First experiences with a new EFSA guidance for evaluating laboratory and field degradation studies

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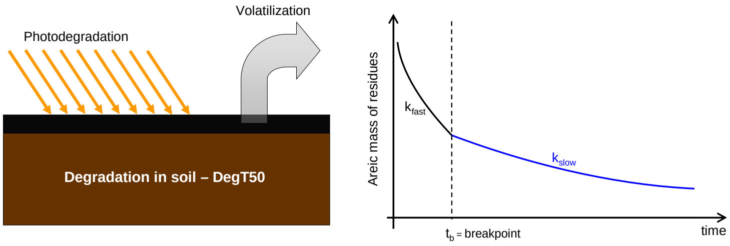
1. The main idea of the guidance

- Terrestrial field dissipation (TFD) studies: usually **surface application onto bare soil**

➔ surface loss processes can influence dissipation (e.g. photolysis, volatilisation)

- However, for multiyear exposure modelling **DegT50 in soil matrix is required** because of mixing into soil by e.g. cultivation or leaching

➔ Need to **differentiate between surface loss** processes and the **degradation in the soil matrix** to obtain DegT50,matrix



- **Null-hypothesis** (EFSA): surface loss processes are …
  … relevant for all substances
  … usually faster than degradation in soil matrix

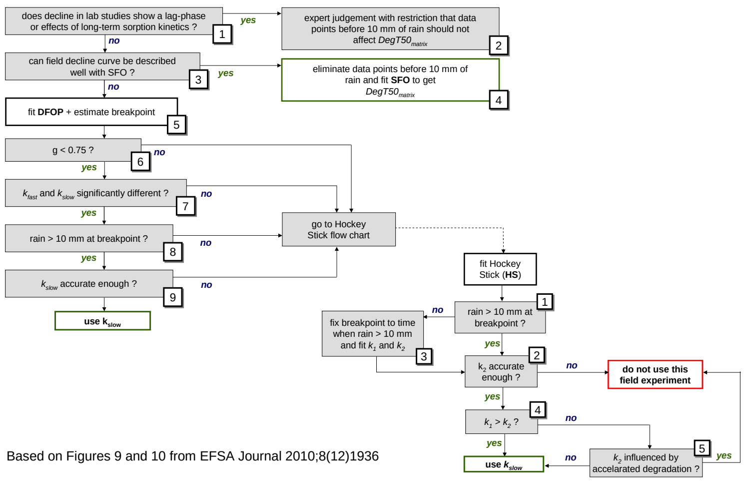
➔ Necessary consequence: **"everything degrades biphasic"**

➔ Scientific **conservative conclusion**: Take DegT50 from the slow phase

2. The major contents of the guidance

Evaluation of field studies in which surface processes are not excluded:

- (Time step) normalisation to reference temperature and moisture
- SFO, DFOP, and HS kinetic models are proposed
- Semi-empirical breakpoint for DFOP introduced
- Data points "count" for DegT50 only after 10mm rain has fallen



Based on Figures 9 and 10 from EFSA Journal 2010;8(12)1936

3. Evaluation of field studies according to the guidance

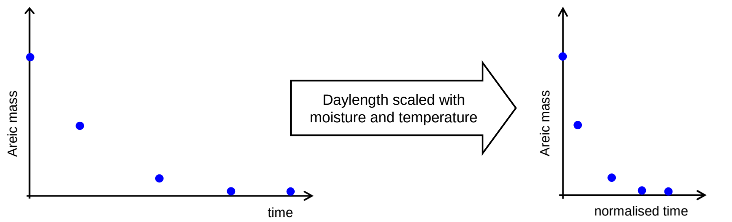
Two Analyses: a) draft guidance for public comments b) final guidance

a) Impact analysis of the draft guidance

- 188 field trials evaluated by BASF + BCS
- FOCUS: DegT50 could be obtained from 100%
- EFSA Guidance: DegT50 could be obtained from ~**14%** studies, ~**86% failures**
- **Revision** based on stakeholder comments ➔ guidance became more clear

b) Impact analysis of the final guidance

- 104 field trials were evaluated by BASF
- 16 substances with various physico-chemical properties
- 84 sites in 5 different regions (temperate EU & North America)
- several different soil types (textures)
- spray application to bare soil
- time step normalisation



4. Results

$DegT50_{matrix}$ obtained from…	Percentage [%] N = 104 (by BASF)
SFO*	16
Slow phase of **DFOP** kinetics (k_2)	11**
Slow phase of **HS** kinetics (k_2)	15
Slow phase of **HS** with fixed breakpoint (k_2)	33
$DegT50_{matrix}$ can be obtained	**75 *****
$DegT50_{matrix}$ can not be obtained	**25 *****
Total	100

* Tested either because of expert judgement or the decline curve followed clearly SFO kinetics
** 10 followed DFOP kinetics in the lab as well
*** Frank Scherr, BCS AG-D-EnSa-EMod, personal communication: **85 % successful**, **15 % failure**

References
EFSA Journal 2010;8(12)1936, FOCUS Kinetics(2006)

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5. Observations

DFOP

- Surface losses may not have the same temperature and moisture response as degradation in soil matrix; with rate normalisation this could be handled

➔ Time step normalisation combined with DFOP model may not be appropriate when initial fast decline is attributed to surface processes

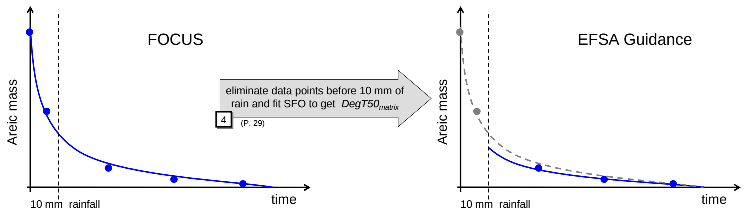
- In 10 of 11 studies under dark laboratory conditions degradation follows already DFOP kinetics (no surface loss processes!)

➔ Biphasic kinetics also expected in the soil matrix. Test criteria, however, are developed for cases where surface loss processes are pre-dominant.

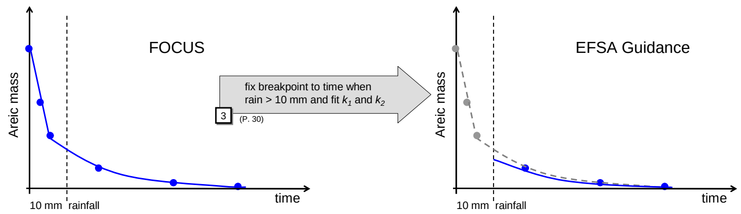
➔ loss of information possible (individual samples or complete dataset)

SFO & HS

- Two examples for unjustified handlings that potentially spoil fit statistics
- **SFO**: the Guidance proposes to discard data points collected before 10 mm rainfall



- **HS**: the Guidance proposes in some cases to fix the breakpoint of the HS kinetic model to the day when cumulatively >10mm rain fell.



6. Conclusions

- Following the EFSA Guidance up to 25 % of the TFD studies could not be used to obtain DegT50, matrix (compared to FOCUS degradation kinetics)
- EFSA Guidance could lead to unnecessary loss of information (lack of flexibility)
- FOCUS kinetics guidance is sometimes more appropriate than EFSA GD
- EFSA Guidance intends to improve kinetic evaluation of terrestrial field dissipation studies, but needs further testing and subsequent revision