

CHALLENGES IN IMPLEMENTING CONSISTENT PUBLIC HEALTH AND ENVIRONMENTAL REGULATORY POLICIES

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NATIONAL LAWS

- ▶ **Constitutional authority**
 - Pest Control Products Act and Regulations in Canada
 - Criminal power
 - Food Quality Protection Act in US
 - Trade and Commerce power
- ▶ **Impact**
 - On transparency and access to data
- ▶ **Risk/benefit**
 - Benefits do not trump risks

SCIENTIFIC CONSENSUS

- ▶ OECD Test Guideline Program
 - Protocols proposed by a country may not reflect the science in others
 - Important to make efforts to come to consensus
 - Although there is not a requirement to use the data from in regulatory decision making, it poses problems

INTERNATIONAL REGULATORY HARMONIZATION

▶ Pharmaceuticals

- International Congress on Harmonization
 - EU, Japan and US. Canada had observer status
 - Protocols
 - Dossiers

▶ Pesticides

- NAFTA - North American Initiative
 - Data requirements
 - Relevant test protocols
 - Dossiers and study report formats
 - Data review and risk assessment practices
 - **Regulatory decision making**
- Expanded to OECD

INTERNATIONAL REGULATORY HARMONIZATION

▶ Commercial Chemicals

- Not as data rich as pesticides or pharmaceuticals
- Lot of catching up to do
- REACH is the Wild Card
 - How willing/able is industry to meet REACH requirements
 - Trade barrier to those who do not
 - How will they embrace a paradigm shift at this time

NEW APPROACHES

- ▶ A Tiered Approach to Systemic Toxicity Testing for Agricultural Chemical Safety Assessment
- ▶ John E. Doe,¹ Alan R. Boobis,² Ann Blacker,³ Vicki Dellarco,⁴ Nancy G. Doerrer,^{5*} Claire Franklin,^{6^} Jay I. Goodman,⁷ Joel M. Kronenberg,⁸ Richard Lewis,^{1E} Eugene McConnell,⁹ Thierry Mercier,¹⁰ Angelo Moretto,¹¹ Canice Nolan,¹² Stephanie Padilla,¹³ Whang Phang,⁴ Roland Solecki,¹⁴ Lorraine Tilbury,¹⁵ Bennard van Ravenzwaay,¹⁶ and Douglas C. Wolf¹³
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IMPLEMENTATION OF TOX 21 FOR PESTICIDES

- ▶ Evolution not revolution
 - Data rich and receptive to new ways
 - Burden on regulators when changing system to:
 - Balance expectations of public, industry, government and international partners
 - Include all groups in the consultations
 - Have realistic deliverables and timelines