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

<table>
<thead>
<tr>
<th>Potential Market</th>
<th>Low</th>
<th>High</th>
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<tbody>
<tr>
<td>Small</td>
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<tr>
<td>Chickpeas (133,000)</td>
<td>$286</td>
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<td>Rye (274,000)</td>
<td>$86</td>
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<td>Barley (2.95 million)</td>
<td>$166</td>
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<td>Oats (1.5 million)</td>
<td>$109</td>
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<td>Sorghum (4.9 million)</td>
<td>$176</td>
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<tr>
<td>Low Value of crop per acre</td>
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<tr>
<td>High Value of crop per acre</td>
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- Oranges (732,000) ($2,400)
- Apples (381,000) ($5,500)
- Artichoke (7,000) ($4,000)
- Carrots (82,000) ($6,500)
- Strawberries (56,000) ($25,000)
‘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

  - 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