

Global Minor Uses Summit, Rome 2007

# Data Generation - Europe

**Sonia Barker,**

Pesticides Safety  
Directorate (PSD),  
UK

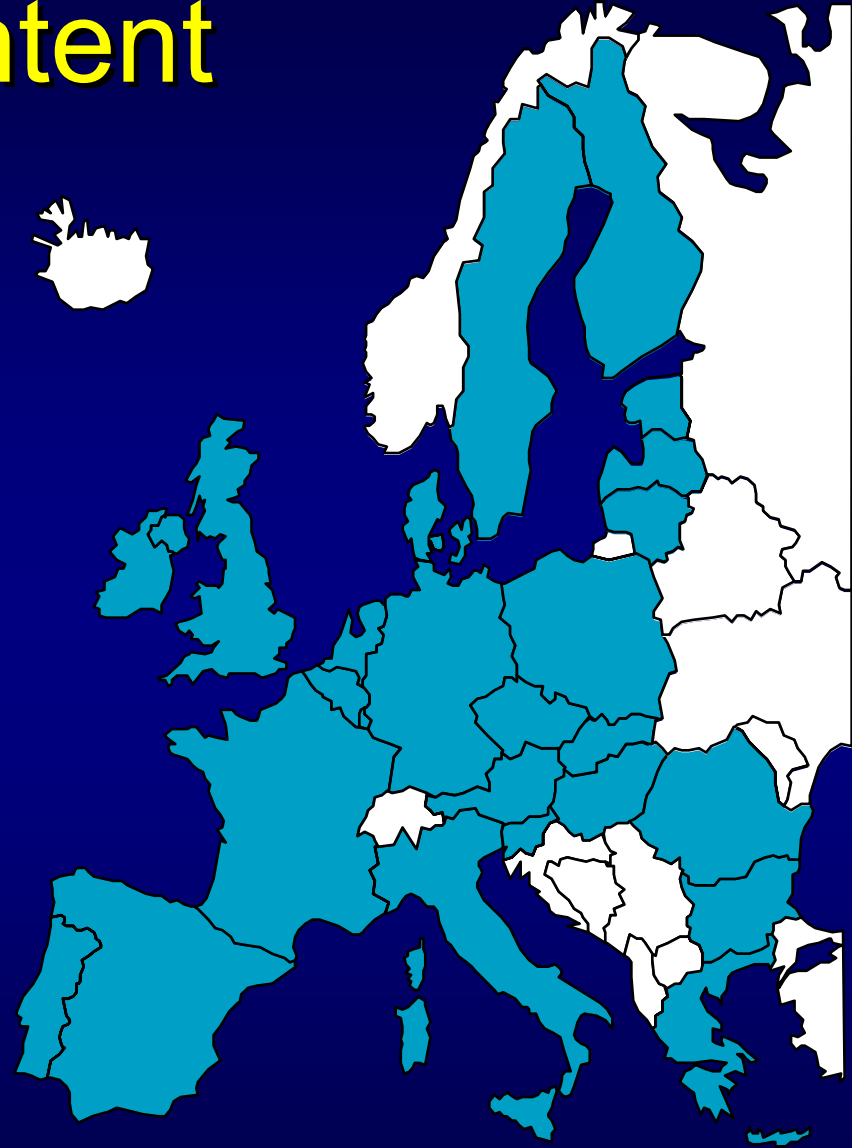
**Dr Karsten Hohgardt,**

Bundesamt für  
Verbraucherschutz und  
Lebensmittelsicherheit  
(BVL), Germany



# Content

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



# Data requirements - EU

- Relevant Legislation:
  - Directive 91/414/EEC and amending directives
  - 96/68/EEC (residues)
  - 96/46/EEC (methods of analysis)
- Guidelines to support data requirements:
  - [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm#residues](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#residues)

# 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
- [http://ec.europa.eu/food/plant/protection/resources/publications\\_en.htm#residues](http://ec.europa.eu/food/plant/protection/resources/publications_en.htm#residues)<sup>KH3</sup>

**Slide 6**

---

**KH3**

**internet address corrected**

K. Hohgardt, 11/18/2007

# Funding for minor uses

|                                 | B<br>E | C<br>Z | D<br>E | D<br>K | EE,<br>SL | F<br>R | H<br>R | L<br>V | N<br>L | P<br>T | S<br>E | C<br>H | U<br>K |
|---------------------------------|--------|--------|--------|--------|-----------|--------|--------|--------|--------|--------|--------|--------|--------|
| <b>Government funding?</b>      | Y      | Y      | Y      | Y      | N         | Y      | Y      | Y      | Y      | Y      | Y      | Y      | N      |
| <b>Exemption from reg fees?</b> | Y      | Y      | Y      | Y      |           | R      |        | R      |        | Y      | R      | Y      | R      |
| <b>3rd party funding?</b>       | Y      | N      | Y      |        | N         | Y      | N      | N      | Y      | Y      | N      | N      | Y      |

- 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)

KH4

## Slide 11

---

**KH4**

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 accross 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
- [http://ec.europa.eu/food/plant/protection/resources/minorcrops\\_en.pdf](http://ec.europa.eu/food/plant/protection/resources/minorcrops_en.pdf)
- EU Minor Uses Group
  - Further collaboration between MS/industry
  - Projects to look at crops grown in specific regions/areas

KH1

Slide 12

---

KH1

internet address corrected

K. Hohgardt, 11/18/2007

Thank – you

