Topical Scientific Workshop on Soil Risk Assessment

Helsinki, 7 – 8 October, 2015

Case studies

Day 1, 7 October 2015

Break-out groups

1. Problem definition and conceptual model for soil risk assessment

Chairs: Marc S. Greenberg (US EPA), Kees Romijn (Bayer CropScience), Janet Cermak (Environment Canada)

Focus:

- Protection goals and ecological relevance
- Risk characterisation and environmental impact assessment
- Scientific consistency and differences within regulatory processes

Case studies:

1) Making soil protection goals based on the ecosystem services concept operational in ecotoxicological risk assessments, Gregor Ernst, Bayer Crop Science
2) Bioavailability-based approaches for soil risk assessment of metals: Regional differences arising from distributions of soil chemical properties, Christian Schlekat, Nickel Producers Environmental Research Association

Making soil protection goals based on the ecosystem services concept operational in ecotoxicological risk assessments

Patrick Kabouw, ecotoxicologist, BASF

What, where and when to protect are fundamental questions that need to be addressed before designing risk assessment schemes. When deciding what, where and when to protect regulators have to obey regulations, follow international treaties, and include the latest science based proposals and evidence while keeping public perception in mind. Recently the millennium assessment initiative and the therein specified ecosystem services concept has been used for a range of chemicals across different regions to define protection goals and to design risk assessment schemes (Ref 1, 2, 3 & 4).

The Millennium Ecosystem Assessment identified several key ecosystem services (EsS). These EsS have a significant contribution to human well-being. Therefore these EsS have to be maintained, restored or compensated if risks to them are identified. These EsS are grouped into regulatory, provisioning, cultural and supporting services. Soil relevant EsS (water purification, food production, erosion control, nutrient cycling, etc.) come from all Millennium Ecosystem Assessment categories and most EsS can potentially be positively or negatively affected by chemicals. These EsS give a relatively precise answer on what to protect and possibly even where to protect these services. Additionally the EsS concept makes definitions of spatial and temporal protection goals possible.

The EsS concept can also be used to design a novel, understandable, and science based proposal for the soil risk assessment with chemicals. A novel soil risk assessment scheme based on these EsS should be workable, scientifically sound and politically acceptable. A clear and well-structured risk assessment scheme needs to reduce uncertainties. It should reduce data gaps concerning organism groups and /or functions potentially at risk. Remaining data gaps should be scientifically justifiable. Protection goals should result in validated test systems, conservative yet not overly conservative triggers, and clear acceptability criteria.

References

[1] EFSA Panel on Plant Protection products and their residues. 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 Journal 8(10):1821
[2] Garcia-Alonso, M & Raybould A. 2013. Protection goals in environmental risk assessment: a practical approach. Transgenic research DOI 10.1007//s11248-ß13-9760-1
[3] SETAC Pellston Workshops: Ecosystem Services, Environmental Stressors and Decision Making**,** 28 September–3 October 2014 | Shepherdstown, West Virginia
[4] ECETOX *Science Approaches in Risk Assessment – Opportunities to Agree,* Chemical risk assessment - ecosystem services, 3 March 2015 | Brussel, Belgium

Bioavailability based approaches for soil risk assessment of metals: Regional differences arising from distributions of soil chemical properties

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The toxicity of metals like Ni to soil organisms is strongly influenced by soil chemical properties, which is an important consideration in soil risk assessment because this can result in broad differences in intra-species ecotoxicity values when a particular species has been tested in different natural soils. Additionally, the natural occurrence of Ni and other metals needs to be considered when interpreting and implementing screening level soil thresholds, as these conservatively based values may be exceeded by concentrations of metals in soil that have geogenic origin. Under the Existing Substances Risk Assessment of Ni, several advanced risk assessment approaches were developed to address these challenges. Among the most critical was the development of empirical bioavailability models that allowed for the normalization of ecotoxicity data to site-specific soil conditions. The principle soil parameter that was shown to affect Ni toxicity to soil microbial processes, plants, and invertebrates was effective cation exchange capacity (eCEC). Another key concept incorporated into the assessment was a correction for leaching and ageing, which accounts for the differences in toxicity between freshly spiked soils and that of aged soils. The leaching/ageing (L/A) factor for Ni was based on soil pH, which reflects the higher rates of insoluble Ni oxide formation at high soil pH. L/A and bioavailability normalization were applied to the chronic Ni toxicity database, which is comprised of > 40 EC10 data for microbial processes and species, plants, and invertebrates. Normalized EC10 data were used to populate Species Sensitivity Distributions (SSDs), from which HC5 values were calculated and used as the basis for determining terrestrial Generic Exposure Scenarios for Ni substances registered under REACH.

Similar approaches were performed for other metals, including Co, Cu, Pb, and Zn.
Recently, REACH-like regulatory frameworks have been initiated in other geographic regions, including China. To determine if the same approach developed in Europe for Cu and Ni could be applied to China, the Metals in Asia research program (MIA) collected ecotoxicity data for Chinese species and determined bioavailability relationships for ranges of typical Chinese soils. The outcome of MIA indicated that the distribution of eCEC and pH in Chinese soils was sufficiently different from European soils that unique bioavailability relationships were required to explain intra-species ecotoxicity variability. For Ni, the most important factor affecting toxicity in Chinese soils was pH, whereas both pH and organic carbon were important for Cu. These results demonstrate the importance of determining relationships between soil properties and metal toxicity to soil organisms, and also that the relationships need to account for distributions of soil parameters within the region of interest.

In Australia, the National Environmental Protection (Assessment of Site Contamination) Measure (NEPM) was amended in 2013 to include natural background and bioavailability issues for several metals (including Cu, Ni, and Zn) as outlined above. Toxicity data for these metals were normalized using the European and Australian bioavailability relationships and background concentrations were predicted using Australian relationships (normalized to soil Fe content). The Australian NEPM also has land-use based criteria with more stringent limits for areas of ecological significance.

2. Environmental exposure and fate assessment

Chairs: Willie Peijnenburg (RIVM), Mark Egsmose (EFSA)
Focus:

- Environmental fate and release patterns related to soil exposure and available tools
- Behaviour processes within soil and its contribution to the bioavailability for soil organisms exposure: distribution, quantification of exposure, formation of degradation products/metabolites, aging, leaching, bioavailability and bound residues, specificities for various groups of chemicals

Case studies:

1) Practical examples on how the EFSA Guidance Document for predicting environmental concentrations of substances in soil can be used, Mark Egsmose, EFSA and Michael Klein, Fraunhofer IME
2) From bioavailability science to regulation of organic chemicals, Jose Julio Ortega-Calvo, Institute of Natural resources and Agrobiology

GUIDANCE OF EFSA

EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil.

Mark Egsmose, European Food Safety Agency[1], Michael Klein, Fraunhofer and Aaldrik Tiktak PBL[2]

ABSTRACT

This European Food Safety Authority (EFSA) Guidance Document (EFSA, 2015a). provides guidance for the exposure assessment of soil organisms to plant protection products (PPPs) and their transformation products in accordance with Regulation EC No 1107/2009 of the European Parliament and the Council.[3] This guidance was produced by EFSA in response to a question posed by the European Commission according to Art. 31 of Regulation (EC) No 178/2002 of the European Parliament and of the Council.[4] The recommended methodology was developed for the assessment of active substances and metabolites in the context of approval at the European Union (EU) level, and it is expected to be used for the assessment of products at the zonal level as well. This guidance document, together with the EFSA Guidance Document on how to obtain *DegT50* values (EFSA, 2014a) and the Forum for Co-ordination of Pesticide Fate Models and their Use (FOCUS) Degradation kinetics report (FOCUS, 2006), is intended to replace the current Directorate-General for Health and Consumer Affairs (DG

[1] Acknowledgement: EFSA wishes to thank the members of the Working Group on PECs in soil, Aaldrik Tiktak, Michael Stemmer, Jos Boesten, Michael Klein and Sylvia Karlsson, and EFSA staff Mark Egsmose and Chris Lythgo for the support provided to this scientific output.

[2] The presentation at this workshop is made by the experts in their personal capacity on behalf of EFSA.

[3] EC (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. OJ L 309/1, 24.11.2009, p. 1–50.

[4] EC (European Commission), 2002. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1–22.

SANCO) Guidance Document on persistence in soil (SANCO/9188VI/1997 of 12 July 2000) (EC, 2000).

The draft EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil was subject to public consultation from 10 July 2014 to 4 September 2014. A technical report has been produced containing the stakeholder comments received during the public consultation and how these comments have been taken into account (EFSA, 2015b).

This guidance document (EFSA, 2015a) is based on the EFSA opinion on the science behind the guidance for scenario selection and scenario parameterisation for predicting environmental concentrations of PPPs in soil (EFSA PPR Panel, 2012a). The goal is to assess the 90th percentile concentration considering all agricultural fields within a regulatory zone (North–Central–South) where a PPP is intended to be used. The guidance considers all types of concentrations that are potentially needed for assessing the ecotoxicological effects, i.e. the concentration in total soil (mg kg^{-1}) and the concentration in pore water (mg l^{-1}), both averaged over various depths and time windows (EFSA, 2009). The guidance also describes how to use older soil ecotoxicological studies in which exposure is expressed in terms of the applied rate (in kg ha^{-1}). The current methodology is restricted to annual crops under conventional and reduced tillage (excluding crops grown on ridges). Guidance for permanent crops, no-tillage systems and crops grown on ridges will be made available at a later stage.

The recommended exposure assessment procedure consists of five tiers. To facilitate efficient use of the tiered approach in regulatory practice, user-friendly software tools have been developed for the first three tiers. This includes the new software tool PERSAM (Persistence in Soil Analytical Model) and new versions of the pesticide fate models PEARL (Pesticide Emission At Regional and Local Scales) and PELMO (Pesticide Leaching Model). The software tools generate reports that can be submitted for regulatory purposes. Users of this guidance are advised to use these software tools when performing the exposure assessment. Models other than PEARL or PELMO are currently not supported unless the process descriptions in such numerical models have a similar or higher level of detail than those in PELMO and PEARL (EFSA PPR Panel, 2012a). Furthermore, it should be demonstrated that the models give similar results to PEARL and PELMO. This is necessary to guarantee consistency of the tiered approach. If a numerical model is to be used, applicants and rapporteurs are advised to report simulations with at least two numerical models (e.g. PEARL and PELMO) and provide the highest Predicted Environmental Concentration (PEC) for regulatory submissions (this procedure is in line with EC (2014)).

The exposure assessment starts with simulations for one predefined scenario per regulatory zone, North–Central–South. Simulations can be carried out with the simple analytical model PERSAM at Tier 1 or with the numerical models (PEARL and PELMO) at Tier 2A. At Tier 1, PERSAM has the advantage that the required number of inputs is very limited and thus the documentation will also require little effort. Tier 2A requires slightly more effort; however, this tier has the advantage that more realistic modelling approaches are used and therefore this tier will deliver less conservative values.

Based on discussions with stakeholders, it was a boundary condition that the exposure assessment can be applied by taking median or average substance properties from the dossiers. Such substance properties are uncertain and inclusion of this uncertainty leads to probability density distributions that show greater spread. As a consequence, this boundary condition led to the need to base the exposure assessment procedure on the spatial 95th percentile concentration instead of the spatial 90th percentile concentration.

The predefined scenarios in Tier 1 and Tier 2A are based on the total area of annual crops in a regulatory zone. However, the exposure assessment goal is based on the agricultural area where a PPP is intended to be used. The applicant may therefore wish to perform an exposure assessment for a particular crop. For this purpose, Tiers 2B and 2C are provided. At these tiers, a spatially distributed version of PERSAM is used and the target percentile is directly calculated from the concentration distribution within the area of a given crop. Should the assessment at Tier 2 still indicate an unacceptable risk to soil organisms, the applicant has the option to move to Tier 3. Tier 3 is also based on the area of a given crop, but uses numerical models (PEARL and PELMO). In Tier 3B crop-specific and substance-specific scenarios are used. Guidance is given on how to select and use these scenarios. This guidance document introduces an easy to use Tier 3A, which uses a refined scenario adjustment factor based on results from Tier 2A and Tier 2B.

Tiers 1 and 2B are based on the assumption that crop interception of the substance does not occur. In Tiers 2A, 2C, 3A, 3B and 4 this can be included. Interception and subsequent dissipation at the crop canopy may be based on simulations with the numerical models. To facilitate harmonisation of the regulatory process, canopy processes in PEARL and PELMO were harmonised. This guidance further introduces a table for the fraction of the dose reaching the soil surface that was created based on simulations with PEARL and PELMO. This table should be used at Tier 2C. The availability of this table simplifies the tiered approach because it is no longer necessary to run Tier 2A before Tier 2C.

The predefined scenarios used at Tier 1 and 2A are based on the 95th spatial percentile considering the total area of annual crops in each regulatory zone. However, the purpose of the exposure assessment is to consider the total area of the crop where the PPP is intended to be applied. Since the 95th spatial percentile of a given crop may be higher, scenario adjustment factors (named crop extrapolation factors in EFSA PPR Panel, 2012a) have been included at Tier 1 and Tier 2A to ensure that these tiers are more conservative than Tiers 2B, 2C, 3A, 3B and 4.

The simple analytical model PERSAM is used in lower tiers. Since it cannot be *a priori* guaranteed that the simple analytical model is more conservative than the more realistic numerical models used in Tiers 2A, 3A, 3B and 4, model adjustment factors have been included in all tiers where the analytical model is used. The model adjustment factors proposed in EFSA PPR Panel (2012a) have been reassessed for this guidance document and the number of factors has been reduced to ease their use in the regulatory process.

Although this EFSA Guidance Document was prepared for exposure assessment of active substances of plant protection products and transformation products of these active substances the guidance may also have applicability to other substances applied to agricultural fields.

Practical examples on how the EFSA Guidance Document for predicting environmental concentrations of substances in soil can be used, including influence of crop canopy processes, pH-dependent sorption of substance and how to handle metabolites following this guidance will be presented.

REFERENCES

EC (European Commission), 2014. Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference SANCO/13144/2010 version 3, 613 pp.

EFSA (European Food Safety Authority), 2009. Scientific Opinion of the Panel on Plant Protection Products and their Residues on the usefulness of total concentrations and pore water concentrations of pesticides in soil as metrics for the assessment of ecotoxicological effects. The EFSA Journal 2009, 922, 90 pp. doi: 10.2903/j.efsa.2009.922

EFSA Panel on Plant Protection Products and their Residues (PPR), 2012a. Scientific Opinion on the science behind the guidance for scenario selection and scenario parameterisation for predicting environmental concentrations of plant protection products in soil. EFSA Journal 2012;10(2):2562, 76 pp. doi:10.2903/j.efsa.2012.2562

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From bioavailability science to regulation of organic chemicals

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The bioavailability of organic chemicals in soil and sediment is an important area of scientific investigation for environmental scientists, although this area of study remains only partially recognized by regulators and industries working in the environmental sector. Regulators have recently started to consider bioavailability within retrospective risk assessment frameworks for organic chemicals; by doing so, realistic decision-making with regard to polluted environments can be achieved, rather than relying on the traditional approach of using total-extractable concentrations. However, implementation remains difficult because scientific developments on bioavailability are not always translated into ready-to-use approaches for regulators. Similarly, bioavailability remains largely unexplored within prospective regulatory frameworks that address the approval and regulation of organic chemicals. Therefore, this case study has been prepared by the four proposing authors that represent a bigger group of authors from academia, industry and regulation (ES&T, 2015, DOI: 10.1021/acs.est.5b02412) who have recently have arrived at an agreement and discussed bioavailability concepts and methods; in addition, we will offer a simple, pragmatic and justifiable approach for use within retrospective and prospective risk assessment.

Part of our proposal relates to nonextractable residues (NERs). For prospective situations, the regulatory approval of chemicals, particularly pesticides, has involved the use of ^{14}C-labelled chemicals in well-defined systems. For most chemicals, persistent, residual ^{14}C-activity often remains in the soil, even after the most aggressive solvent extractions have been performed. This residual ^{14}C-activity is defined as NER. NERs can usually be quantified only if ^{14}C-labelled (and also ^{13}C-labelled) chemicals are used, and they are not a measurable parameter in retrospectively contaminated soil or sediments. NERs may be defined as the chemical itself associated with mineral and/or organic matter fractions. However, if care is not applied, NERs may also describe the transformation products of ^{14}C within microbial biomass (biochemical components), or even ^{14}C-carbonates, and undefined ^{14}C-transformation products. These assimilated residues (known as biogenic NERs) are of no ecotoxicological concern. Thus, in prospective risk assessment, it is important that the potential for the extensive formation of such residues is taken into account when considering the significance of NER and bound residues.

3. Effect assessment

Chairs: Veronique Poulsen (ANSES), Paulo Sousa (Uni Coimbra)
Focus:

- Effect assessment for soil functions, assessment of relevance and available tools
- Effects assessment for soil organisms (including plants) exposed by soil, relevant taxonomic groups acute versus chronic testing and experimental tools
- Effects assessment for soil organisms (including plants) through multiple exposure routes by soil
- Effect assessment in higher tier studies (i.e. acceptability criteria)

Case studies:

1) Application of equilibrium partitioning-based model framework for evaluating soil (and sediment) hazards of lipophlic nonpolar organic substances
   Aaron Redman, ExxonMobil Biomedical Sciences, Inc.
2) Assessing the risks of pesticides to soil communities using terrestrial model ecosystems, Björn Scholz-Starke, RWTH Aachen University

Application of equilibrium partitioning-based model framework for evaluating soil (and sediment) hazards of lipophilic nonpolar organic substances

Redman AD, Leon Paumen M, Bragin GE, Low LK
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The target lipid model (TLM) is a QSAR framework used to predict acute and chronic toxicity of substances based on structure. This framework has been extended for calculation of predicted no effect concentrations (PNEC) of highly lipophilic hydrocarbon substances to support risk assessment activities of single chemicals as well as complex substances such as fuels, solvents, and lubricants. Recently, this framework was extended into soils and sediments using equilibrium partitioning (TLM-EqP) to support hazard evaluation, risk assessment, and read across activities thereby maximizing use of available data. The TLM-EqP framework established the range of sensitivities for common test species (invertebrates, microbial endpoints, plants), which supports read across from the results of one assay to another. This framework was applied to recent dossier updates to address existing data gaps. The approach consisted of a weight of evidence built using TLM-EqP predictions and read across to available data, which allowed an improved experimental design for additional testing. This framework was used to establish the upper limit of the predicted porewater solubility (~100 mg/kg in bulk soil) to avoid potential formation of oily residues, which introduce the potential for physical oiling. While the mechanism of physical oiling could be a true hazard, predicted environmental concentrations in soil for most substances under typical use patterns are very low (<0.01 mg/kg). Confirmatory testing in soil and sediment showed lack of toxicity consistent with model predictions and consistent with existing test data in water and soil. This framework promotes realism in chemical risk assessments by designing tests based on physicochemical properties and likely hazards of the test substance. This presentation will review the technical basis for the framework and illustrate the application of the methodology to available case studies, i.e. dossier updates to insoluble, nonpolar organic substances.

Assessing the risks of pesticides to soil communities using terrestrial model ecosystems

Björn Scholz-Starke, RWTH Aachen University

The thesis at hand aims to bridge the gap between laboratory approaches and field studies using a Terrestrial Model Ecosystem (TME). Chapter I provides a systematic approach that is applied in this thesis. The effects to soil communities and the corresponding detection limits depend largely on the intrinsic variability and the sensitivity of the systems. Since TME are meant to provide a high degree of realism comparable to field studies, the first chapter gives an overview on the characteristics of soil ecosystems and the ecology of the soil organisms. Chapter II gives an overview of the experimental approaches, the test compound lindane (gamma-hexachlorocyclohexane) and the assessment endpoints measured in both TME and field studies. The complex community-level data of different soil organism groups requires a variety of uni- and multivariate statistical methods. Chapter III involves the description and interpretation of effects of the persistent and toxic pesticide lindane on soil microarthropod communities that were detected in a one-year range-finding study in TME. The open, intact soil cores (diameter 300 mm, height 400 mm) included indigenous soil organisms of undisturbed grassland. Forty units were placed outdoors in an experimental facility. The key objective was at first to evaluate the dynamics and stability of microarthropod communities on grassland over a period that is relevant for assessing the intrinsic recovery potential of the TME communities following toxic stress. Sufficient numbers of organisms and replicates of the experimental units ensured that a statistical evaluation could be performed to estimate the sensitivity and the natural dynamics and the variability of the populations upon application of lindane applied at high rates of 7.5 and 75 kg active ingredient (a.i.)/ha. The results showed that TME soil cores maintained communities of soil organisms marked by typical diversity of improved grassland. Lindane applied at excessive rates caused clear dose-related and long-lasting effects on the communities of microarthropods. On the contrary, lumbricids, the total feeding activity and the growth of plant biomass were not affected by both treatments. Based on the results of the first effect study, a modified 'dose-response study' with the same compound lindane was designed (Chapter IV). Further organism groups were included, so that the effects on collembolans, oribatid mites, nematodes, soil fungi and plant biomass could be determined in forty-two TME. Lindane was applied in five concentrations between 0.032 mg a.i./kg dry soil and 3.2 mg a.i./kg dry weight soil, six-fold replicated each. Twelve TME served as untreated controls. Abundance and community structures of oribatids, collembolans, enchytraeids, nematodes and fungi were recorded. Oribatid mites' community responded three months after treatment, although they were not significantly affected by the overall treatment regime. Collembolans in total and species-specific abundance as well as the community endpoints were adversely affected by moderate dosages of lindane. Effects were transient between three and five months after treatment with a recovery within one year. No significant effects have been detected for enchytraeids, nematodes and fungi. The study design and the obtained results allow for calculations of no observed effect concentrations below the highest treatment level for populations and for soil communities as defined entities, as well as effective concentrations as indicators of dose related responses. In Chapter V the ecology of the coring area is described by means of floristic and faunistic surveys. The distribution of collembolans is analysed by geostatistical methods and categorized as patchy or gradiental. These findings lead to conclusions on optimized soil coring strategies, which are proposed as small-scaled as possible to avoid excess variability. The temporal stability of TME is investigated under the propositions of the criteria 'no tendency towards altered abundances and diversity structures' and 'similarity of communities compared to the original state'. The issue 'for which kind of habitat is the particular TME representative' is raised. It has been concluded that a high degree of similarity between field and TME samples remains manifest over time and the pattern persists the large seasonal variation of community structures. Prospective power analyses led to an estimation of the limits of effect detection. On average, the detectable differences of abundances of treatment groups compared to control level (MDD) was between five percent for nematodes and about fifty percent for enchytraeids, collembolans and oribatids, markedly varying between sampling dates.

Day 2, 8 October 2015

Case study 1: Critical comparison of the schemes used to assess soil exposure under pesticide, biocide and REACH legislation

Bruce Callow, Exponent International Ltd

The various schemes used to assess the exposure to soil under Plant Protection Product (1107/2009, both the assessment scheme in force at present and using the PERSAM tool proposed in the Draft EFSA Guidance, 2014), Biocides (PT 18, ENV/JM/MONO (2008) 14) and REACH legislation have been compared using a hypothetical pesticide.

The aim of the work was to examine the differences in the assumptions underpinning each of the relevant assessment schemes and to examine the effects that these may have on the derived PECsoil. It was assumed that a hypothetical insecticide is applied at a rate of 20 mg/m2 or 200 g/a.s. and that it was not readily biodegradable with a DT50 of 100 days in soil and a Koc of 1000 ml/g. For the PPPR use it is assumed that repeated annual applications are made to cereals between BBCH30 and BBCH39 and PECsoil are presented for the current assessment scheme which assumes distribution through the upper 5cm of soil with a density of 1.5 g/cm3, and using Tier 1, 2b and 2c of the PERSAM Tool. For the biocidal use it was assumed that an outdoor barrier spray application was made to soil around the foundations of the house and PECs in soil are presented for direct application to soil and for spray drift to adjoining soil.

The exposure calculations for the PPPR and biocidal PPPR uses are broadly comparable as they both arise from spray application. A hypothetical calculation for a manufacturing use, which would be assessed under REACH, is also presented for another important route of exposure which is assessed; via a sewage treatment plant (STP), which is also relevant to biocidal uses, to illustrate the assumptions used when calculating the PECsoil.

The results of these calculations are presented along with the various assumptions used in their calculation. The results are compared and differences in the calculation methods are highlighted. The influence of the various differing assumptions on the results, their appropriateness and their relevance to the risk assessment is discussed.

Case study 2: Application of improved scientific approaches in support of risk assessment within the European REACH and biocides regulations – a case study on metals

Koen Oorts, ARCHE

Several issues need to be accounted for in order to perform a scientifically-sound risk assessment of metals in soil, including: a) essentiality, b) variability of natural background concentrations, c) variability in soil properties influencing the bioavailability and toxicity of metals, and d) discrepancies in metal toxicity between soils contaminated under typical laboratory test conditions and in typical field scenarios. Deriving Predicted No Effects Concentration (PNEC) values based on the lowest chronic NOEC or EC10 values without considering these aspects may result in PNEC values that are below natural background concentration and within ranges of deficiency for many soil organisms in the case of essential metals.

The obligation for soil risk assessments under the European REACH and the former Existing Substances Regulation triggered extensive research projects for a range of metals (e.g., cobalt, copper, lead, molybdenum, nickel, zinc) to address these issues. Numerous chronic metal toxicity data were generated for various terrestrial species and microbial functions in different soil types. From these data sets, models were developed to predict the bioavailability and toxicity of metals as a function of soil properties. The large amount of chronic toxicity data for different species and functions further allowed the application of the species sensitivity distribution approach to derive soil PNEC values. Further research was performed to compare the toxicity of metals between freshly spiked soils in the laboratory with field contaminated soils. Research results led to the derivation of correction factors to account for the differences in bioavailability and toxicity observed between laboratory and field.

Finally, to assess the range and spatial variability of background metal concentration in soils and of soil properties, an extensive soil monitoring project (GEMAS project) was established. Results from the GEMAS project established the means to quantify the spatial variability of both exposure (metal concentrations) and effect concentrations (considering bioavailability and toxicity through variation in soil properties) and provided a strong basis for more robust and consistent risk assessments at European, regional and local scales.

This case study –using the metal copper as an example- will illustrate how new scientific data have resulted in improved scientific approaches in support of risk assessment within the European REACH and Biocides Regulations. An overview will be presented of the data and models currently available for different metals (Cd, Co, Cu, Mo, Ni, Pb, Zn).

Case study 3: Performing soil risk assessments using aquatic hazard information only: how well can it capture all the risks?

Michiel Claessens, Chemours

In the absence of experimental ecotoxicity data on soil organisms, soil risk assessments are typically performed using aquatic toxicity test results (e.g. within REACH). In such cases, the PNEC value derived for the aquatic compartment is transformed into a PNEC value for the soil compartment using equilibrium partitioning models. Recently, increased attention is being given to the question if this approach is sufficiently protective for the soil compartment in all cases. This case study presents the results of an exercise aimed at answering this question.

A database of substances for which aquatic and soil ecotoxicity data are simultaneously available, has been established. Subsequently, the performance of equilibrium partitioning (EqP) theory to extrapolate aquatic hazard information to the soil and sediment compartments is assessed for different trophic levels. The accuracy of EqP in predicting toxicity towards soil and sediment organisms is discussed in light of different physical-chemical parameters, substance mode of action and other parameters. Finally, the discussion covers cases where the existing aquatic data is sufficient to capture hazards/risks for all the compartments, and on the opposite, where it is not.

Case study 4: Compilation of case studies with challenges in regulatory soil risk assessment

Romanas Cesnaitis, Marta Sobanska, Amaia Rodriguez-Ruiz, Dragan M. Jevtić, Johanna Peltola-Thies, Charmaine Ajao, Derek Knight, Anu Kapanen, ECHA

According to the REACH Regulation, the environmental risk assessment shall also consider the terrestrial compartment, but in a narrow sense, i.e. to non-vertebrate organisms living the majority of their lifetime in the soil and being exposed to substances through the soil pathway.

Various parts of ECHA Guidance documents describe when and under which conditions data on terrestrial toxicity and fate should be generated and provided in the REACH registration dossiers, as well as how these data should be taken into account in the chemical safety assessment.

There are a number of specific issues in regard of data on terrestrial hazards/fate noted and raised within various REACH processes by ECHA and other parties implementing the REACH Regulation.

This presentation will cover some of the general and case-specific challenges addressed by ECHA in cooperation with the MSCAs when considering the adequacy of the available terrestrial hazard and fate information for regulatory risk assessment.

A number of further developments within the integrated testing strategy for effects on terrestrial organisms, underpinned by new scientific and regulatory knowledge, will be exemplified in the presentation.

The issues presented include the application of the equilibrium partitioning method (EPM) in predicting toxicity of soil organisms, relevance and sensitivity of different species and applied test protocols, triggers for terrestrial hazard assessment under REACH, and considerations of the need for further defining the test systems (e.g. temperature).

Furthermore, the soil exposure aspects, including direct and indirect soil exposure pathways and scoping of exposure assessment under REACH, will be discussed. How the results of soil risk assessment are taken into account in decision making on necessity and options for regulatory risk management measures will also be summarised.

Case study 5: Risk assessment for in soil organisms: future approaches and perspective

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The case study describes the tiered approach used for the risk assessment of a generic insecticide. I_{AD} (anthranilic diamide insecticide) is efficacious for control of lepidopteran insect pests, as well as some species in the orders Coleoptera, Diptera and Hemiptera through impairment in the regulation of muscles contraction.

The current risk assessment of active substances used in plant protection products for in soil organisms is conducted according to the SANCO Guidance (SANCO/10329/2002) on terrestrial ecotoxicology under the Directive 91/414/ EEC. The guidance includes lower tier trigger values and requires higher tier assessments, if needed, according to the Regulation (EC) 546/2011 (Uniform Principles for evaluation and authorisation of plant protection products), but it did not define specific protection goals.

The risk is estimated as Toxicity Exposure Ratio (TER). The insecticide shows persistency in soil (soil DT_{90f} >100 days or >365 days), and toxicity to soil organisms for I_{AD} has been derived from toxicity studies to earthworms and other soil macro-organisms. Results at the lower tiers indicated a high risk for soil macro-organisms. To further address the risk identified to soil micro-arthropods 2 litter bag studies representative of different EU soil conditions were submitted. Those studies, however, were not considered useful to further address the risk for soil organisms by the experts in the Peer review meeting organised by EFSA. The main reason for not accepting a litter bag study is not linked to the validity and/or sensitivity of that type of higher tier study but rather to the type of endpoint which can be derived from such a study. According to the principles of the tiered approach all the tiers should address the same protection goals which can be either structural or functional, as defined by the PPR Panel (EFSA

PPR Panel, 2010) and in line with the ecosystem services concept (MEA; 2005).

EFSA PPR Panel was tasked to revise the SANCO terrestrial guidance document and it is currently working on an Opinion on the state of the science on risk assessment of plant protection products for in soil organisms. The revision of the former Guidance Document on terrestrial Ecotoxicology became necessary mainly due to (1) the entry in to force of the new Regulation (EC) No 1107/2009 on authorisation of plant protection products, (2) the revision of the related data requirements, (3) scientific developments and (4) the need of clear protection goals defining what to protect (function *vs* structure), where to protect it and to over what time period.

Exposure has been predicted using the recently published EFSA Guidance for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil (EFSA, 2015).

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