EnviBioSoil
Expertise Conseil
Biologie et Ecotoxicologie du sol

oekotoxzentrum
centre ecotox
Schweizerisches Zentrum für angewandte Ökotoxikologie
Centre Suisse d'écotoxicologie appliquée

Methodology proposal for the derivation of Soil Guideline Values for Plant Protection Product residues

Part 2 – Recommendations for the derivation of Soil Guideline Values

Commissioned by the Federal Office for the Environment (FOEN)

Final Report [April 2023]

Imprint

Publisher

Swiss Centre for Applied Ecotoxicology, 8600 Dübendorf / 1015 Lausanne, Switzerland

Commissioned by

FOEN, Federal Office for the Environment, Soil and Biotechnology Division, Soil Section, 3003 Bern, Switzerland

Coordinators of the Measure 6.3.3.7 of the Action Plan for Plant Protection Products

Gudrun Schwilch from the FOEN and Michael Zimmermann and Katja Knauer from the Federal Office for Agriculture (FOAG)

Authors

Mireia Marti-Roura*, Gilda Dell'Ambrogio*, Janine Wong, Marion Junghans, Mathieu Renaud, Benoit J.D. Ferrari,	Swiss Centre for Applied Ecotoxicology
Sophie Campiche	EnviBioSoil

*co-first authorship: equal contribution to this work

Scientific Support

Daniel Wächter, Vanessa Reininger	Nationale Bodenbeobachtung (NABO), Agroscope, 8046 Zürich, Switzerland

Acknowledgement

This project was funded by the Federal Office for the Environment. The authors would like to acknowledge Gudrun Schwilch and Bettina Hitzfeld from the FOEN and Michael Zimmermann and Katja Knauer from the FOAG for the discussions along the project and for their valuable comments on the report. The authors would like to thank all the persons listed under scientific support for the exchange we had and the advice that we received.

Contact

Gilda Dell'Ambrogio: gilda.dell'ambrogio@centreecotox.ch
Mathieu Renaud: mathieu.renaud@centreecotox.ch

Citation Proposal

Mireia Marti-Roura, Gilda Dell'Ambrogio, Sophie Campiche, Janine Wong, Marion Junghans, Mathieu Renaud, Benoit J.D. Ferrari. 2023 Methodology proposal for the derivation of Soil Guideline Values for Plant Protection Product residues. Part 2 - Recommendations for the derivation of Soil Guideline Values. Swiss Centre for Applied Ecotoxicology, Dübendorf and Lausanne, Switzerland; 57 pp.

Cover photo: Gilda Dell'Ambrogio, Swiss Centre for Applied Ecotoxicology

Summary

The recommendations for the derivation of Soil Guideline Values report is the second part of a two-part report on the methodology for the derivation of Soil Guideline Values for Plant Protection Product (PPP) residues. One of the tasks of the measure 6.3.3.7 of the *Action plan for the reduction and sustainable use of Plant Protection Products* is to derive risk-based reference values for the assessment of the effects of PPP residues on long-term soil fertility. The first part of the report (Marti-Roura et al. 2023) consists of an extensive review of state-of-the-art methodologies with focus on PPP derivation and, when possible, on agricultural land use. To test the derivation procedure of some of the reviewed methodologies it also includes case studies with the herbicide diuron and the fungicide fluazinam. Based on the review and the case studies, some crucial points for the assessment of PPP residues with regard to long-term soil fertility, not covered by the existing guidelines, were identified.

This second part of the report is a list of recommendations proposed by the Ecotox Centre and EnviBioSoil that aims to provide guidance for the derivation of ecotoxicological risk-based reference values (also called Soil Guideline Values (SGV)) for long-term soil fertility, when applied to PPP residues in in-crop areas. The latest findings and discussions in the scientific community are provided and evaluated to support the recommendations proposed in this report.

For the derivation of SGVs, data selection should primarily focus on tests with soil organisms involved in the maintenance of relevant soil functions that regulate soil fertility. A thorough data relevance assessment is mandatory to: 1) avoid target conflicts that may arise when the protection of non-target organisms interferes with the control of the target organisms (e.g. protection of non-target plant species versus pest plant species under herbicide application); and 2) select ecotoxicity tests, endpoints and toxicity parameters that are representative of long-term effects (i.e. selection of population relevant endpoints and selection of the effect concentration). Accordingly, the suitability and/ or the potential adaptation of some of the reviewed methodologies has been evaluated with regard to data selection. Some methodologies were discarded because they were difficult to apply, gave incomplete guidance or were difficult to adapt to the data relevance criteria mentioned above. The final recommendation is largely based on the EC TGD (2003), which is the parent guidance document for all current EU risk assessment guidance documents focussing on long-term exposure. Adaptations were made to tailor it to the relevance criteria and include the latest scientific findings on taxonomy and feeding behaviour of soil organisms (e.g. the re-evaluation of the trophic levels proposed for the deterministic approach) as well as modifications to adapt it to the limitations of soil effect datasets (e.g. the reduction of taxonomic groups for the distribution method).

Case studies with diuron and fluazinam have been conducted using the proposed methodology for SGV derivation in order to better understand the implications of the proposal. SGVs were compared with Predicted Environmental Concentrations (PNECs, derived according to the EC TGD (2003)) to observe the influence of the recommendations in the final assessment. Fluazinam did not show differences between the two assessments. However, for diuron, the uncertainty of the assessment could be reduced due to the use of a more robust derivation approach (i.e., the distribution approach).

This proposal is currently being applied to derive SGVs for a first selection of PPPs. It will be further validated in combination with soil bioindicators at a later stage. The validation may lead to the revision of the SGVs.

Content

Summary i

1 Introduction 1

2 Factors influencing Soil Guideline Values 3

2.1 How are the values applied? 3

2.2 How can SGV protect ecologically relevant soil functions? 4

2.2.1 Which organisms and exposure parameters should be considered for the SGV derivation? 4

2.2.2 How to consider biotests conducted with formulations for the SGV derivation? 9

2.2.3 How to integrate bioavailability in the SGV derivation? 10

3 Derivation methodology for the SGV 13

3.1 Deterministic method 19

3.2 Distribution method 19

4 Case studies: application of the recommendations for the SGV derivation – results and discussion 23

4.1 Diuron 23

4.2 Fluazinam 24

5 Conclusions and outlook 25

6 References and attributions 26

Attributions 31

7 Abbreviations 32

8 Glossary 34

9 Indices 38

9.1 List of Figures 38

9.2 List of Tables 39

Appendix 1 Case studies 40

Policy disclaimer

According to the Action Plan for PPP (AP-PPP) (measure 6.3.3.7), pesticides in soil should be monitored in order to verify the evaluation carried out within the framework of the registration regarding the persistence of pesticides in the environment and their effect on soil organisms and soil functions. Therefore, a suitable method (indicator) for effects of PPP on soil fertility has to be developed and applied in field studies. Risk-based reference values for PPP residues should be available by 2025, and bioindicators for the effects of PPP residues on soil fertility should be developed by 2027.

In response to the AP-PPP and tasked by FOEN and FOAG, experts from the Ecotox Centre and EnviBioSoil have been working since 2018 on an integrative concept to assess the effects of PPP residues in soil. The proposed methodology, one of several possible, and the SGV currently do not have a regulatory nature that goes beyond their intended use within the ongoing AP-PPP project.

1 Introduction

Ecotoxicologically risk-based reference values have been widely used in environmental regulation to identify the potential risk of substances in the aquatic, sediment and soil compartment. Reference values can be used either to anticipate potential risks of chemicals in the environment (prospective risk assessment) or to evaluate actual risks in the environment (retrospective risk assessment). For the aquatic and sediment compartments, the retrospective assessment of risks is well defined and regulated in the EU under the Water Framework Directive 2000/60/EC (WFD, 2000). However, no specific framework to harmonize the retrospective risk assessment of chemicals in soil has been proposed to this point.

Soil protection values[1] to assess the risk of chemicals in soil have traditionally been focused on recognized soil contaminants, such as persistent organic pollutants (POPs) or heavy metals, and are often associated to contaminated sites (Marti-Roura et al. 2023). However, the awareness of soil health has increased in recent years. A global reckoning of the importance of keeping soils not only unpolluted, but healthy has been growing. In the agricultural context, several strategies in the EU have recently been proposed to keep soils in a healthy state by aiming to increase biodiversity and reduce the use and risk of chemicals, pesticides and others, e.g., in the Farm to Fork Strategy (European Commission, 2020), the Biodiversity Strategy (European Commission, 2021a), and the EU Soil Strategy (European Commission, 2020b).

In Switzerland, the *Action plan for the reduction and sustainable use of Plant Protection Products (AP-PPP)* was adopted in 2017 (Swiss Federal Council, 2017). Among others, it contains specific objectives and measures to protect long-term soil fertility in view of Plant Protection Products (PPP) residues in agricultural areas. In this context, the Ecotox Centre and EnviBioSoil were commissioned to develop risk-based reference values (so called Soil Guideline Values (SGV)) and bioindicators to evaluate the effects of PPPs in agroecosystems (Measure 6.3.3.7 of the AP-PPP). For the biomonitoring of PPP residues, the Ecotox Centre and EnviBioSoil propose a combined approach integrating the evaluation of the risks detected by the SGV and the effects observed using the bioindicators (either in field or as bioassays) (Figure 1), in order to assess the impact of PPP residues on soil organisms and functions important for maintaining soil fertility. This approach combining chemical, ecological and ecotoxicological lines of evidence is also known as TRIAD approach. Since it is not possible to carry out a detailed monitoring at all agricultural sites, generic SGVs will be compared to environmental concentrations of the PPP residues in soil and used as a screening tool to identify sites potentially at risk. Since soil organisms are commonly exposed to not only one single PPP residue in agricultural fields, but to multiple residues, the effect of mixtures on soil organisms and functions should also be assessed. Therefore, a mixture assessment with the SGVs will be developed in a next step to be included in the screening. Once the sites potentially at risk are identified, a site-specific assessment including bioindicators will be performed. The information generated with the proposed approach should be used in a feedback loop to evaluate and refine the bioindicator toolbox and the SGVs.

In the first part of this two-part report (Part 1), several methodologies used for the derivation of soil protection values were reviewed and compared (Marti-Roura et al. 2023). Based on this comparison, a list of recommendations about the data selection and the derivation procedure to calculate generic SGVs is presented (Part 2). The proposed methodology will be applied to a first set of ten PPPs (Campiche et al. 2020). Further SGVs will follow in order to evaluate the effects of PPP mixtures on soil organisms and functions.

[1] Limit concentration of a substance in the soil usually expressed in mg active substance/kg soil dry weight (mg a.s./kg d.w.). In this report, the term “soil protection value” is considered a synonym of “risk-based reference value”.

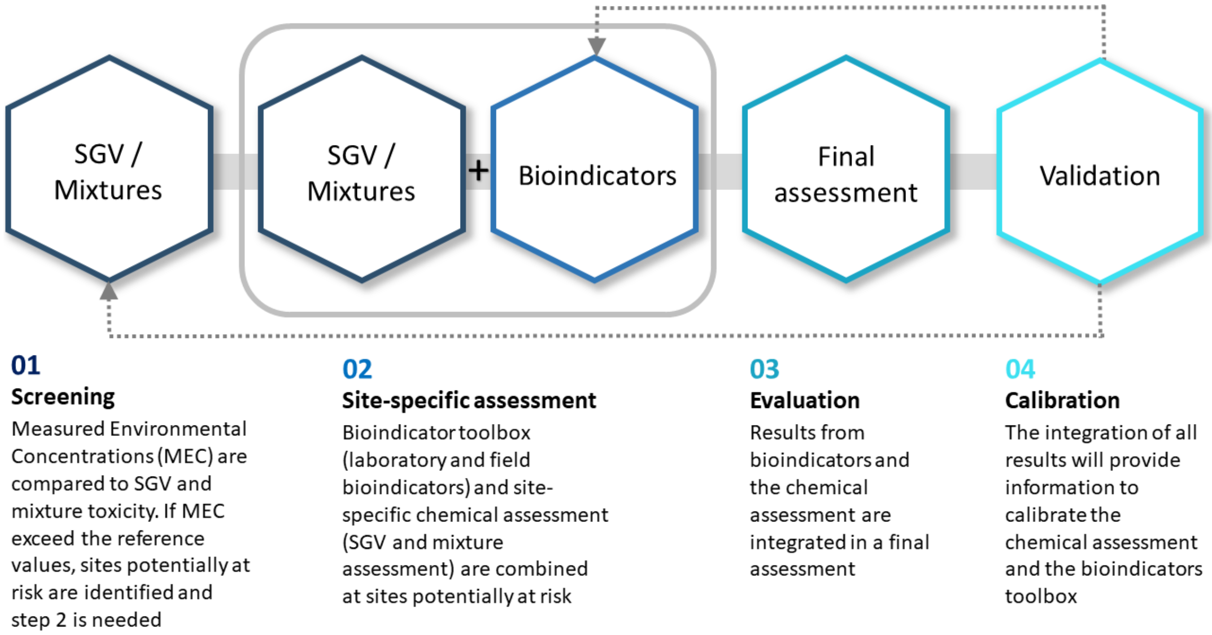


Figure 1: Scheme of the application of the combined approach with SGV and bioindicators.

2 Factors influencing Soil Guideline Values

Soil protection values vary depending on several factors, such as their application and implementation and the specific data considered (see Marti-Roura et al. 2023 for further information). In this chapter, specific considerations that can affect SGVs are presented and recommendations are made on how to take them into account, in order to support the decision on a derivation methodology.

2.1 How are the values applied?

Understanding the differences in the application of soil protection values according to the several approaches and regulations is crucial. As shown in the review presented in Part 1 of this report (Marti-Roura el al. 2023), most of the reviewed countries derive soil protection values to assess the environmental impact of certain chemicals in contaminated sites based on a 'fitness-for-use' approach. Generally, more than one soil protection value for the same substance is derived in order to adapt them to different levels of ecological protection. Some authorities assume that different sites may be influenced differently by human activity and, thus, protection goals are strictly linked to land uses (e.g., Canada (CCME, 2006)). On the other hand, other authorities use different levels of protection to classify the degree of contamination in order to establish site use and management (e.g., the Netherlands (Swartjes et al., 2012)). Also, there are some approaches in the review which are not intended to be applied to a broad spectrum of sites and/or substances. This is the case, for example, for the soil protection values derived by the US EPA (US EPA, 2005), which are intended to be applied only to some of the most frequent soil contaminants of ecological concern at hazardous waste sites. Most retrospective approaches describe methodologies to derive generic values, but some of them also consider a tiered approach with site-specific risk assessments, if needed.

The SGV will be compared to measured concentrations of PPP residues from in-crop areas. Thus, the area of application of the SGVs should be limited to those sites. SGVs are primarily intended to be used as generic screening values to detect sites potentially at risk. They can also be used in a site-specific assessment, if this is triggered (Figure 1). For this, the SGV may have to be adapted to site-specific conditions.

SGVs are designed to assess the hazard of PPP residues in the soil compartment and are intended to assess possible effects on the long-term fertility of agricultural soils. The exposure assessment of the PPP residues in the field will be performed by the Swiss Soil Monitoring Network (NABO) through a long-term monitoring campaign. This monitoring is going to be routinely performed, annually, in winter before the first PPP application to measure the PPP residues remaining in the soil. The interval between the last PPP application in the field and the soil sampling can be from a minimum of 2-3 months to more than a year (for those PPP, which are not applied annually) (personal communication from NABO).

Recommendations

SGV are intended to be screening values and should not be used for remediation purposes. SGV are going to be applied as generic values but might also be used in a site-specific assessment, if this is triggered. When SGV are used for site-specific assessment, there may be some factors influencing the risk assessment of PPP residues, and a further refinement of the SGV may be needed. Some of the possible factors to include for the site-specific SGV are:

- Specific soil characteristics: e.g., very high contents of organic matter in the soil
- Specific cultures or PPP applications
- Specific climatic or geographical conditions
- Other factors

2.2 How can SGV protect ecologically relevant soil functions?

In agricultural soils, some ecological soil functions have been described and considered crucial to maintain natural soil fertility (Steiger et al., 2018). Among them, the habitat function, i.e., the capacity of the soil to provide a habitat for animals, plants and other organisms, has been described in the Swiss National Soil Strategy (Swiss Federal Council, 2020b) as one of the essential soil functions. A reduction in the habitat function may impact other ecological soil functions in agricultural ecosystems, namely the production and the regulating function (water balance, storage of nutrients, transformation and breakdown of organic substances). The role of the soil to act as a habitat for organisms, also in agricultural fields, and the need to protect in-soil organisms and plants as key drivers of ecosystem services has also been emphasized by the EFSA PPR Panel (2017, 2014). It has been described that, in case of long-term chronic exposures to low levels of stress, the potential resilience of soil communities or its components may be impaired (Brock et al., 2018). As a consequence, if the biological activity cannot be maintained or restored, long-term soil fertility may be compromised (Swiss Federal Council, 2020b). Although several factors may have an effect on soil organisms and their functions in agricultural fields (e.g., climate and soil management (Bronick & Lal, 2005)), the use and the subsequent persistence of PPP residues in the soil is also a contributing factor.

2.2.1 Which organisms and exposure parameters should be considered for the SGV derivation?

The goal of PPP application in agricultural fields is to eradicate target organisms (pests), which may affect the crop production negatively. However, PPPs may also affect other sensitive non-target species (RIVM, 1997). Thus, it is mentioned in the Regulation EU No 546/2011 that “Member States shall ensure that the use of PPPs does not have any long-term repercussions for the abundance and diversity of non-target species” (European Commission, 2011). The complexity of avoiding effects of PPPs on sensitive non-target species while allowing effects on target species is evident and has been widely discussed (EFSA PPR Panel, 2014, 2017).

The goal of the SGV is to protect long-term soil fertility from the effects of PPP residues in the soil. Soil fertility is mediated by soil organisms, which are responsible of providing relevant soil functions (Dell’Ambrogio et al., 2023). Moreover, in the Swiss Ordinance relating to Impacts on the Soil (OIS) (Swiss Federal Council, 2020a), it is stated that a fertile soil should ensure 1) that a biologically active community is typical for its location and their characteristic properties should not be impaired; and 2) that natural and man-influenced plants and plant communities are able to grow and develop undisturbed. Thus, one of the outcomes of the 1st and 2nd workshop on Monitoring of PPPs in Swiss Soils was that SGVs should focus on in-soil organisms and plants (Godbersen et al., 2019). The following sections describe the role of those organisms as drivers of important ecological functions in agricultural soils and provide some overview about the existing ecotoxicological tests, endpoints and toxicity parameters and their suitability for the derivation of the SGV.

In-soil organisms

In-soil organisms, i.e., soil invertebrates and microorganisms, have an important role in maintaining soil fertility as drivers of nutrient cycling, soil structure formation and water retention. Many species composing the soil macrofauna (e.g., lumbricids, isopods, millipedes, ants, insect larvae), mesofauna (e.g., collembolans, mites, enchytraeids) and microfauna (e.g., nematodes) are actively involved in organic matter breakdown via their feeding activity, contributing to its efficient and fast decomposition and associated nutrient release (e.g., Briones et al., 1998; Dechaine et al., 2005; Filser, 2002; Ketterings et al., 1997; Schrader and Zhang, 1997; van Eekeren et al., 2008). This transformation and organic matter breakdown is closely related to the function of the microorganisms in the soil, in charge of the biochemical decomposition of organic matter and nutrient transformations (EFSA PPR Panel, 2017). Moreover, some in-soil organisms are involved in biological control of pest and disease, which has been highlighted as an important ecosystem service provided by biodiversity (Wilby & Thomas, 2002).

The prospective risk assessment for authorization of PPPs requires at least studies on sub-lethal effects (growth and reproduction) of earthworms but other chronic studies on collembolans and soil mites may be required as well (European Commission, 2013a) for active substances, and for the formulated products (European Commission, 2013b). It is well accepted that sub-lethal endpoints are good indicators of long-term (i.e., chronic) exposure for soil macro- and mesofauna and are, therefore, preferred for the derivation of soil protection values (e.g., EC TGD, 2003; NEPC, 2013; RIVM, 2007; US EPA, 2005). Reproductive endpoints are considered the most relevant endpoints because they are indicators of the sustainability of the population in the long-term. Other endpoints affecting growth of individuals are also accepted, since they were traditionally measured endpoints frequently extrapolated to impact the population level (US EPA, 2005).

Microbial toxicity tests with single species or strains are rare and the representativeness of one species to the vast microbial genotypic and phenotypic diversity of soils may be questioned (EFSA PPR Panel, 2017). Besides, a big majority of microorganisms cannot be cultured as pure isolates. Thus, community level-tests using field samples (i.e., natural soil) have been suggested to better determine long-term chronic effects induced by PPPs. The most common endpoints for community level-tests can be related to function (activities or processes), biomass or structural properties (community structure or diversity). According to the current EU regulation, only the N transformation test, as a relevant indicator for the functions nutrient cycling and food-web support, is required. In EFSA PPR Panel (2017) other novel methods describing a broad spectrum of functional and structural endpoints (e.g., molecular methods like phospholipid fatty acid analysis (PLFA) or quantitative PCR-based methods) have been described. However, the actual adjustment and standardization for use in risk assessment is still under debate. In general, biomarker studies are based on endpoints, whose relationship to effects at the population level is uncertain. However, some exo-enzymes produced by soil microorganisms can be used as biomarkers of soil fertility and are important in the ecological functioning of the soil (e.g., Filmon et al. (2015), NEPC (2013), RIVM (2007)).

Although the importance of microorganisms and soil microbial processes is widely recognized within the terrestrial systems, the paucity of data and its difficult interpretation may lead to uncertainties according to some methodologies (e.g., US EPA, 2005). For this reason, although there are methodologies with defined protocols of how to include such studies (e.g., EC TGD, 2003; NEPC, 2013; RIVM, 2007, some countries prefer to discard them (e.g., US EPA, 2005) or not consider them as strictly required (e.g., CCME, 2006) for the derivation of soil protection values.

Recommendations

Toxicity data available for soil invertebrates and microorganisms will be examined. Chronic sub-lethal endpoints for macro-, meso- and microfauna will be considered for the derivation of SGV, since they are indicators on a population level. In case of data scarcity, acute endpoints could also be considered in order to fill knowledge gaps for a trophic level.

For microorganisms, all studies evaluating effects on the function, biomass, structural properties at a community level or microbial-mediated enzymatic activities should be included for the derivation of SGV. Single species tests for microorganisms should be evaluated in detail and expert knowledge should be applied to discern whether they can be relevant as key organisms for agricultural ecosystems or not.

Toxicity studies performed in a medium that is not representative of the natural habitat of the tested species, e.g., filter paper, agar, etc. will not be considered for the derivation of SGV. Other soils with specific amendments (e.g., sewage sludge, not allowed in Switzerland for agricultural use) will also not be considered.

Terrestrial plants

The need to protect non-target terrestrial plants[2] (NTTP) growing in in-field and/or in-crop areas (Figure 2) has been highly debated (EFSA PPR Panel, 2014). Because herbicides are intentionally used for

[2] Non-target terrestrial plants: all terrestrial plants affected by pesticides, although they are not the intended target of the pesticides (EFSA PPR Panel, 2014).

targeting weeds in the field, EFSA considered it necessary to define specific protection goals for in-field plant species. Thus, in-field non-target plant species are considered as an important component in the provisioning of some ecosystem services in terms of food web support (food and habitat provision) (EFSA PPR Panel, 2014).

Crop species are the main NTTP to protect, since crop production is the ultimate intended use of in-crop areas. It is acknowledged that the risk assessment for other non-crop NTTP growing within crops cannot receive the same level of protection from effects of pesticide application than off-crop plants. However, non-crop species growing within cropland may include non-weed plant species. In some cases, even some rare or endangered species may grow in in-crop areas and may be of conservation value (Bornand et al., 2016; EFSA PPR Panel, 2014). According to EFSA PPR Panel (2014): “The reduction of weeds and non-weeds in the crop area owing to pesticide application may lead to a situation where the protection of species at higher trophic levels, such as arthropods, birds, mammals or amphibians, is seriously hampered owing to the fact that the scarcity of resources in the crop area cannot be sufficiently compensated for by non-crop areas.” This is especially relevant for crops planted in a non-homogeneous system, e.g., orchards and vineyards planted in rows, where the growth of wild species between the rows may be allowed or even encouraged (Figure 3 in the Glossary).

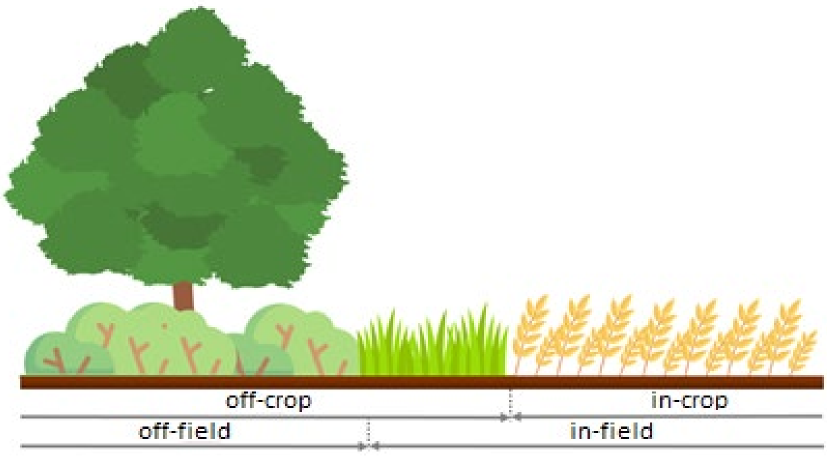


Figure 2: Example of field and crop area definitions in arable crops with a field boundary within the field.

Tests to assess effects on non-target terrestrial plants for PPP authorization are usually performed with crop species because they often have large seeds with no particular requirements for germination, are readily available from seed companies and produce consistent and reliable rates of germination (EFSA PPR Panel, 2014). Thus, crops are used as surrogates for wild species assuming that crop species do not consistently differ from wild plants regarding herbicide sensitivity. There is considerable debate as to whether non-target species sensitivity is adequately represented in these tests though no clear trends of differing sensitivity to herbicides have been detected (Boutin et al., 2004, 2012; Carpenter & Boutin, 2010; Clark et al., 2004; McKelvey et al., 2002; White & Boutin, 2007). Nowadays, the use of non-crop species for the PPP registration is not mandatory but encouraged in some of the guidelines which are available for the registrants (e.g., OECD, 2006a; US EPA, 2012a, 2012b). Ideally, biotests with non-target terrestrial plants should include effects on the whole life cycle (germinating seeds, seedling, juvenile stages, flowering, and seed production as well as germinability). Those tests are especially important in order to assess effects of rare wild species on natural populations in in-crop areas. Unfortunately, although there are some tests available to account for the whole life cycle (e.g., ISO 22030 (2005)), they are not considered in the current regulatory guidelines.

PPP residues should have no phytotoxic effects on crop species. The protection of crop species from PPPs is also emphasized in the Australian approach proposed by NEPC (2013). There, it is mentioned that “the protection of crop species is vital to maintaining the sustainability of agricultural land” and they propose to consider only crop and grass species (not native flora) for the derivation of the soil protection value in agricultural land. Adverse effects of PPP treatments on succeeding crops, e.g., rotational, replacement or catch crops, is equally undesirable. Therefore, according to Commission Regulation 284/2013 (European Commission, 2013b), “data on the impact of a treatment of PPP on succeeding crops should be required to the registrant if significant residues of the active substance, its metabolites or degradation products which have or may have biological activity on succeeding crops, remain in soil or in plant materials […] up to planting time of possible succeeding crops”. The assessment of the persistence and availability of PPP in soil for authorization purposes is examined by the calculation of Predicted Environmental Concentrations (PEC). However, recent studies with measured concentrations of PPP residues in the soil have been reported by several recent monitoring studies showing relevant information about the amount of PPP residues in agricultural fields. A study from Silva et al. (2019), in which agricultural soil samples from 11 EU Member States were collected, reported that 80 % of the samples contained PPP residues and, some of them, occasionally exceeded their PEC in soil. In Switzerland, a study from Chiaia-Hernandez et al. (2017) showed that residues of about 80 % of all applied pesticides in Swiss agricultural fields could be detected with a persistence of more than a decade. Similarly, in Riedo et al. (2021), 100 Swiss fields (conventional and organic) were screened and it was found that several PPP residues were still present even after 20 years of organic agriculture. After all those recent evidences, it seems relevant that crop species (and in-soil organisms) should be protected from possible effects of the persistency of PPP residues in the soil. Besides that, PPP residues in the soil may cause a bigger ecological impact in case of future land use change and re-naturalization of the agricultural area.

Terrestrial plants can be exposed to PPPs via direct contact of the aboveground part of the plant or via the soil, affecting germination of seeds and/or belowground parts of the plants. The tests that registrants must submit for the authorization of PPPs, in order to assess the risk of PPP drift to NTTP in off-field areas, consider the two exposure routes mentioned. Thus, there are mainly two kinds of tests for NTTP. In the first one, PPPs are applied via spray application directly on the aboveground parts of the plants, like in the vegetative vigor test (e.g., OECD 227 (OECD, 2006b); US EPA, 2012a). In the second kind of tests, seeds are exposed to the soil treated with the PPPs, like in the seedling emergence and seedling growth tests (e.g., OECD 208 (OECD, 2006a); US EPA, 2012b). Depending on the expected route of exposure, the test substance is either incorporated into the soil or applied to the soil surface. In general, in the guidance documents for retrospective risk assessment, there is no clear statement of which plant tests should be included for the derivation of soil protection values (the topic is discussed only in the US EPA (2005), see Marti-Roura et al., 2023, US EPA section in Appendix 1). However, for those soil protection values where the information was available, it could be deduced that only tests performed with soil application (i.e., seedling emergence tests) were used for their derivation (see Marti-Roura et al., 2023, RIVM section in Appendix 1).

Recommendations

According to the reasons exposed in this section, toxicity data on NTTP will be included for the derivation of the SGV. Special attention and expert knowledge should be used when validating studies from plant species in case that the PPP is intended to be used as an herbicide. In this case, wild target plant species (weeds considered as pests) should be excluded from the derivation of the SGV, since they are the target of the PPP application. Crop species should be protected. Other non-target species could be protected, as well, and thus accounted for in the derivation, if a need for protection is identified (e.g., rare or endangered species, non-target plants growing in between rows).

Since the goal of the measure 6.3.3.7, and thus of the SGV, is the investigation of effects of PPP residues in the soil, our assessment of the effects differs from the assessment of the effects of PPP drift mentioned previously in this chapter. Exposure via contaminated soil is the only relevant route for the evaluation of effects of soil PPP-residues on plants. For this reason, the direct PPP exposure of aboveground parts of the plants is considered not relevant for the SGV derivation. Therefore, the tests performed with direct application on the green parts of the plant (e.g., US EPA, 2012a (if foliar application), OECD, 2006b, US EPA, 2012b) should not be considered for the derivation of SGV. Also, tests performed with an exposure medium other than natural or artificial soil, e.g. seed germinability tests with direct exposure of the test substance on filter papers or plant exposure via nutrient solutions either with quartz sand or glass beads as the support medium or in a hydroponic system (e.g. US EPA, 2012b), will also not be considered for the SGV derivation, since they are not representative of field scenarios and might consequently lead to unrealistically high exposures (EFSA PPR Panel, 2014; RIVM, 2007).

Which other tests are relevant for assessing the long-term soil fertility?

Single-species tests have limited power when explaining effects on the highly diverse, complex soil communities in the field and their relationship with ecosystem services (Faber et al., 2019). Therefore, in the current European regulatory framework for PPPs, if there are some evidences of risk to in-soil organisms or plants, higher tier studies may be conducted to refine the risk assessment. Those studies include semi-field studies, e.g., multi-species experiments in the greenhouse (for plants), and/or field experiments (for plants and in-soil organisms). Those studies aim to represent, as accurately as possible, the real situation in the field, by including additional factors like community composition, population dynamics, indirect effects (predation or competition effects), chronic exposure (eventually repeated exposure), interactions between and within species and exposure mimicking the actual field situation (EFSA PPR Panel, 2017). For plants, there are no standardized tests available for extended laboratory tests or semi-field studies and field tests. Although for some in-soil organisms, there are some standardized tests available (e.g., the earthworm field test ISO 11268-3; 2014), new technical adaptations are also being considered in order to harmonize the field testing procedure with the risk assessment (UBA, 2020a). Because of the complexity of the field studies and differences in the evaluation of reports between institutions, some methodologies to assess higher tier studies have been developed (EFSA, 2019; RIVM, 2006).

Several micro- and mesocosm tests for in-soil organisms have been developed over the last decade (e.g., Haegerbaeumer et al., 2019; Scholz-Starke et al., 2011). However, there is a lack of those studies in the current regulation, which goes from single-species tests to field-testing levels (van Gestel et al., 2020). Some potential higher tier test systems, like the Terrestrial Model Ecosystems (TMEs), have been proposed for a refined risk assessment. TMEs consist of soil cores from untreated grasslands with natural soil communities, which can be placed outdoor, i.e., exposed to natural weather conditions, or in the laboratory. Then, those cores are exposed to a dose-response design. In TMEs, impacts on natural communities and fate and effect of chemicals are usually monitored and can be investigated in space and time. Results from TME experiments can later be used together with ecological models in order to screen the exposure situation in different soils and under different conditions (UBA, 2020b; van Gestel et al., 2020).

Recommendations
Semi-field and field studies are very important in order to assess effects of PPP at a community level. For this reason, those tests should be considered for the derivation of SGVs. However, due to the diversity and complexity of semi-field and field studies, a thorough quality assessment of those studies should be performed and expert judgement should be used in order to evaluate, not only the reliability of the tests, but also their compliance with the goals of the SGV.

2.2.2 How to consider biotests conducted with formulations for the SGV derivation?

PPPs are usually placed on the market as a mixture of different compounds, forming what it is commonly called “formulation” or “formulated product”. PPPs are composed of one or more active substances (or active ingredients), which have a general or specific effect on certain group of organisms. They may also contain: synergists, which are substances that can enhance the activity of the active substance; safeners, which are added to eliminate or reduce phytotoxic effects of the PPP on certain plants (e.g., crops); co-formulants, which e.g., can increase the solubility of the formulated product; and adjuvants, which enhance the effectiveness of the PPP (Regulation (EC) No 1107/2009 (European Commission, 2009)). Although the active substance is the main driver of the toxicity of the formulated product, the addition of other substances may increase or reduce the effects of the PPP on the organisms, for example, by changing its bioavailability. The composition of each formulation is unique and the information is, usually, not publicly accessible as only the concentration of the active substance must be reported.

Once the PPPs are applied in the field, and in case they reach the soil, PPPs can be transported (e.g., run-off, volatilization, transport with the matrix, bioaccumulation) or transformed (e.g., by environmental dissipation processes such as degradation). In case that the PPP stays in the soil, the time needed for its transformation and dissipation to occur depends on the composition of the formulated product and how this is sorbed to the soil matrix. By means of a monitoring, the concentration of the active substance in the soil can be analyzed. However, sometime after its application, it is not possible to know in which form this active substance is present in the soil, i.e., as part of the formulation, partially attached to some substances of the formulation or as an isolated substance. The bioavailability of the PPP and, therefore its toxicity to in-soil organisms and plants may have changed, as well. For this reason, it is important to compare the potential differences in toxicity between the active substance and the formulation(s). This topic has also recently arisen in one of the last technical reports on general recurring issues in ecotoxicology from EFSA (2019).

According to Regulation (EU) 283/2013 (European Commission, 2013a), it is mentioned that, for the authorization of some PPP types, the use of the formulation instead of the active substance for the ecotoxicological studies may be more appropriate. In those cases, tests required for the authorization like for example, the earthworm reproduction test, tests with soil microorganisms and NTTP, should be performed with the formulation when these organisms will be exposed to the formulation itself. For this reason, it is common to find in (re-)authorization dossiers, tests either with the representative formulation(s) or with the active substance, thus leading to limitations in the number of soil bioassays. The scarcity of publicly available data on soil biotests is a problem already highlighted by Frampton et al. (2006), who observed that for the majority (>95 %) of pesticides approved for commercial use in Europe, few soil biotests were available, with, in many cases, only one test on a single species. Still nowadays, the paucity of ecotoxicological data has been mentioned as one of the points that hampers the characterization of potential risks in the terrestrial environment (Vašíčková et al., 2019).

Generally, in retrospective risk assessment for soils, the use of tests with formulations is either accepted and described in the guidance document (e.g., RIVM, 2007; US, EPA, 2005), or simply accepted without further explanation (e.g., CCME, 2006; (MOE, 2007)) (see Marti-Roura et al., 2023, Appendix 1).

Recommendations

Ideally, the composition of the formulation should be examined and the evaluation of possible effects of synergists, safeners, and/or other co-formulants on enhancing or decreasing the toxicity of the formulation towards in-soil organisms and plants should be performed. Since this information is usually confidential, this evaluation will hardly be possible.

Furthermore, the availability of data from soil biotests is expected to be scarce, especially in the case of pesticides recently placed on the market. In addition, since the current regulation does not always require ecotoxicological tests with both, active substance and formulation, the availability of data can be even more limited. For this reason, both, biotests with the active substance and the formulation, may be included in the derivation of SGV.

Formulation and active substance may present different toxicity towards soil organisms. Thus, in case that sufficient data is available from tests conducted with the active substance and with the formulation, a comparison between their toxicities (expressed in terms of the active substance) should be performed, using the same species and endpoints. It is recommended in EFSA (2019) that differences should be 3 times larger for the formulated product to be considered more toxic. However, expert knowledge on a case-by-case basis should be applied to decide which data must be retained. If a meaningful statistical comparison of the toxicity is not possible, due to the lack of data and if there are no further indications of a difference in sensitivity between tests with the formulation and the active substance, the data sets will be combined.

Tests with formulations containing more than one active substance will not be considered for the derivation of the SGVs, since toxicity effects cannot be clearly assigned to the respective active substances.

2.2.3 How to integrate bioavailability in the SGV derivation?

In soil ecosystems, one of the main factors that influence the toxicity of a chemical is its availability to the living organisms. Thus, it is essential to consider bioavailability conditions when assessing the hazard of substances. Bioavailability is defined as a combination of chemical, physical and biological interactions that determine the exposure of organisms to chemicals associated with soils and sediments (Ehlers & Luthy, 2003). The bioavailability and hence the toxicity of chemicals to soil organisms can be influenced by numerous factors affecting the interaction between the soil, the chemical and the organism. Soil factors such as organic carbon content, pH, ion exchange capacities and clay content may define the adsorption of a substance to the soil matrix (US EPA, 2005). The physico-chemical properties of the substance will also influence its fate and transport in the environment. For example, there are substances that may strongly adsorb and persist in the soil for a longer time than others due to their physico-chemical properties (i.e., substances with high soil adsorption coefficient (K_d) or carbon-water partition coefficient (K_{oc})). Finally, organisms will be less or more exposed to substances adsorbed to the soil depending on their habitat and feeding mode. For example, soil-dwelling organisms that feed on soil particles (e.g., earthworms) will be more sensitive to a chemical adsorbed to the soil compared to a soil organism facing a different exposure route, e.g., via direct contact only (ECHA, 2017).

Generally, PPPs are organic chemicals, i.e., substances that contain carbon atoms (and usually hydrogen atoms). Organic contaminants can bind to the organic carbon in the soil. The extent of this depends on the properties of the contaminant and the amount and type of organic matter in the soil (NEPC, 2013). Thus, the type of soil used for the toxicity tests, and especially the amount of organic matter, will drive the bioavailability of organic contaminants. To account for the differences in bioavailability of organic chemicals in toxicity tests, different strategies have been developed according to different methodologies. For example, US EPA (2005) gives preference to tests performed with high bioavailability conditions (low pH and low organic matter content), since this represents a "worst-case scenario" for the soil organisms. However, others, like CCME (2006), consider studies conducted under very high bioavailability conditions (very low pH and low organic carbon content) not relevant for agricultural land use. Another approach is the use of normalization relationships. Such relationships are an attempt to minimize the effect of soil characteristics on the toxicity data, so that the resulting toxicity data will more closely reflect the inherent sensitivity of the test species to the contaminant (NEPC, 2013). Normalization equations may include several parameters such as pH, clay content, cation exchange capacity and/or organic carbon. Several approaches mention the importance of using normalization relationships to better describe the bioavailability of chemicals in soils (EC TGD, 2003; NEPC, 2013; RIVM, 2007). However, normalization relationships are not always available. In such cases, some authorities, either do not normalize (NEPC, 2013) or apply only normalizations to the organic matter content, since it is considered the main factor influencing bioavailability for organic compounds (EC TGD, 2003; RIVM, 2007).

Normalizations to organic matter content vary depending on the soil type, which is taken as reference. For example, the EC TGD (2003) suggests an EU standard soil with 3.4 % organic matter (corresponding to 2 % organic carbon), while Dutch standard soils contain 10 % organic matter (corresponding to 5.88 % organic carbon) and Australian standard soils contain only 1.7 % organic matter (corresponding to 1 % organic carbon). Compiling data obtained from two monitoring programs from NABO with information of almost 200 agricultural sampling sites (Meuli et al., 2014; personal communication NABO, Biodiversity monitoring (BDM) sites), it could be observed that arable soils in Switzerland have a median organic carbon content around 2 % (corresponding to 3.4 % organic matter). According to this, the organic matter content suggested by the EC TGD (2003) for EU standard soils would be a very good representation of the organic matter content in Swiss agricultural soils as well.

There are still two processes, which may have an influence on the bioavailability of chemicals in the soil: ageing and leaching. Once a substance adsorbs to the soil, its bioavailability decreases. With increasing time, soils may form stronger bonds with the substance, causing decline in bioavailability in a process called ageing (Ren et al., 2018). However, decreasing bioavailability due to ageing does not always translate to a low risk to the soil environment and bound residues of PPP can still be toxic for in-soil organisms (Xu et al., 2020). The second relevant process in the bioavailability of chemicals in soils is leaching. It is described as a process that removes readily soluble soil components such as soil minerals from soils. Soil toxicity results obtained under laboratory conditions are usually from freshly spiked soils. It has been observed that the toxicity of freshly spiked soils, where leaching processes did not occur, increased due to changes in the ionic strength, soil pH and aqueous concentrations of anions and cations compared to leached soils (Stevens et al., 2003). Thus, ageing and leaching are important processes influencing bioavailability in natural soils and especially relevant when considering long-term exposures to chemical residues in the soil. Some work has been done in this field in order to account for ageing and leaching processes in soil toxicity (Smolders et al., 2009). However, most of the studies focused on metals and only little is known for PPPs. Only in NEPC (2013), the application of ageing and leaching factors is included, if available, in the derivation of soil protection values.

Recommendations

Bioavailability of PPPs is a very relevant topic, when assessing the effects of PPP residues in natural soils on a long-term scale. In agreement with the scientific findings described in this section, soil properties should be considered and normalization relationships should be applied, if available. In case normalization relationships are not available, we suggest a normalization of the toxicity data to 3.4 % organic matter (or 2 % organic carbon). Other parameters, such as pH and clay content, which may not only influence the soil bioavailability but also be a representation of the typical soil properties of Swiss agricultural soils, should be considered as well. From the same compilation of NABO data for Swiss arable soils (Meuli et al., 2014; personal communication NABO), information about pH and clay content could also be extracted. According to this data, the pH ($CaCl_2$ method) for Swiss agricultural soils ranges between 4.5 and 7.5 (median 6.0) whereas clay content ranges between 5 % and 50 % (median 20 %). The relevance of toxicity studies performed with natural soils with values of pH and/or clay content much higher or lower than the ones described in this recommendation should be evaluated case-by-case.

Information about ageing and leaching of PPPs is scarce and will therefore not be a requirement for SGV derivation. Yet, if information about these two processes is available, they should be considered and discussed in the respective substance dossier.

In case that the SGV should be applied at sites where soils have special soil characteristics, a more specific risk assessment would be recommended.

3 Derivation methodology for the SGV

The approach proposed for the derivation of the SGVs for Swiss agricultural soils should be the one that best allows for the implementation of the recommendations mentioned in the previous chapters. Those recommendations consider the specific protection goals of the SGVs, i.e., the protection of long-term soil fertility in Swiss agricultural soils, and result from an exhaustive research and consultation with some of the main international authorities in soil risk assessment. Although none of the reviewed approaches perfectly meets the requirements set out for future SGVs, some of the main methodologies mentioned in the review carried out in Marti-Roura et al. (2023) can be adapted in order to make them suitable for use. In Table 1, some of the advantages, limitations and possible suitability of the existing guidance for the derivation of SGVs, as well as the experience collected applying some of the methodologies in the case studies (Marti-Roura et al. (2023), Appendix 2), are described. The table comprises an evaluation of the following approaches: RAC[3]-EFSA (based on the EC SANCO, 2002); EC TGD (2003); CCME (2006); US EPA (2005); NEPC (2013).

Besides the direct toxicity to in-soil organisms and plants, potential risks for higher trophic levels via bioaccumulation in the food chain (secondary poisoning) are commonly evaluated in soil risk assessment. Since the scope of the AP-PPP (Measure 6.3.3.7) should focus on soil fertility, the evaluation of secondary poisoning is considered out of scope. However, and since soil organisms in agricultural areas are an important food source for many birds and mammals living in the surrounding areas, the assessment of the indirect toxicity towards these organisms due to the bioaccumulation of PPPs should be considered and tackled separately from the current project.

Therefore, the methodology proposal in this section describes only effects due to direct toxicity to soil organisms.

[3] Regulatory Acceptable Concentrations.

Table 1 : Advantages and limitations of the main methodologies and applicability for the derivation of SGV for PPP residues in Swiss agricultural soils.

Methodology	Advantages	Limitations	Applicability for SGV derivation
RAC - EFSA	• very well adapted to the agricultural context and PPP application (e.g., differentiation of target and non-target organisms) • easy to apply derivation method	• SANCO/10329/2002 guidance is currently under review and is likely to be updated soon • currently no official guidance on how to derive RAC-values exists making it difficult to integrate toxicity tests for which trigger values are not yet defined, e.g., microbial functions tests and/or field tests • a site-specific effect assessment is not possible • poor representation of the soil ecosystem complexity (e.g., biodiversity, ecosystem functions) with very limited diversity of species included in the RAC derivation, comprising only a small selection of invertebrate model species that were selected to represent key ecological receptors and relevant exposure routes • unique extrapolation method and assessment factor (AF) is used at the first tier. Refinements of the assessment factor to account for higher data availability is not possible • the guidance for the use of field/semi-field studies, which were not performed for the authorization of PPP is not clear • plants are not included in the RAC derivation for soils. There is a separate assessment for non-target plants in the EFSA risk assessment • no normalization to account for soil properties exists (fixed correction only for artificial soils and adsorbing substances)	*Low:* More detailed and developed guidance would be needed to apply the methodology in retrospective risk assessment
EC - TGD[4]	• although no new updates from the original guidance (EC TGD, 2003) exist, some issues have been addressed in more recent TGD-	• not specific for agricultural land use (e.g., no clear distinction between target and non-target organisms)	*High:* Although the methodology is not specific for agricultural land use and/or PPP, it could be adapted to the recommendations proposed in

[4] EC TGD is mentioned as the original guidance but comments refer, as well, to updates applied in newer guidance documents that apply the same methodology and appeared after the EC TGD (2003), e.g., RIVM (2007), ECHA (2017).

Methodology	Advantages	Limitations	Applicability for SGV derivation
	based guidance documents (e.g., RIVM, 2007; ECHA 2017) • methodology used and applied to a broad spectrum of substances, including many PPP • the methodology can be adapted to consider differences between sensitive and non-sensitive species for a specific mode of action (e.g., RIVM for pesticides) • methodology is already implemented in several European countries to derive retrospective soil protection values • gives generic screening values but site-specific risk assessment is also possible • data from new scientific publications can be integrated, thus reducing uncertainty in the hazard assessment. Several methods for the quality evaluation of the studies can be used (e.g., Klimisch, CRED[5]) • multiple extrapolation methods depending on data availability can be used. The aim is to best represent effects of the substance at the ecosystem level. Information of toxicity from multiple trophic levels/taxonomic groups or toxicity under field conditions are preferred over small data sets • normalizations to account for differences in bioavailability (e.g., organic matter (OM) content) between the laboratory conditions and a regional natural soil can be used	• methodology originally used for aquatic risk assessment and then adapted to soil. There are some limitations (e.g., data requirements for species sensitivity distribution (SSD), which are very difficult to fulfill for soils) • bioavailability factors to account for processes affecting chemical residues in natural soils e.g., ageing, leaching not included in the derivation • taxonomic groups and trophic levels are only broadly described in the EC TGD (2003), although some more clarifications are given in more recent guidance documents (e.g., RIVM, 2007)	the previous chapter. This methodology provides options for multiple methods with different degrees of uncertainty depending on data availability that can be used for the derivation. Furthermore, guidance to define parameters for normalizations of SGVs to standard Swiss agricultural soil is given.

[5] Criteria for Reporting and Evaluating Ecotoxicity Data (Moermond et al., 2016).

Methodology	Advantages	Limitations	Applicability for SGV derivation
CCME[6]	• protection levels, methods and exposure routes adapted to the land use • generic screening values but site-specific risk assessment is also possible • methodology used and applied to a broad spectrum of substances including some PPP • quality assessment of publications using "not so strict" criteria • multiple extrapolation methods depending on data availability can be used. Information of toxicity from multiple studies/taxonomic groups or toxicity under field conditions are preferred over small data sets • minimum data requirement for statistical distribution more adapted to soil toxicity datasets (compared to e.g., EC TGD) • bioavailability considerations include texture, organic matter and pH • soil protection value is classified according to its reliability (provisional or final)	• focus on recognized soil contaminants[7] (e.g., metals, POPs) at contaminated sites • use of simple distribution approach (linear distribution) may provide over or underestimation of the protection level • no clear definition of taxonomic groups/trophic levels is provided • evaluation of effects on microorganisms not always possible (might be hampered by limited data) • no normalization to soil properties or ageing/leaching factors recommended but selection of a certain range of soil properties instead. This may lead to the exclusion of potentially useful studies and scarcity of data	*Medium:* Methodology considers agricultural land use and has multiple derivation methods. However, it is quite complex to apply (e.g., several exposure routes) and not in-line with some of the recommendations from the previous chapter (e.g., no normalization but exclusion of studies according to differences in bioavailability).

[6] CCME is mentioned as the original guidance but comments refer, as well, to some Canadian regions, which applied the same methodology and appeared after the CCME (2006), e.g., MOE (2007).
[7] For a definition of "recognized soil contaminants", please refer to section 1 of the Appendix 1 in Marti-Roura et al. (2023).

Methodology	Advantages	Limitations	Applicability for SGV derivation
US EPA	• extrapolation method (i.e., geometric mean) is easy to apply • bioavailability evaluation accounts for pH, OM and log K_{ow} of the substance. Also, specific assessment for organic substances is provided • all kind of toxicity tests for in-soil organisms and plants can be assessed/considered	• focus on recognized soil contaminants at contaminated sites (e.g., metals, POPs). Not specific for agricultural land use/PPP • strict quality assessment might lead to possible exclusion of valuable studies (e.g., unbounded values, specific study designs for PPPs) • unique extrapolation method (geometric mean), independent of data availability (although values are usually based on few studies performed under high bioavailability conditions). The geometric mean may under or overestimate effects if data are widely spread • does not cover relevant trophic levels/taxonomic groups (only distinction between "soil invertebrates" and "plants") • microorganisms not considered • no normalization to soil properties. High bioavailability conditions favored	*Low:* Very strict assessment of the toxicity studies, leading to limitations of the dataset and thus, the representation of the complexity of the ecosystem is limited. Some of the recommendations from the previous chapter could not be included in this methodology (e.g., no normalization for bioavailability, microorganisms not considered).

Methodology	Advantages	Limitations	Applicability for SGV derivation
NEPC	• considers specific land uses, e.g., agricultural land use: specific considerations for the protection of in-soil organisms and plants for the agricultural land use (e.g., different protection levels for in-soil organisms and plants, only crop species considered for plants) • site-specific risk assessment can be considered • multiple extrapolation methods depending on data availability can be used. The aim is to best represent effects of the substance at the ecosystem level. Information of toxicity from multiple taxonomic groups or toxicity under field conditions are preferred over small data sets. Use of a specific distribution approach (sigmoidal distribution) may reduce the risk of over or underestimation • distribution methods adapted to small datasets, more appropriate for soil toxicity datasets • taxonomic groups well defined in the guidance • bioavailability includes multitude of factors (OM, pH, texture, CEC, as well as ageing and leaching) • soil protection value is classified according to its reliability (low, medium or high)	• focus on recognized soil contaminants at contaminated sites (e.g., metals, POPs) • lower level of protection for in-soil organisms than for plants. This leads to different soil protection values, with the value for plants being always lower than for in-soil organisms, regardless of the toxicity and/or mode of action • quality assessment not always appropriate for some specific study designs for PPP (e.g., microbial tests, single concentration tests) • in order to maximize the dataset, estimations of the toxicity parameters may be assumed (e.g., use of conversion factors for toxicity parameters, inclusion of unbounded values in the distribution approach) • bioavailability only considered if bioavailability relationships and/or ageing and leaching factors are available. Normalization only applied when using the distribution method	*Medium:* Good consideration of different land uses. However, there are some assumptions of added toxicity (e.g., due to bioaccumulation) and/or level of protection applied (e.g., between plants and in-soil organisms) that may be not appropriate for PPPs. Nonetheless, some points of the methodology are interesting to be considered (e.g., lower minimum data requirements and a sigmoidal distribution for SSD or more developed considerations for bioavailability).

Soil fertility in agricultural soils can only be maintained in the long-term by having a healthy soil ecosystem. The preservation of the structure and the functions of the soil ecosystem should be the goal of the ecological risk assessment (EC SANCO, 2002, EC TGD, 2003) and this should be accomplished by protecting the organisms at the population level. This was also further developed in Commission Regulation (EC) No 1107/2009 for authorization of plant protection products and Commission Regulation (EU) No 283/2013 and 284/2013 for data requirements for the authorization of active substances and formulations, respectively, explicitly requiring consideration of impacts on non-target species, on their ongoing behavior, on biodiversity and the ecosystem (EFSA PPR Panel, 2017). In the current guidance documents for the risk assessment of PPPs applied on terrestrial organisms (EC SANCO, 2002), biodiversity is not explicitly assessed and, therefore, EFSA acknowledged that an update needs to be done in order to be in-line with the mandates of the current regulation.

Some methodologies in Table 1 are considered very or moderately relevant in the context of the SGV derivation (EC TGD, RIVM, NEPC and CCME). One of the common considerations among them is how biodiversity is addressed from a functional and structural point of view in order to represent, as close as possible, the soil ecosystem. This could be accomplished either with information of field or semi-field studies, or by acquiring the maximum information possible from different trophic and/or taxonomic levels. Although it is still challenging to collect and/or use this kind of data for soil risk assessment, most methodologies (e.g., EC TGD, RIVM, NEPC and CCME) agree that the use of distribution methods, which may better represent the ecosystem, are preferred over more conservative methods, like the deterministic method (AF method) or the equilibrium partitioning method.

3.1 Deterministic method

For the deterministic method, we identified some ambiguity regarding the classification into trophic levels (e.g., producers, decomposers, consumers). This method classifies soil organisms into distinct trophic levels, where the number of trophic levels in turn determines the assessment factor that is applied. Yet, this classification can be sometimes subjective as the same species might belong to a different trophic level depending on the methodology or on the author of the classification. For instance, an earthworm like *E. fetida* can be classified as a consumer, according to the EC TGD[8], being at the similar trophic level as a collembolan like *F. candida*. However, according to the RIVM guidance the same earthworm species would be considered as a decomposer[9], while *F. candida* would be considered a consumer instead. In a general way, the distinction between decomposers (litter transformers) and consumers is not always straightforward, because by consuming organic matter, the 'litter transformers' also eat bacteria and fungi and possibly other smaller organisms (RIVM, 2007).

3.2 Distribution method

The use of distribution methods (e.g., Species Sensitivity Distribution (SSD)) has been largely applied in aquatic risk assessment. However, there is only limited experience of using this method in soil risk assessment. It seems that distribution methods have been well accepted for higher tier studies with plants, where information on multiple species is available (EFSA PPR Panel, 2014). The experience is still limited regarding the combination of toxicity data of in-soil organisms, especially for PPPs (EFSA PPR Panel, 2017).

[8] EC TGD, 2003, p. 287: primary consumers "live mainly on living or dead autotrophic organisms or on microorganisms".

[9] RIVM, 2007, p. 119: decomposers "contribute to the breakdown of organic matter (detritus, humus, litter) rather than predating on other organisms". They can be differentiated into microorganisms, which operate at molecular level, and higher organisms, which fragment/break down organic matter (litter, humus) or plants into smaller pieces.

In contrast to what is currently applied for PPP authorization, where data on plants and in-soil organisms are treated independently, the majority of the reviewed methodologies (Marti-Roura et al. 2023) adopted distribution methods to describe the different sensitivities of both group of organisms together. One of the main difficulties of applying the distribution approach proposed in the EC TGD (2003) is the unrealistic data requirements. When using the distribution approach by gathering plants and in-soil organisms together, it is very difficult to acquire a data set with toxicity data points for at least ten different species covering at least eight taxonomic groups for terrestrial datasets (i.e., the same requirements as for aquatic datasets according to the EC TGD (2003)). This topic has been widely discussed by NEPC (2013) where it is mentioned that the number of species included by the regulating agency is often arbitrary (Pennington, 2003). Indeed, for CCME (2006) at least ten data points (from at least three independent studies including two invertebrates and two plant studies) are required. For NEPC (2013), although it is recognized that a minimum of nine species would be recommended, a minimum of five species or functional processes (from at least three taxonomic groups) can also be used. Although distribution approaches have been proposed and/or used for soil hazard assessment with limited data sets (e.g., Frampton et al., 2006; NEPC, 2013; Renaud et al., 2019), a minimum of 10 to 15 species are generally recommended (Forbes & Calow, 2002; Newman et al., 2000; Wheeler et al., 2002). A minimum of three different taxonomic groups, as proposed by NEPC (2013) or CCME (2006), seems as well more reasonable for the soil compartment than the eight taxonomic groups proposed by EC TGD (2003).

Concerning the distribution method, ambiguity also exists regarding the classification into taxonomic groups itself. The level at which this taxonomic classification should be applied is not further defined in the EC TGD (2003) and could be at the level of the phylum, class, order, family, etc. Consequently, the attribution of an organism to its taxonomic group can be arbitrary, depending on what level is chosen as reference. Other guidance documents (e.g., RIVM, 2007; NEPC, 2013) propose more developed classifications, which are more suitable for soil organisms. The classification of the taxonomic groups that is used in the RIVM (2007) is in accordance with the EC TGD (2003) but outdated[10].

Different methodologies use distinct amounts of effects on a certain percentage of the population when the distribution method is applied. EC TGD (2003) and RIVM (2007) are the most conservative approaches, which allow only a small effect of 10 % (EC_{10} or No Observed Effect Concentrations (NOEC)) in a small fraction of the population (5 %, HC_5). Although agricultural land use is considered as one of the land uses that deserves a high protection (if not the highest) in CCME (2006) and NEPC (2013), both showed a relatively permissive approach compared to the EC TGD (2003). Both methodologies allowed effects up to 25 % and 30 % (EC_{25} and EC_{30}) for CCME (2006) and NEPC (2013), respectively in a relatively high fraction of the population (25 % and 20 % (for invertebrates, only 5% for plants) for CCME (2006) and NEPC (2013), respectively). Those differences may be due to different protection goals. Indeed, the soil protection value derived by EC TGD (2003) is intended to assess effects of a broad spectrum of chemicals on soil organisms, while values derived by CCME (2006) and NEPC (2013) are intended to assess effects for recognized soil contaminants (mainly metals and persistent pollutants) on contaminated soils. According to the Regulation EU No 546/2011, PPPs should not have any long-term repercussions for the abundance and diversity of non-target species. Moreover, according to the goals of the AP-PPP (Measure 6.3.3.7), PPP-residues should also not cause any long-term effect on soil fertility in agricultural soils. The assessment of the PPP residues is going to be performed over winter, when no PPPs are applied in the soils and PPP residues should be at the lowest level. At this point, the effects of the PPP residues on the soil communities at a population level should be negligible. In case that there is, indeed, a chronic effect on soil organisms at this stage, the viability of the whole population in the future can be compromised when new PPP applications occur. For this reason, it seems reasonable to conclude that, for the SGVs, chronic effects on non-target

[10] Collembolans were assigned in the past to the class of Insecta and RIVM (2007) classification is still based on this. However, only recently, collembolans have been considered as a separate class (Gobat et al., 2010).

organisms fulfilling essential functions in agricultural soils should be minimized. Therefore, the protection level suggested by the EC TGD (2003) (10 % effects (EC_{10} and/or NOEC on 5 % of the population of non-target plant and in-soil species (HC_5)) seems reasonable to be applied for the SGV derivation in case a distribution approach is used.

Recommendations

In general, the hazard assessment described in the EC TGD (2003) has a wide acceptance in European risk assessment due to its versatility and easy application to a broad spectrum of chemicals (among them also organic PPPs). This methodology has also been widely applied in retrospective soil risk assessment, since it has a long list of criteria (Table 1) that can be adapted under several frameworks (e.g., for different types of substances and land uses). This flexibility could also allow the implementation of the recommendations for the SGV derivation proposed in this report. Therefore, we suggest the use of this methodology for the SGV. However, some adaptations should be implemented in order to fit the methodology to the evaluation of the effects of PPP residues in agricultural soil systems.

If available, approaches, which may better define effects at a population level (e.g., distribution methods and field and/or semi-field studies) should be evaluated. It is however also recommended to use the deterministic approach (AF method) in order to compare and discuss the final choice of the SGV. In case a deterministic method is used, it is recommended to use the same criteria for the selection of the AF as recommended in the EC TGD (2003). Concerning the equilibrium partitioning method, i.e., the use of aquatic toxicity data to derive a soil protection value, this should be performed as recommended in the EC TGD (2003) as well. This means that it should only be used in those cases where there is no toxicity data for the soil compartment or, together with the deterministic method, when only information on one test result with soil organisms is available.

Specific adaptations regarding the use of data for the SGV derivation

- Quality assessment criteria for publications adapted to the soil compartment should be defined and applied according to CRED (Criteria for Reporting and Evaluating ecotoxicity Data, Moermond et al., 2016), an evaluation method, which has already been used for aquatic and sediment risk assessment in Switzerland (currently under development by the authors of this report).
- Non-target organisms (plants and in-soil organisms) should be used for the derivation (see section 2.2.1).
- Only studies conducted via soil exposure should be used (see section 2.2.1).
- Data from studies performed with formulations and the active substance can be used (see section 2.2.2).
- Normalization of the toxicity data (at least to organic matter content (3.4 %)) and/or considerations of the soil properties representative of Swiss standard agricultural soils should be applied before the derivation (see section 2.2.3).

Adaptations for the deterministic method

- The following classification of trophic levels used already in the case studies is suggested: primary producers (e.g., plants), decomposers (nutrient transformers) (e.g., bacteria, fungi), decomposers (litter transformers)/primary consumers (e.g., earthworms (*Eisenia fetida/andrei*) and collembolans feeding on fungi and/or organic matter like *Folsomia candida*) and secondary consumers (e.g., predatory mites, like *Hypoaspis aculeifer*).

Considerations for the distribution method

- Use of chronic endpoints (NOEC and/or EC_{10} from chronic toxicity tests) for both, non-target plant and non-target in-soil species in the same distribution. Microbial functional processes should not be used in the distribution, but their sensitivity should be discussed with the overall results of the distribution.
- At least ten exact data points and three taxonomic groups should be used for the distribution. The taxonomic groups are classified according to NEPC (2013). The main taxonomic groups proposed by NEPC (2013) for terrestrial species are: Annelida (e.g., enchytraeids, earthworms), Nematoda (nematodes), Hexapoda (e.g., insects, collembolans), Chelicerata (e.g., mites, spiders), Crustaceans (woodlice), Plantae (plants), Fungi, Algea, Bacteria, etc.
- Use of log-logistic or log-normal fitting. An appropriate evaluation of the fit should always be performed: e.g., goodness-of-fit, bimodality or multimodality, evaluation of the potential substance specific mode of action.
- Protection of 95 % of the population (HC_5).
- Use of an AF between 1 and 5 for the final SGV depending on: the overall quality, diversity and representativeness of the dataset, statistical uncertainties, etc.
- Finally, the results should be compared and evaluated on a case-by-case basis when deciding on a final SGV for the soil compartment.

Additional consideration for SGV values

Depending on the availability and/or the quality of the data, the dataset may be more or less representative of the toxicity of the PPPs to the soil ecosystem. The uncertainties or lack of representativeness can be reflected by the derivation method and/or the assessment factor, which are applied for the derivation. For this reason, and in order to assess the reliability of the final SGV, two different categories for the final SGV are suggested:

- *preliminary SGV*: the methods used for the derivation are either the equilibrium partitioning method or the deterministic method with AF > 50.
- *definitive SGV*: the rest of the cases, i.e., if the derivation is carried out with the deterministic method with AF ≤ 50, the probabilistic method and/or using field or semi-field studies.

4 Case studies: application of the recommendations for the SGV derivation – results and discussion

The methodology proposed for deriving SGVs was tested in two case studies (Appendix 1), in order to explore its suitability and provide detailed information on how our recommendations could be applied. SGVs were derived for the same case studies as the ones used in Part 1 of the present report (Marti-Roura et al. 2023, Appendix 2), diuron and fluazinam, in order to compare the different outcomes. The same datasets for diuron and fluazinam applied in Marti-Roura et al. (2023, Appendix 2) were applied for the SGVs as well. Like for the previous case studies, the SGVs derived in Appendix 1 are based on the same limited ecotoxicological dataset. These SGVs are derived exclusively for comparison purposes and for exploring the recommended methodology and can therefore not be considered conclusive values.

The complete comparison between some of the main methodologies applied to PPPs in soil risk assessment can be found in Marti-Roura et al. (2023). The methodology proposed for the SGV derivation is mainly based on the EC TGD (2003) (i.e., same extrapolation methods and normalization). For this reason, the comparison and discussion of the case studies in this section are focused only between the PNEC[11]$_{soil}$ (EC TGD, 2003) and the SGV derived according to our recommendations. The two types of soil protection values resulting from the two case studies for diuron and fluazinam are shown in Table 2.

Table 2: Summary table with the results obtained after the application of the EC TGD (2003) methodology (see description of the derivation process in Marti-Roura et al. 2023, Appendix 2) and of the methodology for deriving SGVs recommended in this report to the case studies diuron and fluazinam (see Appendix 1 of the current report). Values are normalized to 3.4 % of organic matter content. The extrapolation approach used for the derivation (deterministic or distribution method) is shown in brackets. The assessment factor used for the derivation is shown next to the values. Abbreviations: norm. = normalized, OM = organic matter, AF method = deterministic (assessment factor) method, SSD method = species sensitivity distribution method.

Methodology	**Soil protection value**	**Diuron mg a.s./kg d.w. (norm. to 3.4. % OM)**	**Assessment Factor**	**Fluazinam mg a.s./kg d.w. (norm. to 3.4. % OM)**	**Assessment Factor**
SGV proposal	SGV	0.00095 (SSD method)	5	0.008 (AF method)	50
EC TGD (2003)	PNEC$_{soil}$	0.00015 (AF method)	10	0.008 (AF method)	50

4.1 Diuron

The SGV was around 6 times higher than the PNEC$_{soil}$. This difference was primarily caused by excluding data from vegetative vigor tests. According to the goal of the SGV, only the effect of PPP residues in the soil should be considered. Thus, it was suggested in section 2.2.1 of this report, to include only tests performed with soil exposure, since other exposure pathways would not be representative of the exposure conditions in the field. Therefore, only seedling emergence tests (soil application) were considered (see further information in Appendix 1). Because for diuron, toxicity values from seedling emergence were higher than the ones from vegetative vigor

[11] Predicted No Effect Concentration

(see Table A2.2 in Marti-Roura et al. (2023)), the SGV was higher than the $PNEC_{soil}$, which included vegetative vigor tests.

An additional difference between the $PNEC_{soil}$ and the SGV derivation, was the use of the distribution method (SSD) for the SGV as a result of the application of more realistic minimum data requirements for soil ecotoxicological data. On the other hand, for the $PNEC_{soil}$, only the deterministic (AF) method could be applied. While the deterministic method focuses on the most sensitive species only, the use of the distribution method provides a better overview of the overall sensitivity across the species (plants and soil invertebrates) and reduces the uncertainty of the assessment, since a lower AF can be applied.

4.2 Fluazinam

For fluazinam, the obtained SGV and the $PNEC_{soil}$ were exactly the same. The only difference in the dataset was, like for diuron, the exclusion of vegetative vigor plant studies for the derivation of SGV. However, this did not influence the results, since in this case, only the deterministic approach could be used and plants were not the most sensitive organisms. For the two methodologies, the same extrapolation method for direct toxicity (deterministic) was applied, resulting in identical soil protection values.

5 Conclusions and outlook

The proposed list of recommendations intends to provide guidance for the derivation of Soil Guideline Values (SGV) for the protection of long-term soil fertility, mediated by soil organisms, from PPP residues in the soil.

The data quality assessment is an essential step, so that the final SGV can represent, as best as possible, the effects of PPP residues on in-soil organisms and plants in in-crop areas. The scarcity of soil effect data is a recognized long-standing problem. However, and within the limited possibilities, a selection of data with the focus on effects caused by PPP residues (not PPP application) should be performed. Also, for a retrospective soil risk assessment, a methodology that allows the integration of different types of data and extrapolation methods and accounts for different scenarios depending on the quality and quantity of data is an asset.

The case studies (diuron and fluazinam) applied with the recommendations, when compared to the derivation process by strictly using the EC TGD, showed: 1) a better representation of the dataset with effects linked to PPP residues in the soil (rather than PPP application), e.g., by excluding data which does not represent soil exposure; 2) the possibility of using a more robust extrapolation method (i.e. the distribution approach) for the SGV derivation, hence decreasing the uncertainty of the overall assessment.

The use of generic SGVs as a first step in the screening of sites at potential risk can be a very useful economical and time efficient tool. However, the unique use of the SGV for the risk assessment presents some limitations and the overall comprehension of how PPP residues may affect soil organisms in the field may be not fully represented. Therefore, a combined approach with the use of bioindicators in order to better understand the influence of other relevant factors like the interaction of the PPP residues with the soil matrix, the agricultural practices and the environmental conditions is recommended. The validation of the SGVs and the bioindicators is recommended, once more data is generated and field and laboratory assessments are performed.

6 References and attributions

Bornand C., Gygax A., Juillerat P., Jutzi M., Möhl A., Rometsch S., Sager L., Santiago H., Eggenberg S. (2016). Rote Liste Gefässpflanzen. Gefährdete Arten der Schweiz. Bundesamt für Umwelt, Bern und Info Flora, Genf. Umwelt-Vollzug Nr. 1621: 178 S.

Boutin, C., Aya, K. L., Carpenter, D., Thomas, P. J., & Rowland, O. (2012). Phytotoxicity testing for herbicide regulation: Shortcomings in relation to biodiversity and ecosystem services in agrarian sys-tems. Science of the Total Environment, 415, 79–92. https://doi.org/10.1016/j.scitotenv.2011.04.046

Boutin, C., Elmegaard, N., & Kjær, C. (2004). Toxicity testing of fifteen non-crop plant species with six herbicides in a greenhouse experiment: Implications for risk assessment. Ecotoxicology, 13(4), 349–369. https://doi.org/10.1023/B:ECTX.0000033092.82507.f3

Brock, T., Bigler, F., Frampton, G., Hogstrand, C., Luttik, R., Martin-Laurent, F., Topping, C. J., van der Werf, W., & Rortais, A. (2018). Ecological Recovery and Resilience in Environmental Risk As-sessments at the European Food Safety Authority. Integrated Environmental Assessment and Man-agement, 14(5), 586–591. https://doi.org/10.1002/ieam.4079

Briones, M., Carreira, J., & Ineson, P. (1998). Cognettia sphagnetorum (Enchytraeidae) and nutrient cycling in organic soils: a microcosm experiment. Applied Soil Ecology, 9, 289–294.

Bronick, C. J., & Lal, R. (2005). Soil structure and management: A review. Geoderma, 124(1–2), 3–22. https://doi.org/10.1016/j.geoderma.2004.03.005

Campiche, S., Wong, J.W.Y., Marti-Roura, M., Dell'Ambrogio, G., Ferrari, B.J.D. (2020). Concept for long-term biomonitoring of residues from plant protection products within the monitoring measure of the Swiss Action Plan on plant protection products. WP1: Substance selection for Soil Guideline Value (SGV) derivation – selection criteria and procedure. Swiss Centre for Applied Ecotoxicology, Lau-sanne, Switzerland.

Carpenter, D., & Boutin, C. (2010). Sublethal effects of the herbicide glufosinate ammonium on crops and wild plants: Short-term effects compared to vegetative recovery and plant reproduction. Ecotoxi-cology, 19(7), 1322–1336. https://doi.org/10.1007/s10646-010-0519-7

CCME. (2006). A Protocol for the Derivation of Environmental and Human Health Soil Quality Guide-lines. In Canadian Council of Ministers of the Environment.

Chiaia-Hernandez, A. C., Keller, A., Wächter, D., Steinlin, C., Camenzuli, L., Hollender, J., & Krauss, M. (2017). Long-Term Persistence of Pesticides and TPs in Archived Agricultural Soil Samples and Comparison with Pesticide Application. Environmental Science and Technology, 51(18), 10642–10651. https://doi.org/10.1021/acs.est.7b02529

Clark, J., Ortego, L. S., & Fairbrother, A. (2004). Sources of variability in plant toxicity testing. Chemosphere, 57(11), 1599–1612. https://doi.org/10.1016/j.chemosphere.2004.07.044

Dechaine, J., Ruan, H., Sanchez-De Leon, Y., & Zou, X. (2005). Correlation between earthworms and plant litter decomposition in a tropical wet forest of Puerto Rico. Pedobiologia, 49(6), 601–607. https://doi.org/10.1016/j.pedobi.2005.07.006

Dell'Ambrogio, G., Renaud, M., Campiche, S., Marti-Roura, M., Ferrari, B.J.D. (2023). Selection of a bioindicator toolbox for monitoring effects of plant protection products residues. Part 1 – Linking eco-logical soil functions and soil organisms. Swiss Centre for Applied Ecotoxicology, Dübendorf and Lau-sanne, Switzerland; 56 p.

EC SANCO. (2002). Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC - SANCO/10329/2002 rev 2 final, European Commission.

ECHA. (2017). Guidance on information requirements and chemical safety assessment. Chapter R.7c: Endpoint specific guidance. Version 3.0.

EC TGD. (2003). Technical Guidance Document on Risk Assessment (part II). European Commis-sion. Joint Research Centre. EUR 20418 EN/2. https://publications.jrc.ec.europa.eu/repository/handle/JRC23785

EFSA. (2019). Outcome of the pesticides peer review meeting on general recurring issues in ecotoxi-cology. Authors: Arena M. et al.

EFSA PPR Panel. (2010). Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002), EFSA J. 8 1–55. https://doi.org/10.2903/j.efsa.2010.1821.

EFSA PPR Panel. (2014). Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target terrestrial plants. In EFSA Journal: Vol. 12(7) (Issue 3800). https://doi.org/10.2903/j.efsa.2014.3800

EFSA PPR Panel. (2017). Scientific Opinion addressing the state of the science on risk assessment of plant protection products for in-soil organisms. In European Food Safety Authority Journal: Vol. 15(2) (Issue 4690). https://doi.org/10.2903/j.efsa.2017.4690

Ehlers, L. j., & Luthy, R. G. (2003). Contaminant bioavailability in soil and sediment. Environmental Science & Technology, 37(15), 295–302. https://doi.org/10.1017/9780511895562.006

European Commission. (2009). Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. Official Journal of the European Union, L 309, 1–50. https://doi.org/10.3000/17252555.L_2009.309.eng

European Commission. (2011). COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. Official Jour-nal of the European Union, L 155, 127–175.

European Commission. (2013a). COMMISSION REGULATION (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, Official Journal of the European Union.

European Commission (2013b). COMMISSION REGULATION (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) of the European Parliament and of the Council concerning the placing of plant protection products on the market, Official Journal of the European Union.

European Commission. (2020). A Farm to Fork Strategy for a Fair, Healthy and Environmentally-Friendly Food System. COM(2020) 381 Final. Brussels: European Commission. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0381

European Commission. (2021a). EU Biodiversity Strategy for 2030: bringing nature back into our lives. Publications Office of the European Union. https://data.europa.eu/doi/10.2779/677548

European Commission. (2021b). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. EU Soil Strategy for 2030: Reaping the benefits of healthy soils for people, food, nature and climate. COM(2021) 699 Final. Brussels: European Commission. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0699

Faber, J. H., Marshall, S., Van den Brink, P. J., & Maltby, L. (2019). Priorities and opportunities in the application of the ecosystem services concept in risk assessment for chemicals in the environment. Science of the Total Environment, 651, 1067–1077. https://doi.org/10.1016/j.scitotenv.2018.09.209

Filmon, M. N., Voia, S. O., Vladoiu, D. L., Isvoran, A., & Ostafe, A. (2015). Temperature dependent effect of difenoconazole on enzymatic activity from soil J. Serb. Chem. Soc. 80 (9) 1127–1137 https://doi.org/10.2298/JSC141218030F

Filser, J. (2002). The role of Collembola in carbon and nitrogen cycling in soil. Pedobiologia, 46(3–4), 234–245. https://doi.org/10.1078/0031-4056-00130

Forbes, V. E., & Calow, P. (2002). Species sensitivity distributions revisited: a critical appraisal. Hu-man and Ecological Risk Assessment, 8, 473–492.

Frampton, G. K., Jänsch, S., Scott-Fordsmand, J. J., Römbke, J., & Van den Brink, P. J. (2006). Effects of pesticides on soil invertebrates in laboratory studies: A review and analysis using species sensitivity distributions. Environmental Toxicology and Chemistry, 25, 2480.

Gobat, J. M., Aragno, M., & Matthey, W. (2010). Le sol vivant: Bases de pédologie, biologie des sols. 3ème edition revue et augmentée. Presses polytechniques et universitaires romandes, Lausanne.

Godbersen, L., Wächter, D., Bucheli, T., Wong, J., Campiche, S., Walder, F., Gubler, A. (2019). Concept proposal for a long-term monitoring of residues from plant protection products in soil. Report commissioned by the Federal Office for the Environment (FOEN) and the Federal Office for Agriculture (FOAG).

Haegerbaeumer, A., Raschke, R., Reiff, N., Traunspurger, W., & Höss, S. (2019). Comparing the effects of fludioxonil on non-target soil invertebrates using ecotoxicological methods from single-species bioassays to model ecosystems. Ecotoxicology and Environmental Safety, 183. https://doi.org/10.1016/j.ecoenv.2019.109596

ISO 1268-3. (2014). Soil quality - Effects of pollutants on earthworms - Part 3: Guidance on the de-termination of effects in field situations

ISO 22030. (2005). Soil quality - Biological methods - Chronic toxicity in higher plants.

Ketterings, Q. M., Blair, J. M., & Marinissen, J. C. Y. (1997). Effects of earthworms on soil aggregate stability and carbon and nitrogen storage in a legume cover crop agroecosystem. Soil Biology and Biochemistry, 29(3–4), 401–408. https://doi.org/10.1016/S0038-0717(96)00102-2

Klimisch, H.-J., Andreae, M., Tillmann, U., 1997. A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Regulatory Toxicology and Pharmacology 25, 1–5.

Marti-Roura, M., Dell'Ambrogio, G., Campiche, S., Wong, J., Junghans, M., Renaud, M., Ferrari, B.J.D. (2023). Methodology proposal for the derivation of Soil Guideline Values for Plant Protection Product residues. Part 1 - Review and comparison of international methodologies. Swiss Centre for Applied Ecotoxicology, Dübendorf and Lausanne, Switzerland; 156 pp.

McKelvey, R. A., Wright, J. P., & Honegger, J. L. (2002). A comparison of crop and non-crop plants as sensitive indicator species for regulatory testing. Pest Management Science, 58(12), 1161–1174. https://doi.org/10.1002/ps.504

Meuli, R. G., Schwab, P., Wächter, D., & Ammann, S. (2014). Nationale Beodenbeobachtung (NABO) 1985-2004. Zustand und Veränderung der anorganischen Schadstoffe und Bodenbegleitparameter. Bundesamt für Umwelt, Bern. Umwelt-Wissen Nr. 1409: 94 S.

MOE (2007). Rationale for the Development of Generic Soil and Groundwater Standards for Use at Contaminated Sites in Ontario, Ontario Ministry of the Environment.

Moermond, C. T. A., Kase, R., Korkaric, M., & Ågerstrand, M. (2016). CRED: Criteria for reporting and evaluating ecotoxicity data. Environmental Toxicology and Chemistry, 35(5), 1297–1309. https://doi.org/10.1002/etc.3259

NEPC. (2013). Schedule B5b - Guideline on Methodology to Derive Ecological Investigation Levels in Contaminated Soils. In National Environment Protection (Assessment of Site Contamination) Measure May 2013.

Newman, M. C., Ownby, D. R., Mezin, L. C. A., Powell, D. C., Christensen, T. R. L., Lerberg, S. B., & Anderson, B. A. (2000). Applying species sensitivity distributions in ecological risk assessment: as-sumptions of distribution type and sufficient number of species. Environmental Toxicology and Chem-istry, 19, 508–515.

OECD. (2006a). OECD Guidelines for the Testing of Chemicals, No. 208 - Terrestrial Plant Test: Seedling Emergence and Seedling Growth Test. In Organisation for Economic Co-operation and De-velopment. https://doi.org/10.1787/9789264070066-en

OECD. (2006b). OECD Guidelines for the Testing of Chemicals, No. 227 - Terrestrial Plant Test: Veg-etative Vigour Test. In Organisation for Economic Co-operation and Development. https://doi.org/10.1787/20745761

Pennington, D. W. (2003). Extrapolating ecotoxicological measures from small data sets. Ecotoxicolo-gy Environmental Safety, 56(238–250).

Ren, X., Zeng, G., Tang, L., Wang, J., Wan, J., Liu, Y., Yu, J., Yi, H., Ye, S., & Deng, R. (2018). Sorption, transport and biodegradation – An insight into bioavailability of persistent organic pollutants in soil. Science of the Total Environment, 610–611, 1154–1163. https://doi.org/10.1016/j.scitotenv.2017.08.089

Renaud, M., Chelinho, S., Alvarenga, P., Mourinha, C., Palma, P., Sousa, J. P., & Natal-da-Luz, T. (2019). Exploring the Use of Species Sensitivity Distributions to Define Protective Limits for the Use of Organic Wastes as Soil Amendments. Environmental Toxicology and Chemistry, 38(7), 1569–1576. https://doi.org/10.1002/etc.4442

Riedo, J., Wettstein, F. E., Rösch, A., Herzog, C., Banerjee, S., Büchi, L., Charles, R., Wächter, D., Martin-Laurent, F., Bucheli, T. D., Walder, F., & van der Heijden, M. G. A. (2021). Widespread Occur-rence of Pesticides in Organically Managed Agricultural Soils—the Ghost of a Conventional Agricultur-al Past? Environmental Science & Technology. https://doi.org/10.1021/acs.est.0c06405

RIVM. (1997). Maximum Permissible Concentrations and Negligible Concentrations for pesticides. Authors: T. Crommentuijn, D.F. Kalf, M.D. Polder, R. Posthumus, E.J. Van de Plassche. In National Institute for Public Health and the Environment.

RIVM. (2006). A guidance document of the Dutch Platform for the Assessment of Higher Tier Studies - Guidance for summarising earthworm field studies - Authors: F.M.W. de Jong, P. van Beelen, C.E. Smit, M.H.M.M. Montforts. www.rivm.nl/bibliotheek/601506006.pdf

RIVM. (2007). Guidance for the derivation of environmental risk limits within the framework of 'Inter-national and national environmental quality standards for substances in the Netherlands' (INS). Au-thors: P.L.A. van Vlaardingen and E.M.J. Verbruggen. In National Institute for Public Health and the Environment.

RIVM. (2010). A guidance document of the Dutch Platform for the Assessment of Higher Tier Studies. Guidance for summarising and evaluating field studies with non-target arthropods. Authors: F.M.W. de Jong, F.M. Bakker, K. Brown, C.J.T.J. Jilesen, C.J.A.M. Posthuma-Dood.

Scholz-Starke, B., Nikolakis, A., Leicher, T., Lechelt-Kunze, C., Heimbach, F., Theien, B., Toschki, A., Ratte, H. T., Schäffer, A., & Ro-Nickoll, M. (2011). Outdoor Terrestrial Model Ecosystems are suitable to detect pesticide effects on soil fauna: Design and method development. Ecotoxicology, 20(8), 1932–1948. https://doi.org/10.1007/s10646-011-0732-z

Schrader, S., & Zhang, H. (1997). Earthworm casting: stabilization or destabilization of soil structure? Soil Biology & Biochemistry, 29, 469–475.

Silva, V., Mol, H. G. J., Zomer, P., Tienstra, M., Ritsema, C. J., & Geissen, V. (2019). Pesticide resi-dues in European agricultural soils – A hidden reality unfolded. Science of the Total Environment, 653, 1532–1545. https://doi.org/10.1016/j.scitotenv.2018.10.441

Smolders, E., Oorts, K., Van Sprang, P., Schoeters, I., Janssen, C. R., McGrath, S. P., & McLaugh-lin, M. J. (2009). Toxicity of trace metals in soil as affected by soil type and aging after contamination: Using calibrated bioavailability models to set ecological soil standards. Environmental Toxicology and Chemistry, 28(8), 1633–1642. https://doi.org/10.1897/08-592.1

Steiger, U., Knüsel, P., & Rey, L. (2018). Die Ressource Boden nachhaltig nutzen. Nationales For-schungs-programm NFP 68 Gesamtsynthese. Schweizeruscher Nationalfonds zur Förderung der wissenschaftlichen Forschung (SNF).

Stevens, D. P., McLaughlin, M. J., & Heinrich, T. (2003). Determining toxicity of lead and zinc runoff in soils: Salinity effects on metal partitioning and on phytotoxicity. Environmental Toxicology and Chemis-try, 22(12), 3017–3024. https://doi.org/10.1897/02-290

Swartjes, F. A., Rutgers, M., Lijzen, J. P. A., Janssen, P. J. C. M., Otte, P. F., Wintersen, A., Brand, E., & Posthuma, L. (2012). State of the art of contaminated site management in The Netherlands: Policy framework and risk assessment tools. Science of the Total Environment, 427–428, 1–10. https://doi.org/10.1016/j.scitotenv.2012.02.078

Swiss Federal Council. (2017). Aktionsplan zur Risikoreduktion und nachhaltigen Anwendung von Pflanzenschutzmitteln. Bericht des Bundesrates.

Swiss Federal Council. (2020a). Swiss Ordinance relating to Impacts on the Soil (OIS) of 1st July 1998 (Status as of 12th April 2016).

Swiss Federal Council. (2020b). Bodenstrategie Schweiz für einen nachhaltigen Umgang mit dem Boden, Umweltinfo, 64. https://www.bafu.admin.ch/bafu/de/home/themen/ boden/publikationen-studien/publikationen/bodenstrategie-schweiz.html.

Umweltbundesamt (UBA). (2020a). Evaluation of the risk for soil organisms under real conditions - Development of a national position for amending downstream legislations of the new EU Plant Protec-tion Products Regulation - Final Report - Authors:Andreas Toschki, Monika Hammers-Wirtz, Cl.

Umweltbundesamt (UBA). (2020b). Necessary adaptations for a harmonized field-testing procedure and risk assessment of earthworms (terrestrial) - Final report - Authors: Jörg Römbke, Bernhard Föster, Stephan Jänsch, Floria Kaiser, Adam Scheffczyk, Martina Ross-Nickoll, Benjamin Daniels.

US EPA. (2005). Guidance for Developing Ecological Soil Screening Levels. OSWER Directive 9285.7-55. Revised February 2005. In U.S. Enviromental Protection Agency (Issue February).

US EPA. (2012a). Early seedling growth toxicity test. OCSPP 850.4230. EPA 712-C-010, Washington, DC.

US EPA. (2012b). Vegetative vigor. OCSPP 850.4150. EPA 712-C-011, Washington, DC.

van Eekeren, N., Bommelé, L., Bloem, J., Schouten, T., Rutgers, M., de Goede, R., Reheul, D., & Brussaard, L. (2008). Soil biological quality after 36 years of ley-arable cropping, permanent grassland and permanent arable cropping. Applied Soil Ecology, 40(3), 432–446. https://doi.org/10.1016/j.apsoil.2008.06.010

van Gestel, C. A. M., Mommer, L., Montanarella, L., Pieper, S., Coulson, M., Toschki, A., Rutgers, M., Focks, A., & Römbke, J. (2020). Soil Biodiversity: State-of-the-Art and Possible Implementation in Chemical Risk Assessment. In Integrated Environmental Assessment and Management. John Wiley & Sons, Ltd. https://doi.org/10.1002/ieam.4371

Vašíčková, J., Hvězdová, M., Kosubová, P., & Hofman, J. (2019). Ecological risk assessment of pes-ticide residues in arable soils of the Czech Republic. Chemosphere, 216, 479–487. https://doi.org/10.1016/j.chemosphere.2018.10.158

Water Framework Directive (WFD). (2000). Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy.

Wheeler, J. R., Grist, E. P. M., Leung, K. M. Y., Morritt, D., & Crane, M. (2002). Species sensitivity distributions: Data and model choice. Marine Pollution Bulletin, 45, 192–202.

White, A. L., & Boutin, C. (2007). Herbicidal effects on nontarget vegetation: Investigating the limita-tions of current pesticide registration guidelines. Environmental Toxicology and Chemistry, 26(12), 2634–2643. https://doi.org/10.1897/06-553.1

Wilby, A., & Thomas, M. B. (2002). Natural enemy diversity and pest control: Patterns of pest emer-gence with agricultural intensification. Ecology Letters, 5(3), 353–360. https://doi.org/10.1046/j.1461-0248.2002.00331.x

Xu, T., Miao, J., Chen, Y., Yin, D., Hu, S., & Sheng, G. D. (2020). The long-term environmental risks from the aging of organochlorine pesticide lindane. Environment International, 141(April), 105778. https://doi.org/10.1016/j.envint.2020.105778

Attributions

Icons from Figure 2 were designed by DinosoftLabs (wheat and tree), Good Ware (grass) and Freepik (bush) from www.flaticon.com.

7 Abbreviations

AF	Assessment Factor
AP-PPP	Action Plan for Plant Protection Products
CCME	Canadian Council of Ministers of the Environment
CEC	Cation Exchange Capacity
CRED	Criteria for Reporting and Evaluating Ecotoxicity Data
EC TGD	European Technical Guidance Document on Risk Assessment
$EC_{(x)}$	Effect Concentration (causing x % of effect)
ECHA	European Chemicals Agency
EC DAR	European Commission Draft Assessment Report
EC DRAR	European Commission Draft Renewal Assessment Report
EC RAR	European Commission Renewal Assessment Report
EC TGD	European Technical Guidance Document on Risk Assessment
EFSA	European Food and Safety Authority
EFSA PPR Panel	EFSA Panel on Plant Protection Products and their Residues
FOAG	Federal Office for Agriculture
FOEN	Federal Office for the Environment
$HC_{(x)}$	Hazardous Concentration (for x % of species)
$IC_{(x)}$	Inhibitory Concentration (causing x % of inhibition)
ISO	International Organization for Standardization
Kd	Soil adsorption coefficient
Koc	Octanol/Carbon partition coefficient
$LC_{(x)}$	Lethal Concentration (causing x % of lethality)
LOEC	Lowest Observed Effect Concentration
NABO	Swiss Soil Monitoring Network (Nationale Bodenbeobachtung, Agroscope-NABO)
NEPC	National Environment Protection Council (Australia)
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
NOER	No Observed Effect Rate
NTTP	Non-Target Terrestrial Plants
OECD	Organization for Economic Co-operation and Development
OM	Organic Matter
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration (Europe)
POP	Persistent Organic Pollutant
PPP	Plant Protection Product
RAC	Regulatory Acceptable Concentration (Europe)
RIVM	National Institute for Public Health and the Environment (The Netherlands)
RMS	Rapporteur Member State
SGV	Soil Guideline Value (Switzerland)
SSD	Species Sensitivity Distribution

TME	Terrestrial Model Ecosystems
US EPA	United States Environmental Protection Agency
WHC	Water Holding Capacity

8 Glossary

Adverse effect	Change in the morphology, physiology, growth, development, reproductive output or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.
Assessment	Evaluation or appraisal of an analysis of facts and the inference of possible consequences concerning a particular object or process.
Assessment factor	Numerical adjustment used to extrapolate from experimentally determined (dose-response) relationships to estimate the agent exposure below which an adverse effect is not likely to occur.
Bioaccumulation	Net result of the uptake, distribution and elimination of a substance in an organism due to exposure through all routes, i.e., air, water, soil and food.
Dose–response assessment	Analysis of the relationship between the total amount of an agent administered to, taken up by, or absorbed by an organism, system, or (sub)population and the changes developed in that organism, system, or (sub)population in reaction to that agent, and inferences derived from such an analysis with respect to the entire population.
Effect	Change in the state or dynamics of an organism, system, or (sub)population caused by the exposure to an agent.
Effect assessment	Combination of analysis and inference of possible consequences of the exposure to a particular agent based on knowledge of the dose-effect relationship associated with that agent in a specific target organism, system, or (sub)population.
Endpoint	Measurable (ecological) characteristic that is related to the valued characteristic chosen as an assessment point.
Expert judgement	Opinion of a person with extensive expertise in a particular subject.
Exposure	Concentration or amount of a particular agent that reaches a target organism, system, or (sub)population in a specific frequency for a defined duration.
Generic (value)	Indicating that a potential risk might occur. Generic values are not specific to a particular site and are meant to be applicable to all sites independent of their characteristics.
Habitat function (soil)	The ability of soil to sustain organisms and to maintain the diversity of ecosystems, species and their gene pool. The habitat function also covers soil's suitability as a habitat for organisms and as a location for plants.
Hazard	Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system, or (sub)population is exposed to that agent.
Hazard assessment	A process designed to determine the possible adverse effects of an agent or situation to which an organism, system, or (sub)population could be exposed. The process includes hazard identification and hazard characterization. The process focuses on the hazard, in contrast to risk assessment, where exposure assessment is a distinct additional step.

In-crop area	Areas where a crop is grown, which can follow either a natural (e.g., vegetables, cereals), or a systematic spatial heterogeneity (e.g., orchards, vineyards) (see Figure 3).

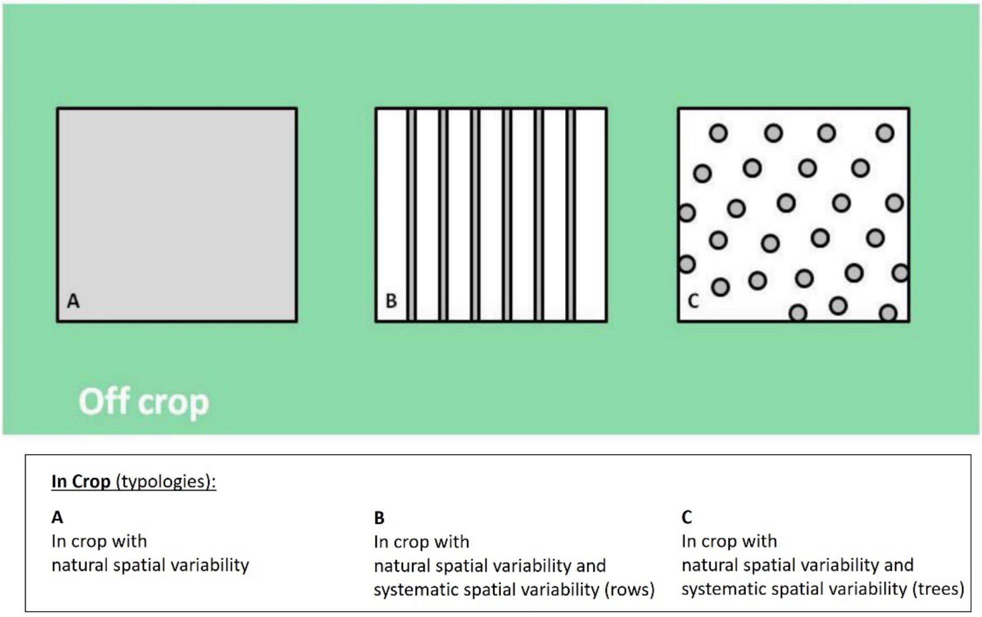


Figure 3: Typologies of in-crop areas as defined in EFSA PPR Panel (2010), colours represent different spatial heterogeneity patterns, grey: cultivated area in-crop, white: uncultivated space in-crop, green: off-crop.

In-soil organisms	Species that dwell primarily in the soil and soil litter (including soil invertebrates and microorganisms) (EFSA PPR Panel, 2017).
Intermediate risk	Situation, defined by a specific contaminant concentration, where potentially adverse effects to exposed organisms cannot be excluded. This concentration commonly triggers further investigations and is often defined as trigger or screening value.
Long-term exposure	Duration of exposure to a contaminant that usually last from several weeks to years. Common long-term effects influence reproductive output, growth or other endpoints observable during the life cycle of the test organism. Often referred to as chronic exposure. Although a clear definition varies from study to study, these tests usually produce NOEC, LOEC or EC/ICx values.
Negligible risk	Situation, defined by a specific contaminant concentration, where adverse effects to exposed organisms cannot be excluded on the long- term. This concentration commonly triggers no or limited action and is often defined as target value.
Prospective risk assessment	Risk assessment approach aiming at predicting the impact that a compound might cause, following a planned activity or release. It is applied in the context of authorization and registration of chemical substances. In this approach, effect concentrations are compared to predicted environmental concentrations.
Production function (soil)	The ability of soil to produce biomass, i.e., food and feedstuffs, as well as wood and other fibers.
Regulating function (soil)	The ability of soil to regulate, buffer or filter water and energy cycles, as well as to transform substances.

Retrospective risk assessment	Risk assessment approach aiming at assessing the quality of a given site. It addresses effects that might have already occurred at a site following an exposure to a given substance after its release. In this approach, effect concentrations are compared to measured environmental concentrations.
Risk	The probability of an adverse effect in an organism, system, or (sub)population caused under specified circumstances by exposure to an agent.
Risk assessment	A process intended to calculate or estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system. The risk assessment process includes four steps: hazard identification, hazard characterization (related term: Dose– response assessment), exposure assessment, and risk characterization. It is the first component in a risk analysis process.
Risk level	Intensity of the risk expected to occur, due to a specific concentration of a contaminant in the medium. Risk levels can be commonly classified as negligible (1), intermediate (2), and unacceptable (3).
Screening value	In this report, this is intended as a generic limit concentration of a substance in the soil which, if exceeded, is expected to cause an intermediate risk to potentially exposed organisms and which generally triggers further investigations.
Short-term exposure/effect	Duration of exposure to a contaminant that usually rapidly induce an effect. A common short-term effect is mortality. Often referred to as an acute exposure. Although a clear definition varies from study to study, these tests usually produce EC50/LC50 values.
Site-specific (value)	addressing the risk for a particular site or location. Site-specific values are adapted, usually from generic values, to site-specific use patterns and characteristics including soil properties and environmental conditions.
Soil Guideline Values	Soil protection values that must be derived for PPPs in the context of the Swiss AP-PPP.
Soil protection value	Generic term describing any limit concentration of a substance in the soil, which is expected to cause no or little harm to potentially exposed organisms. Usually expressed in mg active substance/kg soil dry weight (= mg a.s. / kg d.w.).
Soil fertility	The capacity of a soil to ensure that 1) a biologically active community, as well as soil characteristic properties are typical for its location; and 2) natural and man-influenced plants and plant communities are able to grow and develop undisturbed. Soil fertility relies on three ecological soil functions provided by soil organisms, i.e., the habitat, the production, and the regulating function.
Soil quality	The capacity of a soil to function within ecosystem and land-use boundaries to sustain biological productivity, maintain environmental quality, and promote plant and animal health.
Toxicity	Inherent property of an agent to cause an adverse biological effect.

Trigger value	See screening value.
TRIAD approach	Risk assessment approach which combines chemical, ecological and ecotoxicological lines of evidence for one site of interest.
Unacceptable risk	Situation, defined by a specific contaminant concentration, where effects to exposed organisms are high. This concentration commonly triggers the need for actions, such as remediation activities and is often defined as clean-up value.
Uncertainty	Imperfect knowledge concerning the present or future state of an organism, system, or (sub)population under consideration.
Validation	Process by which the reliability and relevance of a particular approach, method, process or assessment is established for a defined purpose. Different parties define “Reliability” as establishing the reproducibility of the outcome of the approach, method, process, or assessment over time. “Relevance” is defined as establishing the meaningfulness and usefulness of the approach, method, process, or assessment for the defined purpose.

9 Indices

9.1 List of Figures

Figure 1: Scheme of the application of the combined approach with SGV and bioindicators. 2
Figure 2: Example of field and crop area definitions in arable crops with a field boundary within the field. 6
Figure 3: Typologies of in-crop areas as defined in EFSA PPR Panel (2010), colours represent different spatial heterogeneity patterns, grey: cultivated area in-crop, white: uncultivated space in-crop, green: off-crop. 35

9.2 **List of Tables**

Table 1 : Advantages and limitations of the main methodologies and applicability for the derivation of SGV for PPP residues in Swiss agricultural soils.. 14
Table 2: Summary table with the results obtained after the application of the EC TGD (2003) methodology (see description of the derivation process in Marti-Roura et al. 2023, Appendix 2) and of the methodology for deriving SGVs recommended in this report to the case studies diuron and fluazinam (see Appendix 1 of the current report). Values are normalized to 3.4 % of organic matter content. The extrapolation approach used for the derivation (deterministic or distribution method) is shown in brackets. The assessment factor used for the derivation is shown next to the values. Abbreviations: norm. = normalized, OM = organic matter, AF method = deterministic (assessment factor) method, SSD method = species sensitivity distribution method. 23

Appendix 1 Case studies

Table of Contents

1 Introduction 41
2 Case study for the herbicide diuron – proposal for SGV derivation 42
2.1 Data evaluation 42
2.2 Derivation of the SGV 47
3 Case study for the fungicide fluazinam – proposal for SGV derivation 51
3.1 Data evaluation 51
3.2 Derivation of the SGV 55
4 References 57

1 Introduction

The present appendix is intended to provide detailed information on how SGV could be derived according to the recommendations established in the main report[12]. SGV are derived for the same two substances evaluated in Marti-Roura (2023, Appendix 2), i.e., diuron and fluazinam. For an overview of the general data and the ecotoxicological data used for the present case study, please refer to the following sections of Marti-Roura (2023): Appendix 2: 1.1 and 1.2, for diuron, and 2.1 and 2.2, for fluazinam, respectively.

[12] Main report in this Appendix refers to “Methodology proposal for the derivation of Soil Guideline Values for Plant Protection Product residues. Part 2 - Recommendations for the derivation of Soil Guideline Values”.

2 Case study for the herbicide diuron - proposal for SGV derivation

2.1 Data evaluation

According to the recommendations in the main report, data on non-target soil invertebrates, microorganisms, and plants should be evaluated. All available studies for diuron were performed with non-target species and were retained for the derivation of the SGV. Tests performed with direct application on the aboveground parts of the plant, instead of soil application, should not be considered for the derivation of the SGV. Therefore, the results on vegetative vigor from the studies of Heldreth & McKelvey (1996) and of McKelvey & Kuratle (1992) (reported in the EC RAR (2018, Vol. 3 B9)) were not considered.

The quality assessment from the studies was based on the evaluation performed by the Rapporteur Member State (RMS) and no further assessment was performed for the acceptance of the studies. According to the recommendations in the current report, the most relevant toxicity parameters are NOEC, EC_x and/or LC_x and the preferred values are NOEC and/or EC_{10}. Only the values that were considered for SGV derivation are shown in Table A1.1.

According to our recommendations on how to derive SGV, if sufficient data is available, a comparison between the toxicity from tests conducted with the active substance and tests conducted with the formulation should be performed for the same species and endpoints. For diuron, studies with both the active substance and formulations were available for the same species and endpoint for only two plant species (shoot height for *A. cepa* and *Z. mays*). In addition, the duration of the test was slightly different between the tests with active substance and formulation (14 days and 21 days, respectively). For these reasons, a meaningful statistical comparison between formulation and active substance was not possible. However, since no indications of a difference in sensitivity between tests with the formulation and the active substance were detected, the data sets were combined for the SGV derivation.

According to the recommendations in the main report, the ecotoxicological data should be normalized to a standard organic matter (OM) content of 3.4 %. The toxicity values considered relevant for the SGV derivation, i.e., the lowest normalized NOEC/NOER values for each species, are highlighted in bold in Table A.1.

Table A1.1: Soil ecotoxicological data for diuron from EC RAR (2018). *Values resulting from calculations are rounded to two significant figures. The unit conversion and/or calculations are specific for the proposed methodology for deriving SGV. The data used for the SGV derivation is marked in bold. Abbreviations: Conc.=concentration, OC=organic carbon, OM=organic matter, CEC=cation exchange capacity, Appl. = application, a.s.=active substance, lb/ac=pounds/acre.*

Species & Taxonomic group	**Substance tested**	**Test type & Endpoint**	**Duration**	**Parameter**	**Appl. rates** (original units for plant studies in lb or g a.s.)	**Conc. mg a.s./kg d.w.**[13]	**Normalized conc. mg a.s./kg d.w., 3.4 % OM**[14]	**Soil type**	**Source**
Eisenia fetida/andrei (earthworm)	Karmex 80 WG (81.2 % a.s.)	Reproduction	56 days	NOEC	-	10.7	**3.6**	OECD soil: 10 % sphagnum peat, 20 % kaolin clay, 69 % industrial sand and approx. 1 % $CaCO_3$, pH 6.2-6.3	Stäbler, 2001 cited in EC RAR, 2018, Vol. 3 CP B9, p.103
Eisenia fetida (earthworm)	Diuron 80 % SC (63.45 % a.s.)	Survival, weight and reproduction	56 days	NOEC	-	> 31.678	> 10.8	Artificial soil: 10 % sphagnum peat, 20% kaolinite clay, 70 % industrial quartz sand and 0.14 % $CaCO_3$	Ansaloni, 2013 cited in EC RAR, 2018, Vol. 3 CP B9, p.104
Folsomia candida (collembolan)	Diuron 80 % SC (63.45 % a.s.)	Reproduction	28 days	NOEC	-	76.0	**52**	Artificial soil: 5 % sphagnum peat, 20 % kaolinite clay, 74.93 % quartz sand and 0.07 % $CaCO_3$, pH 6.33-6.83	Luna, 2013 cited in EC RAR, 2018, Vol. 3 CP B9, p.108
Hypoaspis aculeifer (mite)	Diuron 80 % SC (63.45 % a.s.)	Reproduction	14 days	NOEC	-	345	**235**	Artificial soil: 5 % sphagnum peat, 20 % kaolin clay, 74.93 % quartz sand and 0.07 % $CaCO_3$, pH 6.38-6.43	Ansaloni, 2013 cited in EC RAR, 2018, Vol. 3 CP B9, p.111
micro-organisms	a.s. (98.2 % purity)	Nitrogen transformation (nitrification)	91 days	10 % inhibition	-	10.7	26	loamy sand, pH 5.3 (KCl), carbon 0.83 % (soil collected at Laacherhod, Germany)	Blumenstock, 1989 cited in EC RAR, 2018 Vol. 3 CA B9, p.120
				25 % inhibition	-	53.3	128		
				3 % stimulation	-	10.7	**17**		

[13] The final results of the non-target terrestrial plant tests were given originally in lb/acre. To derive a SGV, values were converted to mg/kg d.w. following the recommendations from the ECHA (2017, p. 149): “If no information can be derived from the test, a default soil depth of 10 cm and soil density of 1500 kg/m³ dry soil should be used.”
[14] Conversion to a standard Swiss agricultural soil, defined as a soil with an organic matter content of 3.4% (corresponding to 2% organic carbon (main report, section 2.2.3)).

Species & Taxonomic group	Substance tested	Test type & Endpoint	Duration	Parameter	Appl. rates (original units for plant studies in lb or g a.s.)	Conc. mg a.s./kg d.w.[13]	Normalized conc. mg a.s./kg d.w., 3.4 % OM[14]	Soil type	Source
				29 % inhibition	-	53.3	87	loamy silt, pH 4.8 (KCl), carbon 1.23 %, nitrogen 0.17 (soil collected at Höfchen, Germany)	
		Carbon transformation (induced soil respiration)	91 days	2 % inhibition	-	10.7	26	loamy sand, pH 5.3 (KCl), carbon 0.83 % (soil collected at Laacherhod, Germany)	Anderson, 1989 cited in EC RAR, 2018, Vol. 3 CA B9, p.119
				16 % inhibition	-	53.3	128		
				7 % inhibition	-	10.7	17	loamy silt, pH 4.8 (KCl), carbon 1.23 %, nitrogen 0.17 (soil collected at Höfchen, Germany)	
				36 % inhibition	-	53.3	87		
Allium cepa (terrestrial plant)	a.s. (97.3 % purity)	Seedling emergence (shoot dry weight)	14 days	NOEL	0.0889 lb/ac	0.066	0.13	sandy loam, pH 6.3, 1.7 % OM, CEC=4.82 meq/100g	Heldreth & McKelvey, 1996 cited in EC RAR, 2018, Vol. 3 CA B9, p.130[15]
	Diuron 80 % SC (63.45 % a.s.)	Seedling emergence (biomass)	21 days	NOER	17.52 g/ha	0.012	**0.024**	loamy sand soil (75.28 % sand, 16 % silt, 8.27 % clay), 0.98 % organic carbon, pH 8.26	Gimeno, 2013b cited in EC RAR, 2018, Vol. 3 CP B9, p.123
Zea mays (terrestrial plant)	a.s. (96.8 % purity)	Seedling emergence (shoot height)	14 days	NOEL	0.75 lb/ac	0.56	1.1	sandy loam, pH 6.3, 1.7 % OM, CEC=4.82 meq/100g	McKelvey & Kuratle, 1992 cited in EC RAR, 2018, Vol. 3 CA B9, p.126
	Diuron 80 % SC (63.45 % a.s.)	seedling emergence (height)	21 days	NOER	17.52 g/ha	0.012	**0.024**	loamy sand soil (75.28 % sand, 16 % silt, 8.27 % clay), 0.98 % organic carbon, pH 8.26	Gimeno, 2013b cited in EC RAR, 2018, Vol. 3 CP B9, p.123
Triticum aestivum (terrestrial plant)	a.s. (97.3 % purity)	Seedling emergence (shoot dry weight)	14 days	NOEL	1.5 lb/ac	1.1	**2.2**	sandy loam, pH 6.3, 1.7 % OM, CEC=4.82 meq/100g	Heldreth & McKelvey, 1996 cited in EC RAR, 2018, Vol. 3 CA B9, p.130

[15] A study with non-target terrestrial plants from McKelvey & Kuratle (1992) was reported in the EC RAR (2018, Vol. 3 B9 P.126). Due to the use of standard greenhouse fumigants with some of the species tested that could influence the results, US EPA requested a re-test for those species. A new study from Heldreth & McKelvey (1996) was provided with the re-test. The Rapporteur Member State (RMS) concluded in the EC RAR (2018), that the second study supersedes the original data only for the species were fumigants were used or where a more reliable endpoint could be derived (EC RAR 2018 Vol.3 B9 p. 130).

Species & Taxonomic group	Substance tested	Test type & Endpoint	Duration	Parameter	Appl. rates (original units for plant studies in lb or g a.s.)	Conc. mg a.s./kg d.w.[13]	Normalized conc. mg a.s./kg d.w., 3.4 % OM[14]	Soil type	Source
Sorghum vulgare (terrestrial plant)	a.s. (96.8 % purity)	Seedling emergence (shoot height)	14 days	NOEL	0.75 lb/ac	0.56	**1.1**	sandy loam, pH 6.3, 1.7 % OM, CEC=4.82 meq/100g	McKelvey & Kuratle, 1992 cited in EC RAR, 2018, Vol. 3 CA B9, p.126
Beta vulgaris (terrestrial plant)	a.s. (97.3 % purity)	Seedling emergence (shoot dry weight)	14 days	NOEL	0.188 lb/ac	0.14	**0.28**	sandy loam, pH 6.3, 1.7 % OM, CEC=4.82 meq/100g	Heldreth & McKelvey, 1996 cited in EC RAR, 2018, Vol. 3 CA B9, p.130
Glycine max (terrestrial plant)	a.s. (96.8 % purity)	Seedling emergence (multiple endpoints)	14 days	NOEL	>12 lb/ac	>9.0	>18	sandy loam, pH 6.3, 1.7 % OM, CEC=4.82 meq/100g	McKelvey & Kuratle, 1992 cited in EC RAR, 2018, Vol. 3 CA B9, p.126
Brassica napus (terrestrial plant)	a.s. (97.3 % purity)	Seedling emergence (shoot dry weight)	14 days	NOEL	0.188 lb/ac	0.14	**0.28**	sandy loam, pH 6.3, 1.7 % OM, CEC=4.82 meq/100g	Heldreth & McKelvey, 1996 cited in EC RAR, 2018, Vol. 3 CA B9, p.130
Pisum sativum (terrestrial plant)	a.s. (96.8 % purity)	Seedling emergence (multiple endpoints)	14 days	NOEL	>12 lb/ac	>9.0	>18	sandy loam, pH 6.3, 1.7 % OM, CEC=4.82 meq/100g	McKelvey & Kuratle, 1992 cited in EC RAR, 2018, Vol. 3 CA B9, p.126
	Diuron 80 % SC (63.45 % a.s.)	Seedling emergence (mortality)	21 days	NOER	162 g/ha	0.11	**0.22**	loamy sand soil (75.28 % sand, 16 % silt, 8.27 % clay), 0.98 % organic carbon, pH 8.26	Gimeno, 2013b cited in EC RAR, 2018, Vol. 3 CP B9, p.123
Lycopersicon esculentum (Solanum lycopersicon) (terrestrial plant)	a.s. (97.3 % purity)	Seedling emergence (shoot dry weight)	14 days	NOEL	0.0938 lb/ac	0.070	**0.14**	sandy loam, pH 6.3, 1.7 % OM, CEC=4.82 meq/100g	Heldreth & McKelvey, 1996 cited in EC RAR, 2018, Vol. 3 CA B9, p.130
	Diuron 80 % SC (63.45 % a.s.)	Seedling emergence (biomass)	21 days	NOER	17.52 g/ha	0.012	**0.024**	loamy sand soil (75.28 % sand, 16 % silt, 8.27 % clay), 0.98 % organic carbon, pH 8.26	Gimeno, 2013b cited in EC RAR, 2018, Vol. 3 CP B9, p.123
Cucumis sativus (terrestrial plant)	a.s. (96.8 % purity)	Seedling emergence (shoot height)	14 days	NOEL	0.19 lb/ac	0.14	0.28	sandy loam, pH 6.3, 1.7 % OM, CEC=4.82 meq/100g	McKelvey & Kuratle, 1992 cited in EC RAR, 2018, Vol. 3 CA B9, p.126

Species & Taxonomic group	Substance tested	Test type & Endpoint	Duration	Parameter	Appl. rates (original units for plant studies in lb or g a.s.)	Conc. mg a.s./kg d.w.[13]	Normalized conc. mg a.s./kg d.w., 3.4 % OM[14]	Soil type	Source
	Diuron 80 % SC (63.45 % a.s.)	Seedling emergence (biomass)	21 days	NOER	162 g/ha	0.11	**0.22**	loamy sand soil (75.28 % sand, 16 % silt, 8.27 % clay), 0.98 % organic carbon, pH 8.26	Gimeno, 2013b cited in EC RAR, 2018, Vol. 3 CP B9, p.123
Lactuca sativa (terrestrial plant)	Diuron 80 % SC (63.45 % a.s.)	Seedling emergence (height)	21 days	NOER	36.72 g/ha	0.024	**0.050**	loamy sand soil (75.28 % sand, 16 % silt, 8.27 % clay), 0.98 % organic carbon, pH 8.26	Gimeno, 2013b cited in EC RAR, 2018, Vol. 3 CP B9, p.123
Brassica oleracea (terrestrial plant)	Diuron 80 % SC (63.45 % a.s.)	Seedling emergence (biomass, height)	21 days	NOER	77.12 g/ha	0.051	**0.10**	loamy sand soil (75.28 % sand, 16 % silt, 8.27 % clay), 0.98 % organic carbon, pH 8.26	Gimeno, 2013b cited in EC RAR, 2018, Vol. 3 CP B9, p.123
Daucus carota (terrestrial plant)	Diuron 80 % SC (63.45 % a.s.)	Seedling emergence (biomass, height)	21 days	NOER	340.16 g/ha	0.23	**0.46**	loamy sand soil (75.28 % sand, 16 % silt, 8.27 % clay), 0.98 % organic carbon, pH 8.26	Gimeno, 2013b cited in EC RAR, 2018, Vol. 3 CP B9, p.123
Hordeum vulgare (terrestrial plant)	Diuron 80 % SC (63.45 % a.s.)	Seedling emergence (biomass)	21 days	NOER	36.72 g/ha	0.024	**0.050**	loamy sand soil (75.28 % sand, 16 % silt, 8.27 % clay), 0.98 % organic carbon, pH 8.26	Gimeno, 2013b cited in EC RAR, 2018, Vol. 3 CP B9, p.123
Lolium perenne (terrestrial plant)	Diuron 80 % SC (63.45 % a.s.)	Seedling emergence (height)	21 days	NOER	17.52 g/ha	0.012	**0.024**	loamy sand soil (75.28 % sand, 16 % silt, 8.27 % clay), 0.98 % organic carbon, pH 8.26	Gimeno, 2013b cited in EC RAR, 2018, Vol. 3 CP B9, p.123

2.2 Derivation of the SGV

For diuron, data is available for 17 species and four taxonomic groups: Annelida (earthworms), Hexapoda (collembolans), Chelicerata (mites), and Plantae (terrestrial plants), as well as for two microbial mediated processes. Thus, following the proposal in the main report, the minimum data requirements to derive an SGV using the Species Sensitivity Distribution (SSD) would be fulfilled (at least 10 exact data points from at least 3 taxonomic groups). In addition, when an SSD can be performed, it is recommended to use in parallel the deterministic method and compare and discuss the final choice of the SGV. Therefore, SGV were derived, according to both the SSD and the deterministic method.

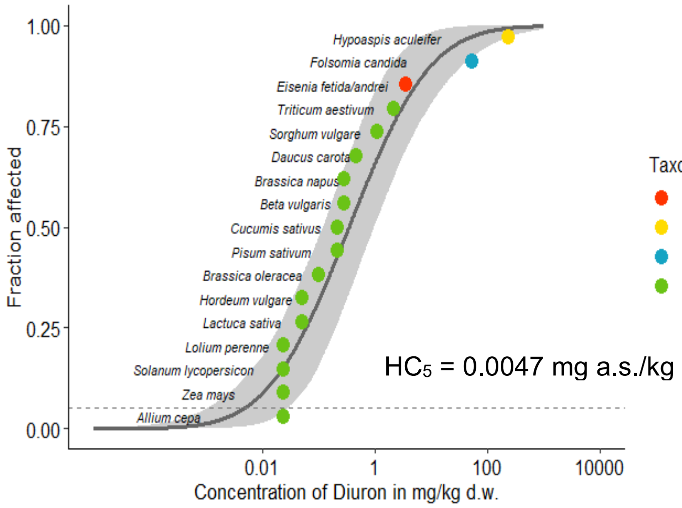
SSD method

The available data, which was considered for the SSD is listed in Table A1.2. Data on microbial-mediated processes, which provides information at a community level, should not be considered together with single-species tests because of fundamental differences between the two. The tests on nitrogen and carbon transformation were thus not retained for the SSD. Unbounded values were not included in the dataset and if more than one NOEC for the same organism but with different endpoint or test duration was available, the lowest value was selected. Data was plotted into a cumulative frequency distribution, which was fitted to a statistical log-normal model (Figure A1.1).

Table A1.2: List of species, taxonomic groups to which they belong and their corresponding NOEC. List sorted in ascending order according to the NOEC values.

Species	Taxonomic group	NOEC* (mg a.s./kg d.w.)
Allium cepa	Plantae	0.024
Zea mays	Plantae	0.024
Solanum lycopersicon	Plantae	0.024
Lolium perenne	Plantae	0.024
Lactuca sativa	Plantae	0.05
Hordeum vulgare	Plantae	0.05
Brassica oleracea	Plantae	0.1
Pisum sativum	Plantae	0.22
Cucumis sativus	Plantae	0.22
Beta vulgaris	Plantae	0.28
Brassica napus	Plantae	0.28
Daucus carota	Plantae	0.46
Sorghum vulgare	Plantae	1.1
Triticum aestivum	Plantae	2.2
Eisenia fetida/andrei	Annelida	3.6
Folsomia candida	Hexapoda	52
Hypoaspis aculeifer	Chelicerata	235

**Concentrations normalized to 3.4 % organic matter*



Results of the 5th percentile (HC_5)		
Value (mg a.s./kg d.w.)	**95 % Confi-dence interval**	**HC_5/$LLHC_5$**
0.00473	0.0008 - 0.0366	6.29

HC_5/$LLHC_5$: Spread between HC_5 and its lower confidence limit

Figure A1.1: SSD distribution of the effect data from Table A1.2 for diuron. The grey shadow corresponds to the 95 % confidence intervals.

The log-normal model showed a good fit of the distribution (Anderson-Darling, Kolmogorov-Smirnov, and Cramer con Mises tests; p-values = 0.736, 0.180 and 0.107, respectively). Therefore, the SSD was considered appropriate and the SGV was calculated using the following equation:

$$SGV = \frac{HC_5}{AF}$$

Where,

HC_5 = Hazardous concentration to 5 % of the tested species, corresponding to the 5th percentile of the SSD distribution [mg a.s./kg d.w. soil]

AF = Assessment Factor

The size of the AF should be between 1 and 5. According to the EC TGD (2003), an AF lower than 5 needs to be fully justified. The main points to consider for the choice of the AF are the overall quality of the database, the diversity and representativeness of the taxonomic groups (as well as the extent to which differences in the life forms, feeding strategies and trophic levels are represented), the knowledge on the presumed mode of action, statistical uncertainties around the 5th percentile estimated, and comparison of the 5th percentile with field and mesocosm studies.

The database represents relatively well the diversity of the taxonomic groups, since it covers four taxonomic groups and 17 different species. Since diuron is an herbicide, plants were expected to be the most sensitive organisms of the dataset. However, the only datapoint available for earthworms was very close to the highest values for plants. This suggests that diuron might exert similar toxicity to earthworms as to some plant species. More data on the sensitivity of earthworms would be needed to have a better knowledge on the toxicity of diuron to this taxonomic group. In addition, the ratio between the HC_5 and its lower confidence limit is relatively high (6.29), which might be an indication of statistical uncertainty. Due to these uncertainties, an AF of 5 was chosen for the derivation of the $SGV_{SSD\ method}$:

$$\boldsymbol{SGV_{SSD\ method}} = \frac{0.00473}{5} = 0.00095\ mg\ a.s./kg\ d.w. = \mathbf{0.95\ \mu g\ a.s./kg\ d.w.}$$

Data on microorganisms was not included in the SSD. However, the reported toxicity values for the carbon and nitrogen tests seemed to indicate that microorganisms are not among the most sensitive group of organisms and the $SGV_{SSD\ method}$ is thus expected to be protective enough for microbial communities.

Deterministic method

When using the deterministic method, the preferred toxicity value for the most sensitive species and endpoints for each trophic level should be selected. For tests on microorganisms, a NOEC can be derived according to the recommendations from ECHA (2017, p. 149). Thus, if at least one concentration shows no statistical difference from the control and has an effect value ≤ 15 %, that concentration is the NOEC. In both available studies on carbon and nitrogen transformation (from Blumenstock, 1989 and Anderson, 1989, respectively), two concentrations were tested and the lowest tested concentrations showed effects lower than 15 %. No significant differences between the lowest concentration and the control were found at the end of the experiment for the loamy silt soil in Blumenstock (1989) and, thus, that concentration was considered the NOEC. In the study from Anderson (1989), the statistical analysis was not reported and, consequently, it was not possible to know if the final values differed from the control or not. For this reason, the lowest concentration (after the normalization) corresponding to the loamy silt soil for N-mineralization was chosen as the most sensitive endpoint. Therefore, the proposed NOEC for microorganisms is 17 mg a.s./kg d.w.

The selected critical toxicity data for diuron is listed in Table A1.3.

Table A1.3: Critical toxicological data of the terrestrial organisms for diuron.

Group	Species & Endpoint	Parameter	Conc. in mg a.s./kg d.w.*	Reference
Primary producer	*Allium cepa, Lycopersicum esculentum* (seedling emergence: biomass), *Zea mays, Lolium perenne* (seedling emergence: height)	NOEL	0.024	Gimeno, 2013b cited in EC RAR, 2018, Vol. 3 CP B9, p.123
Decomposer (nutrient transformer)	Microorganisms - Nitrogen mineralization	NOEC	17	Anderson, 1989 cited in EC RAR, 2018, Vol. 3 B9 CA, p.120
Decomposer (litter transformer) / Primary consumer	*Eisenia fetida/andrei*	NOEC	3.6	Stäbler, 2001 cited in EC RAR, 2018, Vol. 3 B9 CP, p.103
	Folsomia candida	NOEC	52	Ansaloni, 2013 cited in EC RAR, 2018, Vol. 3 B9 CP, p.104
Consumer (Secondary consumer)	*Hypoaspis aculeifer*	NOEC	235	Ansaloni, 2013 cited in EC RAR, 2018, Vol. 3 B9, p.111

**Concentrations normalized to 3.4 % organic matter*

Since NOECs for at least three long-term toxicity tests from different groups of organisms are available, an AF of 10 can be applied. The lowest value available is a NOEC = 0.024 mg/kg d.w. for seedling emergence for the plants *A. cepa*, *Z. mays*, *L. esculentum*, and *L. perenne*, tested with the formulation Diuron 80 % SC (study from Gimeno et al. (2013b)). According to the deterministic method (AF method), this results in a $SGV_{AF\ method}$ of:

$$SGV_{AF\ method} = \frac{0.024}{10} = \mathbf{0.0024\ mg\ a.s./kg\ d.w.}$$

Final soil protection value

Two methods were tested and compared for the SGV derivation: the deterministic method (AF) and the distribution method (SSD). The SGVAF method was approximately 2.5-fold higher than the SGVSSD method. The data requirements for the distribution method were fulfilled, the quality of the dataset was good and the SSD showed a good performance with the data. Because the use of the distribution method gives a better representation of the overall sensitivity between the different groups of organisms (plants and in-soil organisms), this method was considered more appropriate for the derivation of the final SGV. Since the SSD method was used, the SGV derived for diuron was considered as definitive, resulting in a **definitive SGV of 0.95 µg a.s./kg d.w.**.

3 Case study for the fungicide fluazinam – proposal for SGV derivation

3.1 Data evaluation

As for Diuron, studies on earthworms, collembolans, mites, and plants were retained. Because vegetative vigor results from plant tests are not accepted, only the study from Backus (1993a) on seedling emergence could be used.

The most relevant toxicity parameters are the NOEC, EC_x and LC_x. The preferred values are NOEC and/or EC_{10}, although for plants, only an EC_{50} was available. Only the values that were considered for SGV derivation are shown in Table A1.4.

The comparison of toxicity values between studies performed with the active substance and with the formulation was not possible because most of the available values were unbounded. However, no evidences of different sensitivities could be observed between the tests conducted with the active substance and the formulation. Therefore, and because of the limited dataset, all available studies were considered.

All data were converted to a standard OM content of 3.4 %. However, no information on the organic matter content of the soil used in the study from Backus, (1993a) was provided (natural soil amended with 50 % silica sand and supplemental nutrients). As it was the only study available for plants, the toxicity value as provided in the DRAR (NOEC ≥ 1) was retained, but considered to be of low reliability and was not used for the final SGV derivation.

Table A1.4: Soil ecotoxicological data for fluazinam from EC DAR (2006) *and* EC DRAR (2019)*. Values resulting from calculations are rounded to two significant figures. The unit conversion and/or calculations are specific for the proposed methodology for deriving SGV. The data used for the SGV derivation is marked in bold. Abbreviations: Conc.=Concentration, OM=Organic Matter, Appl. = application, a.s.=active substance, WHC= water holding capacity.*

Species & Taxonomic group	**Substance tested**	**Test type & Endpoint**	**Duration**	**Parameter**	**Appl. rates** (original units for plant studies. In g a.s./ha)	**Conc. mg/kg d.w.**	**Normalized conc. mg/kg d.w., 3.4% OM**	**Soil type**	**Source**
Eisenia fetida (earthworm)	Fluazinam techn. (97.3 % a.s.)	Behavior and weight	28 days	NOEC	-	10	**4.3**	artificial soil: 70 % fine silica sand, 20 % kaolinite clay, 10 % sedge peat (79.5% OM) and 10 mg/kg $CaCO_3$. pH 7.0 ± 0.2. OM in soil ~8 %[16]	Edwards & Coulson, 1985 cited in EC DAR, 2006, Vol.3 CA B9, p.532
	MCW-465 500 SC (39.48 % a.s.)	reproduction and weight	56 days	NOEC	-	≥ 3.9	≥ 1.3	Artificial soil: 69 % quartz sand, 20% kaolin clay, 10 % Sphagnum peat and 0.38% CaCO3. pH 6.0 ± 0.5	Winkelmann, 2016 cited in EC DRAR, 2019, Vol. 3 CP B9 - MCW 465 500 SC, p. 180
	Fluazinam 500 SC (38.4 % a.s.)	mortality	14 days	LC_{50}	-	> 682	> 232	Artificial soil: 70% fine silica sand, 20% kaolin clay, 10 % peat and 5 g CaCO3/kg. pH 6.0 ± 0.2	Yearsdon et al., 1991 cited in EC DRAR, 2019, Vol. 3 CP B9 - IKF-1216 500 SC, p. 145
Eisenia andrei (earthworm)	Fluazinam 500 SC (39.4 % a.s.)	reproduction	56 days	NOEC	-	< 0.35	**< 0.12**	Artificial soil: 68-69% fine quatz sand, 20% kaolin clay, 10 % peat and 1% $CaCO_3$. pH 6.0 ± 0.5. pH 6.0 ± 0.5	Römbke & Moser, 1999 cited in EC DRAR, 2019, Vol. 3 CP B9 - IKF-1216 500 SC, p. 146
		weight		NOEC	-	≥ 35.0	≥ 11.9		
Folsomia candida (collembolan)	MCW-465 500 SC (39.48 % a.s.)	mortality and reproduction		NOEC[17]	-	5.4	**3.7**	Artificial soil ISO 1167: 74.8 % fine quartz sand, 20% kaolin clay, 10 % Sphagnum peat and 0.2% $CaCO_3$. pH 6.0 ± 0.5	Lührs, 2008 amendment Lührs, 2016 cited in EC DRAR, 2019, Vol. 3 CP B9 - MCW 465 500 SC, p. 211

[16] Soil organic matter calculated assuming that the only source of organic matter in the artificial soil was from the sedge peat and the organic matter content of the sedge peat is 79.5 %.
[17] An EC_{10} of 5.617 mg a.s./kg d.w. was reported, but the RMS preferred the NOEC.

Species & Taxonomic group	Substance tested	Test type & Endpoint	Duration	Parameter	Appl. rates (original units for plant studies. In g a.s./ha)	Conc. mg/kg d.w.	Normalized conc. mg/kg d.w., 3.4% OM	Soil type	Source
	Fluazinam 500 SC (39.4 % a.s.)	reproduction	28 days	EC_{10}	-	4.5	**1.5**	Artificial soil: 69.5% fine quartz sand, 20% kaolin clay, 10 % Sphagnum peat and 0.5 % $CaCO_3$. pH 6.0 ± 0.5	Klein, 2002 cited in EC DRAR, 2019, Vol. 3 CP B9 - IKF-1216 500 SC, p. 166
		mortality and reproduction		NOEC	-	< 1.2	< 0.42		
	TIFC 500 SC (40.2 % a.s.)	reproduction	28 days	EC_{10}[18]	-	5.63	**3.8**	Artificial soil: 75 % industrial quartz sand, 20% kaolin clay, 5 % Sphagnum peat. pH 6.26	Neri, 2015 cited in EC DRAR, 2019, Vol. 3 CP B9 - TIFC 500 SC, p. 100
		Mortality and reproduction		NOEC	-	6.9	4.7		
Hypoaspis aculeifer (mite)	Fluazinam techn. (99.52 % a.s.)	reproduction	14 days	NOEC	-	≥ 110	≥ 75	artificial soil: 5 % Sphagnum peat, 20 % kaolin clay, 74.7 % industrial quartz sand, 0.2 % calcium carbonate. pH 5.6-5.9, OM 5 %[19]	Schulz, 2016 cited in EC DRAR, 2019, Vol 3 CA B9, p.259
	TIFC 500 SC (40.2 % a.s.)	reproduction	14 days	EC_{10}[20]	-	47	**32**	artificial soil: 75 % industrial quartz sand, 20% kaolin clay, 5 % Sphagnum peat. pH 6.4	Colli, 2015 cited in EC DRAR, 2019, Vol. 3 CP B9 - TIFC 500 SC, p. 103
micro-organisms	Fluazinam 500 SC (39.49 % a.s.)	Nitrogen transformation	28 days	54.9 % stimulation	-	0.27	**0.40**	Natural soil: Sample from Rossdorf (Germany), loamy sandy soil (10.3% clay, 37.5% silt, 52.2% sand), TOC 1.34%, CEC: 14.1 mval Ba/100 g dw,	Reis, 2002 cited in EC DRAR, 2019, Vol. 3 CP B9 - IKF-1216 500 SC, p. 181
				112 % stimulation	-	2.27	3.4		

[18] RMS considered the EC_{10} value as the relevant reproduction endpoint.
[19] Soil organic matter content estimated assuming that the only source of organic matter in the artificial soil comes from the Sphagnum peat and that the organic matter content of the Sphagnum peat is approximately 100%.
[20] The reliability of the EC_{10} is considered poor, but the RMS decided that it should be considered for risk assessment since a reliable NOEC was not possible to determine (effects > 15 %).

Species & Taxonomic group	Substance tested	Test type & Endpoint	Duration	Parameter	Appl. rates (original units for plant studies. In g a.s./ha)	Conc. mg/kg d.w.	Normalized conc. mg/kg d.w., 3.4% OM	Soil type	Source
		Carbon transformation		6.05 % inhibition	-	0.27	**0.40**	total N 1.84 mg/100 mg dw, max WHC 48 ml water/100 g soil. pH 7.4	
				2.89 % inhibition	-	2.27	3.4		
Zea mays *Avena sativa* *Allium cepa* *Sorghum bicolor* *Fagopyrum esculentum* *Cucumis sativus* *Brassica kaber* *Raphanus sativus* *Glycine max* *Lycopersicon esculentum* (Terrestrial plant)	Fluazinam techn. (97.3% a.s.)	seedling emergence (emergence and fresh weight)[21]	14 days	ER_{50}	≥ 1500	≥ 1	-	natural soil amended with 50 % silica sand and supplemental nutrients	Backus, 1993a cited in EC DRAR, 2019, Vol 3 CA B9, p.296

[21] Two different methods were tested in this study: Petri dish seed germination method and pre-emergence bioassay method. Only the last one was included in the table, since no soil was used for the petri dish test.

3.2 Derivation of the SGV

Data is available for earthworms, collembolans, mites, and plants, as well as for two microbial mediated processes. To perform a SSD, a minimum of ten exact datapoints for at least three taxonomic groups are recommended. For fluazinam, and considering the preferred values, only 3 exact values are available for earthworms, collembolans, and mites. Therefore, only the deterministic method could be used.

Deterministic method

The selected critical toxicity data for fluazinam is listed in Table A1.5. Since for collembolans three NOECs/EC_{10} are available for the same species and endpoints, the geometric mean of the three values was considered.

Table A1.5: Critical toxicological data of the terrestrial organisms for fluazinam. If critical values were unbound, they are showed in the table with the appropriate sign. If possible, alternative exact values for the same species/trophic level are also shown in parenthesis.

Group	Species	Parameter	Conc. in mg a.s./kg d.w.*	Literature
Primary producer	*Zea mays* *Avena sativa* *Allium cepa* *Sorghum bicolor* *Fagopyrum esculentum* *Cucumis sativus* *Brassica kaber* *Raphanus sativus* *Glycine max* *Lycopersicon esculentum* *Brassica napus* *Daucus carota* *Glycine max*	ER_{50}	≥ 1	Backus, 1993b cited in EC DRAR, 2019, Vol 3 CA B9, p.299
Decom-poser (nu-trient trans-	Microorganisms - Nitrogen mine-ralization	NOEC	< 0.40 (0.40)	Reis, 2002 cited in EC DRAR, 2019, Vol. 3 CP B9 - IKF-1216 500 SC, p. 181
Decom-poser (lit-ter trans-former)	*Eisenia andrei (Eisenia fetida)*	NOEC	< 0.12 (4.3)	Römbke & Moser, 1999 cited in EC DRAR, 2019, Vol. 3 CP B9 - IKF-1216 500 SC, p. 146 (Edwards & Coulson, 1985 cited in EC DAR, Vol.3 CA B9, p.532)

Group	Species	Parameter	Conc. in mg a.s./kg d.w.*	Literature
/Primary consumer	*Folsomia candida*	NOEC	< 0.42 (Geometric mean = 2.8; from NOEC= 3.7, EC_{10}=1.5 and EC_{10}=3.8)	Klein, 2002 cited in EC DRAR, 2019, Vol. 3 CP B9 - IKF-1216 500 SC, p. 166 (Studies for the geometric mean: Lührs, 2008 amendment Lührs, 2016 cited in EC DRAR, 2019, Vol. 3 CP B9 - MCW 465 500 SC, p. 211; Klein, 2002 cited in EC DRAR, 2019, Vol. 3 CP B9 - IKF-1216 500 SC, p. 166; Neri, 2015 cited in EC DRAR, 2019, Vol. 3 CP B9 - TIFC 500 SC, p. 100))
Consumer (Secondary con-	*Hypoaspis aculeifer*	NOEC	32	Colli, 2015 cited in RAR, 2019, Vol. 3 CP B9 - TIFC 500 SC, p. 103

**Concentrations normalized to 3.4 % organic matter, except for the concentration for plants (first row), for which no normalization was possible*

The dataset includes data for four trophic levels. There are several unbounded values in the dataset and those should not be used for the derivation of the SGV using the deterministic method. Therefore, only reliable exact values from Table A1.5 (in parenthesis) were considered for the derivation of the SGV but the AF was increased from 10 to 50, d due to the uncertainty of the data with many unbounded values. The lowest exact value was a NOEC = 0.4 mg a.s./kg d.w. for the carbon transformation test, resulting in a SGV of:

$$\boldsymbol{SGV_{AF\ method}} = \frac{0.4}{50} = \mathbf{0.008}\ \boldsymbol{mg\ a.s./kg\ d.w.}$$

Final soil protection value

Fluazinam is a fungicide and therefore, fungi would be the potentially most sensitive group of organisms. Unfortunately, there was a data gap to assess the sensitivity of this group of organisms when deriving the SGV for direct toxicity. Thus, the addition of new studies with fungi is strongly recommended in order to have a more reliable SGV. Since an assessment factor of 50 was used, the SGV derived for fluazinam was considered definitive, resulting in a **definitive SGV of 0.008 mg a.s./kg d.w.**

4 References

EC DAR, 2006. Draft Assessment Report for Fluazinam - public version - Rapporteur Member State: Austria.

EC DRAR, 2019. Draft Renewal Assessment Report for Fluazinam - public version - Rapporteur Member State: Austria; Co-Rapporteur Member State: Denmark.

EC RAR, 2018. Renewal Assessment Report for Diuron - public version - Rapporteur Member State: Germany, Co-Rapporteur Member State: Denmark.

EC TGD, 2003. Technical Guidance Document on Risk Assessment (part II). European Commission. Joint Research Centre. EUR 20418 EN/2.

ECHA, 2017. Guidance on the Biocidal Products Regulation: Volume IV Environment - Part B+C Assessment and Evaluation. Version 2.0.

Marti-Roura, M., Dell'Ambrogio, G., Campiche, S., Wong, J., Junghans, M., Renaud, M., Ferrari, B.J.D. (2023). Methodology proposal for the derivation of Soil Guideline Values for Plant Protection Product residues. Part 1 - Review and comparison of international methodologies. Swiss Centre for Applied Ecotoxicology, Dübendorf and Lausanne, Switzerland; 156 pp.