |   |



## 'Minor' crops are anything but minor

U.S. Farm Cash Value (\$ USD Billion)



Source: *Challenges Faced by the IR-4 Project and US Specialty Crops*  
EPPO Workshop on Mutual Recognition of Minor Uses Berlin – 24.10.06



## Cost of Registration Continues to Rise

- **Length:** 10 to 12 years
- **Cost:** US\$200 – \$250 million for entire R&D and registration costs\*
- **Low Success rate:** Only 1 in 15,000 makes it to market
- **New EPA data requirements:** developmental neurotoxicity (\$ 1 million); endocrine disruption, data on inert ingredients

\*Phillips MacDougall source



# Recouping the Investment in a Crop Protection Product

- To recoup their investment, companies need:
  - protection for intellectual property and registration data
  - expand and preserve registrations and uses globally
  - risk (i.e., product liability) mitigation



# Companies protect intellectual property and data through

- Patents – national laws
- Data protection – TRIPs 39.3
- Trade Secrets



# Protection of Safety and Efficacy Data

Examples of statutory protection:

- The Agreement on Trade Related Aspects of Intellectual property Rights (TRIPs)
  - Article 39.3 says that Member countries shall protect test or other data, created as a condition of approving the marketing of agricultural chemical products from unfair commercial use
- Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
  - 10 years of data exclusivity and a concurrent period of 15 years of compensation for data cited by subsequent registrants



# Protection of Safety and Efficacy Data Cont

- Council Directive 91/414/EEC concerning the placing of plant protection products on the market (Under Revision)
  - 10 years of data protection for new active substances (Annex II) and for new products (Annex III data), and 5 years data protection for new Annex II data in the reauthorization of active substances



# Expanding and Defending Uses

- Registration of major uses
- Registration of minor uses (company, grower or IR-4 sponsored)
- Securing MRLs in countries that import commodities from cultivating countries
- Defending reassessments
  - in U.S. – registration review
  - in Europe – Directive 91-414
- Defending reassessment for minor crops is as important as securing minor crops for new active ingredients



# Minor Uses and Registration Review of Existing Chemicals

- Minor uses of older active ingredients may fill up a risk cup
  - because fruits and vegetables, ornamentals may present higher occupational or dietary opportunities



## Risk Mitigation: Minor Uses May Bring Major Liability

- worker protection: minor uses may present more issues
- bystander: minor uses are often closer to major population centers
- environmental: minor uses and proximity to surface water resources may trigger greater environmental oversight:
  - Example: Central Valley, California (fruit, vegetables) watershed triggered Center for Biological Diversity challenge under ESA and San Francisco Bay and Delta
- Proposition 65:
  - California large grower of minor crops; warnings and bounty hunter law suits
- Phytoxicity claims:
  - High value of minor crops: One company -- over \$120 million for claimed damage of fungicide to ornamentals



# Methods Must Be Devised To Shift Risk From Registrant to Financial Beneficiary

- Third party liability:
  - **Florida Fruit and Vegetable:**
    - Third Party Registration, Inc.: holds the registration; assumes full liability for failure of performance and any phytotoxic effects.
    - Grower must be a member of FFVA and must sign a waiver of liability.
  - **Canada: third party liability clause:**

*“Registrant makes no representation or warranty with respect to performance (efficacy) and/or crop tolerance (phytotoxicity) claims for this product when used on the crop(s) ... the Buyer and User assume all liability arising, and agree to hold Registrant harmless from any claims based on efficacy and/or phytotoxicity in connection with the use(s) described on this Supplementary Label.”*



## Other barriers

- Good Laboratory Practices:
  - increased costs; are they really necessary for minor crops; are they worth the additional costs?



# Needed Reforms

- Need for international harmonization of MRLs for minor uses.
  - Expand crop groupings commensurate with public safety and good science
  - international zones:
    - is U.S. winter wheat really different from Canadian winter wheat?
    - Does a Canadian apple really metabolize the same pesticide differently from a NY apple?



# Incentives for Industry to Support Minor Uses

- Regulatory agencies worldwide should align data requirements with market needs and have a fee structure for tolerance and registration maintenance costs which reflect the limited economic return on minor crops.
- Regulators permit different warranties and conditions of sale for major and minor crops.
- Governments must provide additional data protection for core regulatory data (toxicology, environmental) for submissions in support of minor uses:
  - In Canada there is a proposal to provide up to 5 years extra data protection for submission containing minor uses
  - In U.S FIFRA provides 3 extra years of data protection for core regulatory data for additional minor uses



# Incentives for Industry to Support Minor Uses Cont

- Governments can offer expedited review timelines for minor crop use submissions
- Industry/government partnerships such as IR-4 program in the U.S



# Path Forward

- Minor crop user community must become vested and active defend products
- Protect registrant's core regulatory data
- Allow differential pricing of different products because of different liabilities
- Liability Waivers and shifts in certain circumstances
- Publicly funded R&D to establish appropriate minor crop groupings for residues
- Registrants must recoup high cost of development of products for minor crops

