ECHA
EUROPEAN CHEMICALS AGENCY

Topical Scientific Workshop on Soil Risk Assessment

Helsinki, 7–8 October, 2015

Workshop proceedings

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Topical Scientific Workshop: Soil Risk Assessment
Reference: ECHA-16-R-09-EN
Catalogue number: ED-04-16-378-EN-N
ISBN: 978-92-9495-054-3
doi: 10.2823/785130
Date: May 2016
Language: English

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European Chemicals Agency
Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

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List of abbreviations

ADS	Additional data set
AF	Assessment factor
BPR	Biocidal Products Regulation
CDS	Core Data Set
CEN	European Committee for Standardisation
CEPA	Canadian Environmental Protection Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act (Superfund, USA)
CLP	Classification, Labelling and Packaging Regulation
CSA	Chemical safety assessment
DAR	Draft assessment report
DGT	Diffuse gradient in thin film
DSL	Domestic Substance List (Canada)
EC10	Effective Concentration at 10 % inhibition or the concentration that will have an effect of 10 % on the measured endpoint
EC50	Effective Concentration at 50 % inhibition or the concentration that will have an effect of 50 % on the measured endpoint
eCEC	Effective cation exchange capacity
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EcoSSL	Ecological soil screening level (USA)
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ERA	Ecological risk assessment
ES	Ecosystem services
ESD	Exposure scenario document
EPM	Equilibrium partitioning method
GEMAS	Geochemical mapping of agricultural and grazing land soil
GIS	Geographic information system
ISO	International Organisation for Standardisation
Kd	(Solid-liquid) partitioning coefficient
Koc	Soil organic carbon-water partitioning coefficient
Kow	Octanol-water partitioning coefficient
LC50	Lethal concentration 50 % is a standard measure of medium toxicity; concentration that is lethal to 50 % of the sample population
LC-MS	Liquid chromatography with mass spectrometric detection
LC-UV	Liquid chromatography with ultra-violet light detection
LLHC5	Lower limit hazardous concentration
LOE	Lines of evidence

LUFA	Natural standard test soils, which can be obtained from Lufa, Speyer, Germany
MoA	Mode of action
NER	Non-extractable residue
NOEC	No observed effect concentration
NOR	Normal operating range
NTTP	Non-target terrestrial plants
OECD	Organisation for Economic Cooperation and Development
PBPK	Physiologically-based pharmacokinetic model
PBT	Persistent, bioaccumulative and toxic
PCPA	Pest Control Products Act (Canada)
PEARL	Pesticide emission assessment at regional and local scales
PEC	Predicted environmental concentration
PEC_{SW}	Predicted environmental concentration in surface waters
PELMO	Pesticide leaching model
PERSAM	Persistence in soil analytical model
PG	Protection goal
PIECsoil	Predicted initial concentration in soil
PMRA	Pest Management Regulatory Agency (Health Canada)
PNEC	Predicted no effect concentration
PPP	Plant Protection Product Regulation
PPR	EFSA's Panel on Plant Protection Products and their Residues
QSAR	Quantitative structure–activity relationship model
RCR	Risk characterisation ratio
REACH	Registration, evaluation, authorisation and restriction of chemicals
SOM	Soil organic matter
SPG	Specific protection goal
SSD	Species sensitivity distribution
STP	Sewage treatment plant
SVHC	Substances of very high concern
TER	Toxicity exposure ratio
TKTD	Toxicokinetic-toxicodynamic model
TME	Terrestrial model ecosystems
TSWS	Topical scientific workshop
VMP	Veterinary medicine products
VP	Vapour pressure
vPvB	Very persistent and very bioaccumulative
WoE	Weight of evidence

Summary[1]

The European Chemicals Agency's (ECHA) topical scientific workshops (TSWSs) contribute to the Agency's third strategic objective to be a hub to promote good regulatory science.

The TSWS on Soil Risk Assessment was organised in cooperation with the European Food Safety Authority (EFSA), and held in Helsinki on 7-8 October 2015. The joint hosting of the workshop by the two agencies demonstrated the importance of the topic, as well as the willingness to work together on addressing the current challenges from the regulatory perspective.

The main objective of this TSWS was to review the state of the art in soil risk assessment, focusing on the safe use of industrial chemicals, biocides and pesticides. In addition, the workshop aimed to recognise the most critical generic-level improvement needs in soil risk assessment, and identify possibilities for harmonisation between different regulatory approaches.

Bringing together a range of stakeholders fulfilled the TSWS's goal of providing a platform for open discussion. A balanced participation of over 200 regulatory scientists, industry representatives, academic researchers and consultants from Europe and North America ensured an extensive coverage of views on the topics discussed.

The key issues relevant for soil risk assessment were summarised in the thought-starter document, compiled based on participants' responses before the event. In addition to setting the scene at the workshop by presenting the regulatory framework in EU and North America as well as selected case studies, the thought-starter document helped to streamline the discussions taking place on topics recognised as the most relevant.

Three main discussion themes were focused on:

(1) problem definition and conceptual model for soil risk assessment;

(2) environmental exposure and fate assessment; and

(3) effect assessment.

An anticipated outcome was the emergence of new or improved approaches which may be applied in the regulatory framework for soil risk assessment. The relevant topics that were discussed are presented below.

While soil protection goals may differ between different regulatory frameworks, they all aim to maintain soil functions. Defining specific protection goals (SPGs) under different legislations would potentially lead towards the development of risk assessment approaches enabling harmonisation, in relation to both fate and hazard assessment methodologies. SPGs should provide clear definitions of land/soil use, product use, exposure scenarios, and time scales. With the final level of protection being a risk

[1] This publication is solely intended for information purposes and does not necessarily represent the official opinions of the European Chemicals Agency, European Food Safety Authority, European Medicines Agency, US Environmental Protection Agency and Environment Canada. Neither these organisations nor any person acting on behalf of these organisations is responsible for the use that might be made of this publication.

management decision, which may differ among regulations and jurisdictions, underlying SPGs could still be defined based on harmonised methodology.

'Biodiversity' is frequently mentioned as a protection goal. However, the term currently does not represent a unique concept within the regulatory context. Regulatory definition would potentially help to incorporate biodiversity as one of the harmonised protection goals, and specify what we are trying to protect.

For representing what we are trying to protect, a good communication tool is needed. It was agreed that the ecosystem services approach may present such a tool, especially in relation to harmonising the protection goals. The approach is already incorporated in EFSA's guidance, but presents a somewhat new concept for ECHA when it comes to risk assessment.

Harmonisation of approaches was also discussed in a more narrow scope, particularly in relation to exposure and fate assessment. Biodegradation testing was given as one of the most prominent examples in relation to harmonising testing methods and conditions. In respect to bioavailability, the methods for identifying and quantifying non-extractable residues have potential for implementation in the regulatory framework. Exposure modelling was seen as another field that could benefit from harmonisation, since at this point the choice of models varies between different EU regulations.

In terms of effect assessment, microbial communities were singled out. Microorganism testing was recommended for all cases, since predicted no effect concentration (PNEC) derivation for screening purposes does not cover the microbial community.

The need to develop criteria for interpreting the results of the alternative soil microbe tests was highlighted. Another important issue was the lack of guidance for higher tier studies and their validation. While the terrestrial model ecosystems offer many advantages over laboratory studies, guidance is needed for experimental design, site selection, and regional considerations. Taking regional ecological differences into account was seen as a good way to help refine predicted environmental and no-effect concentrations.

Two topics have been in the spotlight in several discussions: the equilibrium partitioning method (EPM) and species sensitivity distributions (SSD) approach. It has been agreed that further in-depth analysis of the available information was needed to define the boundaries of the applicability of the EPM, taking into account the toxic mode of action, substance physical and chemical properties, and the difference in sensitivities between aquatic and terrestrial organisms. The SSD approach was seen as a useful tool in tiered risk assessment, but opinions varied on how the data should be considered for soil organisms. The use of the method was considered to be dependent on setting the protection goals. A need for guidance development was identified, including incorporating functional endpoints.

The overarching topic discussed throughout the workshop was the link between exposure and effects assessment. It has been acknowledged that this link has to be strengthened, and that the information on the terrestrial compartment obtained for industrial chemicals is scarce compared to pesticides, where it is considered crucial. This further stresses the relevance of the equilibrium partitioning method and its applicability boundaries and limitations.

While the workshop resulted in many recommendations for further research and development, the following areas for regulatory science were identified as important by the Scientific Committee:

(1) improving the application of the equilibrium partitioning method and implementation of methods for identification and quantification of non-extractable residues;

(2) further developing the species sensitivity distributions (SSD) approach for soil; and

(3) revisiting soil assessment factors in soil risk assessment.

It was concluded that cooperation between ECHA and EFSA as well as the dialogue between the agencies and their stakeholders leads to the establishment of common goals for the development of improved risk assessment approaches.

The TSWS has given an indication of the way forward, and presented novel ideas that could be implemented within the field of regulatory risk assessment. The agencies will continue to work together with other stakeholders to recognise the regulatory improvement needs for soil risk assessment on a generic level, and identify specific issues that could be jointly addressed.

1. Introduction

The European Chemicals Agency's (ECHA) topical scientific workshops (TSWSs) contribute to the Agency's third strategic objective to be a hub to promote good regulatory science. The TSWSs foster discussions among academia, regulators, industry and other stakeholders on the possible regulatory impacts of the latest scientific developments. Furthermore, TSWSs aim to identify concrete development needs on regulatory approaches and communicate on the identified research needs.

The TSWS on Soil Risk Assessment was the third TSWS organised by ECHA. The previous TSWSs focused on risk assessment of the sediment compartment in 2013 and risk assessment of nanomaterials in 2014.

The TSWS on Soil Risk Assessment was arranged in cooperation with the European Food Safety Authority (EFSA), and held in Helsinki on 7-8 October 2015. The workshop brought together close to 200 experts on soil risk assessment in Helsinki and about 100 more followed the event online. Participants represented academia, regulators, industry and other stakeholders.

The workshop reviewed the state of the art in soil risk assessment focusing on the safe use of industrial chemicals, biocides and pesticides. In addition to the regulatory framework in the EU and North America, the case studies and key issues relevant for soil risk assessment presented in the thought-starter document set the scene for the discussion. An anticipated outcome of this workshop was the emergence of new or improved approaches, which may be applied in the implementing soil risk assessment.

ECHA's Deputy Executive Director Jukka Malm opened the workshop highlighting the international and cross-regulatory context of the event. He acknowledged the importance of the discussions leading to a better understanding of the means in developing updated scientifically-sound principles and approaches for assessing the ecological risks of chemical substances, which are released to or reach the soil. He also challenged the participants to come up with ideas, 'core principles' or just 'rules of thumb', where and how harmonisation of the approaches might bring added value to soil risk assessment.

This proceedings document summarises the content, discussion and outcome of the workshop, structured to reflect the following themes: problem definition and a conceptual model for soil risk assessment; environmental exposure and fate assessment; and effect assessment. In addition, identified needs for further development, taking into account both scientific and regulatory aspects are presented.

While the content of this proceedings document does not represent a consensus view of ECHA or EFSA, the Scientific Committee or the workshop delegates, it serves as a record of on-going activities and highlights remaining needs and potential future directions.

1.1 Workshop organisation

The Chairs of the workshop, *Dr Anu Kapanen* from the European Chemicals Agency and *Dr José V. Tarazona* from the European Food Safety Authority, were supported by an international Scientific Committee. The members of the Scientific Committee were:

Ms Charmaine Ajao, European Chemicals Agency, Finland
Dr Maria Arena, European Food Safety Authority, Italy
Dr Mark Bonnell, Environment Canada, Canada
Dr Charles Eadsforth, Shell, United Kingdom
Dr Mark Egsmose, European Food Safety Authority, Italy
Dr Marc S. Greenberg, US Environmental Protection Agency, United States of America
Dr Derek Knight, European Chemicals Agency, Finland
Dr Paul Henning Krogh, Aarhus University, Denmark
Prof. Dr Willie Peijnenburg, National Institute for Public Health and the Environment (RIVM), The Netherlands
Dr Eleonora Petersohn, Federal environment agency (UBA), Germany
Dr Veronique Poulsen, French Agency for Food, Environmental and Occupational Health & Safety (ANSES), France
Dr Jörg Römbke, ECT oekotoxikologie GmbH, Germany
Dr Kees Romijn, Bayer, Germany
Ms Ilse Schoeters, Rio Tinto, Belgium
Prof. Dr José Paulo Sousa, University of Coimbra, Portugal
Dr Cornelis A.M. van Gestel, Vrije Universiteit, The Netherlands

Local organising committee members (ECHA);

Ms Charmaine Ajao (Chair)
Dr Romanas Cesnaitis
Mr Dragan Jevtic
Dr Anu Kapanen
Dr Derek Knight
Ms Tiina Multasuo
Ms Johanna Peltola-Thies
Ms Lucie Ribeiro
Dr Amaia Rodriguez-Ruiz
Dr Marta Sobanska

1.2 Supporting material

Before the TSWS, the participants were encouraged to get involved in developing the contents of the workshop. ECHA and the Scientific Committee requested the participants to reply to a set of specific questions on the state of the art and development needs in the area of soil risk assessment to identify the key elements to be discussed during the workshop. As a background document, the participants were provided with an introduction to the current regulatory frameworks for industrial chemicals, biocides and plant protection products. The background document included an overview of REACH (Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals), the Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) and Plant Protection Products Regulation (PPPs, Regulation (EC) 1107/2009) as well as the regulatory role of European Medicines Agency (EMA) in the authorisation

and supervision of human and veterinary pharmaceuticals (Regulation EC No 726/2004). Non-EU perspectives were provided by the Canadian government under the Canadian Environmental Protection Act (CEPA) 1999 and Pest Control Products Act 2006 and from the US under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, or Superfund).

Based on the response received from the participants, the thought-starter document was prepared to capture the current views and opinions of the experts (participants) in the field of soil risk assessment. The purpose of the document was to help distinguish key elements to discuss during the workshop by pinpointing the main challenges, the adequacy of the current approaches and potential prospects for future development.

The background document includes the description of the four EU regulatory frameworks as an example of different regulatory needs. The main elements of soil risk assessment are described for REACH, the BPR, PPPs and medicinal products, followed by an overview of related legislation in the USA and Canada.

The thought-starter document captures the current views and opinions of the experts (participants) in the field of soil risk assessment; identifying the main challenges, the adequacy of the current approaches and any future prospects in the development of the risk assessment. It describes the key elements discussed in more depth during the workshop.

Reference documents on **the problem definition and conceptual model, environmental exposure and fate assessment and effect assessment** lead to the relevant guidance documents or scientific publications.

Case studies give practical examples of the approaches taken and discuss challenges faced in soil risk assessment.

2. Setting the regulatory scene

The background and thought-starter documents gave a useful context and prompted discussion. An overview of the relevant regulations was presented at the workshop and a brief summary, including discussions from the plenary session, is provided below.

2.1 Soil risk assessment in Europe

2.1.1 REACH Regulation

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. To place and/or keep substances on the EU market, manufacturers, importers and, where relevant, downstream users are obliged to register their chemicals by submitting information on the intrinsic properties, hazard/risk and tonnages.

Annexes VII to X to REACH list the 'standard information' that registrants should provide to ECHA under the framework of the REACH Regulation when performing their risk assessment. Standard REACH information requirements can be adapted based on column 2 rules for adaptation, as well as the 'general rules for adaptation' listed in Annex XI to the REACH Regulation. This can include weight of evidence (WoE) approaches, qualitative or quantitative structure-activity relationship ((Q)SAR) models, *in vitro* methods, grouping of substances, 'read-across', and tailored exposure-driven approaches.

Chemical safety assessment (CSA) includes human health, physico-chemical, and environmental hazard assessment and persistence bioaccumulation toxicity (PBT) assessment. The principles of soil hazard assessment are summarised in ECHA's *Guideline on Information Requirements and Chemical Safety Assessment* (Chapter R7c). There are currently no legal or scientific PBT criteria for soil bioaccumulation and toxicity, although discussions have been held at the European level to address this. Currently, a WoE approach is used. If, following hazard and PBT assessments, a substance fulfils the criteria for specific hazard classification (relevant classes and categories are listed in Article 14(4) of REACH Regulation) and/or is assessed to be persistent, bioaccumulative and toxic (PBT)/very persistent, very bioaccumulative (vPvB), the exposure assessment and risk characterisation are triggered for such substance. Exposure assessment involves two steps:

- Step 1: generating exposure scenarios for relevant use and exposure categories.
- Step 2: estimating exposure including emission estimation, chemical fate and pathway assessment and estimating exposure levels.

Standard exposure estimates where predicted environmental concentrations (PECs) are identified include soil (agricultural) and the soil food chain. In addition to direct emissions to soil, exposure routes through the application of sewage sludge to soil and deposition through the atmosphere should also be considered when determining PECs. The removal of substances from soil by biodegradation, volatilisation and leaching, should also be considered as well as biomagnification through the terrestrial food chain.

Dr Marta Sobanska (ECHA) gave an overview of REACH and the BPR in her presentation entitled *Soil risk assessment in the regulatory context - REACH perspective*. The full presentation is available to download from ECHA's website[2].

Standard information requirements for the terrestrial toxicity assessment in REACH depend on the annual tonnage, i.e. quantity manufactured or imported by a registrant per year and the choice of toxicity tests depend on the CSA, but generally include:

- Short-term studies on three trophic levels representing invertebrates, microorganisms and plants; and
- Long-term terrestrial toxicity testing for plants and invertebrates, which are preferred for substances that are persistent or that have high potential for adsorption to soil.

Testing is intended to assess the effects of chemicals on different soil ecological processes with the overall aim of the protection of soil organisms to maintain soil functions based on a predicted no effect concentration (PNEC).

Risk is characterised for each exposure scenario and can be considered adequately controlled when PEC ≤ PNEC or when qualitative assessment (by the registrant) indicates that effects are avoided when the exposure scenario is implemented. For substances that meet the PBT criteria, registrants need to recommend risk management measures for downstream users. Exposures and emissions of PBT/vPvB substances need to be minimised in the whole supply chain.

The aim of authorisation is to make sure that the 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 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.

2.1.2 Biocidal Products Regulation

The Biocidal Products Regulations (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.

The background document states the aim of the regulation is to achieve protection of the environment, including soil, through the protection of the structure and function of ecosystems. The approach to risk assessment is comparable to REACH requiring effects/hazard and exposure assessments.

The overall objective of the terrestrial ecotoxicology assessment scheme is to identify the trophic levels of organisms living in the soil compartment that will potentially be adversely affected by a specific substance; and from this derive the predicted no effect concentration (PNEC). In general, long-term ecotoxicity data are required if there is

[2] Presentation slides are available from ECHA's website at: http://echa.europa.eu/view-article/-/journal_content/title/topical-scientific-workshop-on-soil-risk-assessment

potential for continuous exposure to the terrestrial environment. Biocides exposure assessment must consider all stages of the lifecycle of the substance including manufacture, product formulation, application, service life, waste treatment and recycling. Within the BPR, there are 22 product-types covering four main groups (disinfectants, preservatives, pest control and other biocides) where use pattern and exposure routes vary dramatically.

Emissions are calculated using exposure scenario documents (ESDs) which include use pattern, main receiving environmental compartments and equations to calculate exposure. Detailed exposure scenarios have not yet been developed for all product-types. As in REACH, PEC > PNEC suggests the substance may pose an unacceptable risk to the environment. In addition, the BPR also requires an assessment for PBT substances using the criteria laid down in REACH.

2.1.3 Soil risk assessment for plant protection products

The current risk assessment for soil organisms is carried out according to the SANCO/10329/2002 Terrestrial Guidance Document developed under the Council Directive 91/414/EEC. This directive was repealed in 2009 by the (EC) Regulation 1107/2009, while Commission Regulation (EU) No. 283/2013 and 284/2013 laid out new data requirements for active substances and Plant Protection Products (PPPs).

Risk assessment for soil organisms follows the same principles as outlined previously; namely hazard identification, hazard characterisation, exposure assessment and risk characterisation. A tiered approach is used, starting with a simple conservative assessment and moving towards more complex evaluations.

Exposure characterisation involves a comprehensive evaluation of the fate and behaviour of active substances, transformation products in soil, including estimation of PEC and PEC plateau concentrations. The effect assessment involves a comprehensive investigation of the dose-response relationships to derive toxicity endpoints (e.g. LC_{50}, EC_{50}, NOEC), which are compared to PECs. If further risk refinement is required then field studies reflecting the environmental conditions, species exposed and intended uses of the substance or product may be conducted.

Risk characterisation is represented by the calculation of appropriate risk quotients including the calculation of acute and chronic toxicity exposure ratios (TERs). TERs are compared with trigger values defined in uniform principles (Commission Regulation (EU) No. 546/2011) to establish if the risk is high or low. Trigger values are 'assessment factors' that take into account uncertainties in intra- and interspecies variability as well as extrapolation of endpoints from laboratory to field.

Dr Maria Arena (EFSA) described the tiered PPP regulatory framework in which the testing strategy involves chronic testing for sublethal effects on earthworms, effects on non-target soil meso- and macrofauna (other than earthworms), effects on soil nitrogen transformation and effects on terrestrial non-target higher plants in her presentation *Soil Risk Assessment in PPPs regulatory context*.

Tests for acute effects on earthworms and on carbon transformation are no longer part of the assessment. If a high risk cannot be excluded at the lower tier, further refinements may include the use of a more realistic test substrate or exposure regime, field studies or litter bag tests under field conditions or a case-by-case analysis of e.g.

ecological relevance of the observed effects, consequences on soil functions, potential for recovery, etc. The testing framework under the PPP Regulation is similar to REACH but can be seen as more extensive with the possibility of using more field data and increased realism with higher tier testing.

The findings from this TSWS on Soil Risk Assessment will inform current EFSA activities on the development of guidance on the risk assessment for PPPs and complement the following recent EFSA publications:

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

2.1.4 European Medicines Agency – human and veterinary pharmaceuticals

The background document states that human medicinal products intended for marketing within the EU have required an environmental risk assessment since the implementation of the legislation in 1993. Guidance was adopted by the European Medicines Agency in 2006 (EMEA/CHMP 2006).

Phase I comprises environmental exposure assessment, which is based on the dose used and the prevalence of the disease. If the predicted environmental concentration in surface waters (PEC_{SW}) exceeds the threshold value of 10 ng L^{-1}, then studies on physico-chemical properties, environmental fate and effects are performed in Phase II.

The Phase II risk assessment is divided into two parts: Tier A, in which the base data set are determined and Tier B, which allows for further refinement. 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. Specific PEC:PNEC comparisons are made. If one or more of the resulting quotients show an unacceptable risk, further data must be generated in Tier B. In addition, a PBT assessment is performed in accordance with REACH guidance when the logarithm of the octanol-water partition coefficient (Log Kow) is higher than 4.5.

A similar process is required for veterinary medicine products (VMP). Guidance was first prepared by the European Medicines Agency in 1997 and later harmonised with the USA and Japan in 2000, 2004 and 2008. In Phase I, a number of questions concerning application and properties of the VMP direct the environmental risk assessment to the main exposure scenarios, i.e. aquaculture or intensively reared and/or pasture animals. Then, predicted worst-case environmental concentrations (PEC) 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 dry weight in soil, studies on physico-chemical properties, environmental fate and effects on selected non-target species have to be performed in Phase II. For parasiticides used in the treatment of

pasture animals, the PEC_{soil} trigger is circumvented and Phase II studies are independent of PEC_{soil} (similarly, hormones proceed to Phase II too).

In Phase II Tier A, the environmental risk is characterised deterministically by comparing the PEC with the PNEC for several environmental compartments. 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). A range of PECs is derived for the IR and P scenarios, separately for each animal type for the soil compartment. Further refinement to the effects assessment is carried out in Tier B of the Phase II assessment.

2.2 Soil risk assessment in the United States and Canada

A detailed explanation of the regulatory frameworks for the United States and Canada is provided in the supporting background document available from ECHA's website.

2.2.1 Canadian perspective

In Canada, the risk of chemicals to soil is considered under several different programmes and under various federal acts. Janet Cermak (Environment Canada) highlighted a number of policies relating to soil risk assessment in her presentation[3] *Canadian Approaches to Soil Risk Assessment*.

Two of the main acts involving prospective soil risk assessment are the Canadian Environmental Protection Act 1999 (CEPA 1999, administered jointly by Environment Canada and Health Canada 1999) and the Pest Control Products Act (PCPA 2006), administered by Health Canada).

The risk assessment frameworks under these acts are similar to the European REACH and PPP regulations. CEPA 1999 is the principal federal legislative tool for assessing and managing both new and existing chemical substances. PCPA 2006 regulates the evaluation of new and existing pest control products (pesticides and biocides). Consideration of the ecological risk of new pharmaceuticals, personal care products and veterinary drugs is also covered by CEPA 1999.

The risk assessment of new and existing substances includes the consideration of a substance's fate in the environment; persistence and bioaccumulation potential; environmental and human health hazards; and exposure.

Data requirements differ between the new and existing substances programmes. Mandatory datasets are prescribed within the New Substances Notification Regulation depending on the type of substance, the quantity, intended use and circumstances associated with its introduction, although they are oriented towards the aquatic environment.

Additional studies may be requested for the terrestrial environment if exposure is considered critical (e.g. biosludge application). In the existing substances programme,

[3] Presentation slides are available from ECHA's website at: http://echa.europa.eu/view-article/-/journal_content/title/topical-scientific-workshop-on-soil-risk-assessment

there are no prescribed data generation or submission requirements, which means these substances are often "data poor", especially for soils.

Soil risk assessments can consider direct and indirect exposure through soil and the risk to soil organisms (plants, invertebrates) to develop a $PNEC_{soil}$. Impacts to higher organisms (birds, mammals) are considered for those substances that have physico-chemical properties that suggest that transfer through food webs may be important, in which case a PNECwildlife is derived.

A substance is determined to be toxic if it:

- is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
- constitutes or may constitute a danger to the environment on which life depends; or
- constitutes or may constitute a danger in Canada to human life or health.

The risk assessment for pesticides, including biocides, is based on an evaluation of a suite of environmental fate and ecotoxicological studies. Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the PCPA, establishes the data requirements depending on the intended use of the pesticide.

Fate data include physico-chemical properties, chemical and biological transformation studies in soil and water, adsorption/desorption studies, and field dissipation studies. Ecotoxicity studies include terrestrial non-target invertebrates and plants, birds and mammals and aquatic organisms.

The PMRA uses the risk quotient method and a tiered approach to conduct risk assessment, beginning with a screening level, which uses 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 necessary, the PMRA proceeds to higher tier assessments (refinements). This may include an evaluation of higher tier studies (e.g. semi-field and field studies) and the use of more refined modelling techniques or available monitoring data. If a risk is identified, risk mitigation measures are considered. These may include label instructions to restrict use (e.g. application rate, timing of application) and to use specific buffer zones.

2.2.2 United States Environmental Protection Agency perspective

In the background document, it is stated that the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, or Superfund) is the law establishing the environmental programme to address abandoned hazardous waste sites.

This law allows the regulatory agency (US 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.

In his presentation *Soil Ecological Risk Assessment - US Environmental Protection Agency Status*, David W. Charters (US EPA) outlined the risk assessment scheme in CERCLA (or Superfund).

Soil risk assessments are undertaken retrospectively after a chemical has been released into the soil with the aim of assessing present and future risks in the absence of remedial action. Prospective risk assessment schemes exist for food, food additives, human and veterinary pharmaceuticals, cosmetics, pesticides and biocides, although legislation similar to REACH is in preparation in the US for industrial chemicals.

The purpose of the ecological risk assessment (ERA) is to support development of risk-based clean-up levels to determine whether risks are unacceptable and remediation is needed. The assessment is an eight-step process described in ecological risk assessment guidance for Superfund and provides a flexible framework to characterise ecological risks[4]. Steps 1-2 include a screening assessment with a toxicity and exposure assessment and risk calculation where relevant ecological soil screening levels (EcoSSLs) are compared against measured soil concentrations from the site under investigation. In steps 3-7, site-specific data are collected through laboratory and/or field studies and toxicity testing of soil invertebrates and plants are often conducted using soils collected from the site.

Toxicity testing on groups of individual organisms is inferred to the site area population – using survival, growth and reproduction endpoints – for the ERA. Synoptic or observational analyses (e.g. abundance or diversity of insects and plants) are often treated as supplemental lines of evidence (LoE). This information is used for the site-specific risk characterisation and to devise a management plant for the site. EcoSSLs used in Superfund ERA represent concentrations that are protective of ecological receptors that commonly come in to contact with soil or ingest biota that live in or on soil.

A perceived shortcoming of the US framework is the absence of screening levels for amphibians, reptiles and, in particular, soil microorganisms due to insufficient data or uncertainties around the establishment of risk-based thresholds. However, one of the framework's advantages is the inclusion of problem formulation (Step 3). This step includes the definition assessment and measurement endpoints (or protection goals) and the use of conceptual models. These were both topics identified for discussion in Group 1 of this TSWS.

2.3 Discussion

Questions raised in the plenary session following the regulatory presentations generally related to differences between North American and European approaches and, in particular, soil microorganisms. The key points are summarised below:

- Differences between regulatory regimes in relation to microorganism tests were identified within Europe. Where, in specific cases under REACH, the carbon

[4] US EPA (1997). *Ecological Risk Assessment Guidance for Superfund, Process for Designing and Conducting Ecological Risk Assessments*, OSWER 9285.7-25, EPA 540-R-97-006.

transformation test (OECD 217) is requested in parallel to the nitrogen transformation test (OECD 216) for PPPs, the carbon transformation is no longer requested because it is considered rather insensitive. In the US, microbial data are not included in the derivation of EcoSSLs, but these data can be used in LoEs when determining risk, although these data are considered the weakest evidence line. Both the US and Canada shared concerns that it is not yet possible to agree on appropriate microbial protection levels with certainty partly due to rapid microbial recovery. However, where data are available, there is the possibility of data sharing between regulators to improve the general understanding of microbial testing, response and protection levels. According to regulatory experience, the soil risk assessment is quite often not driven by microorganisms.

- There is some commonality under different legislations when data quality (reliability) and relevance are considered. The US considers data quality and aims for national consistency. Europe and Canada use broadly similar approaches to essentially rank studies in terms of robust/critical studies that are highly reliable or as supporting studies. The Canadian system uses qualitative criteria based on expert judgement.
- In terms of moving towards consistency between European agencies in implementing scientific principles in soil risk assessment, the following specific points were raised:

    - Assessments under the PPPs regulatory framework do not currently use the SSD for soil organisms but the approach is under discussion in EFSA's Panel on Plant Protection Products and their Residues (PPR). If there is no difference in sensitivity, toxicity data on invertebrate, plants and microorganisms are generally combined in risk assessments under REACH. The combination of invertebrate data in SSDs for PPPs is under discussion in EFSA, as consideration must be given to the mode of action of a PPP. Although these differences are based on the specific mode of action of pesticides and cannot be considered as scientific inconsistencies, the possibilities for setting general principles for building SSDs based on the ecotoxicological profile (mode of action and expected/observed differences among major taxonomic groups) could be further explored and applied in the different regulatory context, e.g. some chemicals covered by REACH may have specific modes of action.

    - Risk communication and transparency in decision making are important for accepting changes in regulation and for building confidence and understanding in protection goals, particularly around numerical hazard or risk criteria.

3. Case studies

Topic-specific case studies to initiate the discussion were presented within breakout groups. These case studies and related discussions are described in more detail in topic-specific Sections 4, 5 and 6, as appropriate.

The titles of the case studies presented in the three breakout groups were:

1) Problem definition and conceptual model for soil risk assessment
   - *Making soil protection goals based on the ecosystem services concept operational in ecotoxicological risk assessments*, Gregor Ernst, Bayer CropScience AG
   - *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
2) Environmental exposure and fate assessment
   - *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
   - *From bioavailability science to regulation of organic chemicals*, Jose Julio Ortega-Calvo, Institute of Natural resources and Agrobiology
3) Effect assessment
   - *Application of equilibrium partitioning-based model framework for evaluating soil (and sediment) hazards of lipophilic nonpolar organic substances*, Aaron Redman, ExxonMobil Biomedical Sciences, Inc.
   - *Assessing the risks of pesticides to soil communities using terrestrial model ecosystems*, Björn Scholz-Starke, RWTH Aachen University

During the plenary session (Day 2), five case studies linking to the different breakout group themes were presented. These case studies were the basis for the discussion in the breakout groups and are summarised below. The abstracts and the presentation slides can be downloaded from ECHA's event web page[5].

1) *Critical Comparison of the Schemes Used to Assess Soil Exposure Under EU Pesticide, Biocide and REACH legislation* by Bruce Callow (Exponent)

Bruce Callow (Exponent) presented *Critical Comparison of the Schemes Used to Assess Soil Exposure under EU Pesticide, Biocide and REACH legislation* and illustrated the comparison using a hypothetical pesticide.

The aim was to examine the differences in the assumptions underpinning each of the relevant assessment schemes and to examine the influence that these may have on the PECsoil calculated by each scheme. He concluded that tiered approaches to risk assessment are useful but should avoid being overly conservative in the early tiers and increase in complexity at higher tiers. Exposure scenarios need to be realistic, ecologically-relevant and, in his opinion, linked to protection goals. Finally, any

[5] http://echa.europa.eu/view-article/-/journal_content/title/topical-scientific-workshop-on-soil-risk-assessment

assessment scheme should be open to amendment and evolution and not be "set in stone". Continuous dialogue is encouraged to take account of new information, data and scientific developments.

2) *Application of improved scientific approaches in support of risk assessment within the European REACH and Biocides Regulations: a case study on metals* by Koen Oorts, ARCHE

Koen Oorts (ARCHE) presented *Application of improved scientific approaches in support of risk assessment within the European REACH and Biocides Regulations: a case study on metals*.

In the presentation, copper was used as an example to illustrate how new scientific data has resulted in improved scientific approaches, such as simple models and tools that use data on standard soil properties (pH, organic carbon content, clay content and effective cation exchange capacity (eCEC)) for bioavailability correction in PNEC calculations. An overview of the results from the GEMAS project (Geochemical mapping of agricultural and grazing land soil) and models currently available for different metals (cadmium (Cd), cobalt (Co), copper (Cu), molybdenum (Mo), nickel (Ni), lead (Pb), zinc (Zn)) was also presented.

3) *Sufficiency of aquatic hazard information for environmental risk assessment* by Michiel Claessens, Chemours), the ECETOC Task Force

Michiel Claessens (Chemours) represented the ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) Task Force with his presentation *Sufficiency of aquatic hazard information for environmental risk assessment*.

The presentation described results from a case study aimed at assessing the performance of EPM theory to extrapolate aquatic hazard information to the soil and sediment compartments for different trophic levels. The hazard to soil invertebrates relative to aquatic organisms was found to increase with rising soil organic carbon-water partitioning coefficient (Koc) and declining vapour pressure (VP) but the mode of action was unclear.

This affects the outcome of soil risk assessments based only on aquatic data and warrants caution when using equilibrium partitioning method (EPM), particularly on substances with increasing Koc. ECETOC suggests that differences in partitioning and/or equilibrium state between aquatic and soil ecotoxicity studies could be the underlying cause but the full explanation is uncertain. For example, the role of contaminant uptake through food in this remains unclear.

4) *Compilation of (REACH) case studies with challenges in regulatory soil risk assessment* by Romanas Cesnaitis, ECHA

Romanas Cesnaitis (ECHA) presented a *Compilation of (REACH) case studies with challenges in regulatory soil risk assessment*, which portrayed some of the challenges in the evaluation of the adequacy of the available terrestrial hazard and fate information for regulatory risk assessment.

The presentation also covered further developments within the integrated testing strategy for soil toxicity. The relevance and sensitivity of different species and applied

test protocols, triggers for terrestrial hazard assessment under REACH, further refinements to the test systems (e.g. temperature) and scoping of exposure assessment under REACH, were also discussed.

5) *An EFSA perspective on future approaches and perspectives in risk assessment for in-soil organisms* by Maria Arena, EFSA

An EFSA perspective on future approaches and perspectives in risk assessment for in-soil organisms was given by Maria Arena (EFSA).

The SANCO terrestrial guidance document is being revised mainly due to:

(1) the entering into force of the new Regulation (EC) No 1107/2009 on authorisation of PPPs;

(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 over what time period.

The former guidance document (SANCO/10329/2002), for instance, did not define specific protection goals, which created challenges for the soil risk assessments. In this presentation, an overview of such risk assessment and its challenges were given using the risk assessment of a generic insecticide, belonging to the class anthranilic diamides (IAD) as an example.

Case studies 1 and 2 created the most discussion. One clarification was made for case study 1 on the presentation regarding lack of specific protection goals in the persistence in soil analytical model (PERSAM) and its conservativeness.

In PERSAM, protection goals have been set and they were set in consultation with risk managers. A policy decision was agreed by risk managers for the EFSA guidance on PECs in soil to apply the 90^{th} percentile of the area where the substance is used. In PERSAM, the conservativeness of the scheme also does not depend on the simple steps of it (i.e. just lower tiers) but the whole scheme (more information in Section 5.2.6).

Regarding case study 2, one question was raised in relation to considering land use and its effect on soil properties in risk assessment and how changes in future land use could be accounted for (or should they be accounted for).

Koen Oorts concluded that the protection level is the same for all land uses and that soil properties are not expected to change significantly with land use. Soil properties would need to change significantly for the change to have an impact on PNEC values.

4. Problem definition and conceptual model for soil risk assessment

4.1 Setting the scene

José Tarazona (EFSA) provided an overview of protections goals (PGs), their ecological relevance including use of the ecosystem services concept and approaches for setting the attributes of specific protection goals, and the calibration from reference tiers to lower and higher tier risk assessment protocols in his plenary presentation *Protection goals and conceptual models: How science can support risk managers on what to protect?.*

General PGs are defined in the legislation and were summarised by Dr Tarazona as requiring 'a high level of protection of […] the environment' and as follows:

- REACH requires that chemicals placed on the market do not adversely affect […] the environment. A risk is deemed to be adequately controlled if the exposure levels do not exceed the PNEC; and
- BPR and PPP provide criteria for the effects on the environment which are based on:
  - fate and distribution in the environment, contamination of the aquatic compartment (including sediment)/terrestrial compartment (including groundwater) and air (also following long-range environmental transport);
  - impact on non-target organisms; and
  - impact on biodiversity and the ecosystem.

EFSA's Panel on Plant Protection Products and their Residues (PPR) proposed specific protection goals (specific PGs). Specific PGs are defined by the following criteria:

- the entities that need to be protected;
- the attributes and/or functions of those entities;
- the magnitude, temporal and spatial scales of effects on these attributes and/or functions that can be tolerated without impacting the general protection goal; and
- the required degree of certainty with which the defined protection goal could be achieved.

The overarching framework used in the development of specific PGs is the ecosystem services concept. The key is to identify relevant services likely to be impacted by pesticides and to identify the key drivers (taxonomic or functional groups) that provide those services. The PPR Panel's framework for defining specific PGs follows a step-wise process to identify a reference tier for each key driver (taxonomic group or other ecological entity). The process relies on the most sophisticated experimental or modelling assessment method addressing the effects on the key drivers providing the ecosystem service and, as a consequence, the risk for the specific PG, and then uses this realistic reference tier to calibrate lower tiers. Dimensions of protection goals for each service-driver combination are specified by defining the protection goals in a measurable way, based on tolerable effect range.

The aim is to ensure the protection of relevant services, including biodiversity, at the level of protection decided by risk managers. The attributes and links are adapted to the

ecological role of each non-target group considered a service provider. Realistic reference tiers are used for calibration of lower tiers, offering mitigation options (e.g. population recovery). Moving to landscape scale assessments was seen as the next challenge.

Two case studies were presented to the breakout group. In his presentation *Making soil protection goals based on the ecosystem services concept operational in ecotoxicological risk assessments,* Gregor Ernst (Bayer Crop Science)[6] discussed the application of the ecosystem services concept in the definition of protection goals and design of risk assessment schemes.

Different land uses provide different ecosystem services and levels of service. In addition, land uses vary in their levels of protection. The ecosystem services approach may be used to answer what to protect and where to protect these services. The measurement of functional endpoints created a lot of discussion and was seen as a way of providing measurable links with protection goals derived from the ecosystem services concept.

Bioavailability-based approaches for soil risk assessment of metals: Regional differences arising from distributions of soil chemical properties by Christian Schlekat (Nickel Producers Environmental Research Association)[7] presented experiences from European and Asian projects, where advanced empirical bioavailability models were used to normalise ecotoxicity data to site-specific soil conditions for deriving site-specific PNEC values.

Soil properties that had the greatest influence on ecotoxicity varied between European soils and Asian soils. These findings highlight the importance of determining relationships between soil properties and metal toxicity to soil organisms, and that these relationships need to account for distributions of soil parameters within the region of interest.

Key issues for discussion were as follows:

- Relevance of setting specific PGs under REACH and the BPR for soil organisms;
- Relevance of the ecosystem services approach;
- Where would harmonisation of the approaches bring added value in the soil risk assessment?
- Equilibrium partitioning method;
- Species sensitivity distributions;
- Ecological modelling;
- Current approaches for linking exposure and effects (REACH/BPR/PPP);
- Updating/integration of the conceptual model.

[6] http://echa.europa.eu/documents/10162/21838212/soil_risk_assessment_ernst_en.pdf
[7] http://echa.europa.eu/documents/10162/21838212/soil_risk_assessment_schlekat_en.pdf

4.2 Summary of the breakout group discussions

Chairs: Dr Janet Cermak (Environment Canada), Dr Marc S. Greenberg (U.S Environmental Protection Agency) and Dr Kees Romijn (Bayer CropScience)

4.2.1 Are specific protection goals useful for soil risk assessment?

The presentation by EFSA and its experience in the development of guidance on setting specific protection goals (specific PGs) for PPPs prompted a wider discussion on their applicability under other legislations. For example, it was argued that the BPR comprises many different exposure patterns, where the definition of soil compartments and non-target organisms is different than in PPP. For REACH, it was argued that since dossiers have already been submitted, specific PGs should not be applied retrospectively.

Chemical products can be complex mixtures, often making testing difficult, which has implications for establishing harmonised specific PGs.

General protection goals (general PGs) are provided in the legislation. The development of specific PGs, as well as decisions on the acceptability of risk, was viewed as the responsibility of risk managers. However, in reality this is a process requiring a dialogue of risks assessors and risk managers. Risk managers may often not be technical experts and risk assessors have an important role in the specific PG development process by actively proposing specific PGs based on their scientific knowledge, e.g. confirming that the specific PGs can be implemented into risk assessment protocols considering the current scientific knowledge.

Specific PGs provide the link between the legislative context (general PGs) and the risk assessment, and should be measurable. They should consider present and future land (soil) use, product uses and exposure scenarios. These considerations were thought to be within the scope of the competencies of risk assessors, while the decision on acceptability is under the competence of risk managers.

4.2.2 Using the ecosystem services concept to underpin protection goals

The ecosystem services (ES) concept was considered to be a good communication tool which provides a common language between risk assessors and managers. Since the ES concept is based on human well-being and is used to evaluate the benefits that ecosystems provide to humans (and the ecosystem itself), protection goals underpinned by ES would help to more clearly express what we want to protect and at what scale, and why we want to protect the ecosystem.

Biodiversity plays a wide range of functional roles in ecosystems and in the processes that underpin ES. Ecosystem functions tend to be more stable through time with higher levels of biodiversity. This translates to improved levels and stability of ES with increasing levels of biodiversity. Hence, by using ES as an underpinning concept for setting specific PGs, elements of biodiversity can be included to meet legislative protection goals. Biodiversity, however, should be defined in such a way that it is measurable.

In general, the group was of the opinion that protection goals for biodiversity (such as habitat services) should be established at a landscape level, or at a scale that is appropriate to the use (application) of the chemical. These protection goals should be

based on measurable endpoints. The participants thought that this would be consistent with the principles of ES, and would allow a better understanding of the trade-offs between different services (e.g. food production and biodiversity within intensive agricultural systems).

The actual trade-off decisions could be made by risk managers. Risk assessors would be responsible for clearly describing the risks that may arise from product use, the likelihood of such events, and the potential consequences for specific ESs to risk managers. This should also include a clear description of the elements of uncertainty around their assessment.

4.2.3 How to develop specific protection goals for soil?

The central question when setting specific PGs is 'what do we want to protect and where'?

Land (or soil) use provides the context for setting the protection goals. Product use and exposure scenarios should define specific PGs. A specific exposure scenario is important as it may describe localised high exposure over a short timeframe (episodic), or more widespread contamination with low exposure levels but over a long timeframe. The time scale and magnitude of effects, when setting specific PGs, is very much dependent on the exposure pattern.

When developing specific PGs for soil it is important to consider the reference (baseline) condition. The group recognised that the baseline should reflect the current situation, whether this is a heavily modified soil or land with a specific purpose, such as an agricultural soil. The Chair concluded that the question could be rephrased as 'what could the protection goals be, based on the ESs and biodiversity needed to maintain the structure and functions of soil, according to the intended land uses'.

4.2.4 Calibration of lower tier risk assessments for soil

Concerning the calibration of a tiered assessment to a 'reference tier', it was generally recognised that this approach would be of use across other legislative regimes, although different challenges were foreseen. For example, substances under REACH tend to be data-poor in general, and establishment of a reference tier may be more difficult than with data-rich PPPs. However, the use of read-across between similar substances in REACH was seen as an advantage allowing chemicals to be grouped for calibration.

Calibration of lower tiers by means of a definition of a reference tier, at which effects on the specific PGs are measurable (experimentally and/or through modelling), was also considered useful in checking assessment or uncertainty factors (AFs) in different legislations. It was recognised that current regulatory AFs were based on data and expert judgement available at the time the legislation was put in place and that more knowledge (data) has likely become available, which may allow AFs to be reviewed and potentially revised. Such calibration may lead to lower or higher AFs.

4.2.5 Where do we see harmonisation opportunities between different legislative regimes?

General PGs for soil do not differ widely between the various pieces of EU legislation nor between the US and Canada, and hence it would be relatively easy to establish harmonisation at this level.

If specific PGs are to be derived for specific land uses, product uses and exposure scenarios, then by definition there is less scope for harmonisation of specific PGs between PPP (agricultural soil) and REACH or Biocides (generic soils). Yet, harmonisation of specific PGs with those developed for PPP may well be feasible for biocides and industrial chemicals that pass through a sewage treatment plant and are later spread through sludge onto agricultural fields.

In addition, it was considered helpful to harmonise data used in risk assessment for the same or similar substances between different legislative regimes. Other assessment tools such as read-across between substances, the use of weight of evidence approaches for risk-based decision making, and the extension of integrated testing strategies from REACH to the PPP Regulation were also seen as useful approaches for harmonisation.

4.2.6 Equilibrium partitioning method (EPM)

A case study on the adequacy of aquatic hazard information for environmental risk assessment presented by Michiel Claessens (Section 3) compared aquatic and soil toxicity data for the same chemicals (from existing information in eChem portal and ECHA's website) to evaluate whether the EPM method reliably predicted toxicity to soil organisms.

While PNECscreen based on aquatic data appeared to be more conservative than PNECsoil derived with the soil data in 60 % of the cases, approximately 40 % of assessments using soil data indicated a potential hazard when no hazard was identified for aquatic species. This 40 % should be investigated further to understand the reasons for the different outcomes. Different hypotheses were proposed for the differences in the outcomes but these were not discussed in detail. These suggestions therefore represented personal views and not a consensus among the participants. Suggested explanations for the differences in the outcomes included:

- Substance properties such as molecular size, complexity and absorptivity (Log Kow >5 or 6);
- It is an artefact of the assessment factor used for PNEC derivation which may differ between aquatic and soil tests.
- There may be differences in the sensitivities between aquatic and soil organisms;
- There may be differences in the mode of action (MoA) of the chemicals, for example the MoA of PPPs is often very specific and may explain differences between aquatic and soil organism data; or
- It is an artefact of differences in the test methodology, such as different exposure times for aquatic and soil toxicity tests.

It was noted that the EPM method is not applicable to inorganics (metals) as speciation of the metal is important. Similarly, the ecotoxicological theory behind the EPM assumes that the chemical is in a water-soil equilibrium. Where this is unlikely to be the case, the EPM is unlikely to be reliable or relevant to soil organisms.

4.2.7 Species sensitivity distributions

The species sensitivity distribution (SSD) method was considered as a useful tool in tiered risk assessment, but opinions varied on whether all data should be considered together or separated into taxa (e.g. invertebrates, plants, microbes).

Whether or not data from different taxonomic groups can be combined in an SSD depends on the protection goal set for the assessment. If the protection goal (policy) is to protect 95 % of species, then all data should be considered as one data set. If the protection goal is not, for instance, 95 % of all species, but perhaps 95 % of the sensitive species (and as such potentially over 95 % of all species), separating the taxonomic groups for the SSD may be suitable.

Additionally, certain taxa might be much more sensitive to a chemical, such as invertebrates to insecticides or plants to herbicides, and their inclusion could reduce the statistical power of the SSD. Experience from the US suggested the MoA was the key to the distribution. Additional assessment factors are available in some legislations (REACH uses a 1-5 AF) to account for uncertainties around the fifth percentile of the distribution (HC_5).

Currently, the risk assessment under the PPPs legislation, for example, requires separate assessments for different taxa. However, in the future PPP ecological risk assessment scheme, the use of the SSD approach might be proposed as an intermediate tier for in-soil organisms.

REACH guidance on the derivation of a PNEC from an SSD is specific to the aquatic compartment and focuses on the conservation of species diversity. However, it was questioned whether functional and structural endpoints should be considered separately or together in an SSD. Some considered functional and structural SSDs to be different as the concept of ecological redundancy and ecological consequences has different connotations when applied to species and when applied to ecological functions. On the other hand, others noted that functional endpoints are related to the sensitivity of a species providing a functional role and suggested that data could be combined.

The SSD method was considered useful, but development of guidance was needed for its use in soil risk assessment. The inclusion of functional endpoints requires specific attention. Issues relating to SSD method are further discussed in Section 6.2.2.

4.2.8 Ecological modelling

The question posed to the group was why the many mechanistic models available are not readily accepted or used by regulators?

It was noted that limitations included data requirements and difficulties in the identification of uncertainties. It was also commented that, if the ecosystem services approach is used to develop protection goals, it is difficult to link population models to soil function. However, legislation requires the protection of biodiversity, not functions. EFSA noted that there is a panel opinion relating to the conditions under which these models can be used by EFSA and that currently EFSA is working on a scientific opinion on the use of aquatic models, to be followed by an opinion on terrestrial models.

4.2.9 Current approaches for linking exposure and effects (REACH/BPR/PPP)

It was felt that communication could be improved between exposure and effects assessors to improve risk assessments, but also in testing strategies where data may be generated for a range of legislative requirements (and needs to be applicable to all).

The complexity of the exposure system for aquatic settings was felt to be relatively simpler than for soil systems, as soil includes several different compartments such as

air, water, and organic and inorganic soil particles, thus leading to different exposure routes for different species. In addition there is a need to understand the drivers of intraspecies variability in effects assessment, such as pH, temperature, etc. to inform and refine the exposure assessment.

Exposure or a combination of both exposure and effects were considered to be the main source of uncertainty in risk assessments but it depends on the product and its mode of action. The role of the conceptual model and its use in directing a risk assessment was viewed as a useful tool for highlighting areas of uncertainty.

4.2.10 Integrating the conceptual model

Conceptual models for ecological assessments were considered as underutilised. Effects and exposure assessors are encouraged to collaborate early in the derivation of the conceptual model as it is a useful communication and visualisation tool. It was suggested that separate models for human health and the environment could be combined early in the assessment to promote further integration between assessors.

4.3 Suggestions for scientific research

Suggestions for further research by the soil risk assessment research community included the following:

- The ecosystem services concept was considered to be useful for underpinning specific PGs, in particular for PPP and to a lesser extent the BPR and REACH regulations. Risk assessors should actively propose measurable specific PGs to translate general PGs in to relevant, practical and measurable goals, although the final decision on the acceptability of a risk is ultimately a policy decision that lies with the risk managers.
- There remains a challenge in understanding how to apply ecosystem services analysis to chemicals safety assessment and the communication with risk managers. Further research on its application would be welcomed.
- A broader research question lies in determining where the greatest uncertainties lie in risk assessment; exposure or effects assessment or both? A greater appreciation of the areas of most uncertainty could be used to focus future research and refine risk assessment methodology.

4.4 Ideas for regulatory development

Ideas for regulators for further development and identified needs for further guidance included the following:

- Calibration of Tier 1 (lower tiers) by using a reference condition [as proposed by the EFSA PPP Scientific Panel] is considered a useful approach.
- Regulators and the soil risk assessment community are encouraged to seek opportunities to calibrate Tier 1 assessments for specific product use scenarios with available data to determine the validity of current assessment factors.
- Based on the presented case studies, a clear research need was identified into the EPM approach (screening level assessment of toxicity to soil organisms) as the role of e.g. MoA and substance properties remained unclear. It is recommended to clarify the boundaries of the applicability of the EPM method, ultimately leading to the development of criteria and guidance for the use of EPM in the regulatory context.

- It was proposed to explore the role of microbial data in soil risk assessment. In particular, the need for a greater understanding of the sensitivity of soil microorganisms was viewed as important. A suggestion was made that ECHA could conduct a comparison of soil microbial and aquatic test data in the REACH registration databases to assess if EPM is applicable to microorganisms.
- The use of SSD was supported, but it is important that it is linked to PGs and legislative requirements. However, guidance is needed specifically for their use in soil risk assessment, including the incorporation of functional endpoints.
- Several comments were made during subsequent plenary discussions regarding SSD, including reference to recent workshops and publications that may be useful to avoid duplicating effort; for example, a workshop hosted by ECETOC in February 2014 entitled *Estimating toxicity thresholds for aquatic ecological communities from sensitivity distributions* has proceedings available (ECETOC website: www.ecetoc.org/publications); and the Species Sensitivity Distribution (SSD) Working Group as part of the Plants Advisory Group of the Society of Environmental Toxicology and Chemistry (SETAC) reviewed plant ecotoxicology and risk assessment.
- Conceptual models are tools that can help enhance communication between exposure and effects assessors. Their integration between human health and environmental teams should be encouraged.

5. Environmental exposure assessment and in-soil fate processes

5.1 Setting the scene

During his keynote presentation *Overview of processes driving the exposure of chemicals in soil*, the Chair for breakout group 2, Willie Peijnenburg (RIVM, National Institute for Public Health and the Environment) presented an overview of the elements, processes and parameters driving chemical exposure and fate in soil, and the tools and methods currently used in their assessment and potential development needs.

In general, the relevant physical and chemical properties and processes relevant for the exposure assessment are well known for common substances but factors influencing bioavailability and toxicological interfaces with biota are less well understood. The impact of soil composition, decomposition, weathering processes and climate on environmental fate processes was also recognised as an important topic for discussion.

The limited extrapolation capabilities of the models available were indicated. However, this does not mean that new complex models should be developed. Instead there is a need for models capable of handling spatial aspects and geographical information (distribution of key parameters, such as temperature, rainfall, soil type, pH). The applicability of these models for regulatory purposes would need to be assessed, taking into account the purpose of the assessment, e.g. local vs general conditions.

Other issues that were raised included development towards more realistic testing schemes (intermediate scale studies using intact soil cores and more sophisticated lab/semi-field tests), consideration of degradation and dissipation; bioavailability, non-extractable residues (NER) and bioaccumulation; landscape level approaches and

spatially distributed modelling. The need for taking background concentrations into account in risk assessments when developing specific PGs and/or management strategies to reach the goals was also emphasised.

Two case study presentations were made to the breakout group. Mark Egsmose (EFSA) and Michael Klein, Fraunhofer (IME) presented *Practical examples on how the EFSA Guidance Document for predicting environmental concentrations of substances in soil can be used*[8] illustrating practical examples of how the tiered approach in the EFSA guidance document can be used.

The guidance and supporting models are capable of handling spatial aspects and geographical information e.g. distribution of key parameters, such as temperature, rainfall, soil type and pH. Examples portrayed different exposure scenarios from direct soil applications to applications to crop canopy where canopy processes are accounted for. Other examples included exposure assessment of a substance with pH-dependent sorption and metabolites following this guidance.

The practical examples showed that the tiered approach proposed by EFSA works well and that the differences between the models PEARL (pesticide emission assessment at regional and local scales), PERSAM and PELMO (pesticide leaching model) are small. The EFSA Guidance Document may also have utility for deriving PECs of substances in soil from agricultural fields treated with sewage sludge.

From bioavailability science to regulation of organic chemicals was presented by Jose Julio Ortega-Calvo (Institute of Natural resources and Agrobiology)[9] and discussed the concepts of bioavailability and NER formation, their importance to exposure assessment and the methods used in the bioavailability assessment. In addition, a new tiered approach with increasing refinement of the bioavailable fraction for use within retrospective and prospective risk assessment was presented.

Key issues for discussion were as follows:

- What are the key elements and processes to be considered in the environmental exposure and fate assessment?
- How should bioavailability and NER formation be taken into account in soil exposure and fate assessment?
- How are exposure and effect assessments linked today? How could they be better linked in the future?
- Measuring of exposure in ecotoxicity media/studies.
- What modelling tools are available for soil exposure assessment?
- What methodology and tools are available today to carry out exposure assessments at landscape level? What data and tools are needed to make it possible in the future?
- How might background concentrations be taken into account in risk assessment?

[8] http://echa.europa.eu/documents/10162/21838212/soil_risk_assessment_egsmose_klein_en.pdf

[9] http://echa.europa.eu/documents/10162/21838212/soil_risk_assessment_ortega_en.pdf

5.2 Summary of the breakout group discussions

Chairs: Prof. Dr Willie Peijnenburg (RIVM), Dr Mark Egsmose (EFSA)

5.2.1 Key elements in exposure assessment

Overall, general issues that need to be taken into account within regulatory risk/exposure assessment include:

- compartment specific emissions (e.g. air emissions) and mode of application (indirect application vs direct application);
- chemical properties of the substance (such as partitioning coefficients and degradation half-lives);
- environmental parameterisation (distribution, composition and size of compartments); and
- fluxes within and between compartments and properties of the compartment (e.g. temperature within compartments, pH, solid fraction, organic matter and carbon content).

In addition, certain physico-chemical parameters such as desorption rate and dissociation of substances as well as kinetic and thermodynamic parameters were thought to be important.

A key discussion point was the applicability of laboratory test conditions to actual field conditions; care is needed when making extrapolations. Crucial details for the interpretation of the results are the matrix in which the chemical is applied to soil, soil properties and particularly the soil organic matter (SOM) content and its characteristics. Where possible, the test conditions should reflect use scenarios and realistic exposure.

A key aspect in the assessment of bioaccumulation potential is the route of exposure, although this is complicated by the scarcity of published studies for soil organisms. Bioaccumulation tests should be undertaken at ecologically-relevant exposure conditions, i.e. beginning with low concentrations and prolonged exposure rather than using high concentrations of substances over short periods.

Standardised bioaccumulation tests and particularly the duration of the test may not be sufficient for many compounds. Artificial soils were also not considered relevant or appropriate for the assessment. For example, artificial sterilised soils may overestimate bioaccumulation compared to natural soils with microorganisms capable of degrading the test substance.

Variation exists between different legislation in certain test conditions, such as reference temperature in degradation studies and the length of equilibrium period. Justifications behind the differences were discussed and suggestions were made to align these across the regulatory regimes.

5.2.2 Role of bioavailability and NER formation in exposure assessment

Bioavailability was highlighted as an important concept in influencing the exposure to chemicals, but its role in regulatory risk assessment frameworks is not straightforward. A clear definition of the bioavailable fraction is needed as well as standardised chemical

and biological methods for its quantification. The concept would require further research and the development of a generalised model before implementation in regulation.

Non-extractable residues or NERs may be defined as chemical substances that remain in the soil matrix when extracted by methods that do not significantly alter the chemical nature of these residues or the structure of the matrix. NER formation and the methodology for NER determination were presented in a case study by Jose Ortega-Calvo[10].

Although methods for differentiation of the NER types are available, structural identification and quantification of residues is often missing. The definition of NERs is complicated from the regulator's perspective in the absence of standardised analytical tools for their measurement.

The assessment of the formation of bound residues varies between regulations. For PPPs, the formation of residues is not taken into account except when the mineralisation is <5 % active ingredient and NER >70 %. In this latter case, further assessment and characterisation of NERs is required. In the case of REACH and the BPR, it was felt that there is insufficient documented guidance relating to NERs. Within REACH and the BPR, NER formation and its role in persistence determination in PBT assessment is under discussion – see ECHA R11 Guidance. The group concurred that there is need for harmonisation with respect to NERs between different regulations.

5.2.3 How are exposure and effect assessments linked today? How could they be better linked in the future?

General support was found for encouraging the analysis of chemicals as a minimum at the beginning and end of ecotoxicity tests to provide information for the risk assessment in relation to measured exposure concentrations. It was noted that substance-specific extraction and analytical techniques would need to be applied. The extractable fraction may change during the test, for example, the chemical may be more tightly bound to the soil matrix at the end of the test, and harsher extraction techniques may be needed. Due to the possible transformations and fate of the test substance during the testing duration, it should also be ensured that the relevant analytical information at the beginning and end of the test are compared. It was noted by one participant that bioavailable fractions at the beginning and end of the test should be compared.

In addition, exposure timing and duration are important aspects of exposure assessment. In the toxicokinetic-toxicodynamic (TKTD) modelling approach, the model considers absorption, distribution, metabolism and excretion within the test organism and it may have the potential to be a useful tool for linking exposure and effect in the future. Knowledge may be shared from developments from PPP for aquatic assessment, which may also have potential for soil assessment.

One option for improving the connection between exposure and effect assessment could be a comprehensive review of the state-of-the-art of modelling and how it can bring together exposure and effect in integrated assessment. Additionally, more collaboration between regulators from different regulatory frameworks was welcomed. It was

[10] http://echa.europa.eu/documents/10162/21838212/soil_risk_assessment_ortega_en.pdf

recommended that a conceptual model is prepared with consideration of both exposure and effects for the soil compartment before developing a testing strategy.

A better linkage between exposure and effects assessment is crucial in the attempt to increase the realism of the assessments. This approach was taken for PPPs when the PPR Panel proposed the total content and pore water concentrations as relevant for risk assessment to soil organisms. During the discussion, a workshop was proposed for linking exposure and effects for the soil compartment similar to the successful ELiNK project for the aquatic compartment hosted by the Society of Environmental Toxicology and Chemistry (SETAC).

5.2.4 Measurement of exposure in ecotoxicity studies

As discussed in Section 5.2.3, one approach is the analytical verification of the test substance concentration at the start and end of a test. Extrapolation from laboratory studies to field conditions is done using correction factors for metals, based on measured exposure data. For PPPs, the actual exposure concentration in soil is not currently measured and nominal concentrations are used. For REACH purposes, testing according to the standard OECD/ISO test guidelines is requested where verification of exposure concentrations of test substances is not currently implemented. However, there is an on-going consultation on revised OECD soil toxicity test guidelines (drafts of OECD soil toxicity guidelines with revised advice for testing volatile substances are publicly available on the OECD's website) where verification of exposure concentrations in soil is proposed in cases where substance concentration is not stable during the testing.

For metals, a measured total concentration would be straightforward but for organic compounds the situation may be more complicated. For example, highly hydrophobic materials are difficult to quantify at very low concentrations. Use of the LC-MS (liquid chromatography with mass spectrometric detection) approach shows promise but standard LC-UV (liquid chromatography with ultra-violet light detection) is not sufficiently sensitive. Testing of exposure concentrations of other compounds such as metabolites in the standard soil toxicity/fate strategies has its complications. Often very little is known about the metabolites of biocides and organic pollutants and their potential impact. In cases when residues are more toxic than the parent compounds, the trigger values for residues would also need to be lower than that of the parent compound.

Use of time-weighted averages in exposure assessment was thought to be useful in achieving improved realism in ecotoxicity studies. Passive sampling methods were suggested as a potential tool for obtaining data for time-weighted average estimations. Passive sampling has been observed to work well for hydrophobic compounds and methods have been adapted for ionisable chemicals.

Diffuse gradient in thin films (DGT) can be used for metals to get time-weighted averages and different films have been developed for different compounds. These were also considered to be good surrogates for measuring available fractions. The group also suggested that the same soils should be used for ecotoxicity testing and for tests used to determine other properties, such as half-lives and accumulation.

5.2.5 Modelling tools in soil exposure assessment

Generally, model choices vary between PPP, the BPR and REACH and between European countries. A number of intermediate tools and tiers are available to refine the exposure

assessment. However, some substances, such as inorganics, ionic substances, surfactants and organometallics may need non-standard procedures for exposure assessment. For these compounds, models would need to be able to account for pH dependent sorption, physical and chemical adsorption and degradation. Additionally for metals, consideration of speciation is also important in determining their fate and exposure. Thus, careful evaluation of the suitability of available models and input parameters to the substance in question has to be carried out before choosing the model.

The prospect of using and developing modelling tools for exposure in soil in the future is promising. This could be achieved either by improving the current models and/or by developing new software and taking into account robust geospatial soil and weather data. The group felt that researchers should look at the capabilities of the existing models first and refine them before developing new ones. An important aspect of model development is validation to assess whether the model reproduces the system behaviour within acceptable bounds. EFSA has published a panel opinion on good modelling practices, which also states the need for robust validation procedures. Thus, guidance on validating models was identified as one of the important future needs.

5.2.6 What methods are currently available today to carry out exposure assessments at landscape level?

Landscape level assessment is recognised to be important in the future. Due to the inherent diversity in environmental conditions and degree of vulnerability between areas, the ability to capture this variation by landscape risk assessment would be helpful. In the plenary session, Koen Oorts (Arche) presented a case study for copper assessment, where landscape models were used to create geographic information system (GIS)-based maps visualising the areas of Europe where the potential hazard exceeded the PNEC (Section 3).

Despite the clear advantages of the landscape level assessment approach, the group identified certain challenges for landscape assessment. Soil data exists for Eurasia as well as North America. For some assessments, landscape-based approaches would benefit from an increased resolution of the data as in e.g. the EU, only a resolution down to 1x1 km^2 is available.

As the availability, quality and storage of geospatial data varies between Member States, a harmonised data set is needed before an EU-wide GIS database can be created. A model landscape scenario would also need to be created to set the dimensions of a landscape level assessment.

In its guidance document on soil PEC, EFSA was able to provide 1x1 km^2 resolution for which EU crop maps are available (CAPRI). This model landscape scenario may be difficult to establish and at such a small scale the number of scenarios will rise exponentially, which becomes difficult to use. A policy decision was agreed by risk managers for the EFSA guidance on PECs in soil to apply the 90^{th} percentile of the area where the substance is used.

The breakout group concluded that landscape-based assessments may be useful for higher tier assessments for refining the risk but should not be used for standard assessments, which can be completed using simpler approaches. Mapping the risk may

provide advantages in some cases as it can capture the environmental variability and identify vulnerable areas where specific risk mitigation is needed.

5.2.7 Background concentrations

It was felt that a recurring problem in exposure assessment is that background concentrations are not always known for naturally occurring substances. Where data exist, a further problem arises in the selection of appropriate data, particularly, for example, where data are scattered. However, guidance on a systematic review process for collecting and selecting data does exist in EFSA guidance on systematic review.

Robust and representative background concentrations need to be determined. To this end, an understanding is needed on whether there is sufficient and representative data and how the data can be used. The GEMAS project using georeferenced soils data (EU-27, Koen Oorts, Section 3) was again seen as a useful example. When the project researchers initially attempted to gather data held by national authorities, they found data were unavailable, not accessible, or monitoring data were not geo-referenced. Different sampling methods, extraction methods, soil depths and sampling densities had also been used. Greater harmonisation of sampling and analytical methods and data collection and selection techniques would overcome these challenges.

The discussion on how the background concentration should be defined revealed many practical challenges. Should background concentrations from pristine locations be used or does the background reflect present day levels at other locations? Natural background concentration varies depending on the location.

How would the information on background concentration be used if natural background levels were higher than a NOEC level? In many areas, geological background levels of inorganics are above no effect levels and for organics there may be diffuse background levels due to anthropogenic inputs.

Europe has been densely populated for many generations and pristine environments are largely unavailable. 'Natural' backgrounds of what are considered pristine environments are influenced by anthropogenic activities (e.g. diffuse emissions). Natural soils used for ecotoxicity tests, have been influenced by anthropogenic activities as well. Guidance on how to define and use background concentrations in the risk assessment of existing chemicals was developed for metals (*ECHA Guidance on Information Requirements and Chemical Safety Assessment APPENDIX R.7.13-2*).

5.3 Suggestions for scientific research

Suggestions for research needs include the following:

- Development of toxicokinetic-toxicodynamic (TKTD) modelling approaches for ecotoxicity assessment as a way of linking exposure and effect assessment;
- Development of passive sampling for obtaining data for time-weighted average estimations
- Review of the capabilities of the current models for exposure assessment and particularly for the compounds that require specific non-standard procedures for modelling

- Development of a harmonised geospatial soil database for Europe (at EU28 level), including harmonisation of data for a GIS database. European regulators may be able to assist in data gathering from Member State authorities.
- Need for protocols that aim to standardise bioavailability measurements.
- A scientific workshop for linking exposure and effects for the soil compartment was welcomed.

5.4 Ideas for regulatory development

Ideas for development of regulatory science include the following:

- A comprehensive review of the state-of-the-art of modelling and how it can bring together exposure and effect in integrated assessment:
    - A better definition of the compartment of concern (e.g. soil) would enable identification of the most appropriate and crucial tests and making further improvements to the tests.
    - A better organisation and collaboration between regulators from different regulatory frameworks is required to achieve harmonisation;
- Harmonisation of test methods and application of same scientific principles across regulations (a recurring and general theme across all breakout groups);
- Harmonisation of testing and reference conditions across regulations (e.g. temperature and the 'aging issue');
- Promoting the use of similar dose metrics (extraction/analytical methods) as a basis for extrapolations and emphasise the importance of reporting measured concentrations, whilst being aware that different analytical methods might be needed at the start and end of tests. Also ensure extraction methods reflect the assessment question for both exposure and effects assessment (e.g. different methods for NER assessment, persistence, degradability);
- Promote the testing of exposure concentrations of metabolites in the standard soil toxicity/fate strategies using a method tailored to the compounds being measured (define meaningful metabolites);
- Bioavailability assessment and NER formation have potential for implementation in soil exposure and fate assessment;
- A key issue for assessing NER formation is the development of a generalised model to allow for implementation in regulation. Harmonisation effort is needed involving regulators and researchers. It is important to identify what are the extraction methods for e.g. covalently bound non-extractable residues? How may the different fractions be defined unequivocally?

6. Effects assessment

6.1 Setting the scene

In his keynote presentation, entitled *Laboratory and higher tier effect tests in soil ecotoxicology: state-of-the-art and new developments*, Jörg Römbke (ECT Oekotoxikologie GmbH) described the current status, gaps and opportunities in soil ecotoxicological testing. In different EU regulations (REACH, the BPR, PPP, human and veterinary pharmaceuticals) a variety of standardised soil tests are required. A key question was whether relevant standard species are tested. Some important taxonomic

groups are already covered. For the inclusion of new taxa, transparent criteria are needed concerning their ecological relevance, their robustness for culturing, route of exposure, type of endpoint and their sensitivity.

Another issue was related to the suitability of the test methodology used in the regulatory science. An extensive list of standardised OECD and ISO methods are available. If new ones are to be developed, these would require transparent acceptance criteria related to exposure pathways, standardisation, practicability, and relevance. It was remarked that tests with functional endpoints are currently lacking. New ISO and OECD tests for microbial structural and functional diversity, nematodes, earthworms, snails and isopods and the terrestrial model ecosystems (TME) tests were described as potential new developments.

Two further case study presentations were made within the breakout groups. The first one on *Application of equilibrium partitioning-based model framework for evaluating soil (and sediment) hazards of lipophilic nonpolar organic substances*, presented by Aaron Redman (ExxonMobil Biomedical Sciences, Inc.), gave examples of the application of equilibrium partitioning-based model framework (TLM-EPM) for evaluating soil hazards of lipophilic nonpolar organic substances[11]. TLM-EPM is an EPM-based extension of the target lipid model (TLM), a QSAR framework used to predict acute and chronic toxicity of substances and the calculation of predicted no effect concentrations (PNECs) of highly lipophilic hydrocarbon substances. He reviewed the technical basis for the TLM-EPM framework and illustrated the application of the methodology to available case studies of synthetic engine oil and synthetic ester lubricant.

Then, Björn Scholz-Starke (RWTH Aachen University) presented *Assessing the risks of pesticides to soil communities using terrestrial model ecosystems* giving examples of the TME methodology and experimental design.[12] He also explained how to use TME data for ERA characterisation of effects and calibration of higher tier tests results. The TME approach could serve as a reliable higher tier test system with a fit-for-purpose and well developed methodology.

Key issues for discussion were as follows:

- Would better links between exposure and effect improve the risk assessment for soil?
- Are we selecting the relevant species for soil toxicity testing?
- Equilibrium partitioning of lipophilic substances and what are the boundaries of the applicability of the EPM method to predict hazards in soil?
- How to address biodiversity in soil communities?
- How to improve applicability and test design of higher tier testing (semi field/field studies) in a regulatory context? What are the new and applicable higher tier methods?

[11] http://echa.europa.eu/documents/10162/21838212/soil_risk_assessment_redman_en.pdf
[12] http://echa.europa.eu/documents/10162/21838212/soil_risk_assessment_scholz_en.pdf

6.2 Summary of the breakout group discussions

Chairs: Dr Veronique Poulsen (ANSES), Prof. Dr Paulo Sousa (University of Coimbra)

6.2.1 Would better links between exposure and effect improve soil risk assessment?

Considering bioavailability in toxicity testing was seen as a positive way to improve links between exposure and effect assessment. Generally, it was agreed that the bioavailable fraction of a chemical should be used in ERA.

This was already discussed further in Section 5 of this document. There was a general agreement to start with simple approaches, such as considerations of physico-chemical properties and NERs of the substance, and subsequently more complex approaches could be adopted where relevant. Exposure in soil pore water and the concentration gradient along soil depth were found to be important factors and may have different relevance depending on the species of organisms.

Default correction factors are commonly used to refine exposure for bioavailability or to adjust toxicity data and their application varies between regulatory regimes.

The breakout group has questioned the scientific basis of the currently used correction factors. The assessment factors under REACH are dependent on the number of tested species and on the adsorption potential of the test substances.

One option of avoiding the assessment factors under the PPP Regulation could be to normalise the tested concentrations with the organic carbon content of soil and to assess whether the use of a correction factor was still applicable.

The use of standardised natural soil (e.g. LUFA) could be an option to waive the application of the correction factor, even if the OECD guidelines recommend using the artificial soil. Artificial soils recommended by the OECD guidelines have higher organic matter content than standardised natural soils (e.g. LUFA), which makes them inappropriate for certain tests. For example, artificial soils were not considered relevant or appropriate to be used in bioaccumulation tests as the greater organic matter content of artificial soil may lead to underestimation of actual bioaccumulation as a result of greater adsorption.

As in Section 5, the importance of providing the measured concentrations instead of nominal concentrations for both lower and higher tier assessments was highlighted by the group. This is already done for REACH and biocides, while for pesticides only the dose in the solution is measured. In addition, whenever possible, verification of total concentration and pore water concentration was seen to be a desirable way to assess the quality of the test.

Nevertheless, some concerns were expressed about the feasibility and extra costs of these measurements. For products already on the market, the calculation of pore water concentration would make the risk assessment more complex. Yet, at lower-tiers, the application of an assessment factor was considered a reasonable approach. Caution is needed since exposure through pore water is not relevant to all soil organisms. For example, earthworms can be more exposed to pore water while the potential for exposure for mites and collembolans varies between species.

The calculation of pore water concentration will make the risk assessment more complex and thus, the application of an assessment factor was considered the most reasonable approach at lower tiers. The new EFSA *Guidance document on PEC* recommends to calculate the PEC both for total soil and the pore water concentration therefore it was considered reasonable to measure the pore water concentration also in the test system. This can be done when higher assessments are needed.

6.2.2 Are we selecting the relevant species for soil toxicity testing?

Species sensitivity varies and it is difficult to predict whether the most sensitive species are represented in an ecotoxicological testing programme. Sensitivity depends not only on the species but also on the properties and mode of action of the substance. Instead the discussions focused on ways to improve species selection and relevance in soil risk assessment and the use of assessment factors.

Availability of data from greater number of species should lower the AFs because more data are available and the interspecies uncertainty is reduced. In REACH, when a SSD is available a lower AF may be used. The availability of toxicity data on additional species than the standard ones, could lead to reduced assessment factors (AFs).

A proposal could be the use of the lower limit HC5 without AFs instead of the median hazardous concentration at the fifth percentile (HC5) with and additional AF, as a result of the SSD. However, this may not be always appropriate.

Interspecies variation was discussed in reference to protection goals. Field data could be used for calibration of the AFs (covering extrapolation lab-to-field) to be applied at lower tiers. For example, a reduction of 20 % in activity or survival rate means different things to different species. Generally, the use of further AFs should be avoided, but in practice, the use of AFs is a pragmatic option.

The adequate number of data points (species) to allow a feasible SSD for soil organisms was discussed. However, more guidance on how to apply the SSD approaches for soil is needed. It was proposed that combining toxicity data for different soil organisms in SSDs should be decided on a case-by-case basis by considering the mode of action of the substance. For example, for PPPs in the case of insecticides, it is not meaningful to combine toxicity points for different soil organisms. However, for industrial chemicals, a combination of data could be used but for many substances not enough soil toxicity data is available.

Toxicity data obtained from studies using different soil types with varying soil conditions (e.g. SOM content) should be normalised to the same soil conditions to correct for this source of variation and to avoid additional uncertainty on intra- or inter-species variability.

For REACH, all soil organisms, including plants, and microbial functional endpoints have been included in the SSD. In practice, except for metals, there is rarely an adequate amount of information available for industrial chemicals to conduct an SSD assessment. According to the Biocides Guidance, biocides SSDs can only be performed when at least 10 NOECs (and preferably 15 NOECs) are available from at least eight taxonomic groups.

Data on microbial mediated processes and single species tests should be considered separately due to fundamental differences between these tests (functional vs structural test, multi-species vs single species, adapted indigenous microbe community vs laboratory test species, variability of test design and different endpoints etc.). The

results should be compared and evaluated on a case-by-case basis when deciding on a final PNEC for the soil compartment.

The approach of statistical extrapolation is still under debate and needs further validation (*Guidance for BPR: Volume IV Part B Risk Assessment (active substances)* Version 1.0 April 2015). For pesticides, plants could also be included in the SSD considering that studies on seedling emergence are available where the substance is incorporated in the soil. Data from seedling emergence tests is typically expressed in the same units (mg/kg soil) as other soil ecotoxicity tests, while most tests with plants generate data in kg/ha. If the plant data is combined with microbial and invertebrate data in the SSD, all data needs to be in same units.

The relevance of OECD 217 (carbon transformation test) in regulatory hazard assessment was questioned by the breakout group. The use of the nitrogen mineralisation test was supported as it is more sensitive than the carbon transformation test. The experts started a discussion on the relevance of different toxicity tests for plants (ISO or OECD) and on which endpoint to use in the risk assessment. However, for plants it was recommended to check the outcome of the workshop on non-target terrestrial plants (NTTPs), which was held in September in Wageningen to avoid 'reinventing the wheel' as regards to plant tests (OECD 208)[13].

Uncertainty remains about dealing with positive effects, especially for microorganisms, reported in toxicity tests. The positive effects can be more relevant at community level rather than at population level. If we look at the community level, positive effects for microorganisms can be adverse because they may lead to a shift in the structure of the community. Positive effects are not only relevant for microbes but also for other species of organisms. Use of weight of evidence (WoE) approaches may help to judge the relevance of these positive effects and help to manage the data in decision making.

For PPPs other data than the nitrogen/carbon mineralisation data are sometimes submitted as part of dossiers. Dose-response relationships could also be taken into account and as long as the positive effects can be explained (use as carbon source), they should not be considered adverse effects. For PPPs, positive effects are mainly only explained in footnotes but not really considered in the risk assessment. Therefore, how to use potential detected positive effects in the risk assessment remains unclear.

6.2.3 Equilibrium partitioning of lipophilic substances and what are the boundaries of the applicability of the EPM method to predict hazard in soil?

The equilibrium partitioning (EPM) method is used widely in soil risk assessment. The EPM model can be used e.g. to predict the soil toxicity from aquatic toxicity data and the soil/water partitioning coefficient. Some concern was raised at the use of EPM when soil is the major route of exposure. However, some general rules apply, for example, EPM is not advised when the substance is poorly water soluble or the LogPow is >5 (in REACH). The EPM approach is used for hydrocarbons (up to logPow=6) but the water solubility is a limiting factor for the use of such a method.

[13] Second non-target terrestrial plants Workshop 21-22 September 2015, Wageningen, The Netherlands

In his presentation for the ECETOC Task Force (see also Sections 3 and 4.2.6), Michiel Claessens (Chemours) illustrated potential flaws with the EPM method as it may not be sufficiently protective for the soil compartment in all cases. During the breakout group discussions it was questioned whether EPM could be used to predict hazard to soil microbes, or whether the reverse was the case, that the soil compartment is the medium to study for effects on microbes and then extrapolate to sediment and water.

Introducing microorganism specific tests, such as BIOLOG, to give a regulatory context may provide relevant information, but more research and guidance is needed on the interpretation of the results (see Section 4.2.6).

6.2.4 How to address biodiversity in soil communities?

The role of biodiversity in chemicals risk assessment has not yet been clearly defined. It was considered that for PPPs different protection goals should be defined for in-field, edge of field and off-field, allowing different levels of protection (lower to higher going from in-field to off-field).

A clear need exists to better define what to protect and where, since it is not feasible to protect everything everywhere, all of the time. The role of the risk assessor is to propose protection goals to risk managers and after agreement to ensure that the level of protection is achieved in the risk assessment. To propose adequate protection goals, both the key drivers (representatives of the different soil organism groups having an important role in the provision of key ecosystem services) and their normal operating range (NOR) need to be determined. Only by establishing a baseline for biodiversity, will it be possible to define an acceptable change according to the SPGs.

It was recognised that methods for addressing both ecosystem function and structure are needed. The group discussed how to best combine structural (invertebrates and plants) and functional endpoints (e.g. microbial processes) into a single risk assessment. Guidance would be welcomed on this point. Also, defining a NOR for a relevant microbial function would be needed. However, difficulties of translating laboratory results to the field scale were seen as a challenge, especially to define when deviation from NOR is relevant for the functioning of the system.

Definition of what is an acceptable/unacceptable shift in biodiversity is further complicated by the local and global variation in biodiversity. Variation in soil biodiversity is caused by a number of abiotic factors such as differences in land use, soil type, climate and geographic location. Biodiversity also varies between regions due to species-specific geographic range limits. Some species are more globally distributed while other are restricted within a narrower geographical distribution. These differences are common to both retrospective risk assessment (contaminated sites) and prospective risk assessment.

It was thought that better accounting of variation in regional biodiversity could be achieved by the development of the ecoregion concept, where the ecoregions could be defined using trait-based properties. Species traits and the presence of species assemblages could be used to define ecoregions (e.g. the map of European earthworms).

Microbial communities (e.g. data in the UK and France) and plants could be mapped to ecoregions. The ecoregion concept would also allow the test species used in effect

assessment to be tailored according to the region where the product (e.g. PPP) is being applied.

A trait-based approach could be adopted to generalise the effect assessment between groups of organisms living in the same habitat. Use of the ecoregion concept would require reference tiers to be established based on monitoring data for different areas. A suggestion was made to develop specific PGs that account for ecoregions.

6.2.5 How can applicability and test design of higher tier testing be improved in a regulatory context?

When testing multiple species, different effects are revealed than with single species tests. Thus, multiple generation tests and multispecies tests are seen as possible ways of improving the realism and applicability of testing schemes. Particularly toxicity testing with soil microbes should be encouraged before higher tier testing.

The intermediate tier tests, multiple generation tests and multispecies tests are good approaches, but currently their place in a testing strategy is not clear and it should be discussed. Additionally, not very many tests are available. These multiple generation tests and multispecies tests are not yet standardised and several aspects related to their statistical power and reproducibility have to be further studied before they can be integrated in an ERA scheme.

Multiple generation tests were identified as useful as they increase the length of exposure to the chemical, but there is little guidance on how to select appropriate species for these tests. An extensive review of literature on different exposure durations and endpoints, the whole life cycle and aging processes would be a way of providing this much needed information. It was highlighted that after the common agreement on the test set-up, a ring testing scheme should be developed. Additionally, standardisation of the guidelines at the international level would need to follow.

Multispecies tests, either those using a fraction of the natural community of a community assembled by the researcher (e.g. gnotobiotic tests), were also found to be useful due to the possibility to assess both direct and indirect effects. The information gained with these tests in comparison to mesocosm and field tests has to be further discussed, and more guidance on their performance is needed.

Use of the SSD approach was also recognised as a way of improving the realism and applicability of higher tier testing schemes. Generally, the lack of data for soil organisms and the lack of guidance for SSD approaches for soil have limited the use of SSD.

As has been discussed previously, there is uncertainty whether different taxonomic groups can be combined in SSD. The group felt that data from different taxa and trophic levels may be combined but that there may be possible biases and cases where this may not be appropriate. Attention should also be paid to other important factors contributing to the ecotoxicity test results, such as properties of different soil types and the type of effects measured and which effects may be combined.

Other potential tools for higher tier testing include mesocosms, field studies and terrestrial model ecosystems (TMEs). Use of TMEs was also discussed as they offer many advantages over laboratory studies, as they can mimic natural variation in the field conditions and can offer a good surrogate for a reference tier.

Applying TMEs would also offer a possible advantage over the field studies as it will allow distinguishing between the recovery and the recolonisation stages. In field tests, you have to assume the recovery is a combination of both external and internal recovery. With TMEs, there is no external recovery and all recovery is internal. However, it is important to indicate that the TMEs would provide a less realistic scenario.

However, further research and development of guidance for the execution of TME studies and the use of data is required. The key needs include guidance on experimental design (e.g. statistical power and how to tackle recovery), site selection and regionalisation issues and how to deal with data and in particular how to deal with false positives and negatives.

The group recognised that guidance is needed to define common criteria for the selection of sites, sensitive communities (that are not adapted, for example, to pesticides), interpretation of the results, and the kind of classification (different classes of higher tier methods). The group also discussed if TMEs and mesocosms could be used as surrogate reference tiers that could be used to calibrate lower tiers in combination with mechanistic effect modelling. Again, more guidance is needed on those aspects.

The use of these above-mentioned tools would require further research, for example, pairing tests with natural communities in laboratory conditions with tests with communities created in a laboratory. Modelling was also seen as a useful tool for testing hypotheses. Several models are in development, such as *Collembola*, *Daphnia*, plant and community modelling. Modelling of interaction between species is also being attempted and these tools are promising. More effort should be done to study combination of TMEs and modelling to get input data for modelling or to combine the field studies and mesocosms, with the aim to derive single species testing and a connection between risk assessment.

6.3 Suggestions for scientific research

More scientific research is needed to better address issues related to effects assessment as follows:

- A review of assessment factors for soil organisms (PNEC) based on risk assessments, undertaken in the last 15-20 years, to evaluate and possibly redefine these factors;
- Development of a normal operating range (NOR) for biodiversity of soil organisms to evaluate (e.g. using criteria) whether an adverse effect is occurring and whether this can be related to a specific protection goal;
- Consideration and elaboration upon regional ecological differences, for example, on whether an ecoregions approach would help refine PECs and PNECs, and develop define [population] recovery durations:
    - Need of more research on regionalisation (e.g. mapping species and natural soils, data from existing data bases);
    - Need for collection and data sharing on biogeographical data;
- Need to simplify biodiversity evaluation using methods such as genetic barcoding;
- Need to develop a better understanding of interactions of chemicals with other stressors taking place in the environment (e.g. climate change-derived stressors);

- For the further development of ecotoxicity tests for soil organisms, ring testing is needed for tests proposed as intermediate tiers (multispecies or multigeneration);
- Guidance on the validity criteria for SSD in soil organisms (e.g. taxonomic groups to be included in an SSD approach);
- Guidance on the performance of a TME study and on analysing and interpreting data (including defining effect categories) is needed; and
- For the use of TMEs as surrogate reference tiers that could be used to calibrate lower tiers in combination with mechanistic effect modelling, more data using these systems is needed.

6.4 Ideas for regulatory development

Ideas for regulators to further develop and identify needs for further guidance included the following:

- Advice on the use of pore water concentrations in risk assessment;
- How to normalise effect data across soils and products;
- Methods and guidance for addressing both ecosystem function and structure, are needed; more guidance is needed on whether and how to combine structural (invertebrates and plants) and functional endpoints (e.g. microbes) into a single risk assessment; and
- Regulatory guidance specifically on soil risk assessment is needed in relation to:
    - application of SSDs;
    - conduction of TME study (its design and data analysis); and
    - test sites selection for TMEs and field studies.

7. Panel discussion

Panel Members: Dr Mark Egsmose, Dr Marc S. Greenberg, Dr Willie Peijnenburg, Dr Veronique Poulsen, Prof. Dr José Paulo Sousa and Dr Anu Kapanen.

Chaired by: José V. Tarazona

After the summary of the breakout group discussions, the breakout group Chairs were requested to provide their reflection on the following:

- How would they interpret the outcome of the breakout group discussions or if there are any additional observations after hearing the summaries from the other breakout groups?; and
- How and when could harmonisation of the approaches be achieved within the different legislations and diverse soil compartment?

Breakout group 1's Chair emphasised that if specific protection goals (PGs) should be set within general PGs for the ecosystems services, there is a need for more specific concepts and agreed terminology. These PG concepts need to be based on science and must be measurable.

The experts should take this opportunity to provide definitions in terms of ecosystem services and their protection goals and to provide options for policy makers and risk managers that they can choose from. For this purpose, we need to think what the most important services are. The maintenance of soil properties that support the function of healthy soil and its diversity, both of which are required for ensuring the provision of the services, could be a starting point for this discussion.

Breakout group 2's Chairs highlighted the need to link exposure and effect assessments more closely. This could be achieved to a certain extent, for example, by including exposure measurements in ecotoxicity studies. Determining actual exposure concentrations instead of nominal concentrations could be a way to start. The group also stressed the need for harmonisation steps in exposure assessment and testing requirements and testing conditions across legislation. They also acknowledged that the discussion themes were well selected and complemented and supported each other. During the discussions, the advances in implementation of the soil risk assessment in the area of pesticides seemed more developed and the question on how the other regulators would be able to incorporate advanced approaches implemented in EFSA was raised.

Breakout group 3's Chairs underlined the need for more guidance e.g. on SDD derivation for soil organisms. The main points to be covered are the combination of toxicity data on different soil organisms (invertebrates, plants, etc.) and the combination of structural and functional endpoints.

In general, the questions on what we need to protect and what to test created the biggest discussion. The need for common quality and relevance criteria in assessing ecotoxicity data was raised and it was noted that there is already work in progress in this respect e.g. by SETAC. Furthermore, the applicability of the non-testing methods in soil hazard assessment was seen as a potential area for development.

All breakout groups had discussed the needs and challenges in harmonising approaches across legislation. It was noted that there was a dichotomy in the discussions; the need

for harmonisation between the legislations was highlighted, yet it was important to recognise the heterogeneity of the goals of each legislation, and in soil properties locally and globally.

What exactly can be harmonised? What elements can be harmonised while still maintaining the ecological relevance? Currently, testing requirements differ between regulations, some divergences are not justified by differences in PGs or scientific implementations, being the result of historical or parallel evolutions, therefore, testing requirements and methodology could be an area for harmonisation. However, flexibility should be maintained as the use of chemicals and their properties vary. Tier 1 assessments would be easier to harmonise, as well as the data quality criteria but specific use scenarios will differ in higher tiers and those are unlikely to be harmonised.

Increased collaboration between agencies was supported and seen to be most beneficial. It was asked if ECHA and EFSA could work together to produce harmonised guidance. Jose Tarazona pointed out that the agencies have regular meetings and participate in the same working groups, and that they are willing to even increase collaboration between agencies.

Exposure scenarios in the risk assessment frameworks are different and not all areas can be harmonised. However, he stressed that learning opportunities do exist. Anu Kapanen added that even more active collaboration is welcomed and soil risk assessment is a good place to start. Jose Tarazona highlighted the importance of soil for EFSA and food production. He considered that lower tier harmonisation will help to refine the testing needs and emphasised the learning possibilities between agencies.

8. Main outcomes

In the concluding remarks, the Chairs of the Scientific Committee, Anu Kapanen and Jose Tarazona, acknowledged the contribution of the Scientific Committee, the Local Organising Committee, and all the participants and the supporting personnel.

They highlighted the contribution of the workshop to current and future activities in ECHA and EFSA related to soil risk assessment. The joint hosting of the workshop by the two agencies demonstrated the importance of the topic, as well as the willingness to work together to address the current challenges from the regulatory perspective.

Bringing together a range of stakeholders has fulfilled the workshop's goal to provide a platform for open discussion of the burning issues in regulatory soil risk assessment. Having regulatory scientists, industry representatives, academic researchers and consultants from Europe and North America under one roof has provided an input from different risk assessment methodologies and ensured that the positions of all parties involved have been taken into account. The workshop was concluded by summarising the highlights and considerations for future actions:

- Cooperation between the agencies and dialogue between the agencies and stakeholders lead to common goals for the development of improved risk assessment approaches being established.
- Identifying possibilities for harmonisation was one of the aims of the workshop. Defining specific protection goals under REACH would potentially lead towards the

development of risk assessment approaches enabling harmonisation, in relation to both fate and hazard assessment methodologies. EFSA's approach where the risk managers define specific protection goals supported by scientists was seen as beneficial and may have potential to be incorporated in other regulations. It has been noted that a realistic harmonisation scenario may be applied at a lower tier, helping to save financial resources and reduce animal testing.

- The ecosystem services approach is already incorporated in EFSA guidance, but presents a somewhat new concept for ECHA when it comes to risk assessment. The approach may represent a good communication tool when it comes to harmonising the protection goals.
- 'Biodiversity' currently does not represent a unique concept when approached from different aspects. Clearly defining the term within the regulatory context would help to potentially incorporate biodiversity as one of the harmonised protection goals.
- Exposure and fate assessment was another area where harmonisation of approaches was recognised as one of the priorities, with biodegradation testing given as one of the most prominent examples. In respect to bioavailability, it has been noted that the methods for identifying and quantifying non-extractable residues have potential for implementation in the regulatory framework.
- Links between exposure and effects assessment have to be strengthened. It has been acknowledged that the information on the terrestrial compartment obtained for industrial chemicals is scarce when compared to pesticides, where it is considered crucial. This further stresses the relevance of the equilibrium partitioning method and its applicability boundaries and limitations. It has been agreed that more research is needed on this topic before providing further recommendations on its use.

The workshop gave an indication of the way forward, and presented novel ideas that could be implemented within the field of regulatory risk assessment. The multi-partite format of the meeting has shown learning from each other to be crucial for defining and achieving common goals. While the different methodologies have been developed in isolation, there seems to be potential to use them across the regulations.

The outcome of the meeting will be utilised by both workshop organisers. ECHA has obtained an input for its future work in terms of implementing potential changes into the REACH Guidance. EFSA will work on incorporating presented concepts into the opinions of the Panel on Plant Protection Products and their Residues (PPR). The agencies will continue mutually-beneficial cooperation in this area.

9. Conclusions from the Scientific Committee

On behalf of the Scientific Committee, we would like to thank all the participants for their contribution in making this workshop a success. The outcome of this workshop has exceeded our expectations. The scope of the workshop created a considerable interest not only among the regulatory scientists and industry but also in the academic community, and provided an excellent opportunity for exchanging views on the best practices for using scientific knowledge in regulatory processes.

The Scientific Committee was pleased with the high level of the scientific discussions during the workshop. The focus was clearly on the key elements that are relevant for supporting the implementation of REACH, the BPR and PPP as well as other European and non-European regulatory processes connected to soil risk assessment.

During the workshop, it became evident that there are several topics where harmonisation of the approaches and international collaboration would bring added value for the soil risk assessment. Some of these identified areas for development were the following: defining specific protection goals, considering bioavailability in soil risk assessment and defining the concept of soil biodiversity in the regulatory context.

In addition, the Scientific Committee agreed that it is important to increase communication e.g. through activities in SETAC meetings. There were also suggestions under the broad topic of bioavailability to launch activities on clarifying the boundaries for applicability of the EPM approach, and on considering non-extractable residues within a regulatory context. Other areas for development were providing guidance on the application of SSDs for toxicity to soil organisms, and the possibility to revisit the currently applied AFs in the soil risk assessment.

Appendix 1 List of presentation titles

Day 1, 7 October 2015

- Soil Risk Assessment in the regulatory context
  - *Soil risk assessment in the regulatory context - REACH perspective*, Marta Sobanska, ECHA
  - *Soil Risk Assessment in PPPs regulatory context*, Maria Arena, EFSA
  - *Soil Ecological Risk Assessment*, US Environmental Protection Agency Status, David W. Charters, US EPA
  - Canadian Approaches to Soil Risk Assessment, Janet Cermak, Environment Canada
- *Protection goals and conceptual models, How science can support risk managers on what to protect?*, Jose Tarazona, EFSA
- *Overview of processes driving the exposure of chemicals in soil*, Willie Peijnenburg, RIVM
- *Laboratory and higher tier effect tests in soil ecotoxicology: state-of-the-art and new developments*, Jörg Römbke, ECT GmbH
- *Making soil protection goals based on the ecosystem services concept operational in ecotoxicological risk assessments*, Gregor Ernst, Bayer CropScience AG
- *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
- *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
- *From bioavailability science to regulation of organic chemicals*, Jose Julio Ortega-Calvo, Institute of Natural resources and Agrobiology
- *Application of Equilibrium partitioning-based model framework for evaluating soil (and sediment) hazards of lipophilic nonpolar organic substances*, Aaron Redman, ExxonMobil Biomedical Sciences, Inc.
- *Assessing the risks of pesticides to soil communities using terrestrial model ecosystems*, Björn Scholz-Starke, RWTH Aachen University

Day 2, 8 October 2015

- *Case study 1: Critical comparison of the schemes used to assess Soil exposure under Pesticide, Biocides and REACH legislation*, Bruce Callow, Exponent International Ltd
- *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
- *Case study 3: Performing soil risk assessments using aquatic hazard information only: how well can it capture all the risks?*, Michiel Claessens, Chemours
- *Case study 4: Compilation of case studies with challenges in regulatory soil risk assessment*, Romanas Cesnaitis, ECHA
- *Case study 5: Risk assessment for in soil organisms: future approaches and perspective*, Maria Arena, EFSA

Appendix 2 List of poster titles

Topic 1: Problem definition and conceptual model for soil risk assessment

Number	Organisation / Country	Submitter	Title / Authors / Poster
1	DuPont Crop Protection, GermanyDuPont Crop Protection, Germany	Dr Axel Dinter	**A Comparison of Functional and Structural Soil Testing for Risk Assessment of Plant Protection Products** Axel Dinter, Alan Samel and Stefania Loutseti
2	Institute for Environmental Research, Germany Institute for AgroEcology, Germany gaiac, Germany	Dr Martina Roß-Nickoll	**Biodiversity and structural diversity in the agricultural landscape – An overall concept relevant for soil risk assessment?** Martina Roß-Nickoll, Mark Deubert, Richard Ottermanns, Andreas Schäffer, Björn Scholz-Starke, Lucas Streib, Andreas Toschk, Matthias Trapp
3	gaiac - Research Institute for Ecosystem Analysis and Assessment, Germany	Dr Andreas Toschki	**Iterative adaptive monitoring to link the gaps in current risk assessment** Andreas Toschki, Martina Roß-Nickoll, Monika Hammers-Wirtz
4	Monsanto Europe S.A., Belgium	Dr Georg von Mérey	**Soil risk assessment for glyphosate and AMPA** Georg von Mérey, Philip S. Manson, Steven L. Levine, Peter Sutton
5	BASF SE Bayer CropScience AG Dow AgroSciences Syngenta Adama DuPont Cheminova	Dr Matthias Bergtold	**Making soil protection goals based on the ecosystem services concept operational in ecotoxicological risk assessments** Matthias Bergtold, Patrick Kabouw, G. Ernst, J. Bendall, M. Coulson, B. Garlej, P., S. Loutseti, A. Sharples

6	University of Sadat City, Egypt University of Helsinki, Finland Minufiya University, Egypt	Prof Mohamed Fathy Salem	**Innovative Biofumigation Technologies for Soil risk Assessment** Mohamed Fathy Salem, Priit Tammeorg, Mahmoud F. Seleiman, Ahmed A. Tayel
7	ECHA, Finland	Mr Dragan M. Jevtić	**Making use of publicly available studies within the REACH Regulation: An overview of submitted terrestrial toxicity data** Dragan M. Jevtić, Marta Sobańska, Andrea Gissi, Tomasz Sobański, Anu Kapanen
8	Ramboll Environ UK	Dr Samantha Deacon	**How can soil risk assessment data be used in ecosystem services analysis for agrochemicals regulation?** Samantha Deacon (Ramboll Environ UK) and Anne Alix (Dow AgroSciences, UK)

Topic 2: Environmental exposure and fate assessment

Poster number	Organisation / Country	Submitter	Title / Authors / Poster
9	Istituto Superiore di sanità, Italy	Dr Gianfranco Brambilla	**Environmental risk assessment of agriculture soils towards food safety and food security requirements** Gianfranco Brambilla
10	University of Reading, United Kingdom	Prof Chris D. Collins	**Towards a unified approach for the determination of the bioaccessibility of organic pollutants** Chris D. Collins, Mark Craggs, Sonia Garcia-Alcega, Katerina Kademoglou, Stephen Lowe
11	French agency for food, environmental and occupational health safety (ANSES), France	Dr Arnaud Conrad	**French Regulatory Feedback on new EFSA guidance for predicting concentration of active substances of plant protection products in soil: Impact on the risk assessment** Conrad A, Brulle F; Vuillemard P; Farama E, Boivin A, Poulsen V

12	Norwegian Institute of Bioeconomic Research (NIBIO), Norway	Dr/Prof Ole M Eklo	**Comparing PRZM, PEARL and MACRO using field data from a case study of pesticide leaching in Norway** Gomez-Aledo P, Balderacchi M, Benoit P, Bolli R, Eklo OM, Kværner J, Pot V & Trevisan M
13	BASF SE, Germany	Dr Bernhard Gottesbüren	**Degradation, persistence and exposure of pesticides in soil under different environmental scenarios - simulation and measurements** Bernhard Gottesbüren
14	Pest Management Regulatory Agency, Canada	Dr Lai Gui	**Unsaturated column for evaluation of pesticide behavior in soil**Lai Gui, Ian Kennedy, Robert W. Gillh
15	University of Helsinki, Finland	Ms Inka Reijonen	**Chemical bioavailability of vanadium species in soil – effect of soil pH and organic matter** Inka Reijonen
16	NGU-Norway Federal Institute for Geosciences and Raw Materials-Germany Geological Survey of Sweden Rio Tinto, Belgium	Dr Ilse Schoeters	**GEMAS: An overview of the distribution of metals in agricultural soil at the continental (European) scale** Clemens Reimann, Manfred Birke, Anna Ladenberger, Ilse Schoeters
17	PBL Netherlands Environmental Assessment Agency, Netherlands	Dr Aaldrik Tiktak	**European standardised scenarios for exposure of soil organisms to pesticides** Aaldrik Tiktak, Michael Klein, Mark Egsmose
18	Finnish Food Safety Authority Evira Finnish Environmental Institute (SYKE) Finnish Partnership for Research on Natural Resources and the Environment (LYNET)	Mr Kimmo Suominen	**Hazardous organic compounds in biogas plant digestates — Soil burden and risk to food safety** K. Suominen , M. Verta, S. Marttinen

Topic 3: Effect assessment

Poster number	Organisation / Country	Submitter	Title / Authors / Poster
19	The University of Sheffield, United Kingdom BayerCropscience, Germany Agroscope, Switzerland BASF SE, Germany Dow AgroSciences - Environmental Regulatory Sciences, Italy DuPont Crop Protection, United States ANSES - French Agency for Food, Environmental and Occupational Health & Safety,France European Food Safety Authority (EFSA), Italy	Dr Gertie H.P.Arts	**Ecosystem services approach to pesticide risk assessment and management of non-target terrestrial plants: recommendations from two SETAC Europe workshops** Gertie H.P.Arts, Lorraine Maltby, Margit Dollinger, Eva Kohlschmid, Christoph Mayer, Giovanna Meregalli, Hugo Ochoa-Acuña, Véronique Poulsen, Franz Streissl
20	International Lead Zinc Research Organization (ILZRO), USA Katholieke Universiteit Leuven, Belgium Ohio State University, USA. ARCHE, Belgium	Dr Mohammed Jasim Chowdhury	**Approaches and tools to correct ageing effects and bioavailability in ecological risk assessment of lead in soil** Mohammed Jasim Chowdhury, Erik Smolders Roman Lanno, Koen Oorts
21	Syngenta, United Kingdom	Dr Mike Coulson	**Re-calibration of the earthworm tier 1 risk assessment of plant protection products** Coulson M, Christl H, Bendall J, Bergtold M, Dinter A, Garlej B, Hammel K, Kabouw P, Sharples A, von Mérey G, Vrbka S, Ernst G

22	Bayer CropScience AG, Germany	Dr Gregor Ernst	**Soil functional test systems for an in-crop soil risk assessment of plant protection products** G. Ernst, J. Bendall, M. Coulson, B. Garlej, P. Kabouw, S. Loutseti, A. Sharples
23	EFSA, Italy	Dr Prof Ettore Gardi	**Environmental risks of biochar in soils: ecotoxicological effects on plants and microarthropos** F.D. Conti, C. Gardi, G. Visioli, C. Menta
24	Wca-environment, United Kingdom	Dr Graham Merrington	**Using higher-tier data in the nickel terrestrial effects assessment: reducing residual uncertainty?** Graham Merrington, Christian Schlekat, Beverley Hale, Yamini Gopalapillai, Tyson Jennett, Julie Kikkert, Wilson Lau, Mike McLaughlin
25	New Castle University, United Kingdom	Dr Philip Probert	**Tracking soil contaminants using in vitro toxicity assays** Probert, PME., Meyer, SK., Cooke, MP., Dunn, M., Blake L., Wright, MC.
26	University of the Basque Country, Spain		**Assessment of the impact of an abandoned dump site on the health of adjacent soil ecosystems by in vivo and in vitro testing with *Eisenia fetida*** Amaia Irizar, Nerea Garcia, Daniel Buey, Javier Etxebarria, Nestor Etxebarria, Ionan Marigómez, Manu Soto
27	NERC-CEH, United Kingdom University of Granada, Spain NanoHealth & Safety group, Spain NERC-CEH, United Kingdom University of Kentucky, Lexington, USA	Dr Claus Svendsen	**How well can standard soil tests provide the needed evidence for risk assessment of nanomaterials?** Claus Svendsen, Elma Lahive, Marianne Matzke, Ana Romero-Freire, Maria Diez Ortiz, Alan Lawlor, Daniel Starnes, Olga Tsyusko, Jason Unrine, David Spurgeon and Steve Lofts
28	ECHA, Finland	Dr Romanas Cesnaitis	**Intergrated testing strategy for effects on terrestrial organisms under the REACH Regulation** Romanas Cesnaitis, Marta Sobanska, Vincent Bonnomet, Dragan M. Jevtić, Amaia Rodriguez-Ruiz, Anu Kapanen

29	ECHA, Finland	Dr Marta Sobanska	**Analysis of experimental terrestrial toxicity studies submitted in the framework of the REACH Regulation** Marta Sobanska, Amaia Rodriguez-Ruiz, Dragan M. Jevtić, Romanas Cesnaitis, Andrea Gissi, Tomasz Sobanski, Anu Kapanen

Appendix 3 List of participants

Final list of participants

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

9 Oct 2015

SURNAME	NAME	ORGANISATION/ COUNTRY
A MARCA	Ms Maria	Federal Office for the Environment / Switzerland
ALANI	Dr Rose	University of Lagos / Nigeria
ALVAREZ	Dr Fernando	European Food Safety Authority / Italy
AMORIM	Dr Mónica	University of Aveiro / Portugal
ANDERSEN	Dr Sjur	Norwegian Environment Agency / Norway
ANDERSON	Ms Claire	Chemicals Regulation Directorate / United Kingdom
ANDREOU	Dr Kostas	Cyprus University of Technology / Cyprus
ANTHE	Dr Mechthild	Dr Knoell Consult GmbH / Germany
ARTS	Dr Gertie HP	Alterra Wageningen University and Research Centre / Netherlands
BALDERACCHI	Dr Matteo	Matteo Balderacchi / Italy
BAYAR	Dr Canan	Ministry of Health / Turkey
BERGTOLD	Dr Matthias	BASF SE / Germany
BIZZOTTO	PhD Elisa Chiara	Ramboll Environ / Italy
BJØRGAN	Dr Marie	Yara International ASA / Norway
BRAMBILLA	Dr Gianfranco	Istituto Superiore di sanità / Italy
BRANDT	Ms Charlotte	Federal Public Service (FPS) Health, Food Chain Safety and Environment / Belgium
BRENTRUP	Dr Frank	Yara International, Research Centre Hanninghof / Germany
BRULLE	Dr Franck	ANSES / France
BUSSIAN	Dr Bernd M	Federal Environment Agency / Germany
CALLOW	Mr Bruce	Exponent International Ltd / United Kingdom
CANTRELL	Dr David	Arch Timber Protection (A Lonza Company) / United Kingdom
CAPRI	Dr Prof Ettore	Università Cattolica del Sacro Cuore / Italy
CERMAK	Dr Janet	Environment Canada / Canada
CHARTERS	Dr David W.	US EPA, Office of Superfund Remediation and Technology Innovation / United States of America
CHOWDHURY	Dr Mohammed Jasim	International Lead Zinc Research Organization (ILZRO) / United States of America
CIEŚLAK	Dr Małgorzata	The Office for Registration of Medicinal Products Medical Devices and Biocidal Products / Poland
CLAESSENS	Dr Michiel	Chemours / Belgium
COLLINS	Prof Chris	University of Reading / United Kingdom
CONRAD	Dr Arnaud	French agency for food, environmental and occupational health safety (ANSES);

		Regulated Products Department / France
CONRAD	Dr Ines	Exponent International Limited / United Kingdom
CORNELIS	Dr Geert	University of Gothenburg / Sweden
COULSON	Mr Mike	Syngenta AG / United Kingdom
DAILEY	Dr Roger	Goodyear Chemical Group / United States of America
DE JONG	Dr Frank	RIVM / Netherlands
DEACON	Mrs Samantha	Ramboll Environ / United Kingdom
DELBEKE	Dr Katrien	European Copper Institute / Belgium
DINTER	Dr Axel	DuPont Crop Protection / Germany
EGERER	Dr Sina	Umweltbundesamt / Germany
EINOLA	Dr Juha	Finnish Safety and Chemicals Agency / Finland
EKLO	Dr/Prof Ole Martin	NIBIO / Norway
EKLUND	Prof Britta	Stockholm University / Sweden
ENRICI	Mrs Marie-Hélène	SOLVAY / France
ERICHER	Ms Fabienne	Cambridge Environmental Assessments / United Kingdom
ERNST	Dr Gregor	Bayer CropScience AG / Germany
FAUPEL	Dr Annekathrin	Troy Chemie GmbH / Germany
GIARDINA	Ms Silvia	ISPRA - Italian National Institute for Environmental Protection and Research / Italy
GOTTESBUEREN	Dr Bernhard	BASF SE / Germany
GROSSMANN-VEN	Ms Stéphanie	Federal Public Service Health, Food Chain Safety and Environment / Belgium
GROTH	Dr Torsten	LANXESS Deutschland GmbH / Germany
GUI	Dr Lai	Pest Management Regulatory Agency / Canada
GURINOVA	Dr Erika	Water Research Institute / Slovakia
GUTLEB	Dr Arno	Luxembourg Institute of Science and Technology / Luxembourg
HODSON	Prof Mark	University of York / United Kingdom
HOFMAN	Dr Jakub	Masaryk University, Faculty of Science, RECETOX / Czech Republic
HORNEK-GAUSTERER	Dr Romana	Umweltbundesamt / Austria
HOY	Mr Simon	Chemicals Assessment Unit, Environment Agency / United Kingdom
ISMERT	Dr Muriel	EDF / France
JENSEN	Dr John	Aarhus University / Denmark
JÄÄSKELÄINEN	Mr Miiro	Prime Soil Oy / Finland
KANT	Ms Krista	Agricultural Board / Estonia
KAUKONIEMI	Mrs Sanna	Tukes / Finland
KLEIN	Dr Michael	Fraunhofer IME / Germany
KOERNER	Dr Oliver	ADAMA Europe / Germany
KOHLER	Dr Esther	Agroscope / Switzerland
KOIKKALAINEN	Dr Katariina	Ramboll Finland / Finland
KOIVISTO	Dr Sanna	Finnish Safety and Chemicals Agency / Finland
KONDZIELSKI	Dr Igor	Institute of Environmental Protection - National Research Institute / Poland
KOZINA	Dr Antonela	Croatian Centre for agriculture, food and rural affairs - Institute for plant protection / Croatia

KRODER	Dr Stefan	Dr Knoell Consult Schweiz GmbH / Switzerland
LAGERSTRÖM	Mrs Maria	Stockholm University / Sweden
LAJQI MAKOLLI	Mrs Violeta	Ministry of Environment and Spatial Planning / Kosovo
LEON PAUMEN	Dr Miriam	ExxonMobil / Belgium
LINDERS	Prof. Jan	European Commission, DG Health and Food Safety, SCHER / Luxembourg
LOFTS	Dr Stephen	NERC Centre for Ecology and Hydrology / United Kingdom
LOUTSETI	Mrs Stefania	DuPont De Nemour / Greece
MALTBY	Prof Lorraine	The University of Sheffield / United Kingdom
MANNINEN	Mrs Noora	Helsinki University / Finland
MARTINSEN	Ms Kine	Norwegian Environment Agency / Norway
MASON	Dr Paul	SC Johnson EurAFNE Ltd / United Kingdom
MENDONÇA	Dr Elsa	Portuguese Environment Agency / Portugal
MERRINGTON	Dr Graham	wca / United Kingdom
MOCHEN	Ms Claudia	OXON Italia / Italy
MOERMAN	Mr Hiram	apeiron-team NV / Belgium
MUKAETOV	Prof Dusko	Institute of Agriculture / fYROM
MUNARI	Mr Tomaso	EuCheMS / Belgium
MUSTAJÄRVI	Dr Kaisa	Ramboll Finland / Finland
MÄKELÄ	Mr Jaakko	Natural Resources Institute Finland (Luke) / Finland
MÄKELÄ	Mrs Minna	University of Helsinki / Finland
NIEBRZYDOWSKA	Ms Agnieszka	The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products / Poland
NUREDINI	Ms Orela	Environmental National Agency / Albania
OLIVER	Dr Robin	Syngenta / United Kingdom
OORTS	Dr Koen	ARCHE / Belgium
ORTEGA	Dr Jose-Julio	Institute for Natural Resources and Agrobiology, CSIC / Spain
OVESEN	Ms Rikke Gleerup	EPA / Denmark
PALMQVIST	Dr Annemette	Roskilde University / Denmark
PARSONS	Dr John	University of Amsterdam / Netherlands
PAZ	Dr Marina	Ministerio de Agricultura, Alimentación y Medio Ambiente / Spain
PEPPER	Dr Catherine	HSE CRD / United Kingdom
PETER	Mr Sven	BASF / Germany
PIEPER	Dr Silvia	German Federal Environment Agency (UBA) / Germany
PILLING	Dr Ed	JSC / United Kingdom
PORTOLES	Dr Marta	Ministerio de Agricultura, Alimentación y Medio Ambiente / Spain
PREUS-OLSEN	Ms Gunnhild	Norwegian Environment Agency / Norway
PROBERT	Dr Philip	Newcastle University / United Kingdom
PUSKA	Ms Reetta	Yara Suomi Oy / Finland
REDMAN	Mr Aaron	ExxonMobil / United States of America
REIJONEN	Ms Inka	University of Helsinki / Finland
REINIKAINEN	Mr Jussi	Finnish Environment Institute, SYKE / Finland
RELIĆ	Dr Dubravka	University of Belgrade, Faculty of Chemistry / Serbia

ROß-NICKOLL	Dr Martina	RWTH Aachen University, Institute for Environmental Research / Germany
SALMINEN	Mr Jani	SYKE Finnish Environment Institute / Finland
SANKA	Dr Milan	Masaryk University, Brno / Czech Republic
SCHÄFFER	Prof Dr Andreas	RWTH Aachen University / Germany
SCHLEKAT	Dr Christian	Nickel Producers Environmental Research Association / United States of America
SCHMIDT	Ms Jana	Federal Environment Agency / Germany
SCHMIDT	Dt Thomas	Harlan Laboratories Ltd / Switzerland
SCHOLZ-STARKE	Dr Björn	RWTH Aachen University / Germany
SIX	Dr Laetitia	Fertilizers Europe / Belgium
SOTO	Prof Manu	University of the Basque country / Spain
SPURGEON	Dr David	Centre for Ecology and Hydrology / United Kingdom
STEFFENS	Dr Karin	Swedish Chemicals Agency / Sweden
STRACZEK	Dr Anne	ANSES / France
STRECK	Mr Georg	European Commission, DG GROW / Belgium
SVENDSEN	Dr Claus	NERC - CEH / United Kingdom
SUOMINEN	Mr Kimmo	Elintarviketurvallisuusvirasto Evira – Finnish Food Safety Authority Evira / Finland
TAFAJ	Ms Lindita	Institute of Public Health / Albania
TAHIRI	Mr Enver	Ministry of Environment and Spatial Planning / Kosovo
TAMMEORG	Dr Priit	University of Helsinki / Finland
TENCALLA	Dr Francesca	ToxMinds bvba / Belgium
THEYSKENS	Mr Benoît	Service Public de Wallonie - DGO3 / Belgium
TIKTAK	Mr Aaldrik	PBL Netherlands Environmental Assessment Agency / Netherlands
TOLVANEN	Ms Hanna	Ramboll Finland / Finland
TOMLINSON	Mrs Josie	APC / United Kingdom
TOSCHKI	Dr Andreas	gaiac - Research Institute / Germany
TOSUN	Ms Elif	Ministry of Health / Turkey
TUSHA	Mr Ademr	Ministry of Environment and Spatial Planning / Kosovo
UZOMECKAS	Mr Zilvinas	Environmental Protection Agency / Lithuania
VAN DER LINDEN	Mr Ton	National Institute for Public Health and the Environment (RIVM) / Netherlands
VIRTANEN	Mrs Virpi	Finnish Safety and Chemicals Agency / Finland
VOIGT	Dr Astrid	EBRC Consulting GmbH / Germany
VON MÉREY	Dr Georg	Monsanto Europe SA / Belgium
WERMEILLE	Mrs Christiane	Federal Office for the Environment / Switzerland
ZIDAROVA	Ms Elena	Ministry of Environment and Water / Bulgaria

SCIENTIFIC COMMITTEE

AJAO	Ms Charmaine	European Chemicals Agency / Finland
ARENA	Dr Maria	European Food Safety Authority / Italy
BONNELL	Dr Mark	Environment Canada / Canada
EADSFORTH	Dr Charles	Shell / United Kingdom
EGSMOSE	Dr Mark	European Food Safety Authority / Italy
GREENBERG	Dr Marc S.	U.S Environmental Protection Agency / United States
KAPANEN	Dr Anu	European Chemicals Agency / Finland [co-chair]
KNIGHT	Dr Derek	European Chemicals Agency / Finland
KROGH	Dr Paul Henning	Aarhus University / Denmark
PEIJNENBURG	Prof Dr Willie	National Institute for Public Health and the Environment (RIVM) / Netherlands
PETERSOHN	Dr Eleonora	Federal Environment Agency (UBA) / Germany
POULSEN	Dr Veronique	French Agency for Food, Environmental and Occupational Health & Safety (ANSES) / France
ROMIJN	Dr Kees	Bayer / France
RÖMBKE	Dr Jörg	ECT oekotoxikologie GmbH / Germany
SCHOETERS	Dr Ilse	Rio Tinto / Belgium
SOUSA	Prof Dr José Paulo	University of Coimbra / Portugal
TARAZONA	Dr José V.	European Food Safety Authority / Italy [co-chair]
VAN GESTEL	Dr Kees (C.A.M.)	Vrije Universiteit / Netherlands

ECHA PARTICIPANTS	
SURNAME	**NAME**
BRAUNSCHWEILER	Hannu
DEMI	Rossella
GUTIERREZ ALONSO	Simon
HEINONEN	Jari
HELMINEN	Ulla
JOHANSSON	Matti
KARJALAINEN	Anne-Mari
KLAUK	Anja
MAARANEN	Janne
MALM	Jukka
NETZEVA	Tania
NYMAN	Anna-Maija
PELLIZZATO	Francesca
PINEROS GARCET	Juan
PREVEDOUROS	Konstantinos
PROVOOST	Jeroen
SCHIMMELPFENNIG	Heike
SOBANSKI	Tomasz
TAI	Kaihsu
VALENTINI	Marco
VERSONNEN	Bram
WIK	Anna

ECHA LOCAL ORGANISING COMMITTEE	
SURNAME	**NAME**
AJAO	Charmaine [chair]
CESNAITIS	Romanas
JEVTIC	Dragan
KAPANEN	Anu
KNIGHT	Derek
MULTASUO	Tiina
PELTOLA-THIES	Johanna
RIBEIRO	Lucie
RODRIGUEZ-RUIZ	Amaia
SOBANSKA	Marta
TASKILA	Jonna