Global Minor Uses Summit, Rome 2007

Data Generation - Europe

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Content

- EU Data requirements
- EU Data generation programmes
- The future
- Rest of Europe ??
Data requirements - EU

• Relevant Legislation:
  – 96/68/EEC (residues)
  – 96/46/EEC (methods of analysis)

• Guidelines to support data requirements:
Data requirements - EU

- Supervised residue trials underpinned by relevant:
  - Plant metabolism
  - Freezer storage stability of residues
  - Methods of analysis
  - Animal metabolism/ livestock feeding studies/ processing studies/ following crop studies as necessary
Supervised trial requirements

- Major crop = 8 trials
- Minor crop = 4 trials
- Major or minor crop?
  - Importance in the diet
  - Area grown
  - Production
Extrapolation of data

- SANCO 7525/VI/95 rev. 7 of 12 June 2001

- Major crop → minor crop
- Major crop → whole crop group
- Minor crop → minor crop
- Minor crop → whole minor crop group

# Funding for minor uses

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<th>CZ</th>
<th>DE</th>
<th>DK</th>
<th>EE, SL</th>
<th>FR</th>
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<th>UK</th>
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<tbody>
<tr>
<td>Government funding?</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
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<td>Exemption from reg fees?</td>
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<td>R</td>
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</tbody>
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- Y = Yes, N = No, R = Reduced
Data Generation Programmes -UK

- Horticultural Development Council (HDC)
- SOLA Programme
- Identify needs
- Residues data for specific uses for approval
  - Consultation/ agreements with Industry
  - Generation of own data/trials
  - EU standards/ guidelines
Data Generation Programmes -DE

Plant Protection Service of the Federal States

- identify needs
- discuss proposals with industry (round table) organised by BBA
- identify priorities and plan the work in small working groups
- generate data according to EU standards/guidelines, sometimes in cooperation with industry (analytical part)
EU Minor Uses Group

- Information exchange
  - Individual MS projects
- Identify problem areas
- Target areas where there are needs
- Collaboration between MS/industry
  - Sharing available data
  - Sharing costs of data generation
The future

- **Proposed EU data requirement revisions**
  - GEP instead of GLP for residue trials for minor uses
  - Reduction in number of trials for minor crops
  - OECD guidelines
  - EU guidance to be revised

- Regulation 396/2005 (EC MRLS)
We have this exemption today in a guidance document. I believe that this provision will only work within the EU but not in cases where we may share data across the European borders (Germany discussed something like this in the past for hops).

K. Hohgardt, 11/18/2007
The future

- EU project: SANCO/D3/SI2.396179: Scope for extending extrapolations to reduce the need for residues trials on minor crops


- EU Minor Uses Group
  - Further collaboration between MS/industry
  - Projects to look at crops grown in specific regions/areas
Thank – you