ECHA
EUROPEAN CHEMICALS AGENCY

Topical Scientific Workshop on Soil Risk Assessment

Helsinki, 7 – 8 October, 2015

Background document

Topical Scientific Workshop on Soil Risk Assessment[1], 7-8 October 2015

The primary objective of this workshop is to review the state of the art regarding soil risk assessment in view of developing updated scientifically-sound principles and approaches for assessing ecological risks of chemical substances (i.e. industrial chemicals, pesticides and biocides), which are released to or reach the soil. The workshop also provides a platform for academia, regulators and other stakeholders to address how the main long-term challenges from the regulatory perspective can be reflected and employed in the current and future research topics on soil risk assessment. The discussions will be reinforced by information on the recent scientific developments and on risk assessment methodologies applied in chemicals management both within and outside the European Union.

1 Introduction

Soil is generally defined as the upper layer of the earth's crust transformed by weathering and physical/chemical and biological processes. It is composed of mineral particles, organic matter, water, air, and living organisms organised in genetic soil horizons (ISO 11074:2005). In soil ecotoxicology and regulatory science, the organic litter layer on top of the mineral soil and the uppermost layer of the mineral soil (including the organisms living there) is usually considered to be the part of the soil that is most essential in supporting vital ecosystems services and is therefore primarily included in risk assessment procedures.

Soil performs a multitude of key environmental, economic, social and cultural functions. It is a source of food, biomass and raw materials. It serves as a platform for human activities, and plays a central role as a habitat and gene pool (biodiversity). It stores, filters and transforms substances such as water, nutrients and carbon. These functions must be protected because of their environmental and socio-economic importance (EC 2006a). In addition to the composition and related physicochemical properties of the soil, diversity and abundance of soil organisms play a major role in determining soil's ability to perform its functions.

Soil has not been subject to a specific protection policy at EU level. Provisions for soil protection are spread across many areas, from environmental protection to agriculture and rural development. However, the need for a systematic approach within the EU was articulated in the first Communication on soil protection (EC 2002a). Non-binding elements of the soil strategy were presented as a new Communication entitled "Thematic

[1] **Disclaimer:** This summary has been prepared as a background document for facilitating the workshop discussions and does not represent a position of the European Chemicals Agency, European Food Safety Authority and European Medicines Agency. Readers are referred to the legal texts and guidance documents produced by the responsible European institutions (a summary of relevant guidance documents is also available as workshop background material). The views or opinions expressed herein are solely those of the author and do not necessarily represent the policy or guidance of the U.S. Environmental Protection Agency or of Environment Canada.

Strategy for Soil Protection" (EC 2006a). Binding measures were also suggested, in a proposal for a Soil Framework Directive (EC 2006b). Although this proposal has been withdrawn, the Commission remains committed to protecting soil and will examine options on how to best achieve this.

The Thematic Strategy for Soil Protection and the unsuccessful Soil Framework Directive Proposal identified eight main threats to European soils. One of these threats was soil contamination, addressing both the prevention of soil contamination (prospective assessment) and the management and remediation of contaminated sites (retrospective assessment).

Prevention of soil contamination relies on the safe use of chemicals. While the protection goals may differ between different chemicals regulatory frameworks, they are all aimed at maintaining soil functions. These functions are biomass production; storing, filtering, and transforming nutrients and water; hosting the biodiversity pool; acting as a platform for most human activities; providing raw materials; acting as a carbon pool and storing the geological and archaeological heritage (EC 2006b).

Environmental risk assessment (ERA) is one of the most valuable tools ensuring the safe use of chemicals. Several frameworks have incorporated soil within ERA, considering soil risk assessment essential for supporting decision-making in the regulatory context.

This joint ECHA and EFSA Topical Scientific Workshop on Soil Risk Assessment focuses on the safe use of industrial chemicals, biocides and pesticides, aiming to prevent soil contamination. Reflecting the current state of science on soil ecotoxicology, the following themes are foreseen to be covered in the workshop:

- Current regulatory frameworks for chemicals, including biocides and pesticides, risk assessment for soil organisms, role of screening/standard approaches and strategies for higher tier testing;
- Consideration of the commonalities and differences, including protection goals, in current regulatory schemes focusing on industrial chemicals (REACH), biocides and plant protection products, aimed at identifying synergies and developing harmonisation principles;
- Key elements of direct/indirect soil exposure according to the use patterns and technological processes (including chemicals reaching the soil through industrial and municipal waste management processes, as well as emission and exposure scenarios for pesticides and biocides resulting in soil exposure) and the subsequent environmental fate processes in soil;
- Identification of relevant ecological endpoints related to organisms exposed through soil or through soil application/deposition;
- The risk assessment of in-soil dwelling organisms and plants exposed through soil, excluding broader terrestrial environmental processes, such as secondary poisoning and risk assessment for birds and mammals;
- Combining and linking different types of information, i.e. modelling, laboratory and field evidence on ecotoxicity, exposure, persistence, bioaccumulation, bioavailability in soils, and ecosystem quality/function;
- Testing strategies applied in soil risk assessment with particular focus on higher tier studies; and
- Developing new alternative approaches for soil risk assessment and their applicability in a regulatory context.

Remediation of contaminated sites, secondary poisoning and risk assessment of nanomaterials and mixtures are outside the scope of this workshop.

Four EU regulatory frameworks are presented below as an example of different regulatory needs. The main elements of soil risk assessment are described for REACH (Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals), the BPR (Biocidal Product Regulation), PPP (Plant Protection Products) and Medicinal Products, followed by the overview of related legislation in the USA and Canada.

2 Soil risk assessment in the EU

2.1 REACH

Scope and main principles of the REACH

The REACH Regulation (Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals) entered into force on 1 June 2007 (EC 2006c).

Registration and evaluation

According to the REACH Regulation, to place and/or keep substances on the EU market, EU manufacturers, importers and, where relevant, downstream users are obliged to register their chemicals with ECHA by submitting information on the intrinsic properties of the chemicals following clearly defined information requirements that are tonnage, hazard and/or risk related.

Annexes VII to X of REACH in column 1 describe the "standard information requirements" that registrants should provide to European Chemicals Agency (ECHA) under the framework of the REACH Regulation when performing their risk assessment.

Standard REACH information requirements can be adapted on the basis of column 2 rules for adaptation, as well as on the basis of the 'general rules for adaptation' listed in Annex XI of the REACH Regulation.

These general rules are applicable to all endpoints and include weight of evidence (WoE) approaches, qualitative or quantitative structure–activity relationship ((Q)SAR), *in vitro* methods, grouping of substances and read-across, indications that testing is technically not possible, and tailored exposure-driven approaches.

The aim of registration is to make sure that EU manufacturers, importers and downstream users take full responsibility for the risk management of their substance.

ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment.

Two types of evaluation are foreseen in the REACH Regulation:

- Dossier evaluation. This is carried out by ECHA and includes:
    - Examination of testing proposals submitted by registrants.
    - Compliance check of the dossiers submitted by registrants.
- Substance evaluation carried out by Member State competent authorities [MSCAs]:
    - Substance is evaluated to clarify a concern.

Once the evaluation is done, registrants may be required to submit further information on the substance. In all evaluation cases, apart from the main party performing evaluation (either ECHA or any of the MSCAs), other MSCAs and ECHA share the responsibility for the conclusions made in the evaluation process.

When the manufacturers or importers are preparing a registration dossier (under Title II of REACH – Registration) and when ECHA is evaluating the registration dossier (under Title VI of REACH – Evaluation, Chapter 1), compliance with the information requirements listed under REACH or clear adaptation of justifications needs to be ensured.

On the other hand, when MSCAs carry out an evaluation of a substance (under Title VI of REACH – Evaluation, Chapter 2) they can request information that goes beyond the standard information requirements of REACH.

This can include any information/data on substance use, properties, hazards, exposure, etc., as well as any relevant and necessary information on soil hazards/exposure. This is because a registered substance is evaluated under REACH to clarify whether it is a risk to human health or to the environment. Hence, substance evaluation is a concern-driven process. Depending on the concern, more sophisticated experimental data or information on exposure (e.g. measured data enabling the use of higher tier risk assessment approaches) may be requested for the priority substances.

Authorisation and restriction

In addition to information on ecological impacts of substances to the soil compartment within the registration and evaluation titles under REACH described above, the soil compartment is also relevant to the authorisation and restriction titles of REACH. The aim of authorisation (Title VII of REACH) is to make sure that risks of substances of very high concern (SVHCs) are properly controlled and that these substances are progressively substituted, where this is technically and economically viable. Restriction (Title VIII of REACH) is a safety net to address unacceptable risks to human health or to the environment arising from the manufacture, use or placing on the market of substances which need to be addressed on a Community-wide basis.

Of specific relevance to restriction and authorisation is the socio-economic analysis, where the benefits of a use or uses of a chemical are weighed against the corresponding risks to human health or to the environment. An authorisation for a substance where it is not possible to determine a "safe threshold" (non-threshold substance) can only be granted where it can be shown that there are no alternatives for a particular use (based on considerations of cost, technical performance and potential for an overall reduction in risk) and that the socio-economic benefits of the use outweigh the risks. A particular use of a substance may be restricted when the aggregation of the exposure may lead to risks which may not be adequately controlled even when risk management measures are in place or else due to exposure/risk from degradation products.

Impacts on the soil compartment are relevant to the socio-economic analysis of restrictions and authorisations, most notably for persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances (ECHA 2014a). The environmental impact assessment on the soil compartment in a socio-economic analysis may include the assessment of changes in risks to biodiversity (e.g. the number of species and varieties/races), flora, fauna and/or landscapes (e.g. the scenic value of protected landscape) or land use which may affect the environment (e.g. affect the balance between urban and rural land use, or reduction of 'greenfield' sites).

Monetising the estimated changes in environmental impacts (e.g. determining the economic value of lost forests) has many challenges, especially with regards to the quantification of the impacts of substance properties for which a PNEC cannot be determined such as PBT or vPvB properties.

The ECHA guidance on socio-economic analysis (Authorisation) (ECHA 2011) uses a cost-benefit analysis type approach which involves recognising that not all impacts can be quantified or monetised. As such, it is proposed that the analysis should involve quantifying and monetising impacts as far as is practicable (and appropriate) and combining the monetised results with qualitative and/or quantitative descriptions of all non-monetised impacts.

Opinions on restrictions and authorisations for PBT or vPvB substances are currently based on emissions of substances to the soil compartment, rather than their impacts. Emissions are used as a proxy for the damage. However, applicants are requested to

include factors or situations that may indicate that the particular PBT or vPvB substance would be likely to cause either more or less damage.

Soil compartment in the chemical safety assessment under REACH

A chemical safety assessment (CSA) of a substance under REACH includes the following steps:

1) human health hazard assessment (main principles are described in section 1 of Annex I to the REACH Regulation);
2) physicochemical hazard assessment (main principles are described in section 2 of Annex I to the REACH Regulation);
3) environmental hazard assessment (main principles are described in section 3 of Annex I to the REACH Regulation);
4) PBT/vPvB assessment (main principles are described in section 4 of Annex I to the REACH Regulation).

Environmental hazard assessment where predicted no effect concentrations (PNECs) are derived, considers:

- the aquatic (including sediment) compartment;
- the terrestrial compartment;
- the atmospheric compartment;
- accumulation through the food-chain; and
- microbiological activity of sewage treatment systems.

The overall objective of the terrestrial toxicological assessment scheme proposed by REACH is to identify the trophic levels of soil organisms (micro-organisms, invertebrates, plants) that might potentially be adversely affected by a specific substance when present in the soil, and to derive a scientifically reliable soil upper threshold concentration of no concern (predicted no effect concentration for soil — PNECsoil) for those substances.

The scope of the terrestrial effect assessment under the REACH Regulation is restricted to soil organisms 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. It should be noted that secondary poisoning risks to predators following chronic exposure to a substance through the terrestrial (soil earthworm) food chain should also be assessed by registrants.

The REACH "standard information requirements" are listed in Annexes VII to X to the REACH Regulation. The minimum dataset defined by REACH depends on the annual tonnage, i.e. quantity manufactured or imported by a registrant per year. The larger the quantity manufactured or imported by a registrant per year, the more data that the registrant should provide in their registration dossier.

This principle also applies to the terrestrial dataset. For registrations from 100 to 1 000 tonnes per annum (tpa), results of short-term toxicity studies on soil invertebrates and plants should be provided together with the results of toxicity study for soil microorganisms. When the registration tonnage is above 1 000 tpa, long-term toxicity studies with soil invertebrates and plants should be provided in the registration dossier.

For highly adsorptive (log Kow > 5) and very persistent substances (half-life in soil > 180 days), long-term toxicity data instead of short-term data should be provided for substances even at tonnage from 100 to 1 000 tpa.

According to column 2 of REACH Annexes IX and X, the terrestrial toxicity studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. Moreover, the equilibrium partitioning method (EPM) may be applied to assess the hazard to soil organisms. EPM is based on the assumption that soil toxicity expressed in terms of the freely-dissolved substance concentration in the pore water is the same as

the toxicity of the substance to aquatic organisms. The applicability of the equilibrium partitioning method has been evaluated less for soil than for sediment-dwelling organisms.

It should be recognised that substitution of terrestrial toxicity data by aquatic toxicity data should be done with caution. This is because the effects on aquatic species can only be considered similar to effects on soil organisms if the soil organisms are exposed exclusively to the soil pore water. This may be appropriate only for terrestrial organisms with a water-permeable epidermis. Furthermore, studies have shown that the equilibrium partitioning method can give significant over- or underestimations, due to inaccurate partitioning coefficients or differences in species sensitivities (ECHA 2008).

The principles of soil hazard assessment are summarised in ECHA's *Guidance on information requirements and chemical safety assessment, Chapter R7c, Section R.7.11* (ECHA 2014b). It summarises the integrated testing strategy for effects on terrestrial organisms. It is necessary to consider all available information on substance properties, especially on water solubility, octanol/water partitioning (log Kow) and/or soil sorption potential (e.g., log Koc), vapour pressure, biotic and abiotic degradation, and the potential for soil exposure.

The choice of the appropriate tests depends on the outcome of the chemical safety assessment (ECHA 2014b), taking into account all available (eco)toxicity and physicochemical data. When aquatic toxicity data are not available, i.e. a PNEC for water cannot be derived or the EPM method is not applicable, the full set of soil toxicity experimental data would need to be provided in the registration dossier.

When aquatic toxicity and environmental fate data are available, the substances can be categorised into four different soil hazard categories (Table R.7.11-2 in ECHA 2014b). Different adaptations of the testing requirements are possible depending on the soil hazard category to which the substance belongs. The full dataset, including long-term toxicity studies on terrestrial invertebrates and plants and on microorganisms, is expected for chemicals that belong to soil hazard category 4, which are characterised by high adsorption (e.g. log Kow > 5) and/or high persistence in soil (i.e. DT50 in soil > 180 days), and high aquatic toxicity (i.e., EC/ LC50 <1mg/l) (Versonnen et al 2014).

Furthermore, currently ECHA follows the practice that information on toxicity to soil microorganisms is included by default in all cases where a hazard is indicated for the soil compartment (hazard category 2, 3 and 4), independently of whether concern is driven by the physical-chemical properties of the substance, aquatic toxicity data or both. Nevertheless, ECHA acknowledges that the registrant may provide a specific and scientifically acceptable justification for waiving soil microbial testing.

When requesting missing terrestrial hazard information, ECHA currently includes the following test guidelines into the decision for Annexes IX and X 9.4 information requirements;

- Short-term toxicity to invertebrates; Earthworm acute toxicity tests (EU C.8./OECD 207, OECD 1984);
- Long-term toxicity to invertebrates; Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (OECD 222, OECD 2004b), or Enchytraeid reproduction test (OECD 220, OECD 2004c), or Collembolan reproduction test in soil (OECD 232, OECD 2009a);
- Short-term toxicity to soil microorganisms; Soil microorganisms: nitrogen transformation test, (EU C.21/OECD 216, OECD 2000);
- Short-term toxicity to plants; Terrestrial Plants Test (OECD 208, OECD 2004a), with at least three species tested (with as a minimum one monocotyledonous species and two dicotyledonous species);
- Long-term toxicity to plants; Terrestrial Plants Test (OECD 208), with at least six species tested (with as a minimum of two monocotyledonous species and four

dicotyledonous species), or Soil Quality – Biological Methods – Chronic toxicity in higher plants (ISO 22030:2005).

The information on long-term avian toxicity is used to assess the secondary poisoning risks to predators following exposure to a substance through the earthworm food chain. Given that mammalian toxicity is considered in detail for human health protection, the need for additional data for birds must be considered very carefully. Secondary poisoning is out of scope of this workshop and therefore not described here in detail.

As underlined above, CSA under REACH also covers a *PBT/vPvB assessment*. The main aim of the PBT/vPvB assessment is the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) by using criteria laid down in Annex XIII to REACH (ECHA 2014c). Section 1 of Annex XIII includes degradation half-lives in soil as part of the persistent/very persistent criteria and the soil simulation testing is a standard information requirement under Annex IX 9.2.

There are currently no legal or scientific PBT/vPvB criteria for soil bioaccumulation and soil toxicity. However, discussions have been held at the European level to suggest approaches for the development of non-aquatic bioaccumulation and toxicity criteria for PBT/vPvB assessment (European Commission – Joint Research Centre 2014).

Where data exist showing potential for bioaccumulation or toxicity to soil organisms, these should be considered along with other data in a weight-of-evidence approach to the bioaccumulation and the toxicity criteria (see Sections 3.2.2 (b) and 3.2.3 (f) of Annex XIII). The weight-of-evidence determination enables the use of all (screening and assessment) information types listed in Section 3 of Annex XIII to REACH in the PBT/vPvB assessment for comparing with the criteria, although not all of these information types can be directly (numerically) compared with the criteria. If available data shows potential bioaccumulation or toxicity in soil organisms and the substance is persistent, further information on bioaccumulation and subsequently on toxicity must be generated by the registrant to conclude on the PBT/vPvB assessment.

The REACH Regulation states that where the manufacturer or importer concludes that the substance fulfils the criteria for some respective hazard classes or categories set out in Annex I to the Classification, Labelling and Packaging Regulation (CLP) (Regulation (EC) No 1272/2008) or is assessed to be a PBT or a vPvB, the chemical safety assessment must also include exposure assessment and risk characterisation steps.

Exposure assessment entails two steps (main principles are described in Section 5 of Annex I to the REACH Regulation):

Step 1: Generation of exposure scenarios or relevant use and exposure categories containing information on:

- Operational conditions;
- Risk management measures.

Step 2: Exposure estimation which entails three sub-steps:

- Emission estimation;
- Assessment of chemical fate and pathways;
- Estimation of exposure levels.

Standard exposure estimates for the environment where predicted environmental concentrations (PECs) are identified include:

- Water pelagic (freshwater, marine);
- Water sediments (freshwater, marine);
- Aquatic food chain (freshwater predator, marine predator and marine top predator);

- Sewage treatment;
- Air (e.g. impact on the ozone layer);
- Soil (agricultural);
- Soil food chain.

In the REACH Regulation, it is specified that the exposure assessment must consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses, and cover any exposures that may relate to the identified hazards.

ECHA's *Guidance on information requirements and chemical safety assessment, Chapter R.16: Environmental Exposure Estimation* (ECHA 2012a) provides guidance on how to estimate environmental exposure for REACH purposes. Exposure estimation for the soil compartment is important with respect to exposure of terrestrial organisms.

Furthermore, crops are grown on agricultural soils for human consumption, and cattle, producing meat and milk, are grazing on grasslands. For soil, three different predicted environmental concentrations (PECs) are calculated, for different endpoints:

- PEC for local soil (averaging time - 30 days) for the terrestrial ecosystem;
- PEC for local agricultural soil (averaging time – 180 days) for crops for human consumption;
- PEC for local grassland (averaging time – 180 days) for grass for cattle.

Exposure routes through the application of sewage sludge in agriculture and dry/wet deposition from the atmosphere are taken into account for the calculation of the PEC for local soil. Accumulation of the substance in soil may occur when sludge is applied over consecutive years. The concentration will be high just after sludge application and lower at the end of the year due to removal processes. Therefore, exposure concentrations need to be averaged over a certain time period. For the ecosystem, a period of 30 days after application of sludge is used. To determine biomagnification effects and indirect human exposure, it is more appropriate to use an extended period of 180 days.

The following processes are considered for the removal of the substance from the soil:

- biodegradation;
- volatilisation of the substance from soil; and
- leaching to deeper soil layers.

Biomagnification may occur through the terrestrial food chain. The food-chain soil-earthworm-worm eating birds/mammals are used for assessing secondary poisoning through the terrestrial food chain.

For that purpose, the PECoral,predator is calculated which is equal to the total concentration of the substance in the worm as a result of bioaccumulation in worm tissues and the adsorption of the substance to the soil present in the gut (further details on the calculation method are provided in ECHA 2012a).

If the substance fulfils the criteria or is considered to be a PBT or vPvB in the registration dossier, an emission characterisation must be conducted comprising the relevant parts of the exposure assessment as described above. In particular, the exposure assessment must contain an estimation of the amounts of the substance released to the different environmental compartments during all activities carried out by the manufacturer or importer and all identified uses, and an identification of the likely routes by which humans and the environment are exposed to the substance.

The risk characterisation (main principles are described in Section 6 of Annex I to the REACH Regulation) must be carried out for each exposure scenario and presented under the relevant heading of the chemical safetyr. Risk can be considered adequately controlled when the PEC ≤ PNEC or qualitative assessment indicates that effects are avoided when the exposure scenario (generated by the registrant) is implemented.

For substances satisfying the PBT and vPvB criteria, registrants have to implement on their site and recommend risk management measures for downstream users, which minimise exposures and emissions to humans and the environment. CSA is documented by the registrant in the chemical safety report (CSR) which has to be submitted to ECHA in the registration dossier.

2.2 Soil risk assessment under the BPR

The Biocidal Products Regulation (BPR) (Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products) entered into force on 1 September 2013 (EC 2012).

The common principles for the evaluation of dossiers for biocidal products, covering also the risk assessment for soil, are provided in Annex VI to the BPR.

The current general practice of performing environmental risk assessments for biocides aims to achieve a general level of protection for the environment. The main goal is protecting the structure and function of the ecosystems in general without considering ecological, temporal or spatial differences caused by different emission patterns, differences among ecosystems or different ecosystem functionalities or services.

According to the ECHA Guidance on the Biocidal Products Regulation (ECHA 2015), replacing the former technical guidance document of 2003, an environmental risk assessment for a biocidal product includes the following steps:

- Effect/hazard assessment
- Exposure assessment
- Risk assessment

In the **environmental effect/hazard assessment** for soil, predicted no effect concentrations (PNECs) are derived following the basic principles described in ECHA's Guidance on the Biocidal Products Regulation.

The overall objective of the terrestrial toxicological assessment scheme is as proposed by REACH to identify the trophic levels of organisms living in the soil compartment (micro-organisms, invertebrates, plants) that will potentially be adversely affected by a specific substance when present in the soil, and to derive a scientifically-reliable upper threshold concentration of no concern for the substance in the soil compartment.

The information requirements to perform the hazard assessment under the BPR are listed in Annexes II and III to the BPR; it is distinguished between a core data set (CDS) and an additional data set (ADS).

The core data set (CDS) is considered as the basic data set which should, in principle, be provided for all active substances. It is mandatory for all product-types. This information always has to be submitted, unless the rules for adaptation of standard information are applicable. The additional data set (ADS) might be required to perform the risk assessment under the following conditions:

- ADS information on physical chemical properties, methods of detection and identification and on the toxicological profile is required depending on the intrinsic properties of the active substance or the biocidal product.
- ADS information on the ecotoxicological properties and the environmental fate and behaviour of the active substance or biocidal product is required depending on the product-type, i.e. the foreseen use and route of exposure.
- ADS information on the ecotoxicological properties and the environmental fate and behaviour might be required to refine the initial risk assessment.

Studies on terrestrial organisms are part of the ADS and are triggered depending on the release pathways of the substance (e.g. if direct release to soil occurs). Moreover, the equilibrium partitioning method (EPM method) may be applied to assess the hazard to soil organisms. Further information on data requirements for each specific product-type can be found in the Guidance on information requirements (ECHA 2014d).

In general, long-term ecotoxicity data are required if there is potential for continuous emission to the terrestrial environment e.g. because of leaching from a biocidal product or a treated article. If the release is intermittent or the intended use is limited to small or closed spaces with insignificant release, initial short-term tests providing acute ecotoxicity data may be sufficient to meet the additional testing requirements, unless there are concerns that chronic effects may arise when taking into account, for example, the mode of action or the expected environmental fate of the substance.

Exposure assessment for soil consists of the following steps:

- Assessment of chemical fate and behaviour in the different environmental compartments;
- Emission estimation based on the exposure pathway which mainly depends on the type of use; and
- Calculation of predicted environmental concentrations (PEC).

For biocides, exposure assessment must consider all stages of the life-cycle of the substance including manufacturing, service life and waste treatment and recycling.

The exposure characterisation must be carried out for each type of use and consider all metabolites and degradation products that may occur in concentrations above 10%.

For biocides, one of the main challenges when performing exposure estimations is related to the wide variety of uses (i.e., product-types) of the different biocidal products. In the BPR, there are 22 product-types (PT) covering four main groups (disinfectants, preservatives, pest control and other biocides) where the use pattern and the exposure routes vary dramatically.

Emissions are calculated using exposure scenario documents (ESDs) which describe the use pattern in detail, the main environmental compartments affected and the equations needed to calculate the exposure. Detailed exposure scenarios have not yet been developed for all 22 product-types or all uses within a product-type.

Depending on the product-type, soil can be exposed either **indirectly** through, e.g. sewage sludge application, manure application in agriculture or wet/dry deposition from air, or **directly** by losses during application or leaching from a treated commodity during service life.

For **indirect release** as under REACH, three different predicted environmental concentrations (PECs) are calculated:

- PEC for local soil (averaging time = 30 days and soil depth = 20 cm), endpoint for the terrestrial ecosystem;
- PEC for local agricultural soil (averaging time = 180 days and soil depth = 20 cm), endpoint for crops for human consumption;
- PEC for local grassland (averaging time = 180 days and soil depth = 10 cm) endpoint for grass for cattle.

In addition to REACH, the PIECsoil (predicted initial concentration in soil) after manure application is calculated for the relevant product-types (e.g. in PTs 3 and 18).

For **direct release,** which occurs in different product-types, three different time scales are normally considered:

- initial concentrations: these are the environmental concentrations immediately after the last application (e.g. at the end of the application day). Degradation processes are not considered (worst-case).

- short-term concentrations: these are the environmental concentrations cumulated over the first 30 days of emissions (initial leaching period). They are expressed as actual concentrations. Degradation processes (i.e. degradation, volatilisation and leaching to groundwater) during this period can be considered
- long-term concentrations: these are the environmental concentrations expressed as time weighted average concentrations for time periods of > 30 days. Depending on the characteristics of the substance and the service life of treated commodities, time periods up to several years of service life may need to be assessed

For all cases in direct release, a soil depth of 50 cm and a distance of 50 cm to the source are considered.

With regards to the soil properties to be used in the calculations, standard soil properties as described in Vol IV Environment – Part B Risk Assessment (ECHA, 2015) are used.

In the **soil risk assessment** the PEC estimated during the exposure assessment is compared with the PNEC estimated during the effect/hazard assessment; if PEC > PNEC, then there is a potential risk.

In addition to the risk assessment for soil, a PBT/vPvB assessment is also required by the BPR for the assessment of exclusion and substitution criteria laid down in Article 5 (1) and Article 10(1) of the BPR, respectively.

The main aim of the PBT/vPvB assessment is the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) by using criteria laid down in Annex XIII to REACH. For further information on the PBT assessment related to soil, please refer to the respective paragraph for REACH in Section 2.1 above.

2.3 Soil risk assessment for plant protection products

SANCO/10329/2002 Terrestrial Guidance and data requirements for in soil organisms

The current risk assessment for in soil organisms is carried out according to the SANCO/10329/2002 Terrestrial Guidance Document (EC 2002c) developed under the **Council Directive 91/414/EEC** (EC 1991).

This Directive was repealed in 2009 by the **(EC) Regulation 1107/2009** (EC 2009), while the Commission **Regulation (EU) No 283/2013** (EC 2013a) and **284/2013** (EC 2013b) laid down the new data requirements for active substances and plant protection products (PPPs), respectively. Therefore, only the parts of the SANCO/10329/2002 covered by the regulations will be considered in the following paragraphs.

The risk assessment of in soil organisms follows the principle of the risk assessment paradigm: 1) hazard identification, 2) hazard characterisation, 3) exposure assessment, and 4) risk characterisation.

A tiered approach is used. The concept of tiered approaches is to start with a simple conservative assessment and to go towards more complex evaluations, when necessary. The general principles of tiered approaches are:

(i) lower tiers are more conservative than higher tiers,

(ii) higher tiers are more realistic than lower tiers,

(iii) lower tiers require less effort than higher tiers

Exposure assessment

The exposure characterisation is represented by a comprehensive evaluation of fate and behaviour of active substances and pertinent transformation products in soil of the treated area, including the estimation of predicted environmental concentrations (PEC_s).

The initial PEC_s values after single or multiple applications and PECs plateau (concentration in soil reached when a pesticide is relatively persistent and may accumulate) are calculated according to the FOCUS model (FOCUS 1997). The choice of the relevant PECs to be used for risk assessment will depend on the characteristic of the active substance (e.g. persistence in soil) and on the intended uses.

Effect assessment

The effect assessment is represented by a comprehensive investigation of the dose-response relationships, to derive toxicity endpoints (e.g. LC_{50}, NOEC) which can be compared with the predicted environmental concentrations.

According to the new data requirements, the studies listed below should be conducted and reported, unless it is proven that the contamination of soil is unlikely. It is highlighted that the acute toxicity study on earthworms is not anymore a data requirement.

- Test for sub-lethal effects on earthworms (*Eisenia fetida* or *Eisenia Andrei*). The test is conducted according to the guideline OECD 222 (OECD 2004b) and information on the effects on growth, reproduction and behaviour of the earthworm should be reported. The relevant endpoint might be either/both EC_{10}, EC_{20} or/and NOEC.

- Test on *Folsomia candida* (OECD 232, OECD 2009a) and *Hypoaspis aculeifer* (OECD 226, OECD 2008a) for plant protection products applied directly to soil as soil treatments. For plant protection products applied as a foliar spray, data on soil invertebrates other than earthworms may be required if concerns have been identified in the risk assessment of non-target arthropods, as data on both *Aphidius rhopalosiphi* and *Typhlodromus pyri* may be used in an initial risk assessment. The relevant endpoint might be either/both EC_{10}, EC_{20} or/and NOEC.

- Test on the impact of active substances and plant protection products on soil microbial activity, in terms of nitrogen transformation (OECD 216, OECD 2000). The results in the rates of nitrate formation between the lower treatment (i.e. the maximum predicted concentration) and control are reported in percentages.

If further refinements of the risk are triggered, field studies reflecting the intended uses of the plant protection product, the environmental conditions likely to arise and testing species that will be exposed, should be conducted.

Field studies evaluate the effects on abundance and biodiversity, taking into consideration the likely level of effects, the species/groups affected, population recovery (within one year) as well as information on the application and fate of the plant protection products (EPPO 2003)

The risk to soil organisms other than earthworms can be further refined using a more realistic test substrate or exposure regime.

Risk assessment

The risk characterisation is represented by the calculation of appropriate risk quotients. For earthworms and other soil macro-organisms, SANCO/10329/2002 recommends calculating the acute and chronic toxicity exposure ratios (TERs = LC50, ECx or NOEC

/PEC). However, based on the new data requirements, only the chronic TER would be currently relevant.

TERs are compared with trigger values defined in the Uniform Principles (Commission Regulation (EU) No 546/2011, EC 2011) to establish whether the risk is low or high.

Triggers are "safety factors" that should take into account uncertainties in the intra- and inter-species variability and the extrapolation of toxicity endpoints from laboratory to field (including uncertainties with regard to the actual exposure in the field). For earthworms and soil macro-organisms, the current trigger value is 5. If the TER values are below 5, a high risk is identified.

For soil micro-organisms, the magnitude of effects is directly assessed in terms of risk. According to Regulation 546/2011, a low risk to micro-organisms is demonstrated if the percentage of effects is below 25% after 100 days.

Public consultation on SANCO terrestrial Guidance (SANCO/10329/2002)

In view of the revision of the current risk assessment for terrestrial organisms, in 2008, EFSA launched a public consultation on the SANCO Guidance Document on Terrestrial Ecotoxicology (EFSA 2009).

The aim of the public consultation was to collect issues and gaps identified by different stakeholders to be used as inputs in the revision of the terrestrial guidance.

A total of 32 comments were received from different stakeholders on the chapter of soil organism (Chapter 6 of the SANCO guidance). The main comments were the following:

- Development of specific protection goals for soil organisms.
- More clarity on the level of assessment (structure *vs* function).
- More guidance on persistent substances.
- More guidance on how to consider bioavailability when interpreting effect test results and the need for more standardised test design (% peat, addition of feed, application of the test item, correction factor).
- Earthworms field studies: more guidance on the evaluation of effects and acceptability criteria (% effects based on total earthworms numbers, biomass, safety factor, etc.). The use of the guidance on how to summarise earthworm field studies was suggested.
- Introduction of semi-field tests (e.g. TME).
- More guidance on the interpretation of effects on soil microflora.
- More guidance on the exposure assessment (measurement of the concentration in the test, selection of the appropriate PEC, persistence, etc.).

EFSA activities on risk assessment for in soil organisms

In the context of the revision of the SANCO Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) and Persistence in Soil (SANCO/9188VI/1997 of 12 July 2000), in the last five years, EFSA has tasked the panel on plant protection products and their residues (PPR Panel) to produce several opinions including the scientific updated knowledge both for the exposure and effect assessment for in soil organisms. Opinions have been or will be followed by EFSA guidance's documents focusing on the development of methodological approaches on how to carry out the risk assessment.

Stakeholders have been involved and consulted throughout the revisions of the SANCO documents starting with the *"Improved Realism in Soil Risk Assessment" (IRIS)* work shop organised with EFSA and the Joint Research Centre (JRC) in 2009. Proceedings are available at: http://www.efsa.europa.eu/de/search/doc/338r.pdf.

Furthermore, EFSA has organised public consultations on opinions and guidance documents to provide stakeholders the opportunity to comment on the drafts of those documents. The stakeholder comments have been taken into consideration before publishing the final documents.

PPR opinions and EFSA guidance documents related to development of in soil risk assessment methodologies are listed below.

Exposure assessment

- Scientific opinion of the PPR Panel on emissions of plant protection products from greenhouses and crops grown under cover: outline for a new guidance (EFSA PPR Panel 2010a).
- Scientific opinion on clustering and ranking of emissions of plant protection products from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments (EFSA PPR Panel 2012)
- EFSA Guidance Document on clustering and ranking of emission.ns of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments (EFSA 2014a).
- EFSA PPR Panel Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of plant protection products in soil (EFSA PPR Panel, 2010b).
- EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil (EFSA 2014b).
- Scientific opinion on outline proposals for assessment of exposure of organisms to substances in soil (EFSA PPR Panel 2010c).
- 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 PPR Panel 2012).
- EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil (EFSA 2015).

Effect assessment

- Scientific opinion on the development of a soil eco-regions concept using distribution data on invertebrates (EFSA PPR Panel 2010d).
- Scientific opinion on the importance of the soil litter layer in agricultural areas (EFSA PPR Panel 2010e)
- Scientific opinion addressing the state of the science on risk assessment of plant protection products for in soil organisms. This activity is on-going and the opinion will be finalised by June 2016.

The opinion will be followed by a guidance document which, according to the mandate, should be issued by the second quarter of 2018.

2.4 European Medicines Agency (EMA): human and veterinary pharmaceuticals

Human medical products (HMP)

Since 1993, the environmental risk of medicinal products intended for marketing within the European Union (EU) requires evaluation (EC 1993). A guidance document on environmental risk assessment (ERA) was adopted by the European Medicines Agency in 2006 (EMEA/CHMP 2006). This document suggests a tiered approach for the environmental risk assessment.

In **Phase I**, environmental exposure is assessed based on the dose used and the prevalence of the disease. If the predicted environmental concentration in surface waters (PECSW) exceeds the threshold value of 10 ng L-1, studies on physico-chemical properties, environmental fate and effects have to be performed in Phase II.

Irrespective of the quantity released to the environment, environmental risks have to be investigated in Phase II, if there are environmental concerns such as potential effects on reproduction of organisms at concentrations below the threshold value by applying a tailored risk assessment strategy (EMEA/CHMP 2006).

According to EMEA/CHMP (2006) a PBT (persistent, bioaccumulative and toxic) assessment is required, if the logarithm of the octanol-water partition coefficient (log K_{OW}) is higher than 4.5. In EMA/CHMP (2011) it is specified that the PBT assessment should be performed according to Annex XIII to the REACH Directive (EU 2011) and REACH guidance R.11 (ECHA 2014c).

The **Phase II** risk assessment is divided into two parts: Tier A, in which the base set data are determined, and Tier B.

In Tier A and in accordance with the main exposure route for human pharmaceuticals to water through sewage treatment plants (STPs), a deterministic quantitative risk assessment is conducted for surface water, groundwater and micro-organisms in water; i.e. the specific PEC values are compared with the respective predicted no effect concentrations (PNECs). If one or more of the resulting risk quotients show an unacceptable risk, further data have to be generated for a refined risk assessment in Tier B.

Additionally in Tier A, adsorption-desorption (K_{OC}), ready biodegradability and, if the substance is not readily biodegradable, transformation in aquatic sediment systems is evaluated. If the log K_{OW} (determined in Phase I) is higher than 3, the bioconcentration factor should be determined in Tier B. If the log K_{OC} is higher than 4, a risk assessment for the terrestrial compartment is required in Tier B, since it is assumed that considerable amounts of the substance may reach agricultural fields through sewage sludge.

For the experimental characterisation of environmental fate and effects of the substance, standardised study protocols, preferably OECD guidelines, are suggested to make sure that data is comparable. In Tier B, all compartment-specific risk characterisations should indicate acceptable risks, i.e. PEC-PNEC ratios < 1.

Although the marketing authorisation of an HMP may not be refused because of environmental concerns, risk mitigation measures have to be considered and included in the product information if there are unacceptable risks. However, to date, hardly any appropriate risk mitigation measures exist for human pharmaceuticals. In any case, disposal advice needs to be included in the package leaflet.

According to EMEA/CHMP (2006), an assessment of the potential risk of human pharmaceuticals in the terrestrial compartment is only required, if the log K_{OC} of the substance is > 4. In such a case, the following tests have to be performed:

- Aerobic and anaerobic degradation in soil (OECD 2002);
- Soil microbes: nitrogen transformation test (OECD 2000);
- Terrestrial plant test (growth) (OECD 2004a);
- Acute earthworm test (OECD 1984);
- Collembola reproduction test (OECD 2009).

In all terrestrial tests, organisms are exposed to concentrations of up to 1 000 mg/kg dw. This concentration was proposed already in 1984 in the context of earthworm testing (OECD 1984) as the highest concentration to be tested since it is much higher than any concentration which is likely to occur in the environment (here, in agricultural soils after application of sewage sludge contaminated with an HMP).

Since the publication of the first ERA documents, it became clear that the acute earthworm test shows an inherent low sensitivity. Therefore and in analogy to the requirements for the environmental risk assessment of veterinary pharmaceuticals (VICH 2004), the earthworm reproduction test should be used instead of the acute earthworm test (OECD 2004b).

Veterinary medical products (VMP)

Like for HMPs, the environmental risk of medicinal products intended for marketing within the European Union (EU) requires evaluation (EC 1993). A first guidance document on how to perform the ERA was prepared by the European Medicines Agency in 1997 (EMEA/CVMP 1997). Based on this document, the EU, the USA, and Japan harmonised the ERA procedures and prepared two guidelines, of which the first focuses on exposure assessment (Phase I, VICH 2000) and the second on a tiered risk assessment (Phase II, VICH 2004). In the EU, additional guidance in support of the VICH guidelines is provided by EMEA (2008).

As for HMP, all fate and effect studies required for an ERA should be performed according to international guidelines (e.g., OECD or ISO).

In **Phase I**, a number of questions concerning application and properties of the VMP direct the ERA to the main exposure scenarios, i.e. aquaculture, intensively reared and/or pasture animals (VICH 2000). Then, predicted worst-case environmental concentrations (PECs) are estimated based on the dose and frequency of the product applied. If, for intensively reared and pasture animals, the PEC exceeds the trigger value of 100 µg/kg dw in soil, studies on physico-chemical properties, environmental fate and effects on selected non-target species have to be performed in Phase II (VICH 2004). For parasiticides used in treatment of pasture animals, the PECsoil trigger is circumvented and Phase II studies are necessary independent of PECsoil (similarly, hormones have to proceed to Phase II too).

In **Phase II Tier A**, the environmental risk is characterised deterministically by comparing the PECs with the predicted no effect concentrations (PNECs) for several environmental compartments.

Phase II Tier A assessment relies on a base set of data on physico-chemical properties, environmental fate and effects determined in single-species tests under laboratory conditions. VMPs may enter the terrestrial compartment through the spreading of manure from intensively reared (IR) animals on arable land or by excretion of dung by animals on pastures (P scenario).

Likewise, they can be released directly to surface water through treated animals (e.g. cattle) standing in shallow water bodies. Thus, for the soil compartment, a range of PECs has to be derived for the IR and P scenarios, separately for each animal type. For persistent compounds (DT90 soil > 1 year), accumulation in soil after the application of manure during successive years is possible and hence, a PECsoil plateau at a steady state should be calculated. Finally, initial PECs also have to be determined for the dung compartment.

As required by VICH (2004), these terrestrial tests have to be performed regularly (microbial and plant tests are not obligatory required in case the parasiticide has a PEC < 100 µg/kg soil):

- Aerobic and anaerobic degradation in soil (OECD 2002);
- Soil microbes: nitrogen transformation test (OECD 2000);
- Seedling emergence and seedling growth test (OECD 2004a);
- Earthworm reproduction test (OECD 2004b).

Since some EU authorities require information on the toxicity to non-target arthropods for parasiticides for the IR scenario, collembolan reproduction tests have to be conducted too (OECD 2009a). If the VMP is a parasiticide, i.e. used to treat livestock on pastures, tests with dung beetles and dung flies are also required in Tier A (OECD 2008b; OECD

2009b). These tests could also be performed using dung from treated cattle – an approach which is not recommended in the OECD-guideline, but it is considered to be appropriate for higher tier testing, since it reflects a more realistic exposure scenario.

To derive PNECs for the terrestrial compartment, the EC50 of the plant and the LC50 of the dung organism toxicity tests are divided by an assessment factor (AF) of 100, while the NOECs from the chronic earthworm and collembolan toxicity tests are divided by an AF of 10. Risk quotients are calculated either with the initial or with refined PECs.

If, in Phase II Tier A, a compartment-specific PEC exceeds the organism specific PNEC, an environmental risk is indicated. At this stage, further refinement of the exposure is possible (e.g. by using results of metabolism studies). Otherwise, in Tier B testing for the specific compartment including the organisms of concern is required.

In **Phase II Tier B**, no further guidance regarding effect testing with soil or dung organisms is provided by VICH (2004). Laboratory tests with additional species (e.g. predatory mites (OECD 2008a) as well as semi-field and field studies are mentioned by EMEA (2008) as possible further procedures. Recently, Adler et al. (2013) published a proposal to fill this gap in guidance on higher-tier testing, using dung beetles as an example. More or less in parallel, another option for higher-tier testing, especially for the evaluation of the effects of parasiticides on dung organism communities was discussed in detail by Jochmann et al (2011).

Finally, it should be mentioned that – assuming there is enough basic ecological information available for these dung organism communities – modelling of the effects of VMPs on the field or landscape level could be an option in the future (Jensen, pers. Comm).

Persistent, bioaccumulative and toxic (PBT) as well as very persistent and very bioaccumulative (vPvB) substances are of particular concern, since their effects are difficult to reverse and are often not detected at an early stage. Therefore, a guidance document has been prepared by EMEA/CVMP (2012) which is still under discussion.

This document refers to the PBT and vPvB assessment according to Annex XIII of the REACH Directive (EU 2011) and REACH guidance R.11 (ECHA 2014c). Recently, the outcome of a public consultation regarding the content of the draft guideline has been published (EMA/CVMP 2014).

Based on the outcome of the ERA, risk mitigation measures (RMMs) may be necessary to avoid the possible entry of VMPs into the environment. The requirement and definition of RMMs within the registration and authorisation procedures for veterinary pharmaceuticals is a common practice (EMA/CVMP 2011).

However, different entry pathways resulting from different application methods have to be considered and measures have to be specifically tailored. Therefore, further research is needed to identify appropriate RMMs for VMPs.

It may, for example, be appropriate to recommend to farmers to keep treated animals in the stable for a certain time following treatment to reduce the risk to dung organism communities. The respective time intervals should be fixed based on excretion data for the treated animal species, drug formulation and route of application.

2.5 Non EU regulatory frameworks

2.5.1 Soil risk assessment – Canadian context

In Canada, the risk of chemicals to soil is considered under several different programmes and under various federal acts. The main federal programmes which consider soil risk

include the assessment of new and existing substances under the Canadian Environmental Protection Act, 1999 (Canada 1999) and the assessment of pest control products under the Pest Control Products Act (Canada 2002).

Human exposure to industrial soil contaminants is considered by Health Canada. This document, however, will focus on the ecological aspects of soil risk assessment under the two key federal acts above which give a legal mandate to both Environment Canada and Health Canada to perform the assessment of chemicals in the environment.

The following is a general overview of soil risk assessments conducted by the above programs.

Assessment of new and existing substances under the Canadian Environmental Protection Act 1999

The principal federal legislative tool for assessing and managing chemical substances in the Canadian environment is the Canadian Environmental Protection Act, 1999 (referred to as CEPA 1999), jointly administered by Environment Canada and Health Canada. It was first promulgated in 1988 and then updated in 1999.

In 1994, under CEPA, the Domestic Substance List (DSL) was created, and consisted of approximately 23 000 substances used, imported or manufactured in Canada for commercial purposes between 1 January 1984 and 31 December 1986.

Under CEPA 1999, substances on the DSL were categorised for the purposes of prioritising them for further assessment. Categorisation classified each substance according to specific human and ecological criteria (i.e. persistence, bioaccumulation potential, inherent toxicity, and potential for exposure) and identified approximately 4 300 substances that required further assessment for human and ecological risk.

The assessment of these priorities is ongoing. Substances introduced to Canadian commerce following the creation of the DSL are considered to be "new" and must undergo assessment before their introduction into the Canadian marketplace in accordance with the New Substances Notification Regulation (NSNR).

Consideration of ecological risk of new pharmaceuticals, personal care products and veterinary drugs is also covered by CEPA 1999. The DSL includes a variety of substances, including discrete organics, inorganics, organometallics, polymers, and substances of unknown or variable composition complex reaction products or biological material (UVCBs). These substances are considered to be existing commercial substances and may not have been assessed for their potential risk to the environment or human health. The assessment of new and existing substances is part of the Canadian government's Chemicals Management Plan (CMP).

Assessments of new and existing substances are done to see if they meet the definition of toxic as defined in Section 64 of CEPA 1999 (Canada 1999):

"A substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that:

a. have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
b. constitute or may constitute a danger to the environment on which life depends; or
c. constitute or may constitute a danger in Canada to human life or health."

The risk assessment of new and existing substances includes the consideration of the substances':

1. fate in the environment;
2. persistence and bioaccumulation potential;
3. environmental hazard;

4. human health hazard; and
5. exposure.

CEPA prescribes that a weight-of-evidence and precautionary approach shall be used as guiding principles for assessment to see whether or not a substance meets the criteria for toxic as defined in CEPA 1999.

For new substances, minimum datasets are prescribed within the NSNR in accordance with the type of substance, the quantity, the intended use and the circumstances associated with its introduction.

Additional studies can be requested if they are critical. The assessment of existing substances generally proceeds based on publically available data or that voluntarily submitted by industry, the result being that many substances on the DSL are "data poor", especially regarding data associated with non-aqueous media such as soils. There are no prescribed data generation and submission requirements for existing substances in Canada and data must be collected by Environment and Health Canada.

Ecological soil risk assessment

Soil is often a medium of concern and a risk assessment of the soil compartment follows the above steps. The risk assessment can consider the substance itself and its metabolites, if appropriate. The risk to soil organisms through direct soil contact is important; however, indirect impacts on higher organisms (mammals, birds) can also be considered, especially for those substances with intrinsic properties that suggest that transfer through the foodweb may be important. In addition, impacts on soil quality (e.g. texture) can be considered.

Fate in the environment

For industrial chemicals, direct application to soil is not common. Therefore, determination of chemical distribution in the environment, including soil, is conducted using mass-balance multimedia models (e.g. equilibrium criterion model), similar to those employed in EUSES (i.e. SimpleBox).

These models can be employed to examine the intermedia transfer of chemicals to soil even though they may not be emitted to soil (e.g. atmospheric deposition). A simulation of regional level (i.e. 100 000 km^2) fate using a default emission rate to all environmental compartments simultaneously is often conducted, but where chemical release can be apportioned to specific modes of entry (water vs air vs soil), a more realistic fate scenario can be devised.

Normally, Environment Canada incorporates only the mass distribution and partitioning information from regional level multimedia models but in some cases the environmental concentrations from the model can be used for exposure assessment at regional levels (e.g. very dispersive releases).

Fate models can also be used to characterise long-range transport and atmospheric deposition to soil as well as air dispersion models for more localised fate scenarios. In cases where these models cannot be applied (e.g. permanently ionised chemicals, metals), fate is evaluated according to the physicochemical properties of the substance and the mode of entry into the environment.

Persistence and bioaccumulation

Persistence and bioaccumulation data are critical aspects of the assessment. These intensive properties are used for determining exposure potential (e.g. residence time in the environment, long-range transport) and for estimating tissue residues for evaluation of ecotoxicity as well as ADME properties. Specific indicators of bioaccumulation or trophic transfer such as soil bioaccumulation factors (BAFs), biota-soil accumulation factors (BSAFs), biomagnification factors (BMFs) or trophic magnification factors (TMFs) can be calculated or gathered from the literature and used as lines of evidence to assess the potential for harm in terrestrial foodwebs.

According to CEPA 1999, however, substances that meet the regulatory criteria for persistence and bioaccumulation as set out in the Persistence and Bioaccumulation Regulation (Canada 2000), meet the CEPA definition for toxic and are mainly anthropogenic in origin, are of high concern for the environment and human health and the risk management of these substances strives for virtual elimination of their release to the environment.

Canadian regulatory criteria for persistence are based on half-lives (days) which can be determined for all media (air, water, soil and sediment) based on empirical and/or modelled data. The Canadian criterion for soil persistence is a half-life ≥ 182 days. The bioconcentration factor (BCF) and BAF regulatory criteria (≥ 5 000) are for aquatic species, and there are currently no agreed upon regulatory criteria for soil bioaccumulation.

Environmental hazard assessment

Similar to other jurisdictions, the objective of the environmental hazard assessment for soils is to characterise the inherent potency of organic and inorganic chemicals to soil-associated organisms as well as derive a predicted no effect concentration (PNEC) in soil (PNECsoil) or in wildlife exposed through soil and/or the foodweb (PNECwildlife).

For exposure through direct contact with soil, toxicity data on invertebrates, microbial communities and plants are considered, when available. Environment Canada has developed several test methods for soils based on relevant Canadian species and soils, including methods for earthworms (Environment Canada 2004), agronomic plants (Environment Canada 2005), boreal plants (Environment Canada 2013), and collembola (including a boreal species) (Environment Canada 2014), and is currently developing a method for mites.

Other data may also be considered, including estimating body burdens from soil concentrations and biota-soil accumulation factors, or measured tissue residues.

Impacts on microbial communities are noted in assessments, however, difficulty in interpreting how these data impact higher levels of organisation results in these data having less weight in assessments. Impacts on higher organisms (e.g. avian soil insectivores, rodents, other mammals) through exposure through water, incidental soil ingestion and diet can also be considered. In this case, a PNECwildlife can be derived from repeated oral dose toxicity tests on laboratory rodents that have been normalised to the body weight of the wildlife predator of interest. A similar procedure for wildlife is used by the USEPA for Superfund sites (US EPA 1989).

Environmental exposure assessment

Exposure scenarios for soil risk assessment are dependent on the substance under consideration and its properties, manufacture and use patterns and can consider any stage of its life cycle. Exposure scenarios can include direct release or application during manufacture, transport, and/or use; removal of the substance from waste water to sludge and application of this sludge to agricultural soils; deposition from air; or ingestion of contaminated soil, water and/or food by wildlife.

The ultimate aim of the exposure assessment is to derive a predicted environmental concentration (PEC) against which the PNEC can be compared. PECs can be derived based on empirical data and/or modelled data. PECs are typically calculated as soil concentrations (PECsoil) to account for direct contact with the medium or for subsequent foodweb modelling. Bioenergetics foodweb modelling (e.g. soil-earthworm-shrew-fox) is used to estimate the total daily intake (TDI) exposure in the food of a tertiary or quaternary predator on a mg/kg body weight/day basis.

The TDI is used as the PECwildlife which can then be compared to the PNECwildlife. A critical body burden approach (McCarty and MacKay 1993; Escher et al. 2011, McCarty et al. 2013.) can also be used to determine the tissue residue values of narcotic organic chemicals in organisms such as earthworms and other invertebrates provided that soil

concentration data and robust soil invertebrate BSAFs or BAFs are available. Exposure scenarios are developed in tiers, with initial scenarios requiring less effort and being more conservative. If the initial scenarios indicate risk, further refinement of the scenario is conducted to increase its realism.

Environmental risk characterisation

As required under CEPA 1999, a weight-of-evidence approach is taken when characterising the risk of a substance in the environment. Lines of evidence are collated and examined for level and direction of uncertainty, strength (fit-for-purpose concept) as well as relevance in the assessment.

Those lines of evidence deemed to have a higher weight will contribute more to the overall conclusion of whether a substance meets the definition of toxic under CEPA 1999. Lines of evidence can include quantitative comparisons of PNECs to PECs, as well as information on the substance's persistence, bioaccumulation potential, presence in the environment, fate, mode of action, long-range transport, intrinsic properties (e.g. metabolism rate, bioavailability, physico-chemical properties) as well as current and anticipated future release patterns including frequency and magnitude of releases. Lines of evidence are specific to the behaviour of the substance and will vary from assessment to assessment.

Soil risk assessment for pest control products

The Pest Management Regulatory Agency (PMRA) is responsible for evaluating pest control products in Canada. In Canada, pesticides, including biocides, are defined as any product, device, organism, substance or thing that is manufactured, represented, sold or used as a means for directly or indirectly controlling, preventing, destroying, mitigating, attracting or repelling any pest.

The focus of this discussion will be on the evaluation of these inherently toxic substances as they pertain to soil and soil-dwelling organisms after deliberate application to agricultural lands. The main objective of an environmental risk assessment of such substances is to characterise the exposure and effects of pesticides on non-target biota to determine risk, such that measures can be identified to mitigate impacts.

Four steps are involved in the risk assessments:

1. data acquisition;
2. data analysis (exposure and ecological effects);
3. risk characterisation; and
4. risk mitigation.

Data acquisition

Before registering a pesticide, registrants are required to submit a suite of fate and ecotoxicology studies, dependent on the intended use of the pesticide. Fate data include physico-chemical properties, chemical transformation studies (e.g. hydrolysis and phototransformation), transformation studies in soils, adsorption/desorption studies, and field dissipation studies.

Ecotoxicity studies include acute and/or chronic studies on non-target soil-dwelling invertebrates and plant seedling emergence studies, and may include higher-tier studies more reflective of field conditions. For some pesticides, particularly systemic insecticides, toxicity studies on foliar-dwelling arthropods are required. Toxicity studies on birds and mammals are also required as they may be exposed to pesticides through ingestion of invertebrates and seeds that contain pesticide residues. If transformation products formed in significant amounts (> 10% of the parent compound) and/or have high toxicity, data may also be needed on these transformation products.

In general, laboratory studies are conducted with active ingredients and field studies are conducted with formulated end use products. In addition, the PMRA also considers information from international regulatory organisations, published scientific literature

and other available information such as monitoring data and incident reports from credible sources, particularly when assessing older pesticides that are undergoing re-evaluation.

Data analysis

- Exposure

During this step, the submitted fate data is analysed to determine the persistence and mobility of pesticide active ingredients and their major transformation products. Taking into consideration use patterns (application rate, timing, and interval), and based on the analysis of the fate data, estimated environmental concentrations (EECs) for various media, including soil, are determined. The PMRA also estimates the daily exposure of birds and small mammals through the ingestion of contaminated insects and plant seeds.

- Ecological effects

Toxicity to plant seedlings, earthworms, and for some products, soil arthropods is considered for direct soil contact. Toxicity to foliar arthropods that consume plants exposed to systemic pesticides is also considered. Acute and/or chronic toxicity data are considered, and if high toxicity is noted, higher-tier studies such as aged residue tests, semi-field tests and field tests are used to determine toxic effects.

Other organisms, such as birds and small mammals, may be adversely affected through ingestion of food (earthworms, insects and plants) containing pesticide residues. The PMRA considers ingestion of contaminated insects and plants (of various diet compositions, including 100% of a contaminated item) in its analysis. Acute and reproductive effects data for birds and mammals are considered for this scenario.

Risk characterisation

The PMRA uses the risk quotient method and a tiered approach to conduct risk assessments. An initial screening level assessment is used with the most conservative assumptions to efficiently identify pesticides that are not likely to pose a risk.

When a potential risk is identified and further characterisation is warranted, higher-tiered studies (e.g. semi-field and field studies) are used to determine a more realistic exposure scenario. For instance, refinements to the exposure scenarios may consider spray drift of pesticides off-site to habitats adjacent to the treated field or interception of a sprayed pesticide by plants when calculating an EEC; and may also consider different toxicity endpoints. In addition, refinements may also include the use of modelling techniques or monitoring data, if such data are available from Canada or the United States.

Risk mitigation

Risk mitigation measures for earthworms and soil-dwelling organisms may include label instructions to restrict application rate, timing, number of applications or application intervals, and reduce the amount of treated area (e.g. band row instead of broadcast application, untreated field margins).

If it is determined that the risk to soil dwellers cannot be adequately reduced by such measures, a cost/benefit analysis of the proposed use and/or labelling of the product may be considered.

2.5.2 U.S. Environmental Protection Agency (EPA)

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, or Superfund) is the law establishing the environmental programme to address abandoned hazardous waste sites in the U.S.

This law allows the EPA to clean up such sites and to compel responsible parties to perform clean-ups or reimburse the government for EPA-lead clean-ups. The statute charges EPA to protect human health, welfare, and the environment by reducing risks to acceptable levels. Therefore, an ecological risk assessment (ERA) is an important and necessary component in the remedial investigation of a hazardous waste site.

The ERA under CERCLA is conducted at hazardous waste sites to determine whether there are acceptable or unacceptable levels of risk to ecological receptors. Superfund ERAs are conducted to characterise present and future risks in the absence of remedial action. The Ecological Risk Assessment Guidance for Superfund (US EPA 1997) describes an eight-step process for assessing ecological risk at CERCLA sites.

The process contains three primary phases—screening-level ERA, refinement of preliminary contaminants of concern, and baseline risk characterisation. If the result of the site-specific baseline ERA is that ecological risk is unacceptable for one or more contaminants, then a risk-based ecologically protective clean-up value for the site media (e.g. soil) should be developed. The clean-up value is most often based on literature or site-specific exposure-effects relationships developed during the ERA. The risk-based clean-up value is critical information needed by risk managers for remedy evaluation and final clean-up decisions for the hazardous chemicals that pose unacceptable risks.

The eight-step process for conducting ERAs under Superfund in the U.S. is shown in Figure 1. One feature worth noting is that there are several scientific-management decision points (SMDPs) throughout the ERA. An SMDP is a point during the eight-step process where the risk manager – using the information provided by the risk assessor – determines whether the information is sufficient to arrive at a decision regarding risk management strategies and/or the need for additional information to characterise risk.

The screening-level ERA (SLERA) occurs within steps 1 and 2 and includes a general problem formulation and the use conservative exposure assumptions (e.g. 100% bioavailability of contaminants) and soil screening values such as the EPA ecological soil screening levels (EcoSSLs; US EPA 2005).

The screening assessment involves comparing contaminant concentrations in abiotic media to the screening levels. At the conclusion of the SLERA, there is an SMDP to determine whether ecological threats are negligible or the process should continue to a more detailed ERA (steps 3 through 7).

An important note is that in cases where screening levels do not exist for a given contaminant, the contaminant is not excluded from the baseline ERA. The baseline problem formulation is next (Step 3) and the assessment team more specifically defines the conditions and assumptions under which the baseline ERA will be completed for the ecological assessment endpoints (AEs).

The AEs are explicit expressions of the actual environmental values (e.g. ecological receptors) that are to be protected and they generally focus on survival, growth, and reproduction of receptors. Risk questions or hypotheses are posed for each AE and a conceptual site model is developed by describing the various exposure routes to be evaluated in the risk assessment relative to the AEs.

Step 3 also includes a refinement of preliminary contaminants of concern, which can allow for consideration of science-based modifying factors related to contaminant bioavailability assumptions.

Finally, Step 3 includes specifying the measurements that are needed to evaluate the risk questions for the AEs.

Steps 4-6 involve generating the work plan for collection data and other information that is needed for the ERA, verifying the field sampling design for any site-specific data collection needed for the ERA, and conducting the investigation.

Risk characterisation (Step 7) is comprised of the analysis of the exposure and effects data for the AEs to present a risk range for site-specific decision making. This risk range defines the threshold for effects on a given assessment endpoint as a range between contamination levels identified as posing no ecological risk and the lowest contamination levels identified as likely to produce adverse ecological effects.

Therefore, the risk range in most cases is expected to be reported as either the NOAEL-to-LOAEL risk range (US EPA 1997, 1998), or an effect concentration $(EC)_x$-lower to EC_x-upper risk range. The site-specific Superfund ERA can then be used in risk management decision-making in Step 8.

An important element of the decision is establishing the clean-up value, the development of which should consider the risk ranges for the AEs that were characterised during Step 7 of the ERA.

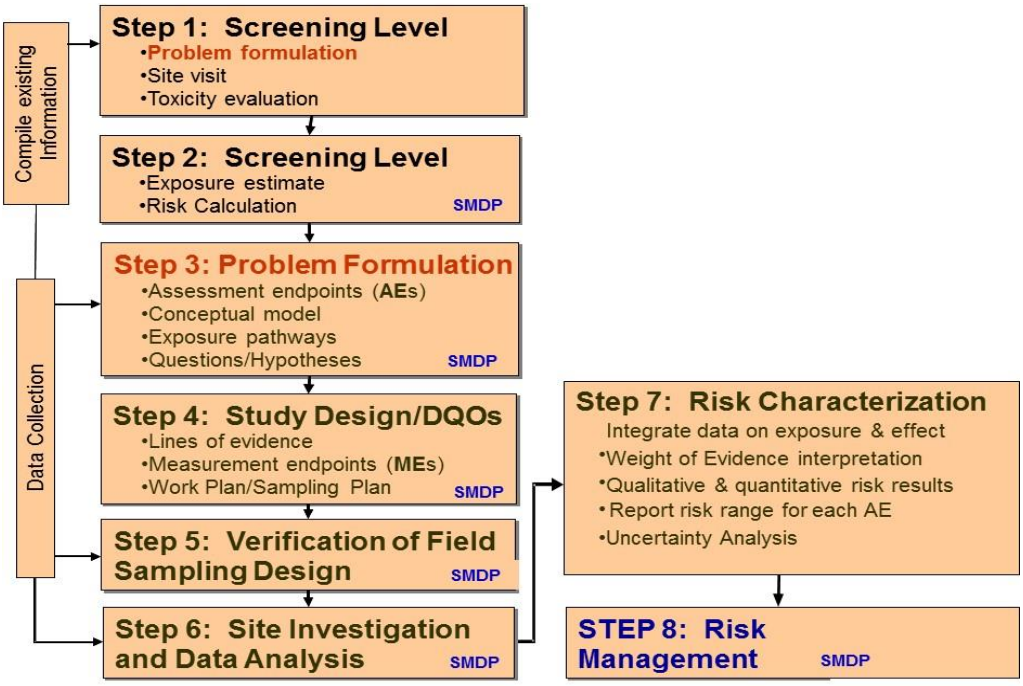

Figure 1. Eight-step ecological risk assessment process for Superfund (EPA, 1997).

It is important to clarify that different regulatory programmes within EPA have different risk assessment goals.

Superfund ERAs are considered retrospective because they focus on whether risk conditions are acceptable or unacceptable after a release to the environment has occurred. If the risk is unacceptable, then the information from the ERA can be useful when EPA seeks remediation of the site to address the ecological impacts. However, other programmes such as EPA's pesticide registration programme may seek to minimise the risks associated with releases before they occur (i.e. prospective risk assessment).

There are general technical documents for ERA that the Agency has released and these assist in providing consistency in implementing the ERA principles used across the various environmental programmes (See U.S. EPA 1998, 2003).

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