



# Steps towards a Harmonised Minor Use Authorisation Procedure in the EU

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Association



# Presentation Overview

- Minor Use procedures today
- European Regulatory Environment
- Cooperative ventures
- Proposals for the future
  - Data requirements
  - Operational elements
  - International relationships
  - Underlying principles
- Conclusions



# Minor Use Procedures - Today

- Multitude of national procedures
- Operationally distinct
  - 'On-label' v 'Off-label'
  - Data requirements varied
  - Liability obligations – national law
- Stakeholder involvement diverse
- Increasing use of Mutual Recognition



# European Regulatory Environment

- Registration of active substances at European level – **Annex I of Directive 91/414/EEC**
- Registration of individual products at national level by harmonised procedure - **Annex VI of Directive 91/414/EEC**
- MRLs established at European level – **Regulation (EC) 396/2005**
- Development of new Authorisations Regulation with increased likelihood of reduced product availability



# Status of Cooperative ventures

- EU Expert Group on Minor Uses (Joint COM/MSs)
  - Steering Group – Oversight role
  - North and South Technical Groups
- Commission's contractor developing extrapolation guidance
  - Residue
  - Efficacy
- Guidance for Bilateral and Multilateral co-operation
- Stakeholder participation increasing



# What is needed ?

## Evolution or Revolution

- Piecemeal adaptation of 'Best features' from the national systems – 'Bottom-up' process
- Establishment of a Key Stakeholder group, under Commission direction, charged with design and development of EU-wide system ('Top down' process)
  - Creative solutions
  - Transparent, practical and reasonable
  - Prioritisation principles
  - Interactivity internationally



# Data requirements

- Must be appropriate to situation, not 'standard set' established for major crops
- More extensive use of 'expert judgement' for indicative efficacy situations
- Establishment of Expert Panels to develop guidance, especially extrapolations (efficacy, residues, risk assessments)
- Development of a 'Toolbox' – different solutions for different problems



# Operational elements

- New definition for 'Minor' - % or area of cultivation in individual MSs is irrelevant
- Incentives for support of Minor Uses, particularly those of small economic value e.g. reduced notification fees
- Pragmatic but 'agreed' approach to data extrapolation, ideally harmonised internationally
- Steering body to encourage development of co-operative ventures (Government/Growers/CP Industry)
- Mutual Recognition encouraged by improved access to underlying rationale for positive decision



# Operational elements

- Responsive to grower needs
- Fast track MRL establishment process
- Central funding and budget development
- EU wide but with a global view
- Harmonisation of reduced liability for manufacturer involvement
- Resolution of Proprietary data ownership issues
- Database repository for Minor Use data



# Supporting activities from International bodies

- OECD – Development of Guidelines
- EPPO – Development of Standards e.g. Principles of extrapolation regarding efficacy and crop safety of PPP for Minor Uses
- FAO – Participation in international oversight role
- IR4 – A working example



# Underlying Principles

- Protection of Public Health (consumers, operators, workers etc), Livestock and the Environment (structural elements and wildlife) is paramount
- Early involvement with Crop Protection industry during planning stages of new product development to identify potential in Minor Use arena
- Identification of strategically important Minor Uses in European agriculture with limited options for pest control



# Conclusions

- Streamlined Authorisations procedure needed
- Top-down system designed jointly by all Stakeholders
- Transparent, responsive and functional across MSs
- Development of new Authorisation Regulation to superceed Directive 91/414/EC represents unique opportunity to address Minor Use arena



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**Thank you for your consideration**

