Critical Comparison of the Schemes Used to Assess Soil Exposure Under EU Pesticide, Biocide and REACH legislation

Presented by

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Outline

- Summarise and compare the exposure assessment schemes for soil used for plant protection products, biocides and industrial chemicals under EU legislation
- Compare the PECsoil calculated by each scheme
- Provide comments on each of the approaches
- Conclusions and general thoughts

Introduction

- Exposure of soil can occur both directly and indirectly from the uses of pesticides, biocides and industrial chemicals
  - Direct exposure – actual exposure during the use, e.g. to the soil in the field when a plant protection product is applied
  - Indirect exposure – exposure does not occur during use but due to another event – e.g. spreading of sewage sludge on agricultural land
- There is the potential for risk to soil organisms and soil processes
- Schemes to assess the risk have therefore been developed to assess the potential risk from this exposure under the various regulatory regimes.
- Due to the nature of the industries and regulatory schemes involved there is some commonality in the approaches but in some instances there are significant differences.

Representative chemical

- In instances calculations are presented; the following chemical properties have been assumed.

Parameter	Value
Molecular weight (g/mol)	350
Solubility (mg/L)	1
Vapour Pressure (Pa	1 x 10-5
Degradation	Not readily biodegradable (DT50 soil 1000 days)
Koc (ml/g)	1000
Rate applied	200 g a.s./ha; 20 mg/m^2
Crop & growth stage	Winter cereals (BBCH 30-39) (PPP) N EU Oct-Feb (ECPA-LET)
Crop interception	80% (PPP) Full canopy (70%) ECPA-LET

Plant Protection Products – Current Approach

- Defined by FOCUS 1997, but it's use pre-dates this.
- Considers direct exposure at the field scale
- Simple calculation assuming distribution through a soil depth of 5 cm and a soil density of 1.5 g/cm^3.
- Crop interception accounted for, and defined by EFSA 2014 and is dependent on crop and growth stage.
- Accumulated concentrations calculated for persistent substances (DT_{90} >365 days), by assuming distribution of plateau concentration through either plough layer (20 cm, annual crops) or 5 cm permanent crops).
- PEC initial – 0.053 mg/kg dry weight
- Accumulated concentration – 0.099 mg/kg

Plant Protection Products – Current Approach

Comments

- Quick, simple easy to use and understand
- Choice of 5cm depth, arbitrary, based on expert judgement. (Germany use different depth for national assessments)
- Ecological considerations of soil organisms or soil function not taken into consideration
- Protection goals not defined.
- Many years use (>20 years) and fairly good agreement with residues in soil dissipation field studies
- No evidence from the field that the approach is not sufficiently protective. (e.g. from litterbag studies, earthworm field studies)

Plant Protection Products – PERSAM

- Published by EFSA in 2014
- Approach consists of 5 Tiers.
- PECs in soil are produced for each regulatory zone (North, Central and South) across a number of depths.
- PERSAM software tool and the PEARL and PELMO simulation models are used for the calculations.
- Tier 1 calculations using PERSAM are highly conservative with canopy processes excluded.
- Tier 2A (using PEARL and PELMO) then uses similar assumptions but takes factors such as canopy processes into account.

Plant Protection Products – PERSAM

- Adjustment factors are included at Tier 1 and 2A to ensure that the concentrations exceed those at higher tiers.
- Tier 2 (2B and 2C, using PERSAM) - the target percentile soil concentration is calculated from the concentration distribution within the crop area.
- Tier 3 - crop specific concentrations are calculated using either pre-defined crop and substance specific adjustments (3A, though require results from PEARL/PELMO at 2A) or using substance specific parameters and specific crop scenarios defined within the PEARL and PELMO models (3B).
- Tier 4 is the use of spatially distributed modelling.
- Tier 5 is the use of post registration monitoring.

Plant Protection Products – PERSAM

- Calculated PECs using PERSAM (mg/kg dwt)

Tier 1	1 cm depth	2.5 cm depth	5 cm depth	20 cm depth
N EU	20.991	13.412	10.886	8.991
C EU	11.278	6.707	5.183	4.040
S EU	9.069	5.135	3.824	2.840
Tier 2b	**1 cm depth**	**2.5 cm depth**	**5 cm depth**	**20 cm depth**
N EU	8.731	5.491	4.430	3.632
C EU	6.395	3.881	3.041	2.410
S EU	5.134	2.963	2.241	1.698
Tier 2c	**1 cm depth**	**2.5 cm depth**	**5 cm depth**	**20 cm depth**
N EU	1.746	1.098	0.886	0.726
C EU	1.279	0.776	0.608	0.482
S EU	1.027	0.593	0.448	0.340

Plant Protection Products – PERSAM

Comments

- Considers direct exposure at the field scale
- Selection of depths given, but ecological relevance not established.
- Specific protection goal not defined
- Model is complex
  - Large amount of data available
  - Represents a black box
- Tier 1 PECs up to 110X those calculated using current method. Are they realistic?
- Higher tier tools (PELMO/PEARL) are introduced early (Tier 2A)

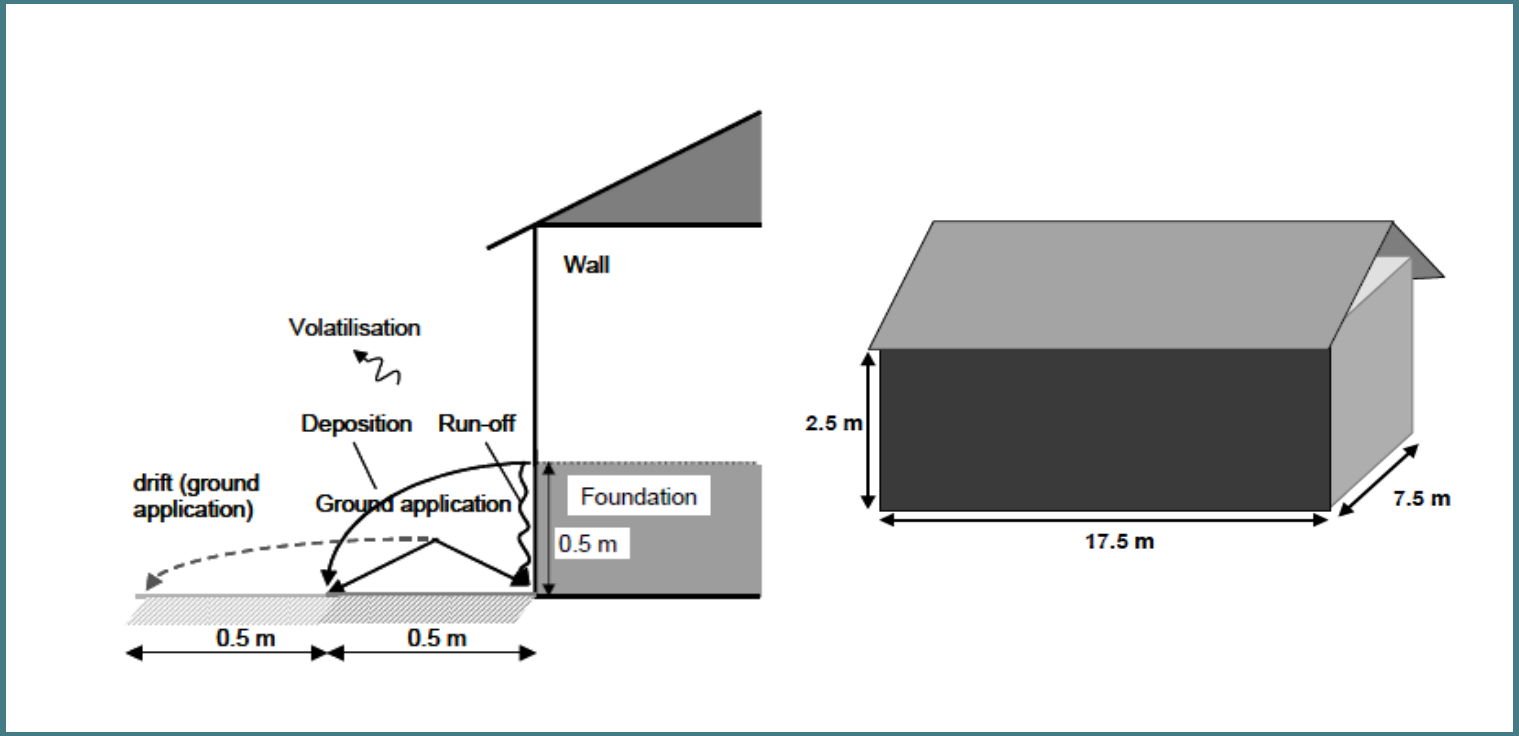
Plant Protection Products – PERSAM

Comments

- Tiers appear artificial
- Calculations using the higher tier models (PEARL/PELMO) are required to obtain values close to those obtained using the current model
- Assessment scheme seems to be more conservative; has a regulatory or risk assessment need for a more conservative approach has been identified?

Biocide – Outdoor Barrier Treatment

- Defined in the OECD scenario for PT18 (OECD 2008), many assumptions defined in the TGD.



Biocide – Outdoor Barrier Treatment

Assumptions for the calculation for a soil barrier treatment:

- 0.5m band treated around a house of 17.5 x 7.5 m
- Area soil treated 26 m^2
- 99% assumed to reach soil
- 0.42% drift assumed to drift to adjacent soil
- Soil depth of 50 cm assumed (previously 10cm but not considered ecologically relevant), therefore soil volume directly exposed 13 m^3
- Adjacent soil volume exposed via drift - 14 m^3

Biocide – Outdoor Barrier Treatment

- Bulk density of soil 1700 kg/m^3 (wet)/1500 kg/m^3 dry)
- PECsoil treated area
  - 0.023 mg/kg wwt (0.026 mg/kg dwt) treated area
- PECsoil non-treated area:
  - 9.2 x 10^{-5} mg/kg wwt (1.0 x10^{-4} mg/kg dwt)

Biocide – Outdoor Barrier Treatment

Comments

- Assessment of application area and immediate surroundings
- Relatively simple calculation - easy to use
- Considers both direct and indirect application
- No consideration of ecological relevance appears to have been made when defining the scenario.
- Dimensions of exposed compartments set arbitrarily. Depth originally 10 cm, then changed to 50 cm.
- For outdoor barrier treatments actual treated area of soil is assessed

Biocide – Indoor Surface Treatment

- Defined in the OECD scenario for PT18 (OECD 2008), many assumptions defined in the TGD.
- Assumed direct exposure does not occur, but wastewater from cleaning goes through municipal STP and sludge from the STP is spread on agricultural land.
- Indoor general surface treatment assumes 22 m^2 per house is treated.
- Behaviour in STP modelled by the SimpleTreat model
- Default simultaneity factor (Fsim) assumes 5.5% of houses treated per day in an STP catchment of 4000 houses (equivalent to 80,300 treatments per STP catchment per year).

Biocide – Indoor Surface Treatment

- Total emission:
  - 1.86 kg/day, industrial
  - 0.0488 kg/day, household.
- 11% directed to sludge in STP, Concentration in sludge – 259 mg/kg
- Sludge assumed to be applied at 0.5 kg dwt/m^2/yr to agricultural land and 0.1 kg dwt/m^2/yr to grassland
- PECs for household use:
  - PEC agric soil (30 d TWA, 20 cm depth) – 0.0978 mg/kg dwt
  - PEC agric soil (180 d TWA, 20 cm depth) – 0.0971 mg/kg dwt
  - PEC grassland (180 d TWA, 10 cm depth) – 0.0336 mg/kg dwt

Biocide – Indoor Surface Treatment

- PECs for Industrial use:
  - PEC agric soil (30 d TWA, 20 cm depth) – 3.73 mg/kg dwt
  - PEC agric soil (180 d TWA, 20 cm depth) – 3.7 mg/kg dwt
  - PEC grassland (180 d TWA, 10 cm depth) – 1.28 mg/kg dwt
- Assumptions used to calculate indirect exposure of soil identical to those used for industrial chemicals under REACH.

Biocide – Indoor Surface Treatment

Comments

- Model considers large scale wide dispersive use by a population of 10,000 individuals (4000 households)
- 100% of the sewage sludge is assumed to contain residues
- Relatively simple model – simplifying a variety of complex processes
- Dimensions of exposed compartment defined based on sludge mixing depth.
- No consideration of ecological relevance
- Protection goals not specifically defined

Biocide – Indoor Surface Treatment

Comments

- Quality of data on which the Fsim is based is very poor
- There are indications that the current default assumptions (i.e. 80,000 treatments per year to 4000 households and magnitude of losses from wet cleaning) could be severely overestimating exposure

Biocide – Use in Animal Houses

- Defined in the OECD scenario for PT18 (OECD 2006)
- Soil assumed to be exposed indirectly from spreading of slurry on agricultural land
- Sludge application rates are calculated based on phosphate and nitrogen emission standards. Initial concentration calculated in upper 10cm in grass land and upper 20 cm in arable land
- Application to veal calf slurry as a larvicide:
  - PECsoil arable land – 5.68×10^{-3} mg/kg dwt (Phosphate); 6.78×10^{-3} mg/kg dwt (Nitrogen)
  - PECsoil grassland – 7.76×10^{-3} mg/kg dwt (Phosphate); 7.16×10^{-3} mg/kg dwt (Nitrogen)

Biocide – Use in Animal Houses

Comments

- Model considers fairly moderate scale exposure from spreading 100% treated slurry on agricultural land
- Fairly simple calculation
- Degradation in slurry can be taken into consideration
- Dimensions of exposed compartment defined based on slurry mixing depth.
- No consideration of ecological relevance
- Protection goals not specifically defined

REACH – PPP co-formulants

- SpERC defined by the ECPA-LET guidance:
- Closely follows the approach used for Plant Protection Products using assumptions used for FOCUS surface water
- Soil mixing depth of 5 cm assumed in soil with a density of 1700 kg/m^3 (1500 kg/m^3 dry soil)
- Soil PEC calculated as a 30 day time weighted average following a single application.
  - PECsoil = 0.0716 mg/kg dry weight
- Simple calculation – comments made on current PPP method apply

Comparison of PECsoil

Assessment Scheme	Depth	PECsoil (mg/kg dwt)
PPP (FOCUS)	5 cm	0.053 – 0.099
PPP (PERSAM) Tier 1	5 cm	3.8 – 10.9
PPP (PERSAM) Tier 2b	5 cm	2.2 – 4.4
PPP (PERSAM) Tier 2c	5 cm	0.4 – 0.9
ECPA LET	5 cm	0.072
Biocide Outdoor	50 cm	0.026
Biocide Indoor	10–20 cm	0.03 to 3.7
Animal House Biocide	10–20 cm	0.006 – 0.008

Observations

- The calculations presented are for a range of situations under differing regulatory regimes.
  - Direct comparison not always possible.
  - Range of scales very localised to wide scale
- All exposure schemes use total soil concentration (wet or dry weight)
- Models vary in complexity
- Some cross referral – sometimes developed in isolation

Observations

- Some schemes provide Tier 1 estimates, with no guidance on how such estimates can be refined
- In no instances have the protection goals or ecological relevance of the scenarios or the assumptions used been explicitly defined when creating the scenarios.
- Differing assumptions regarding what is an ecological relevant mixing depth for the same exposure route. From 5 cm for PPPs to 50 cm for biocides.

Observations

- In instances where direct comparison is possible some differences are clearly evident
  - PERSAM calculations significantly higher than the current PPP calculation
  - Slight differences between the ECPA-LET and current PPP calculation due to differences in the assumptions used for the same processes in assessing different compartments for PPPs.
- PECs for the indoor biocides use from indirect exposure are comparable (household) or significantly in excess of (industrial) some PECs for direct exposure. Overestimation of exposure?

General Thoughts and Conclusions

- When creating exposure scenarios the ecological relevance and protection needs/goals need to be considered.
  - What is relevance and protection goal in assessing a 0.5 m strip around a house?
- Assumptions used in any assessment scheme need to be realistic and not lead to significant under or overestimation
- The information which the assessment scheme is based needs to be reliable.
  - Data used for Fsim for indoor biocides is not appropriate

General Thoughts and Conclusions

- Tiered approaches:
  - Usefulness of overly conservative Tier 1 estimates where everything fails is limited
  - Complexity should increase as you go up the tiers with quick and simple (back of envelope?) calculations at lower tiers and more complex calculations as you go up the tiers.
  - Higher tier models should not be used as lower tier tools
  - Question the benefit where multiple tiers can be run quickly and simultaneously, surely this can be a single tier?
  - Artificial tiers must be avoided (e.g. creating unnecessary extra steps, or applying arbitrary factors to adjust lower tier estimates)

General Thoughts and Conclusions

- Assumptions used should be relevant to the exposure profile but there should be consistency
  - Within regulatory regimes (e.g. mixing depths for biocides vary between PTs, crop interception varies when assessing surface and groundwater for PPPs)
  - Preferably also between regulatory regimes where appropriate
- When creating an assessment scheme an assessment of it's impact should be performed before its introduction.
  - Allows a critical review of the assumptions
    - Assess their realism
    - Assess their impact in the 'real world'
  - Increases quality of regulatory decision making
  - Reduces need to amend assumptions after introduction

General Thoughts and Conclusions

- Complexity is not always necessary
  - Is a simple model adequate for the task?
  - All processes do not need to be modelled mechanistically
  - Remember! - Models and assumptions used are approximations and do not represent reality
- Where possible any assessment scheme needs to be validated with real-world data.
- Any assessment scheme must be open to amendment and evolution and not be “set in stone”. New information/data /science will come to light and lessons will be learnt from use. There should be a continuous dialogue.

Thank you for your attention

Any questions?

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