Persistence of plant protection products as cut-off criterion

- Scientific problems and solutions when implementing this criterion -

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Outline

- Background
- Scientific problems with persistence hazard based cut off criterion for pesticides
- Scientific and practical solutions for the dilemma

Introduction

- In the new regulation for plant protection products (PPPs) that will replace Directive 91/414/EEC hazard based POP, **PBT** and vPvB cut –off criteria are implemented.

- An active substance, safener or synergist shall only be approved if it is not considered to be a persistent, bioaccumulative and toxic (PBT) substance.

- An active substance fulfils the persistence criterion where:
  – the half-life in marine water is higher than 60 days, or
  – the half-life in fresh or estuarine water is higher than 40 days,
  or
  – the half-life in marine sediment is higher than 180 days, or
  – the half-life in fresh or estuarine water sediment is higher than 120 days,
  or
  – the half-life in soil is higher than 120 days.

- Assessment of persistency in the environment shall be based on available half-life data collected under appropriate conditions, which shall be described by the applicant.

➢ ***Sort out upfront substances, that will not pass the risk assessment***

➢ ***Use available data, appropriate conditions !***

POP: persistent organic pollutant; PBT: persistent, bioaccumulative, toxic; vPvB: very persistent, very bioaccumulative

First look („helicopter view“)

- At first sight the implementation of a persistence based cut-off criterion in the new regulation looks simple
  - it seems to ensure harmonization to other existing regulations like REACH
  - it seems relatively easy and transparent
    - to be controlled by authorities and
    - to be understood by the interested public (as no scientific debates on acceptable risk should ensue).

Basis of scientific problem with „Persistence “ as an intrinsic property

- The persistence (P) in the environment as a substances intrinsic property is utilized in the PBT assessment as a cut-off criterion in conjunction with bioaccumulation (B) and environmental toxicity (T).

- However,
  the **basic assumption of the P-criterion**, that persistence in a given compartment is solely a substance intrinsic property,
  is **scientifically incorrect**.

Why is persistence not only an intrinsic pesticide property?

- In an environmental context, persistence is commonly understood as “residence time of a substance in a defined environmental compartment” (i.e. soil, sediment or water).
- Residence times of substances in environmental compartments are determined by
  - inherent substance properties

  as well as

  - by compartment properties (such soil microbial activity)

  as well as

  - environmental factors (such as temperature)

  as well as

  - transport processes.

Scientific issue:
Influence of compartment properties

- Persistence is strongly influenced by the activity of soil microorganisms

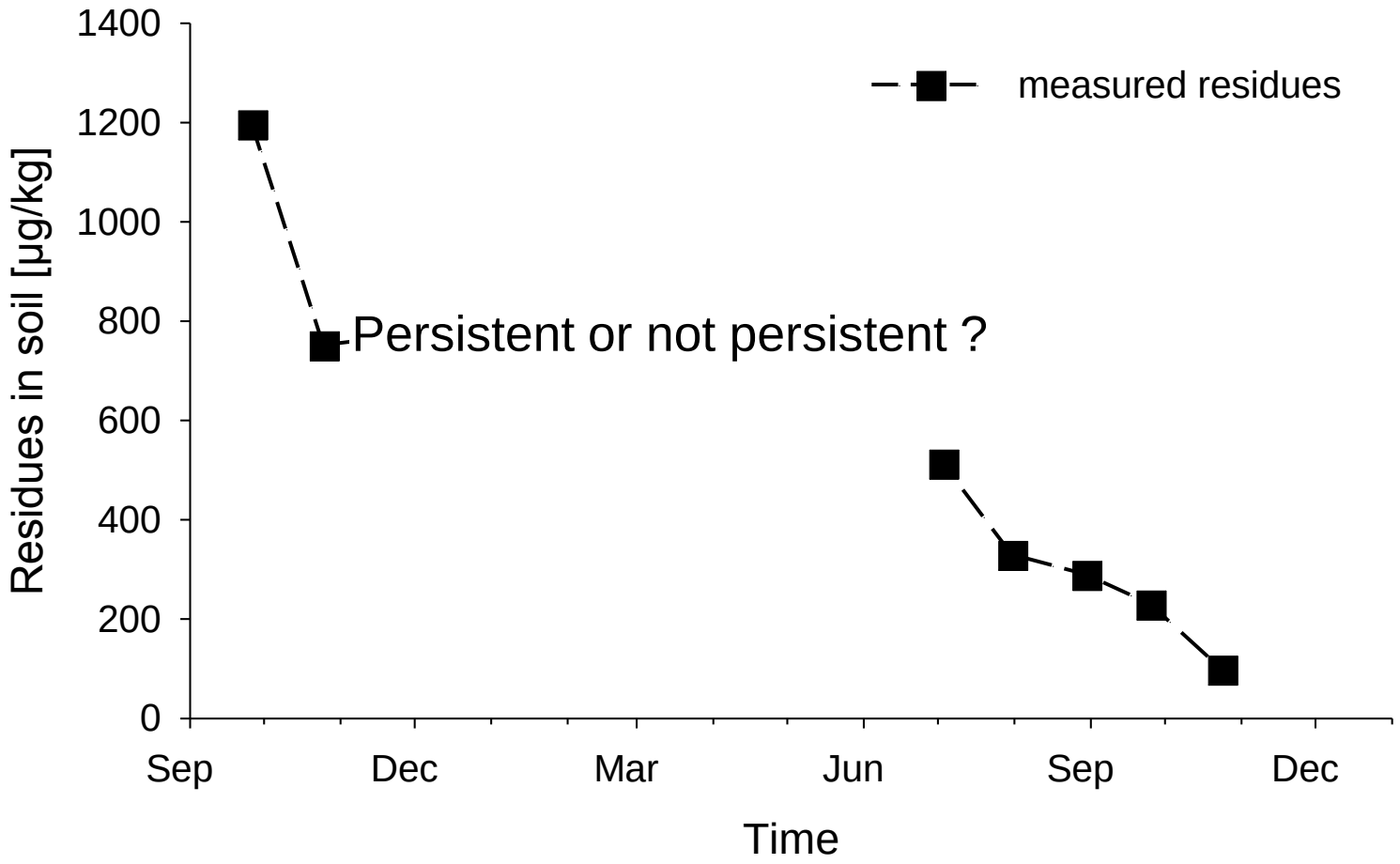
Parameter	Compound	
	A	B
DT50 in aerobic soil	< 1 d	33 d
DT50 anaerobic soil	< 1 d	396 d
DT50 sterile soil	> 180 d	-

long storage

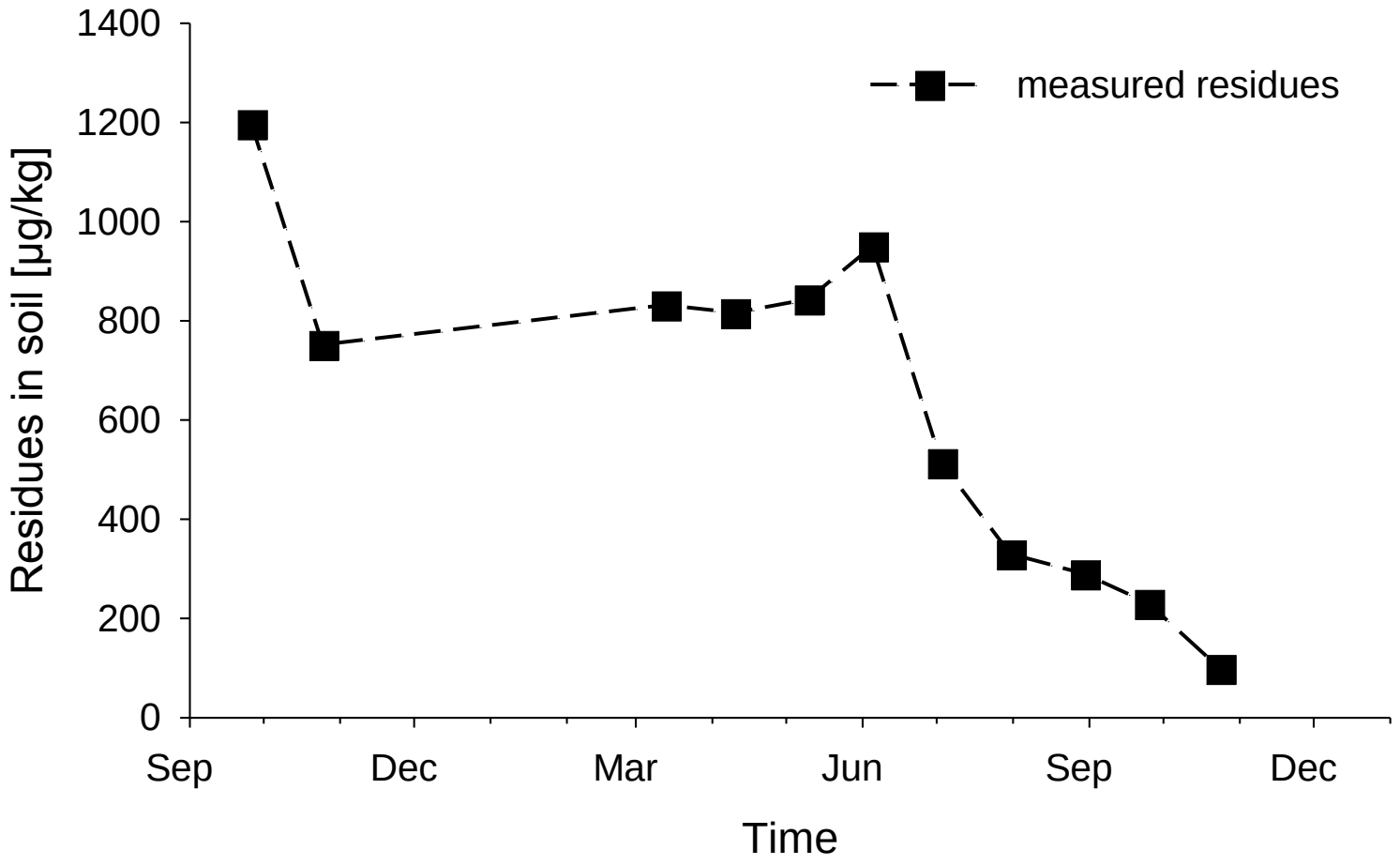
freshly sampled

Compound C	DT50 aerobic
Soil 1	7 d
Soil 2	25 d
Soil 3 (old)	130 d
Soil 3 (fresh)	25 d

Scientific issue:
Influence of environmental factors

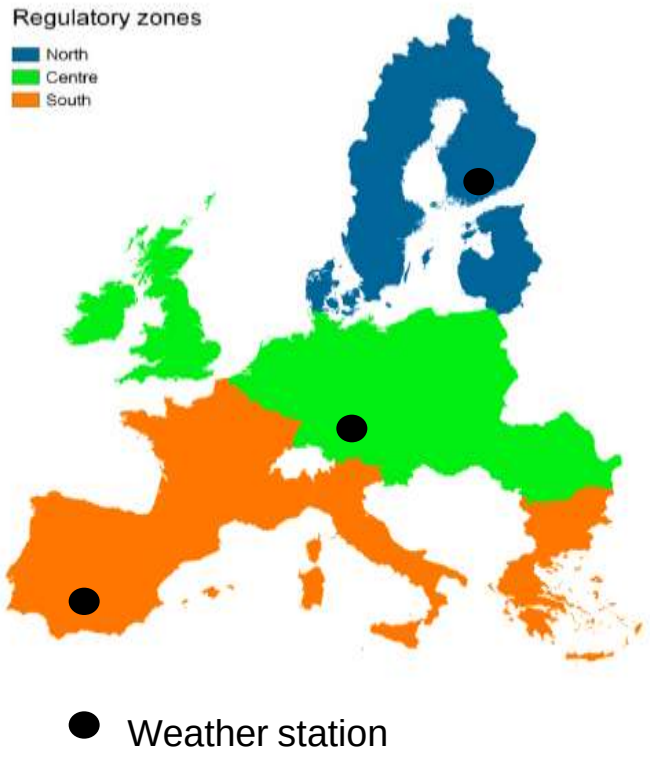


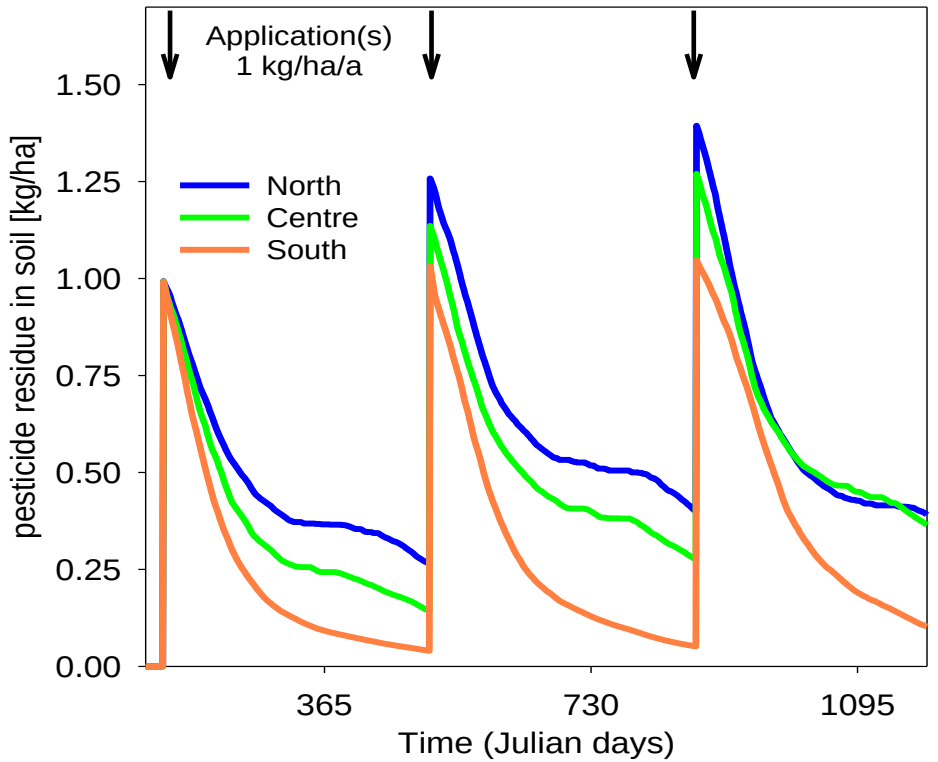
Scientific issue:
Influence of environmental factors



Scientific issue:
Influence of environmental factors

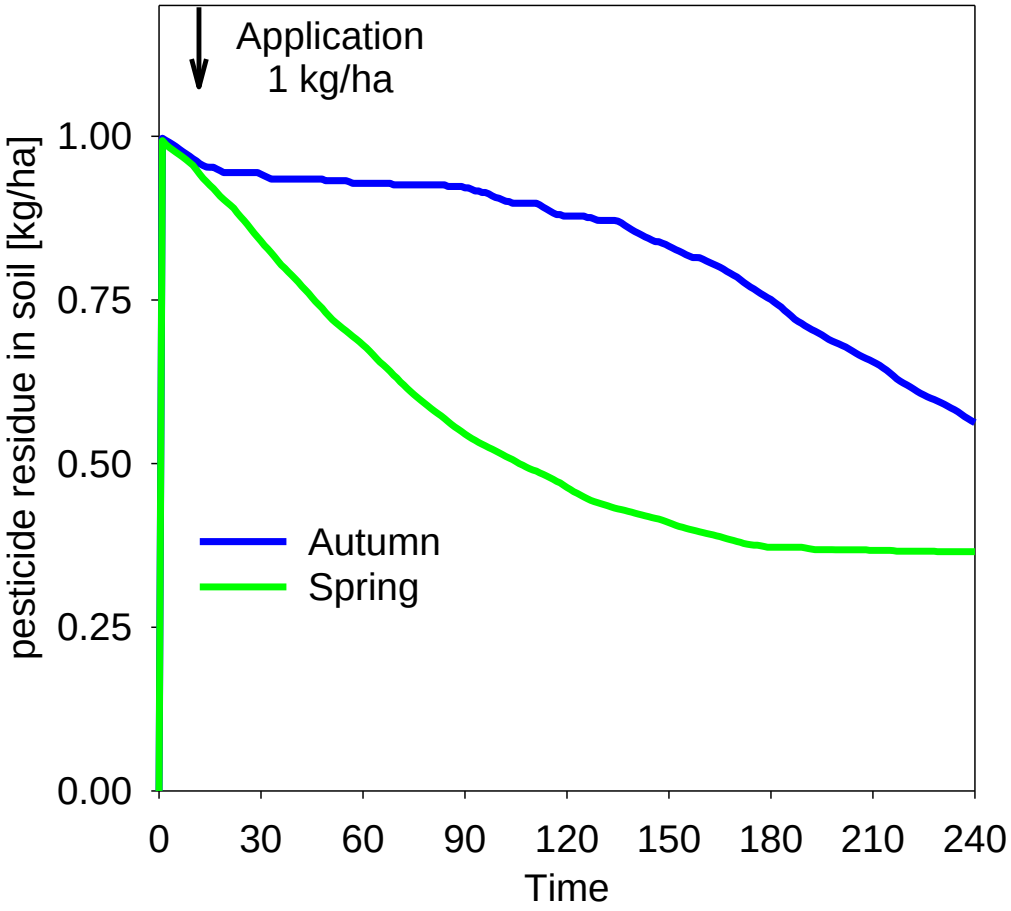
- The residence time depends on where the compound is applied





Scientific issue:
Influence of environmental factors

- The residence time depends on ***when*** the compound is applied



- In the colder Northern Zone of the EU in *autumn* the P-trigger can easily be exceeded

- The same compound may however not be classified as persistent if the application is made in *spring*

Scientific issue:
Study types / Experimental setup

- The DT50 can be influenced by incubation systems

DT50 ~ 120d

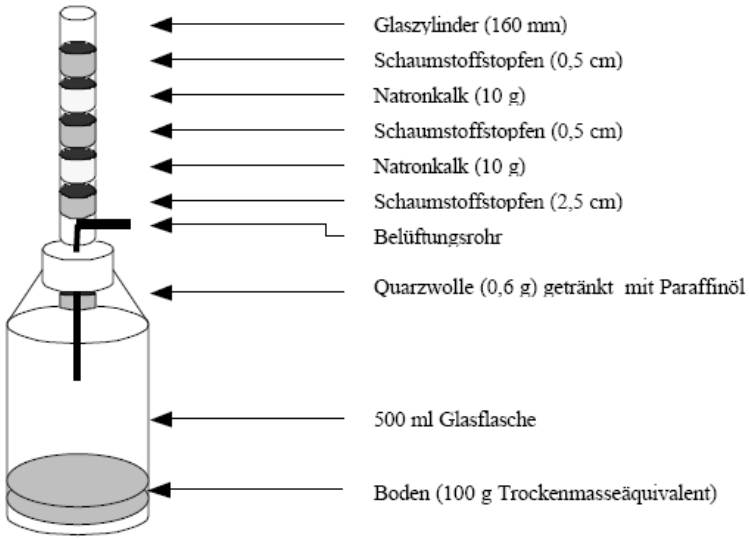


Abbildung 3: Testsystem Abbauversuch

DT50 ~ 11-40 d

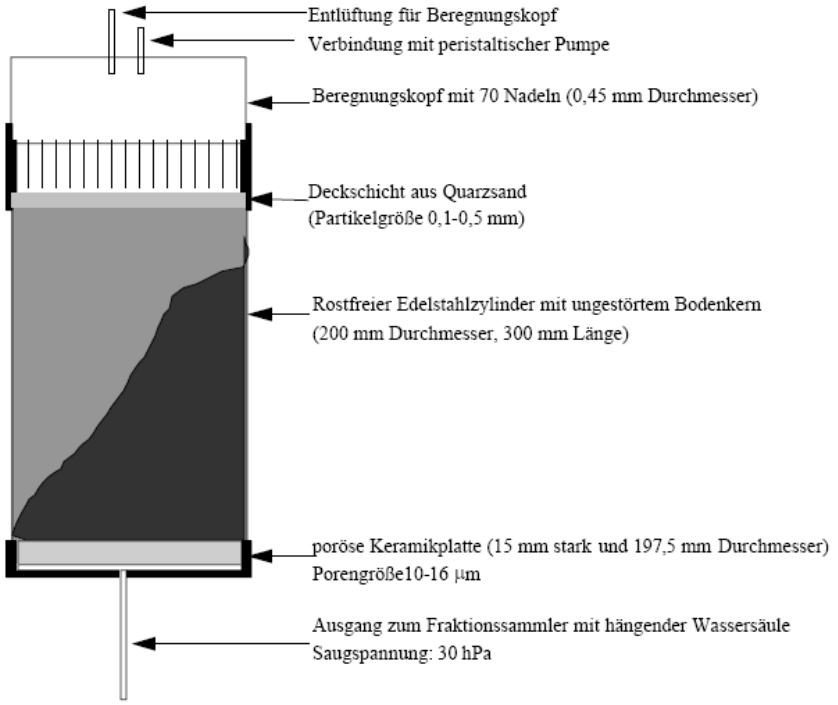
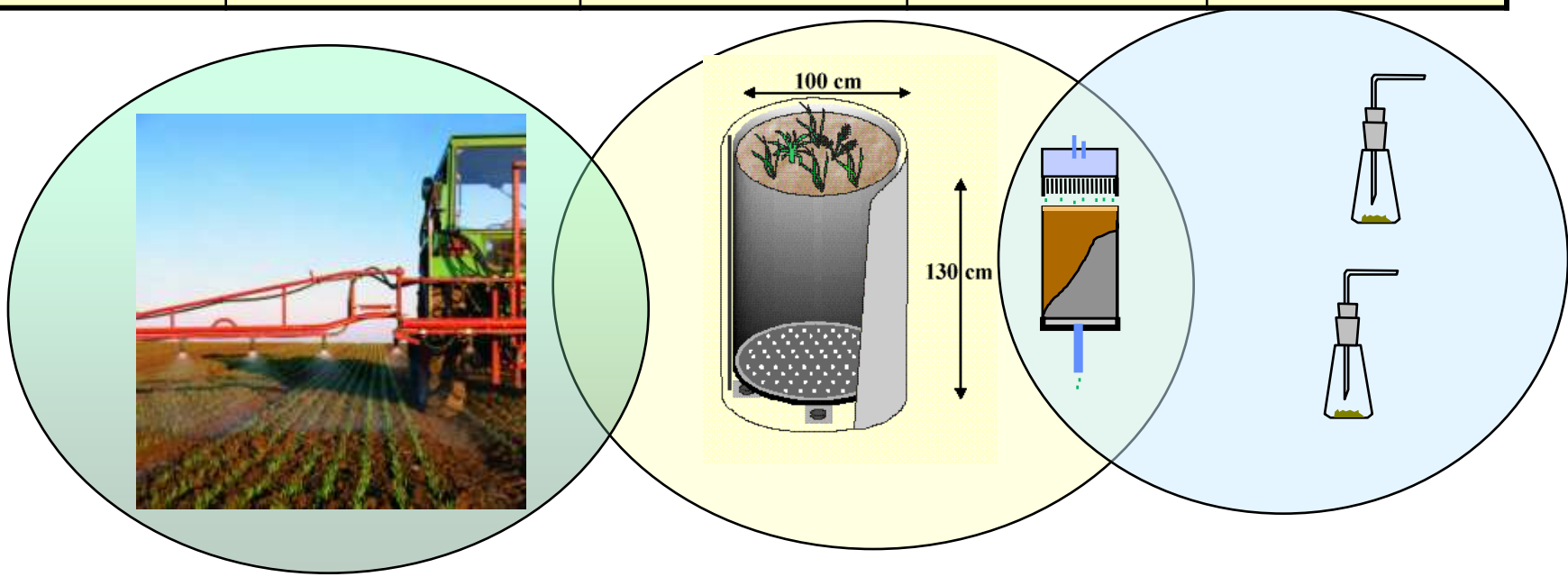


Abbildung 5: Testsystem Mikrolysimeterversuch (nach Heistermann, 2001)

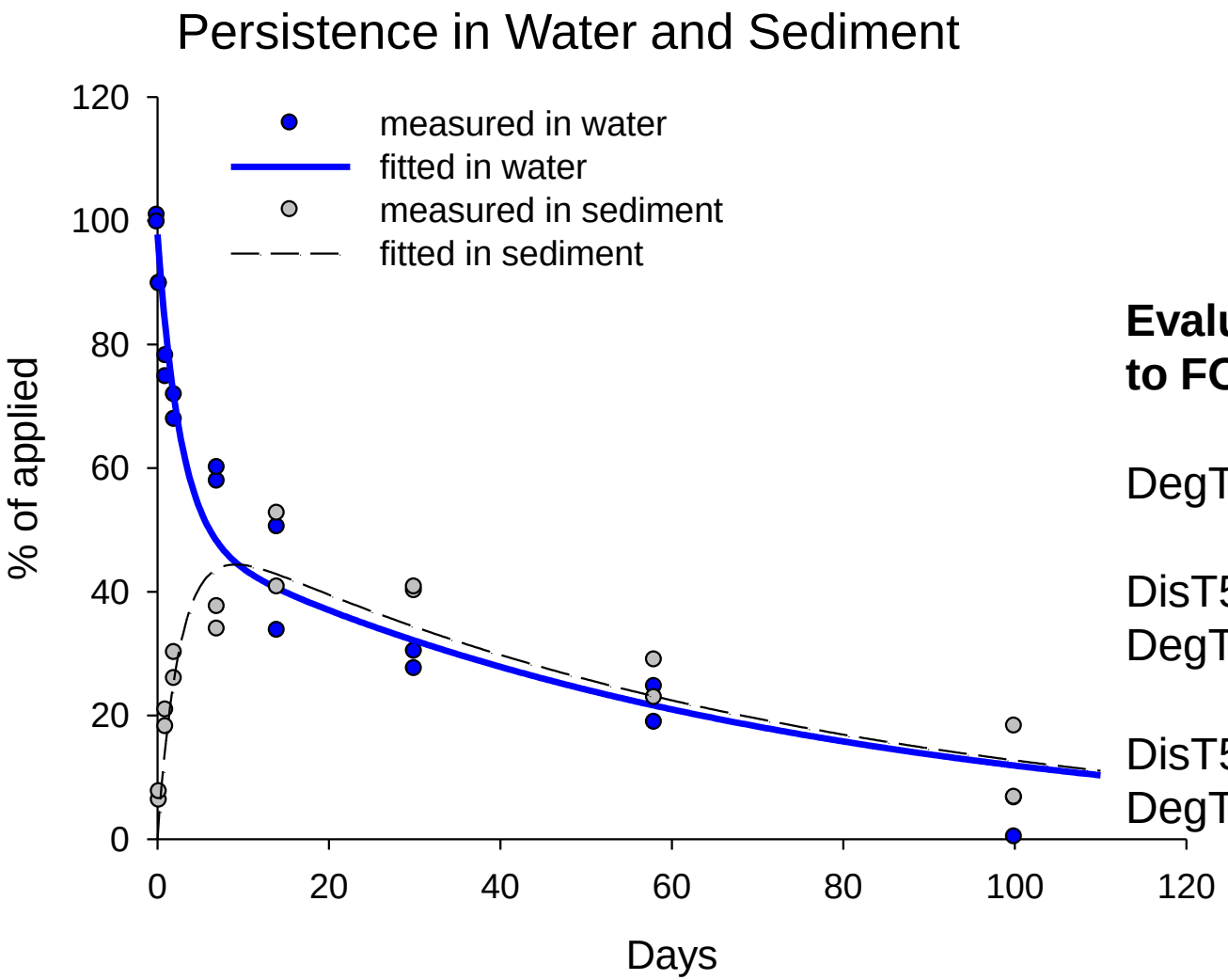
Scientific issue:
Study types / Experimental setup

- The DT50 can be influenced by incubation systems

Compound B	Field	Outdoor lysimeter	Micro-lysimeter	Laboratory incubation
DegT50 ref. in soil	13 d	10-14 d	12 d	40 d



Scientific issue:
Parameter estimation problem



Evaluation according to FOCUS kinetics

DegT50 whole system = 48 d

DisT50 water = 4 d
DegT50 water = n.c. (>1000 d)

DisT50 sed. = 48 d
DegT50 sed. = 25 d

Scientific issue:
Parameter estimation problem

- Persistence in Water and Sediment
  - The situation for water/sediment studies is complex.
  - Kinetic models are most often not able to identify DegT50 values for the different phases of water and sediment.
  - Therefore it is possible that the degradation in e.g. water yield values above 120 days, although the DT50 in the whole system might be significantly below the trigger value.
  - This is rather a parameter estimation problem (it can not be separated where the degradation occurs) than a compound inherent property.

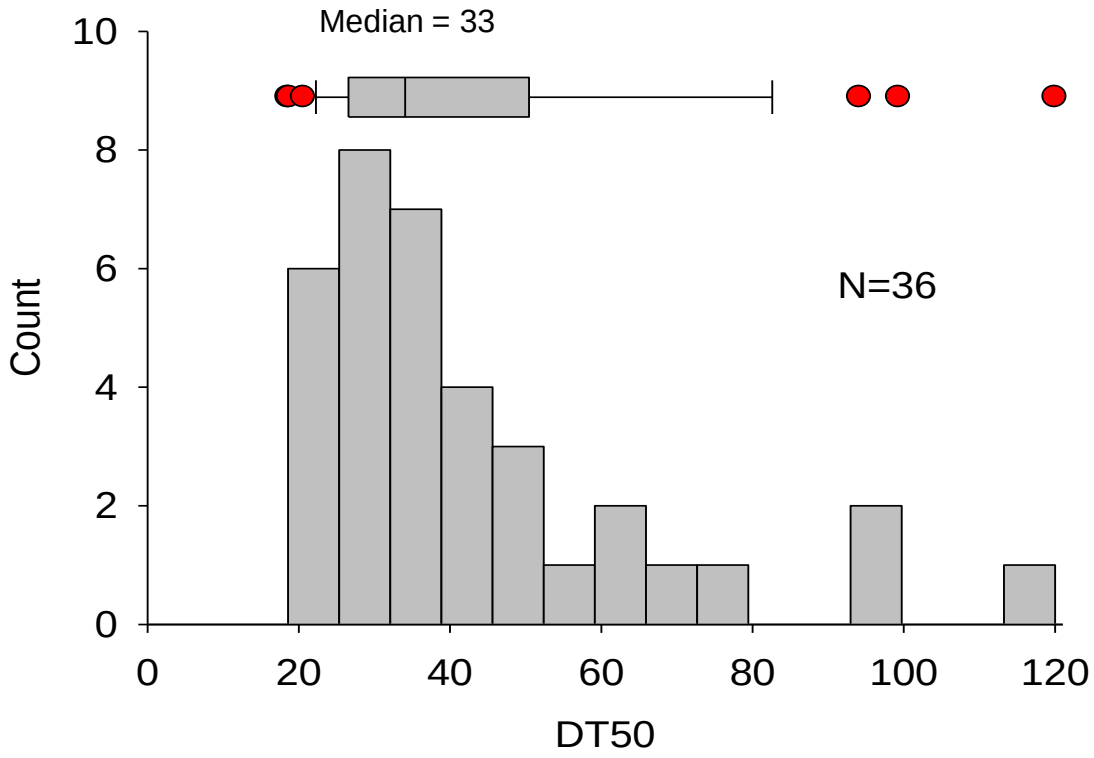
Scientific issue:
Choice of representative value for P

In contrast to other chemicals there are several DT50 values available for pesticides

Increased number of measurements

-> improved characterisation of behaviour profile

Risk of excedance by improving database ?????



Scientific issue:
Choice of representative value for P

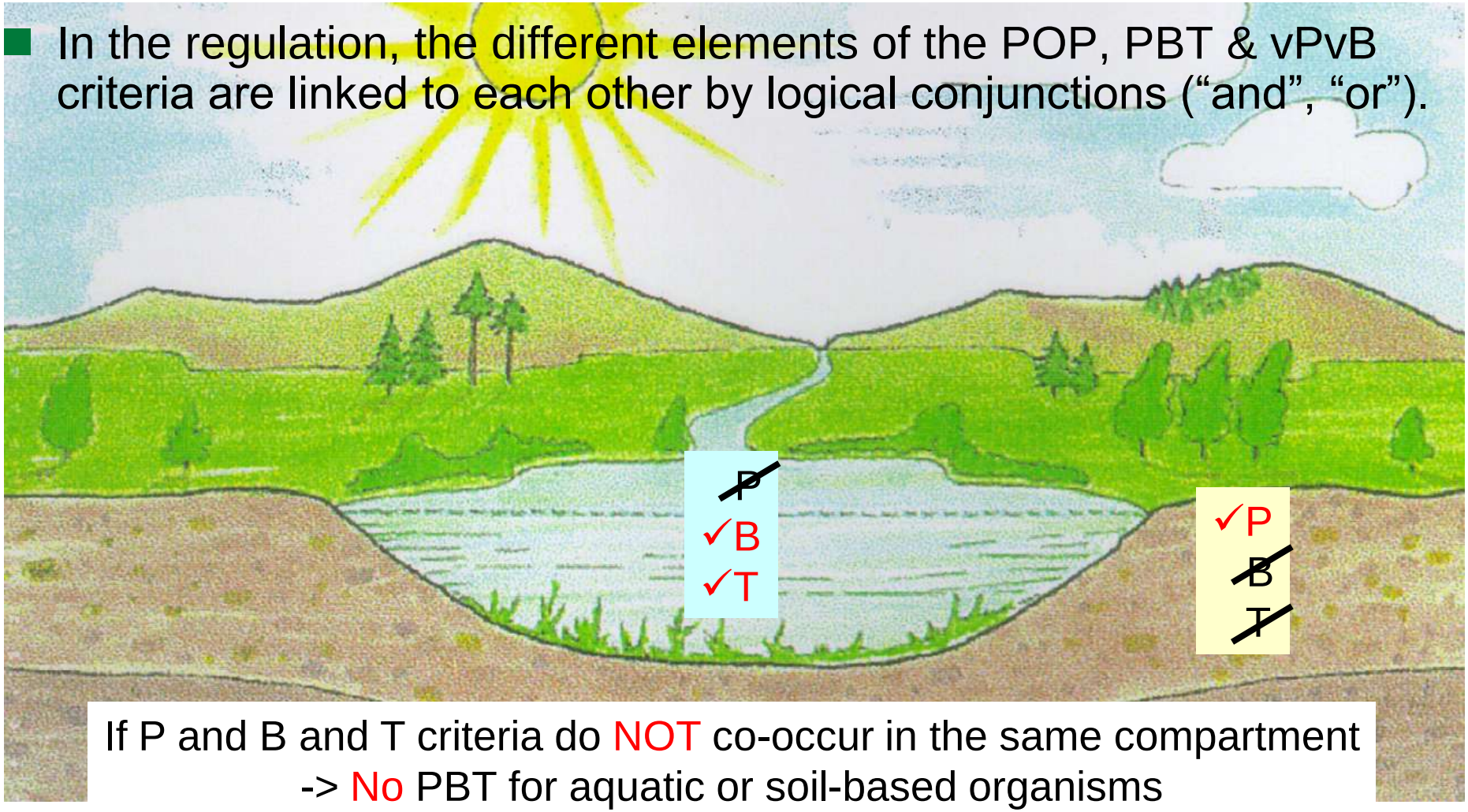
- For pesticides several DT50 values are available
  - Considerable reduction of uncertainty
    - Increased number of DT50 -> improved estimate of typical behaviour

- Most probable P-values for the compartments is the logical choice for cut-off triggers in hazard assessment

- An extreme data point (like a worst case (or best case) DT50) is unsuitable because it is a number with a low probability

Scientific issue:
P-B-T linkage in same compartment

- In the regulation, the different elements of the POP, PBT & vPvB criteria are linked to each other by logical conjunctions (“and”, “or”).



If P and B and T criteria do NOT co-occur in the same compartment
-> No PBT for aquatic or soil-based organisms

Proposed Solutions

- Choice of appropriate realistic study type
  - Higher tier (more realistic) studies should be the basis for P classification. i.e. field studies as relevant for intended use conditions as well as the DisT50 for the water phase and the DT50 for the whole water/sediment system.
- Choice of representative parameter value for P
  - For hazard assessment the most probable parameter value should be chosen for the P criterion (not extreme worst or best case)
- Choice of relevant environmental conditions
  - For P_soil: Characteristic disappearance (DT50) in agricultural soils for the intended use conditions
  - For P_water:
    Characteristic dissipation (DT50) in water
  - For P_sediment:
    Characteristic dissipation (DT50) in whole water sediment system

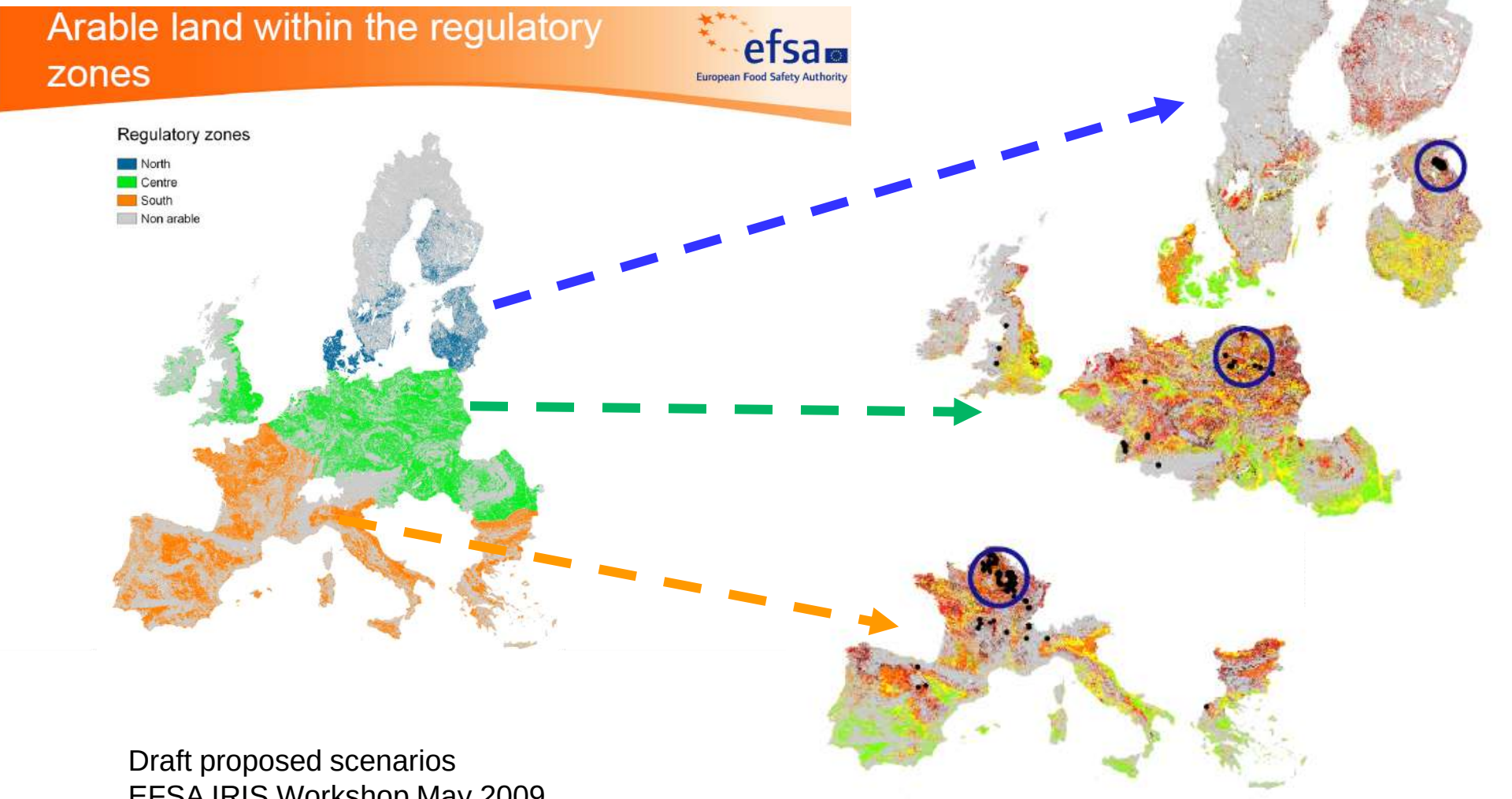
Conclusions:

The basic assumption, that persistence is solely a substance intrinsic property, is scientifically incorrect.

- The correct metrices for P classification need to be defined clearly.
  - Choice of appropriate realistic study type
  - Choice of representative parameter value for P
  - Choice of relevant environmental conditions
  - P-classification shall not be biased by parameter estimation problems
- The co-occurrence of the P, the B, and the T criteria in the same environmental compartment (soil or, water or sediment) at the same time is a basic logical pre-requisite to apply the PBT criteria as “cut-off”.

for P, B and T see Dohmen & Weltje: PBT CRITERIA - PROPOSAL FOR AN EVALUATION SCHEME.- SETAC Special Science Symposium 2009

A persistence risk assessment as proposed by EFSA for areas of use would be a more sound scientific solution in order to overcome the pitfalls of a scientifically weak hazard-based assessment.



Draft proposed scenarios
EFSA IRIS Workshop May 2009

Thank you very much for your attention!

Recent Discussions

SETAC Pellston Workshop 2008

Science-Based Guidance and Framework for the Evaluation and Identification of PBTs and POPs: Summary of a SETAC Pellston Workshop

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Summary of the SETAC Pellston Workshop on Science-Based Guidance and Framework for the Evaluation and Identification of PBTs and POPs, 28 January–1 February 2008, Pensacola, Florida USA

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Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Use of substance-inherent properties of active substances for regulatory decision making of plant protection products (PPP)

- Which fate and effect data should be used to address cut-off criteria of upcoming PPP regulation?

Table 1: PBT and vPvB criteria (environment only)

P	soil	DT50 ≥ 120 days
	water	DT50 ≥ 40 days
	sediment	DT50 ≥ 120 days
B	BCF	≥ 2000
T	NOEC aquatic	≤ 10 µg/L
vP	soil	DT50 ≥ 180 days
	water	DT50 ≥ 60 days
	sediment	DT50 ≥ 180 days
vB	BCF	≥ 5000

Abbreviations:
P = Persistent; B = Bioaccumulating; T= Toxic; v= very; DT50 = half-life; BCF = Bioconcentration Factor

1 Cut-off criteria for PBT (environment only) according to REACH-regulation

As a novelty and new challenge in the regulation of PPP also substance inherent properties will be used as a final cut-off criteria for authorisation (see table 1). Some work has been done on the possible impact of cut-off criteria on availability of active substances. It has been clearly demonstrated that one key issue will be the development of guiding principles regarding how the relevant criteria are to be used. Relevant triggering schemes for identification of POP, PBT and vPvB substances are defined in the REACH-regulation. However these trigger values are not very specific and it will be therefore difficult to come to consistent decisions at an European level for PPP. In the following the problem will be illustrated in further detail by evaluation of selected data sets.

2 Analysis of data sets:

By analysis of anonymized data sets for 3 existing substances (see table 2) the main problems for regulatory decision making concerning identification of PBT or vPvB substances are demonstrated. All three active substances could be classified as PBT (AS 1 and AS 2) or vPvB (AS 3) in a preliminary worst case data evaluation. The huge data packages which are provided for an approval of PPP are challenging because there are often several results for the same trigger value. For all candidates of "P" criteria it can be assumed that field data are available as higher tier data. Also it has to be taken into account that the data sets vary considerably if describing degradation/dissipation kinetics especially in sediment.
BCF data are always available for PPP if the log Pow value is > 3.
Only the amount of existing data could be the driving factor for decision-making (see example of AS 2 and the BCF and the question how to take higher tier data into account). But also for the toxicity of AS 3 it could be that the NOEC value would be below the 10 µg/L criterion if NOEC data were available for algae toxicity.

Table 2: Overview of three PBT/vPvB candidates (Numbers in bold meet criteria of table 1)

	AS 1 (herbicide)	AS 2 (insecticide)	AS 3 (fungicide)
Persistence			
DT_{50} soil	lab (20-22 °C) and 30 - 40% MWHC): 32 - 118 d, 184 d (60 % FC); geomean 62,3 d (norm.) field: 31 - 186 d, SFO; geomean 77,7 d	lab (norm., 20 °C, pF 2; SFO): 60 - 360 d; geomean 184 d; field: 3,0 - 28 d, SFO; geomean 6,8 d	lab (20°C): 224 - 609 d; mean 374 d; field: 13 - 180 d
DT_{50} water	3,2 - 5,6 d	0,01 d	3-7 d
DT_{50} sediment	92 - 1000* d (in sediment, SFO) * no decline	864 - 718 d (whole system, SFO)	42 - 311 d (in sediment)
Bio-accumulation			
BCF	2000 (whole fish)	7800 - 8100 (whole fish) Outdoor mesocosm: 1071	6040 (whole fish)
Toxicity (environment only)			
Chronic toxicity to fish	NOEC 6 µg/l (35 d juvenile growth test)	NOEC 1,47 µg/l (93 d); NOEC 20 µg/l (78 d mesocosm)	NOEC 29,6 µg/l (28 d early life stage)
Chronic toxicity to daphnia	NOEC 16 µg/l (21 d)	NOEC 1,47 µg/l (21 d)	NOEC 27,8 µg/l (21 d)
Chronic toxicity to algae	EC_{50} 6,7 µg/l (96 h static-biomass); EC_{50} 6,9 µg/l (96 h static-growth rate)	EC_{50} > 312 µg/l (5 d* biomass)	EC_{50} 27 µg/l (5 d* growth rate); EC_{50} 28 µg/l (5 d* inhibition)

3 Identification of key questions:

Even by comparison of such a small amount of data it is well understandable that the following points have to be further addressed:

(1) Which value is relevant: min, max, median, mean of normalised or not normalised data?
(2) How to deal with the difference between dissipation and degradation with regard to choice of appropriate degradation kinetics (e.g. SFO)?
(3) How to deal with differences between laboratory and field data or higher tier data in general?
(4) Is an extrapolation from degradation behaviour in the whole system (water/sediment) to degradation behaviour in sediment acceptable?
(5) Are results from outdoor microcosm acceptable to release a substance from the bioaccumulation "B" suspicion?
(6) For herbicides algae or higher plant toxicity is crucial for risk assessment but no NOEC values are available.

4 Which key question can be answered by existing guidance in PPP approval:

In course of the implementation of Directive 91/414/EEC reference to further guidance is given as there are SETAC Procedures and OECD Guidelines. Furthermore several guidance documents were developed. For questions (1), (2), (3) and (4) there will be guidance in the document "On Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticide Registration". On question (5) no guidance is given up to now. Concerning question (6) by following the same systematic approach it would be necessary to include NOEC values into assessment due to equal relevance of fish, daphnia and algae or higher plant values for risk assessment of PPP.

5 Conclusion:

According to the presented guidance used in PPP approval on European level and also for national authorisation, the following can be concluded:

For the presented substances it is clearly established that the fate of endpoints without the detailed study information is not sufficient for PBT identification. Nevertheless there are always enough data available for decision making when dealing with PPP. Guidance exists for some questions but data evaluation needs to be peer-reviewed by the scientific community.

For "P" criterion the realistic worst case value from field data should be used for soil. For sediment the DT50 for the whole system could be used.

For "B" the BCF whole fish is available.

For "T" NOEC from chronic Daphnia and fish study is available, for algae and higher plants NOEC must be made available. Higher tier data (e.g. mesocosm) should be used

Further guidance is needed for higher tier studies especially designed for disproving PBT suspicion. A harmonised approach for consolidation of existing guidance in the context of PBT assessment on a European level is needed.

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