Introduction to use of existing field studies not tailored for DegT50 (legacy studies)

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Outline

Introduction

- Derivation of DegT50 values from existing (legacy) studies
- EFSA endpoint selector



Introduction

Overview of the guidance development process in EFSA

- EFSA guidance opinion on field persistence studies in 2010
- EFSA guidance: "cookbook"
- Public consultation autumn 2013
- Publication May 2014

Now:

EFSA Technical Meeting with stakeholders





Introduction

Contour plot of FOCUS leaching concentration (µg/L)



- Okehampton scenario (FOCUSPEARL 4.4.4)
- application of 1 kg/ha in winter cereals

Sensitivity of leaching to DegT50 is extremely large, so guidance important



Introduction

Two-step approach

 assessment of individual field studies to derive a defensible DegT50 from a single field



estimate median/geomean
DegT50 for required
exposure scenario
considering all relevant
DegT50 values from lab
plus field studies



Introduction to use of existing field studies not tailored for DegT50 (legacy studies)



Surface processes (e.g. photolysis) should not influence DegT50 because it is used in the simulation models for the degradation within the soil matrix



 DegT50 values from field studies have to be normalised to 20°C and moisture content at field capacity via inverse modelling (time-step normalisation)

Inverse modelling based on number of assumptions:

- Arrhenius activation energy of 65 kJ/mol for temperature dependence
- exponent B of 0.7 for moisture dependence
- adequate simulation of soil moisture and temperature with simulation models
- so, a field DegT50 is not a solid parameter as a lab DegT50







surface processes



- χ² test for goodness of fit
- t-test for confidence in DegT50



surface processes



- χ² test for goodness of fit
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fit DFOP to complete dataset + estimate breakpoint 5

• DFOP = Double First-Order Parallel



Remaining fraction of dose (-)



breakpoint 15 d

breakpoint 15 d







g = fraction in fast compartment







Procedure when field DegT50s that are longer than lab DegT50s:

- Check whether any individual field DegT50 is significantly longer than the population of lab DegT50s (statistical test)
- Very unlikely that field study with a soil shows longer DegT50 at same temperature and moisture than a lab study with this soil
 - Recommendation:
 - repeat inverse modelling with Arrhenius activation energy of 115 kJ/mol instead of 65 kJ/mol and with moisture exponent B of 1.5 instead of 0.7
 - if new field DegT50 is not anymore significantly longer than DegT50 from labstudies then discard field DegT50





EFSA DegT50 Endpoint Selector

Statistical test in guidance

- Single field DegT50 longer than lab DegT50s ?
- EFSA developed user-friendly spreadsheet for testing of this hypothesis (see following presentations)





Thank you !