Appendix E

Soil organisms

APRIL 2019

INTRODUCTION

The assessment of the effects and risks of chemicals for the terrestrial environment is a complex matter. This complexity comes, among others, from factors such as the need for sharing of the available landscape among urban/industrial activities, agricultural production in the form of agro-systems, and supporting terrestrial ecosystems. In addition, terrestrial systems are not associated with a single compartment, but with the interface between soil and the atmosphere.

General adverse effects on the soil organisms include effects on soil functions and on organisms (invertebrates, micro-organisms) important for proper soil function and nutrient cycle conservation. There is a common understanding that the ecological risk assessment aims not at individuals but at the protection of populations. In general, the continuance of populations of non-target organisms should be ensured. Structural and functional endpoints should be regarded of equal importance.

Soil organisms are species that dwell primarily in the soil and soil litter. Soil organisms are exposed to active constituents from contact and oral uptake routes of exposure in the surrounding soil compartment. A ‘healthy’ soil supports a range of ecosystem functions or services (such as nutrient cycling) that are essential for supporting the growth of crops as well as the organisms that depend on those crops. Soil communities of invertebrates and microorganisms are the most diverse part inhabiting agricultural landscapes.

The general protection goal is to protect biodiversity and ecosystems. EFSA (2017) has proposed specific protection goals for soil organisms being key drivers for relevant ecosystem services in agricultural landscapes such as nutrient cycling, soil structure, pest control and biodiversity. Considering the time-scales and biological processes related to the dispersal of the majority of soil organisms, risk assessment are made at in- and off-field scale considering field boundary levels.

For outdoor situations, the following applications are considered to have negligible soil exposure:

- when precautions are taken to prevent contact with the soil (eg when pots/containers are placed on plastic sheets)
- when crop is not cultured in soil, but on other substrates
- wound healing with pastes
- use under glass
- use on timber or felled trees
- use of baitboxes against rodents with their subsequent removal.

Soil sterilants and similar products are, in most cases, designed to have broad-spectrum activity against the soil microflora, and so will evidently show strong activity when tested according to the subscheme. The environmental risk posed by such products should be judged on other criteria, particularly on the basis of persistence, mobility, and effects on other non-target organisms.

TOXICITY FIGURES

In general, toxicity testing should be conducted using the technical grade active constituent. However, certain study types may be conducted with a formulated product instead of the active substance. This may be applicable to, for example, the earthworm reproduction test and the soil micro-flora test.

If testing with formulated product, it should be representative of the formulation proposed for registration. Refer to EC (2002) for guidance on when testing of soil metabolites are required.

Acute:

- *Eisenia fetida*: LC_{50} (OECD guideline 207).

Chronic:

- *Eisenia fetida*: NOEC (OECD guideline 222)[1]
- *Folsomia candida*: NOEC (OECD guideline 232)[2]
- *Hypoaspis aculeifer*: NOEC (OECD guideline 226)
- soil nitrification: NOEC (OECD 216)
- carbon mineralisation: NOEC (OECD 217)
- litter bag test: NOEC (2004 draft OECD guideline)[3].

The availability of lipophilic products in soil and therefore their toxicity to soil macro-organisms depends on the organic matter content of the soil (EPPO 2003). For chemicals with log Kow >2, sorption is expected to be linearly related to soil organic matter content. A factor of two (division of all toxicity end-points) is used to correct the toxicity data from macro-organism studies conducted in artificial soil with 10 per cent peat content. Typical agricultural soil has not more than 5 per cent organic matter. Soils with extreme characteristics, such as very sandy or peaty soils, are not taken into account as they are not normally used for agricultural purposes. The use of this correction factor depends upon the compound (EPPO 2003). For some compounds, it can be shown that this factor does not apply since sorption and exposure is not dependent on soil organic matter. However, this has to be adequately demonstrated.

[1]Not required when DT_{90f} <100d and <3 applications

[2]Required when DT_{90f} >100 days and risks to other non-target arthropods (*Typhlodromus pyri* and *Aphidius rhopalosiphi*) are not acceptable at the screening level

[3]Refer to EC (2002) for when this test is required

RISK ASSESSMENT

Direct exposure of soil means exposure at the time of the application, either because soil itself is treated or as a result of crop treatment with incomplete interception of the product by the crop. Exposure is also possible when a treated substrate for growing crops or manure from treated animals is disposed on land. A third route of exposure involves plant material, treated with pesticide prior to planting (eg stored potatoes or dipped bulbs).

Screening level assessment

The acute and chronic risks to soil organisms are assessed using a tiered approach, which is in line with current EC (2002), EPHC (2009), and EPPO (2003) guidance. A screening level risk assessment assumes the worst-case scenario of a direct overspray of soil without interception in order to identify those substances and associated uses that do not pose a risk to soil organisms.

The Australian assessment first calculates a regulatory acceptable concentration (RAC) for acute and chronic exposure scenarios for the most sensitive species in each taxonomic group as indicated in Table E1.

Litter bag studies

If the difference in litter mass loss is ≤ 10 per cents at 12 months, the risk is considered to be low. If the difference is > 10 per cents at 1 year, or it is clear that decomposition rates are still diverging, a refined or higher-tier risk assessment should be performed. This may involve extending the existing study (eg by burying new bags) or conducting a new study under more realistic conditions. Alternatively the risk can be considered high and regulatory action taken, or risk reduction options may be considered. Risk/benefit analysis should be done in any case if the difference is > 25 per cent after 12 months, as the risk is considered to be unacceptable under these conditions.

Refined assessment

If it is necessary to refine the assessment for any particular taxonomic group or process, crop interception should be considered as a first step. Ideally, the crop and its growth stage at the time of application should be specified. If such data are not available, data for similar crops may be adequate. Crop interception factors presented for surface water in EFSA (2014) are preferred.

If further assessment is necessary, higher tier studies can be considered. Higher-tier tests may take the form of limited community/population studies (eg terrestrial model ecosystems, soil mesocosms) or field studies (including, if appropriate, litter-bag studies). Other groups (eg earthworms, microbial functions) may also be tested in the same study. It is important that the timing, levels and routes of exposure reflect, as far as possible, those of the proposed use of the product. Key effect end-points include: changes in community and population structure; species diversity; number and biomass of key species/groups; and if appropriate, organic matter breakdown. An ‘effect’ can be defined as a statistically significant deviation from the control for any key parameters at any time. This relies on the validity of the study and the level of significance that can be achieved. A reference product helps to determine validity. An effect at a single time may point to a short-term impact, but the potential for recovery should also be considered. ‘Recovery’ is indicated if significant effects compared with the control are no longer

observed within one season or one year (whichever is most ecologically relevant). Expert judgement should be used to evaluate higher-tier studies and to determine ecological relevance.

RISK ASSESSMENT TABLES

Table E 1: Regulatory acceptable concentrations for soil organisms

Taxonomic group	Exposure	Endpoint	Assessment factor	RAC
Macro-organisms	Acute	LC_{50} XX mg ac/kg dry soil	10	XX mg ac/kg dry soil
	Chronic	NOEC XX mg ac/kg dry soil	1	XX mg ac/kg dry soil
Micro-organisms	Chronic	NOEC XX mg ac/kg dry soil	1	XX mg ac/kg dry soil

Assessment factor as per EPHC (2009)

RAC = regulatory acceptable concentration = endpoint / assessment factor

Table E 2: Screening level assessment of risks to soil organisms

Taxonomic group	Exposure	Application rate (g ac/ha)	PEC (mg ac/kg dry soil)	RAC (mg ac/kg dry soil)	RG
Macro-organisms	Acute				
	Chronic				
Micro-organisms	Chronic				

Cumulative application rate is based on maximum single application rate, number of applications, interval between applications and soil DT50

PEC = predicted environmental concentration in top 5-cm soil (mg ac/kg dry soil) = rate (g ac/ha)/750

RAC = regulatory acceptable concentration (from Table E1)

RQ = risk quotient = PEC / RAC, where acceptable RQ ≤1

RISK MITIGATION

Risk mitigation options for soil organisms are limited. There are possibilities to reduce the exposure (reduction of application rate and/or number of applications and/or restriction on glasshouse use only), but these measures must be compatible with the agricultural objectives. The same is true for restrictions concerning the amount of treated area (eg band row instead of broadcast application, untreated field margins). If the risk to organic matter decomposition is determined to be sufficiently high and it cannot be adequately managed, then a cost/benefit analysis of the proposed use and/or risk labelling of the product may be considered.

REFERENCES

EC (European Commission), 2002, *Guidance document on terrestrial ecotoxicology under Council Directive 91/414/EEC*, SANCO/10329/2002 rev 2 final, available at ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf.

EFSA (European Food Safety Authority), 2014, *EFSA guidance document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil*, EFSA Journal 12(5):3662, 37 pp, doi:10.2903/j.efsa.2014.3662, available at www.efsa.europa.eu/en/efsajournal.

EFSA (European Food Safety Authority), 2017, *Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms*, EFSA Journal 15(2):4690, 225 pp, doi:10.2903/j.efsa.2017.4690, available at www.efsa.europa.eu/en/efsajournal/pub/4690.

EPHC (Environment Protection and Heritage Council), 2009, *Environmental risk assessment guidance manual for agricultural and veterinary chemicals*, ISBN 978-1-9221173-38-7, available at www.nepc.gov.au/resource/chemical-risk-assessment-guidance-manuals.

EPPO (European and Mediterranean Plant Protection Protection Organization), 2003, *Environmental risk assessment scheme for plant protection products, Chapter 8: Soil organisms and functions*, EPPO Bulletin 33, 147–9.