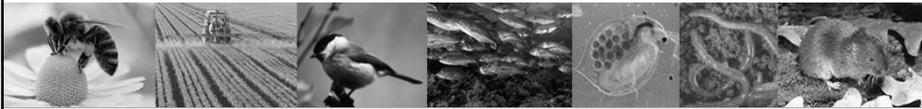


RISK ASSESSMENT FOR IN-SOIL ORGANISMS



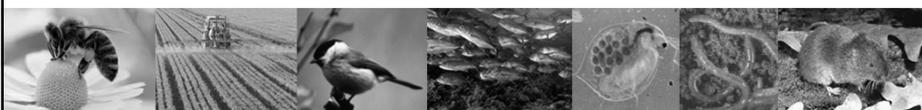
SILVIA PIEPER, Federal Environmental Agency, Germany
JOSÉ PAULO SOUSA, DCV – University of Coimbra, Portugal

Umwelt
Bundes
Amt
Für Mensch und Umwelt



Risk Assessment Calculations for In-soil Organisms

- ▶ All groups will work on the same data
- ▶ The risk for in-soil organisms resulting from the intended use of Compound E and Phenmedipham will be assessed
- ▶ Compound E and Phenmedipham have different physical and chemical characteristics and different toxicity
- ▶ The intended uses for Compound E and Phenmedipham are different.



COMPOUND E

The applicant "KlaubergCrop" is requesting for authorization of PPP

KillTech with compound E as active substance.

The regulatory scenario is as follows:

Regulatory scenario:

Intended use	Target	Crop & Growth stage	Application pattern
001	Dicotyledonous weeds	Field crops Beet (after emergence, 20% interception)	1 application of 600 g/ha a.s. every year;

Compound data:

- DT50f: 108 days; DT90f: 360 days
- LogKow: 2.7



COMPOUND E

Ecotoxicological data:

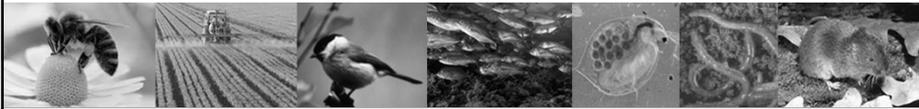
Species	Substance	Exposure, system	Results	Ref.
Eisenia fetida	Comp E	14d acute lab (10% OM)	Mortality LC50 (mg a.s./Kg DW soil): 20	Study 1
Eisenia fetida	Comp E	14d acute lab (5% OM)	Mortality LC50 (mg a.s./Kg DW soil): 11	Study 2
Eisenia fetida	Comp E	56d chronic lab (5% OM)	Reproduction NOEC (mg a.s./Kg DW soil): 4.1	Study 3
Folsomia candida	PPP `Killtech` with Comp E	28 d chronic Lab (5% OM)	Reproduction NOEC (mg a.s./Kg DW soil): 2.2	Study 4
Folsomia candida	PPP `KillNow` with Comp E	28 d chronic Lab (5% OM)	Reproduction NOEC (mg a.s./Kg DW soil): 0.9	Study 5
Nmin	PPP `Killtech` with Comp E	28d field; tested concentration (mg a.s./Kg DW soil): 0.4, 0.8, 4.0	< 25% effect compared to control	Study 6
Litterbag	PPP `Killtech` with Comp E	275d field; tested rates (g a.s./ha): 300, 600, 3000	3.3% effect compared to control	Study 7

COMPOUND E

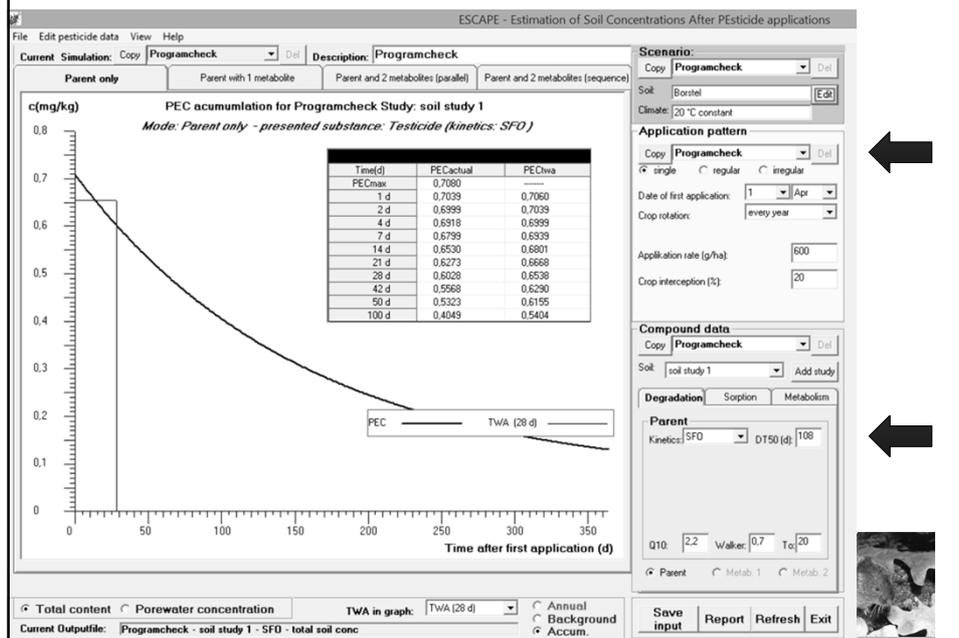
- ▶ Assess the risk for in-soil organisms resulting from the intended use of PPP “KillTech” formulated with Compound E.
- ▶ For calculations of the Predicted Environmental Concentrations in Soil (PECsoil) use the ESCAPE software. Use soil total concentration as relevant type of concentration.
- ▶ Use the current ERA scheme for soil organisms (earthworms and other soil non-target organisms).

Note 1: For standard NTA test the $HQ > 2$

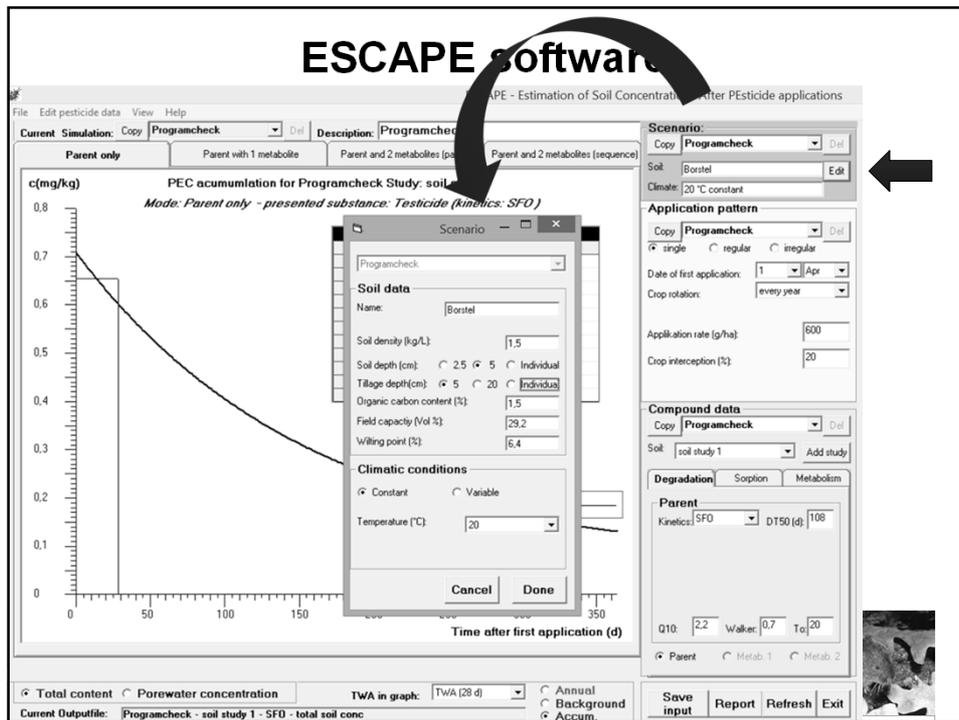
Note 2: In the litterbag study the background concentration is covered



ESCAPE software

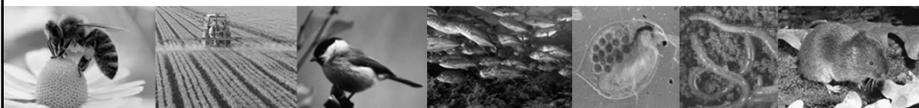


ESCAPE software



COMPOUND E

- ▶ STEP 1 - Exposure
Calculate PECmax for the regulatory scenario (intended use 001).
- ▶ STEP 2 - Ecotoxicology
Select the appropriate endpoints and check for data completeness according to the ERA scheme
- ▶ STEP 3 – Risk calculations
Derive risk values according to the ERA scheme



COMPOUND E

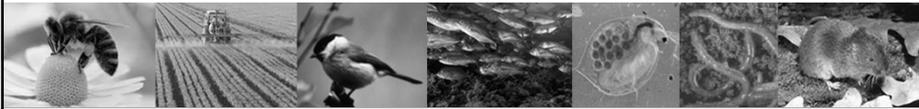
► STEP 4

Currently the litterbag test is accepted when addressing risk to soil mesofauna. In future, this will not be the case.

How should the applicant address the risk of PPP “KillTech”?

Present possible mitigation measures, for example, considering different application patterns (recalculate PEC values and associated Risk values). See which application pattern allows the use of the PPP “KillTech”.

Are there other ways to address the risk?



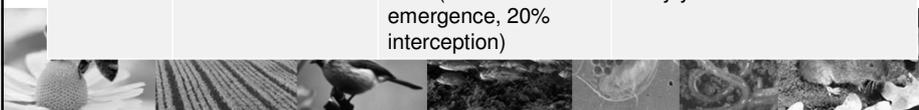
Phenmedipham (PMP)

The applicant “KlaubergCrop” is requesting for authorization of PPP “ATTACKE” with compound PMP as active substance.

The regulatory scenarios are as follows:

Regulatory scenarios:

Intended use	Target	Crop & Growth stage	Application pattern
001	Dicotyledonous weeds	Field crops Beet (after emergence, 20% interception)	1 application of 600 g/ha a.s. every year
002	<i>Poaceae</i> grasses	Field crops Beet (after emergence, 20% interception)	2 applications of 800 g/ha a.s. every year
003	Super weeds	Field crops Beet (after emergence, 20% interception)	7 applications of 400 g/ha a.s. every year



Phenmedipham (PMP)

- ▶ STEP 0 - Database
Select the relevant parameters for exposure and effect assessment from the EU official list of endpoints.
- ▶ STEP 1 - Exposure
Calculate PECmax for the 3 regulatory scenarios (intended use 001, 002 and 003).
- ▶ STEP 2 - Ecotoxicology
Select the appropriate endpoints and check for data completeness according to the ERA scheme
- ▶ STEP 3 – Risk calculations
Derive risk values according to the ERA scheme for each regulatory scenario

Phenmedipham (PMP)

- ▶ STEP 4
Check open literature for additional information on toxicity of PMP and discuss the usefulness of the data found. If so, what consequences have these information for the assessment of the risk for soil organisms for the intended uses of PMP.
Discuss possible amendments of the scheme

