Implementation of science into regulations:
A recent example from the European Union

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1. First thoughts – and „definitions“

► Science?
No definition intended - just a common understanding that at least chemistry, toxicology and ecology are covered here.

► Regulations?
Could be everything between the European Charta and an OECD Guideline – here understood as all documents related to the market authorization of a pesticide (PPP).

► European Union?.
Region and authority most relevant for most of us today – and the source of an impressive number or regulatory documents.
2. Clarification of the subject

- Discussion of the (multiple, demanding, variable) relationships between science and regulations in general?
  No.
  Very interesting but much too complex (for me) in the context and the format of this conference.

- Presentation of a recent (and relevant) example?
  Yes, in three steps:
  - Scientific evidence for an environmental problem;
  - Regulatory actions by international agencies;
  - Implementation of testing and assessment methods.
  Soil and soil organisms will be taken as example.
3. Scientific evidence: History

- Ecotoxicology became an own science in the late 1960s, mainly based on observations in aquatic systems (e.g. Truhaut 1969; 1977; Butler 1978)
- First descriptions of side-effects of PPPs on soil organisms were published already in the 1960s (e.g. Bauer 1964)
- However, regulatory actions took time (mainly Seventies);
- The soil was addressed later than aquatic systems. Scientific evidence was differently developed in the two compartments, but – probably more important – public attention was much higher (i.e. due to dead fish) towards aquatic systems.
5. Regulatory actions on soil I.


► Testing requirements are given for “other (= non-aquatic) non-target organisms”, i.e. bees, NTAs, earthworms and other soil non-target macro-organisms believed to be at risk.

► Regular performance of acute and, slowly, chronic tests according to OECD and BBA (1984; 2004) guidelines. First field test (i.e. with earthworms) already in 1999 (ISO).

But: No tests with other species; no guidance on test schemes or data assessment.
6. Regulatory actions on soil II.

Details came much later:


Short and concise document, focusing on various issues, such as:

► “…Ecological risk assessment aims not at individuals but at the protection of populations. ... Structural and functional endpoints should be regarded of equal importance.”

► Clarification of testing requirements, e.g.:
  - Description of a tiered approach, incl. characteristics and trigger values;
  - Risk assessment via the TER approach.
7. Regulatory actions on soil III.

Today, PPPs are regulated by EC No.1107/2009 (+ documents covering active ingredients and formulations).

► The main document is asking for information being sufficient in order to evaluate the impact of PPPs on non-target species; biodiversity and the ecosystem, including an evaluation of short and long-term risks for non-target species, populations, communities and processes;

► In complimentary documents more than earthworm tests (i.e. springtails, predatory mites) could be required.

SANCO (2002) is still relevant for testing…..
8. Regulatory actions on soil IV.

Soil invertebrate species currently being regularly tested:

► Earthworms: *Eisenia fetida/andrei*
► Micro-arthropods: *F. candida, H. aculeifer*

But: Species representing other exposure pathways not covered

► Uptake of PPPs via feeding on organic material
   Wood-lice: *P. scaber, P. pruinosus* ?
► Uptake of PPPs via feeding on prey
   Predatory mite: *H. aculeifer* ?

More species needed for SSDs from various groups (tests for all of them are already available).
9. Regulatory actions on soil V.

From a scientific point of view EC No.1107/2009 has various gaps:

► Protection goals for in-soil organisms, being the key drivers for relevant ecosystem services, are lacking;
► Only a small number of species are actually tested, i.e. neither the diversity nor the functions of the community are covered;
► Differences in the properties of soils as well as the composition of soil organism communities are not reflected;
► In order to address species recovery and long-term impacts of PPPs, the use of population models is also proposed.

Therefore, the European Food and safety Authority (EFSA) was asked to review the PPP requirements and propose improvements.
In 2017, **EFSA** published a **Scientific Opinion** on the assessment of the risk of PPPs on in-soil organisms” (15(2):4690). In detail, 7 relevant ecosystem services (ESS) were highlighted:

- Genetic resources, biodiversity (esp. micro- and mesofauna;
- Nutrient cycling, esp. degradation of dead organic matter .
- Education, aesthetic values and cultural diversity.
- Regulation of pest populations and of disease outbreaks.
- Soil remediation, natural attenuation.
- Soil-structure formation and water regulation.
- Food provision, food-web support (incl. linking below- and aboveground food webs).

But: Do we have the appropriate methods for this approach?
From a methodological point of view at least the following 5 issues have to be addressed:

A. **Organism groups:** How many and which groups have to be covered? How to select them?

B. **Species:** Which species is representative for the group – and can it be tested?

C. **Endpoints:** Which endpoints are relevant – and are they practical?

D. **Soils:** Do we need more than Artificial Soil – and if yes, which ones and how many?

E. **Regions:** Currently, Europe is divided in 3 administrative regions – is this sufficient?
12. EFSA Scientific Opinion III.

A. Organism groups to be covered:

- Earthworms (Lumbricidae): soft-bodied macrofauna
- Potworms (Enchytraeidae): soft-bodied mesofauna
- Woodlice (Isopoda): hard-bodied macrofauna
- Springtails (Collembola; Acari): hard-bodied mesofauna
- Roundworms (Nematoda)
- Snails (Gastropoda)
- Mycorrhiza, other fungi and protozoa
- Soil bacteria and Archaea
13. Science supporting EFSA I.

B. Proposal for new test species:

  Pro`s: Easy to identify, to handle and to culture; model species.
  Con`s: Relatively low level of experience in soil, but growing.

► **Helix aspersa** (Gastropoda): ISO 15952 (ISO 2005)
  Pro`s: Experience from contaminated soil studies; accumulating.
  Con`s: No reproductive endpoint; exposure only via soil surface.

► **Oppia nitens** (Oribatida): Environment Canada (2018)
  Pro`s: Easy to identify and to handle; various endpoints.
  Con`s: Reproduction cycle complex; long duration.

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14. Science supporting EFSA II.

C. Considerations for natural soils:

► Standard for general comparisons: OECD artificial soil (AS).
Regional variations needed for practicability reasons:
e.g. Tropical Artificial Soil (TAS) – coconut dust instead of peat.

► Set of standard field soils covering a range of the most important soil properties (mainly: OM content, pH, texture, CEC)
E.g.: LUFA 2.2, typical for continental/Atlantic Europe;
Set of Mediterranean reference soils (Chelinho et al. 2011)
15. Science supporting EFSA III.

Natural standard soils (incl. LUFA 2.2):
Main properties:
- Regional distribution;
- Representability;
- Practicability;
- Availability;
- Costs.
16. Science supporting EFSA IV.

E. Division of Europe in registration regions

In PPP registration: 3 “political” zones: North, Central, South

Biogeographically defined 9 regions (EEA 2009)

Zones of comparable climate for efficacy evaluation trials on PPPs (EPPO 2005)
### 17. Science supporting EFSA V.

**Number of regions:** Combination of EEA and EPPO, i.e. 3.

Ideally, for each ecologically defined groups one species; such as:

<table>
<thead>
<tr>
<th></th>
<th><strong>Boreal</strong></th>
<th><strong>Atlantic / Continental</strong></th>
<th><strong>Mediterranean</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Macrofauna: Hard-bodied</td>
<td>To be identified</td>
<td><em>Porcellio scaber</em> (to be standardized)</td>
<td><em>Porc. pruinosus</em> (to be standardized)</td>
</tr>
</tbody>
</table>

Species from other groups (e.g. mites, Nematoda) to be discussed.
18. Further Recommendations I.

► **Multi-generation tests**, e.g. springtails or enchytraeids

**Advantage**: Inclusion of sensitive life stages, additional endpoints, long-term exposure, and cover of aging processes;

**Disadvantage**: Lack of testing experience, few background data (e.g. physiology), no standardization so far (e.g. ring-tests).

► **Laboratory/semi-field tests with assembled (= gnotobiotic) or natural communities (= multi-species test)**

**Advantage**: Direct/indirect effects measurable

**Disadvantage**: Many designs proposed for gnotobiotic assays but not for natural communities;

==> Critical review needed
19. Further Recommendations II.

Higher tier tests methods potentially useful for PPP testing:

Semi-field tests, especially Terrestrial Model Ecosystems (TMEs):

- Best-known example of semi-field tests (Toschki et al. 2018)
- Experience available (incl. interlaboratory comparison tests)
- Several modifications possible, such as larger diameter in order to take multiple samples without destroying the cores;
- Inclusion of large earthworms possible.
20. Further Recommendations III.

Problem: Lack of functional tests on all tiers, but:

– Multitude number of **microbial enzyme tests**, e.g. ISO/TS 22939, ISO 20130; no experience with PPPs;

– **Mycorrhiza test** (ISO/TS 10832); few PPP experience and further development needed;

– **Bait-lamina-test** (ISO 18311); mainly in the but also in the lab;

– **Cellulose degradation Test** (ISO 23265; under development);

– **Water infiltration rate test** (DIN 12616); quite laborious.
21. Further Recommendations: IV.

Higher tier tests potentially required for PPP testing in the European Union: Field tests

So far, there is only one standard method, the earthworm field test (ISO 11268-3), which is currently under revision while being transferred to OECD. Several improvements are planned and/or tested:

► Inclusion of more organism groups in one test run (e.g. testing of earthworms and Collembola at the same site and time;

► Increase of the power of the current test by modifying the design - details are currently investigated.
Last but not least – a proposal:

Fate considerations (including PEC calculations)?
- Few personal experiences, esp. regarding new developments within the last ten years (see resp. EFSA documents)

Modelling approaches?
- See above. Very well developed methods available for fate studies, but much less experience regarding effects.

Combination of modelling and experimental data on different test levels, especially for indirect effects and for recovery processes?

The way forward. Various proposals have been made on the individual as well as the population level. This is especially true for the evaluation of results from higher tier methods.

Problem: Do we have the necessary ecological information?
Acknowledgements

Thank you for your attention!

Many thanks to the members of OECD and ISO standardization groups and to the EFSA WG of in-soil organisms!