



# Soil Risk Assessment in PPPs regulatory context

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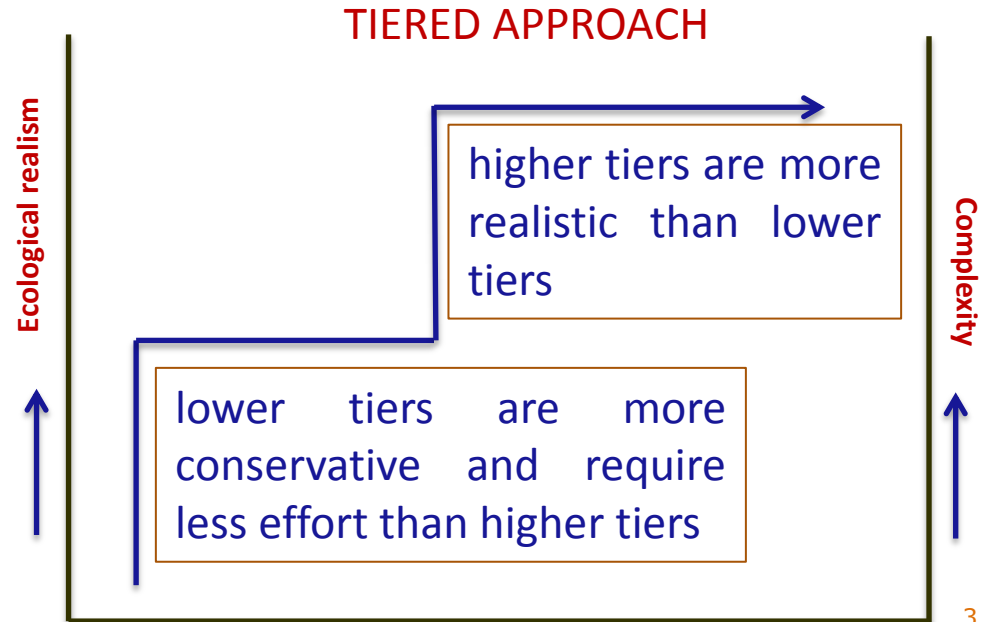
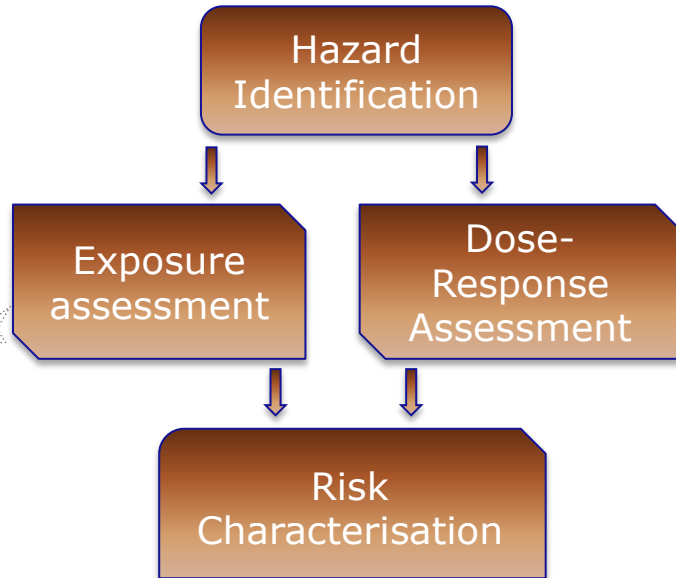
# OUTLINE

- Legal framework
- Current Risk assessment
- Gaps and needs
- EFSA activities on soil risk assessment



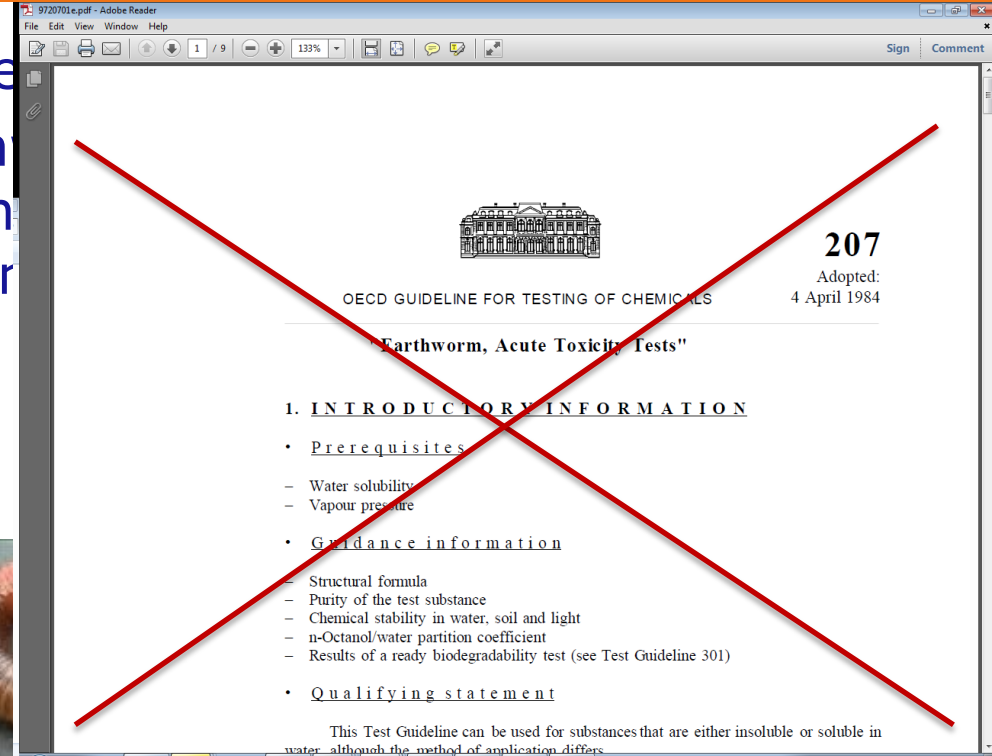
# CURRENT RISK ASSESSMENT

The current risk assessment is carried out according to the terrestrial guidance SANCO/10329/2002



# REGULATION 283/2013 AND 284/2013

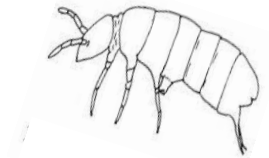
- Earthworms-sublethal effects
- Sublethal effects on earthworms where the a.s. can come in contact with soil should be considered. Test methods should provide information on the relationship between the test substance and earthworm behaviour. Testing shall include the relationship between the test substance and the EC<sub>10</sub>, EC<sub>50</sub> and EC<sub>90</sub>.



## REGULATION 283/2013 AND 284/2013

- Effects on non-target soil meso- and macrofauna (other than earthworms)-OECD 232 and 226

Testing shall determine a dose-response relationship and the EC10, EC20 and NOEC



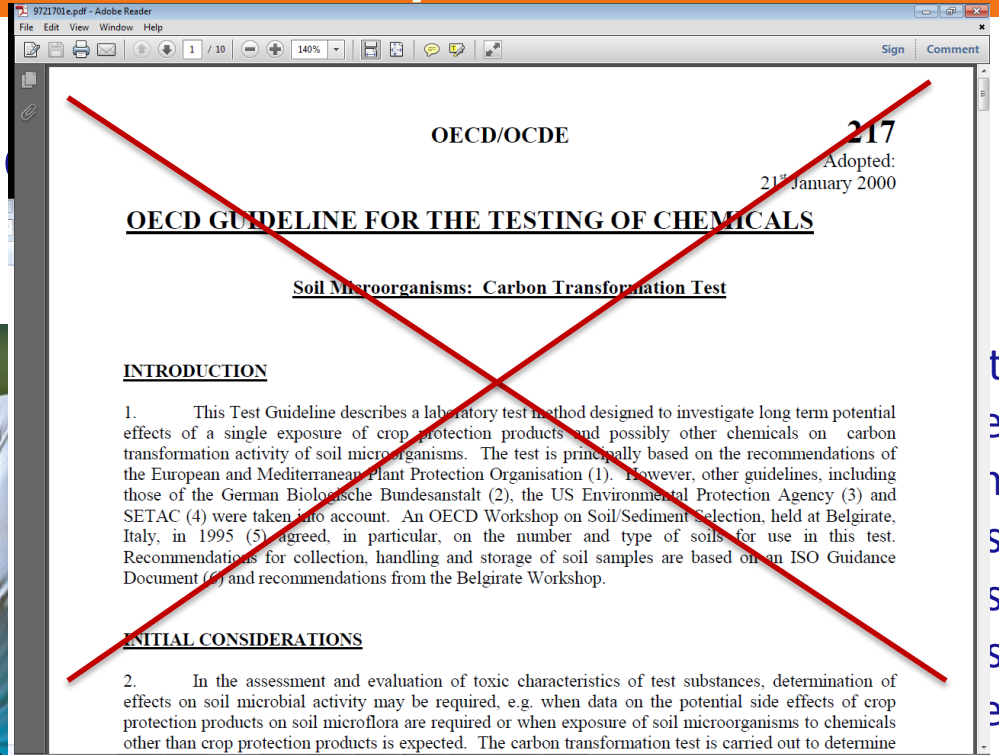
Waiver of toxicity test on soil invertebrates other than earthworms:

- situations where soil organisms are not exposed
- for plant protection products applied as a foliar spray when data are available on both *Aphidius rhopalosiphii* and *Typhlodromus pyri* these may be used in an initial risk assessment.



# REGULATION 283/2013 AND 284/2013

## ■ Effects on soil nitro



designed to measure rates of recovery following treatment.

# REGULATION 283/2013 AND 284/2013

- Effects on terrestrial non-target higher plants

Screening data shall establish whether test substances exhibit herbicidal activity. Substances with herbicidal mode of action-OECD 208 and OECD 227. A test shall provide the **ER<sub>50</sub>** values of the active substance to non-target plants.



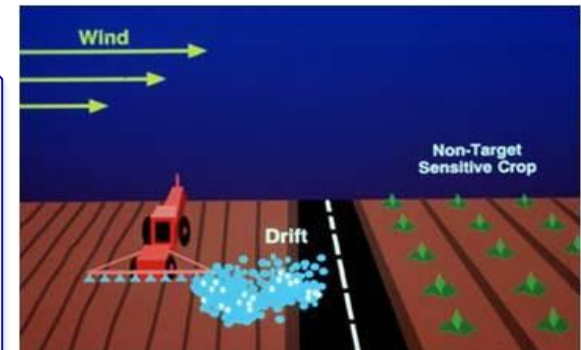
# EXPOSURE ASSESSMENT



**Soil invertebrates** : The exposure is represented by the predicted in-field concentration of the substance. Initial PEC values are decisive in this context. In the case of repeated applications, the PEC after the last application is relevant. In case of persistent substances the plateau concentration is relevant.

**Microorganisms**: no separate exposure assessment

**Plants**: Spray drift is considered the relevant route of exposure. The drift model is the one developed by Ganzelmeier (1995). The initial assessment should be conducted for a distance of 1 m from the field edge for field crops, vegetables or ground applications such as for herbicides, and 3 m for other crops





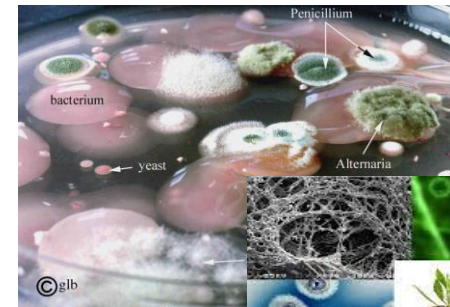
## RISK CHARACTERISATION

- According to the Reg 546/2011, low risk for soil invertebrates is identified if:

$$TER = \frac{ECX \text{ or } NOEC}{PEC} > 5$$



- Nitrogen transformation process in laboratory studies is not affected by more than 25 % after 100 days.



# RISK CHARACTERISATION

- Van Gestel, 1992: if  $\log K_{ow} > 2$ , use a factor of 2 to consider that the toxicity was higher in field soils

foc of the soil



Adsorption

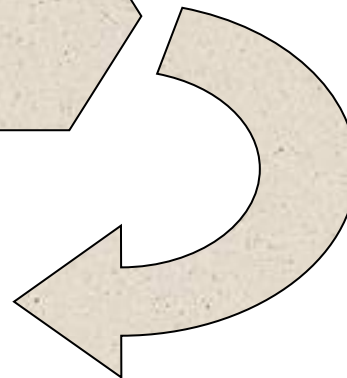
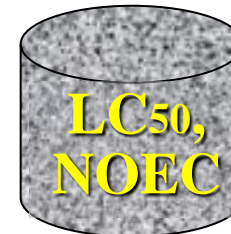


Pore water conc.  
(bio-availability)



Field soils

Artificial soil

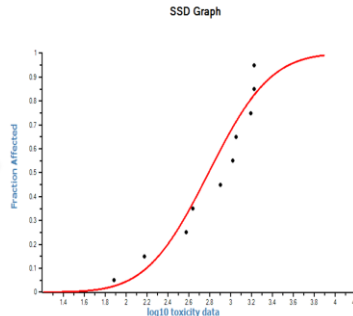


# RISK CHARACTERISATION

- According to the Reg 546/2011, low risk to non target terrestrial plants is identified if:

$$TER = \frac{ER_{50}}{PER} > 5 \longrightarrow \text{Deterministic approach}$$

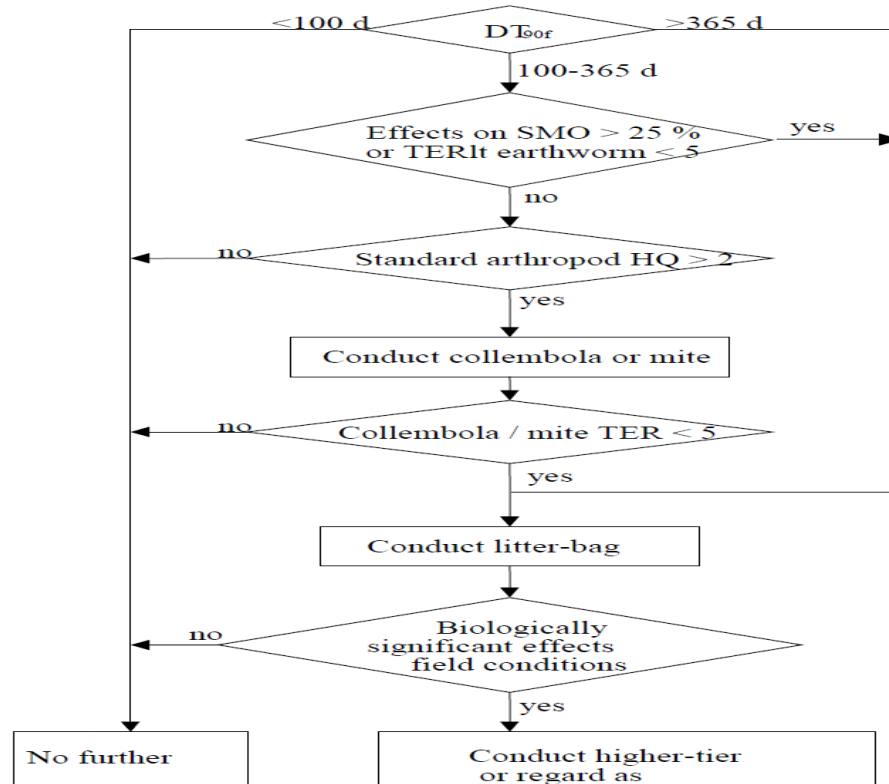
If toxicity data on 6-10 species are available



$$TER = \frac{HR_5}{PER} > 1$$

Probabilistic approach

# REFINEMENTS OF THE RISK



## REFINEMENTS OF THE RISK

- If a high risk cannot be excluded at lower tiers, further refinements are required. Refinement options could be:
  - use of a more realistic test substrate
  - use of a more realistic exposure regime
  - Field studies or litter bag test under field conditions
  - Case by case analysis, e.g. ecological relevance of the observed effects, consequences on soil functions, potential for recovery, etc.





## PUBLIC CONSULTATION ON SANCO/10329/2002

In view of the revision of the terrestrial guidance, EFSA launched a public consultation on the current guidance in 2009.

AIM: collection of issues, gaps and needs




# OUTCOME OF THE PUBLIC CONSULTATION

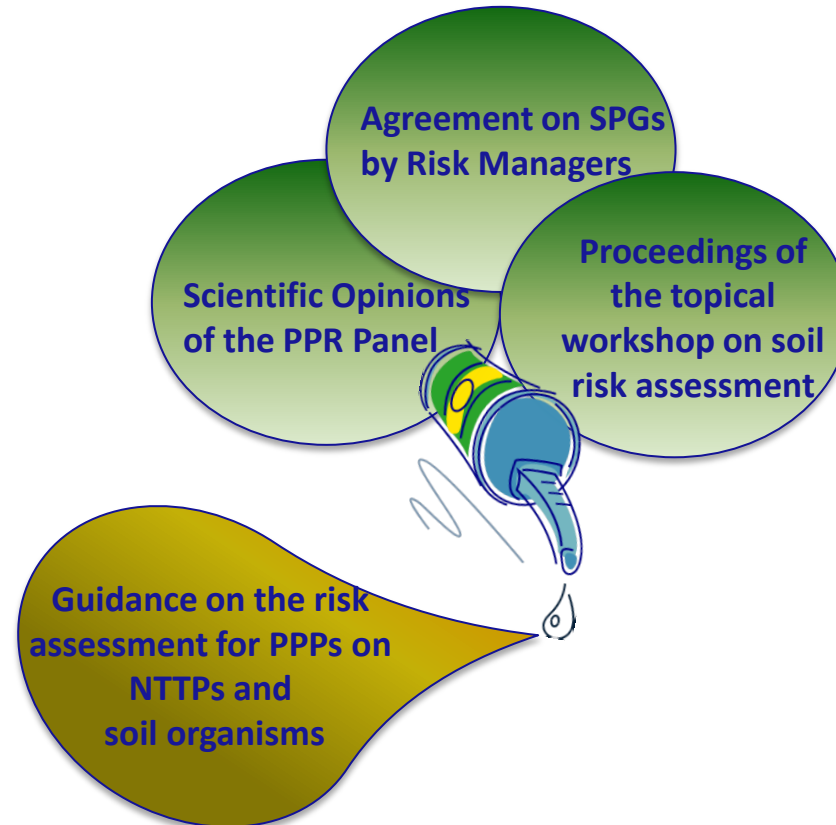
- ❑ Revision of the GD considering the revision of the data requirements and the entry into force of the Regulation 1107/2009
- ❑ Definition of SPGs (structural or functional)
- ❑ Multiple exposure
- ❑ Inclusion of additional and more sensitive species in the RA
- ❑ More guidance on statistical analyses
- ❑ Usefulness of litter bag studies and more guidance on how to evaluate field studies
- ❑ Coverage of all possible routes of exposure
- ❑ Exposure concentrations
- ❑ Persistent substances
- ❑ Bioavailability



## EFSA ACTIVITIES ON SOIL RISK ASSESSMENT

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- EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil-[EFSA Journal 2015;13\(4\):4093](#)
  - Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target terrestrial plants-[EFSA Journal 2014;12\(7\):3800 \[163 pp.\]](#)
  - Public consultation on the draft Opinion for in soil organisms
  - Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in soil organisms-[June 2016](#)

# EFSA ACTIVITIES ON SOIL RISK ASSESSMENT





**THANK YOU**  
for your  
**ATTENTION!**

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