MS experience with soil exposure methodologies

Michael Stemmer
AGES - Austrian Agency for Health and Food Safety

Environmental risk assessment of pesticides: 25 years of scientific advancements since the adoption of Directive 91/414/EEC, Parma, Italy, 15-16 November 2016

Overview of presentation

- Historical background
- Status quo of the current soil exposure assessment
- Pros & Cons in a regulatory framework
- Scientific limitations
- Outlook

Historical background

1991: Council Directive 91/414/EEC

- Largely undefined environmental fate section
- No guidance on exposure assessments or models

1995: Commission Directive 95/36/EC

(amending Council Directive 91/414/EEC)

- Data requirements (active substance and ppp) specified
- Predicted environmental concentrations (PEC values)
- Soil exposure framework specified
  - Soil density of 1.5 g/cm^3
  - Soil depth of 5 cm (soil surface appl.) or 20 cm (incorporation)
  - 50 % crop interception if ground cover is present

Historical background

1997: Soil persistence models and EU registration (EC Document 7617/VI/96)

- Soil Modelling Work group of FOCUS
- Specification of the simple exposure model
  - Model description based on first order degradation/dissipation
- Higher tier options
  - Field dissipation rates
  - More detailed models (numerical models)
- First work on „European soil scenarios"
- No recommendations on estimation of degradation/dissipation rate parameters

Historical background

2000: Guidance Document on Persistence in Soil
(EC Document 9188/VI/97 rev. 8)

- Commission & MSs working document
- Adds more guidance on
  - Lab and field studies
  - Soil accumulation potential
  - Non-extractable residues
- Basic instructions on estimation of degradation/dissipation rate parameter in lab and field studies
  - Regression analysis (≥ 5 sample points)
  - First order degradation preferred, $r^2 \geq 0.85$
  - Bi-exponential degradation (expert decision)

Historical background

2001: FOCUS groundwater scenarios in the EU review of active substances (SANCO/321/2000 rev. 2)

- Crop interception for individual crops and BBCH codes specified → used for soil exposure as well

2006: FOCUS GD on estimating persistence and degradation kinetics from environmental fate studies (SANCO/10058/2005, ver. 2)

- Detailed guidance on fitting procedure and statistical evaluation
- Trigger vs. modelling endpoints
- PEC soil calculation amended with non first-order degradation

Historical background

2009: Regulation (EC) 1107/2009
(replacing Council Directive 91/414/EEC)

- Introduction of persistence trigger endpoints for persistent organic pollutants (POP, BPT and vPvB)
- PEC soil should be based on *appropriate soil layer depth* (soil density not specified anymore)

2014: EFSA GD for evaluating laboratory and field dissipation studies (EFSA Journal 2014;12(5):3662)

- Updated crop interception values

Current soil exposure assessment

Predicted environmental concentrations in soil (PEC_S)

- *"The level of residues in the top layer of the soil to which non-target soil organisms may be exposed (acute and chronic exposure)"*
- *„Realistic worst case estimation*"
- Required for active substance and metabolites, breakdown and reaction products > 10 % (> 5 % in Regulation (EC) 1107/2009)
- Single and multiple application, short- and long-term PECs, accumulation in soil
- Soil processes other than degradation/dissipation shall be considered

Current soil exposure assessment

Single application:

$$Initial\ PEC_S = \frac{A \times (1 - f_{int})}{100 \times depth \times bd}$$

PEC_S	Predicted environmental concentration in soil (mg/kg)
A	**Application rate (g/ha)**
f_{int}	**Fraction covered by the crop (-)**
depth	Soil depth (cm) = 5 cm (20 cm if incorporated)
bd	Bulk density (g/cm^3) = 1.5 g/cm^3

Current soil exposure assessment

Multiple application:

$$PEC_S = Initial\ PEC_S \times \frac{1 - e^{-n \times k \times i}}{1 - e^{-k \times i}}$$

Time-weighted average concentrations:

$$Average\ PEC_S\ over\ t\ days = Initial\ PEC_S \times \frac{1 - e^{-k \times t}}{k \times t}$$

Long-term concentrations and build-up:

$$Plateau\ maximum\ PEC_S = \frac{Initial\ PEC_S}{(1 - e^{-k \times i})}$$

k	**Degradation/dissipation rate (days^{-1}) = ln(2) / *DT50***
	→ Worst case from available data
i	Time between applications (days)
n	Number of applications (-)
t	Time (days)

Current soil exposure assessment

Calculation tools

- No "official" calculation tool
- Self-made spread sheet calculations at MS level
- Sometimes harmonisation issues amongst MSs
- One more advanced ready-to-use tool (ESCAPE, Germany)
  - Well defined and user friendly
  - Handles non-SFO degradation/dissipation as well
  - Different tillage options
  - Irregular application patterns

Pros & Cons in a regulatory framework

Working process for soil exposure assessment

Basic study evaluation (lab & field)
→ Reliable degradation/dissipation experiments

↓

Kinetic evaluation (soil residues)
→ Degradation/dissipation endpoints

↓

Soil exposure assessment
→ PEC_S for patent and metabolites

Pros & Cons in a regulatory framework

Soil sampling, handling and storage for laboratory studies

- Test methods/guidance
  - **OECD 307 (2002): Aerobic and anaerobic transformation in soil**
  - **ISO 10381-6 (2009): Soil quality – sampling (collection, handling, storage)**
- Poor harmonisation with respect to validity judgment of entire study or parts of the study
  - Soil history?
  - Soil storage conditions?
  - Soil pre-incubation conditions?

Pros & Cons in a regulatory framework

Laboratory soil degradation studies (aerobic, anaerobic)

- Test methods/guidance
  - **OECD 307 (2002): Aerobic and anaerobic transformation in soil**
- Rather strict and straightforward
- Extraction procedure for soil residues completely undefined (has to be "appropriate")
- How to handle soils that do not fit the selection criteria (OM, pH)?

Pros & Cons in a regulatory framework

Field studies

- Text methods/guidance
  - **US EPA OCSPP 835.6100 (2008): Terrestrial field dissipation**
  - **EFSA (2014): EFSA GD for evaluating laboratory and field dissipation studies**
  - **ENV/JM/MONO 6 (2016): Guidance Document for Conducting Pesticide Terrestrial Field Dissipation Studies**
- Plenty of room for individual expert judgment (in particular with respect to legacy studies)
  - How representative with respect to intended use?
  - Location issues (Northern vs. Southern Europe)?
  - Appropriateness of sampling strategy (timing, depth)?

  → **A lot of discussions in EFSA's peer review meetings**

Pros & Cons in a regulatory framework

Evaluation of the degradation rate

- Guidance
  - **FOCUS GD on estimating persistence and degradation kinetics from environmental fate studies** (generic guidance)
- Quite extensive and rather complex document (434 pp)
- Different interpretation of the guidance (significant uncertainty and increased workload)
- Regular and controversial discussions in EFSA's peer review meetings
  - Fit reliability (statistics)?
  - When to deviate from simple first order (SFO)?
  - How to deal with metabolites not showing a decline phase?

Pros & Cons in a regulatory framework

Exposure assessment

- Guidance
  - **FOCUS GD on estimating persistence and degradation kinetics from environmental fate studies** (generic guidance)
- Fast and simple (compared to groundwater and surface water exposure assessment)
- Less harmonisation "outside" of the basic approach
  - Tillage
  - Row treatments, permanent crops, seed treatments, etc.
  - Implementation of non-first-order degradation kinetics
- No higher tier or refinement options
  (no agreed soil scenarios for numerical models)

Pros & Cons in a regulatory framework

Recommendations (personal view)

- More guidance to judge on validity of older (legacy) degradation/dissipation studies
- Reduced workload with respect to fitting procedures to derive degradation endpoints
  - Simplification
  - More pragmatism
  - Stay with first-order degradation as far as possible
- More guidance on fitting persistent metabolites
  - Acceptance of kinetic fits without decline phase
  - Metabolites tend to degrade faster in metabolite dosed studies
- **Balance between scientific vs. regulatory needs**

Limitations from a scientific point of view

- No guarantee to cover „realistic worst case" conditions
  - Degradation may be too optimistic for cold areas if derived from a 20 °C lab study
  - Soil density of 1.5 g/cm^3 is rather best than worst case
- Worst-case *DT50* has low statistical significance → high uncertainty in exposure assessment
- Dissipation processes other than degradation not included (if lab study)
- Crop interception considered to be a sink (no wash off)

Outlook

EFSA GD on PECs in soil (working group member view)

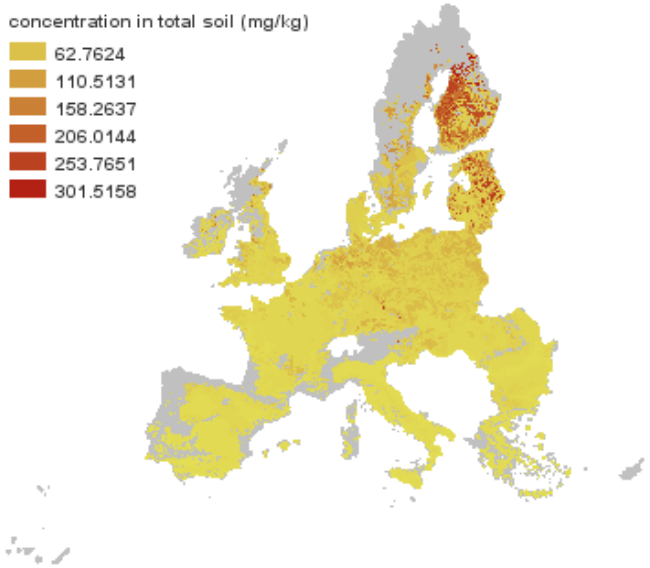
- Revision of the current soil exposure assessment
- Commission mandate for GD to EFSA in 2012
- "Goal": ***Realistic worst-case soil exposure represented by the 90th percentile concentration in time and space for a given crop in a Regulatory Zone***
- Covers annual & permanent crops, crops grown on ridges, in rows, soil incorporation, grassland, etc.
- Mixture of a simple analytical model and more advanced numerical models (tiered approach)
- 2 public consultations (2015, 2016)
- Final publication foreseen by **end of 2017**

Outlook

EFSA GD on PECs in soil – cont.

- Based on EU-wide spatial soil, weather and crop data

→ Exposure mapping



→ Risk mapping and landscape based approaches for active compounds and PPP

Thanks for your attention!

Michael Stemmer
AGES - Austrian Agency for Health and Food Safety
michael.stemmer@ages.at