

NORDIC WORKING PAPERS

Chemical exposure via the environment

Report from a NEXPO Workshop on human exposure
to chemicals via the environment

Line Småstuen Haug, Cathrine Thomsen and Amrit Kaur Sakhi

<http://dx.doi.org/10.6027/NA2017-922>
NA2017:922
ISSN 2311-0562

This working paper has been published with financial support from the Nordic Council of Ministers. However, the contents of this working paper do not necessarily reflect the views, policies or recommendations of the Nordic Council of Ministers.

Report from a NEXPO Workshop on human exposure to chemicals via the environment

A Nordic Exposure Group project 2017

**Authors: Line Småstuen Haug, Cathrine Thomsen and Amrit Kaur Sakhi, Department of
Environmental Exposure and Epidemiology, Norwegian Institute of Public Health**

- in cooperation with NEXPO

Content

Abbreviations	3
Background.....	4
Summary of presentations	5
ECHA session	5
Databases and real data.....	6
Discussion points.....	9
Recommendations	11
List of helpful references and webpages.....	12
Useful documents and web pages	12
Databases	13
Models.....	13
Other useful links	13
Appendix A: Invitation to the workshop	14
Appendix B: Workshop programme.....	17
ECHA session	19
Appendix C: Abstracts	20
Examples illustrating overestimation and underestimation based on the current approach for assessing exposure of man via environment	20
Introduction to indirect exposure assessment under REACH.....	20
Estimating releases of chemicals to the environment under REACH.....	21
Exposure assessment for man via the environment in the EUSES model.....	22
Refining indirect exposure assessments: site-specific and generic approaches.....	22
Inventory of databases on occupational, consumer and environmental exposure And "Retooling Vannmiljø "	23
EFSA databases on food consumption and contaminant levels in the diet	23
Exposure assessment of chemicals in drinking water	24
Contaminant levels in fish and link between REACH and WFD.....	24
Plant uptake	25
The European Human Biomonitoring Initiative - HBM4EU.....	26
Stationary sampling of ambient air in Europe.....	26
Cadmium in food (vegetables, crops) - estimation of contributions from cadmium in fertilizers and deposition.....	27
Appendix D: List of participants	28

Abbreviations

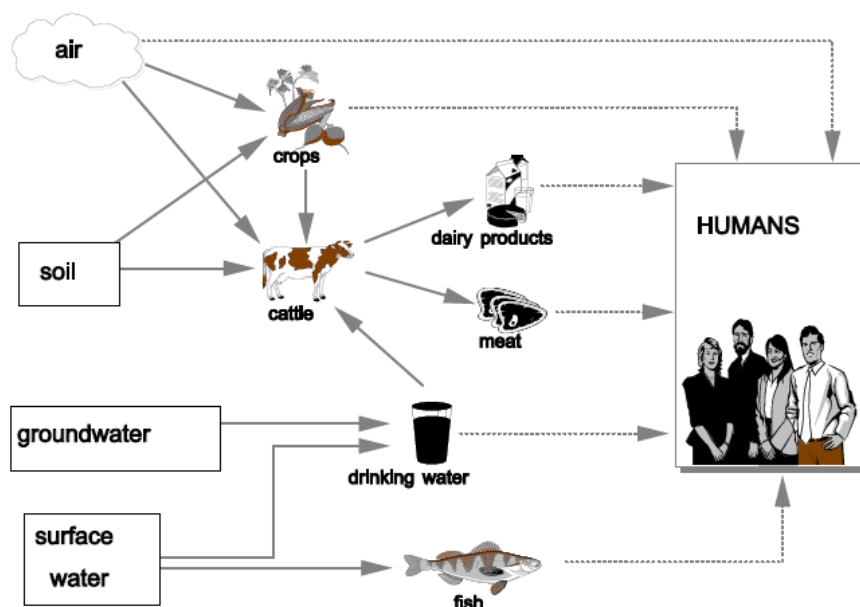
BCF	bioconcentration factor
BMF	biomagnification factor
CHESAR	Chemical Safety Assessment and Reporting Tool
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
ERC	Environmental Release Category
EUSES	European Union System for the Evaluation of Substances
HBM4EU	The European Human Biomonitoring Initiative
I&M	Dutch Ministry of Infrastructure and Environment
IPCHEM	The Information Platform for Chemical Monitoring
IVAM	IVAM UvA BV
NEXPO	Nordic Exposure Group
NKG	Nordic Chemical Group
PBPK	Physiologically based pharmacokinetic modelling
POPs	Persistent organic pollutants
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006 with amendments and corrigenda)
RIVM	National Institute of Public Health and the Environment
SCCS	Scientific Committee on Consumer Safety
SPERC	Specific Environmental Release Category
WFD	Water Framework Directive

Background

Humans are exposed directly to chemicals in occupational settings and as consumers, but also indirectly due to contamination of the environment, which leads to exposure from air, food and drinking water. All exposure sources and pathways are relevant when conducting exposure assessments. The relative importance of these may vary between chemicals both due to the physico-chemical properties of the chemical, but also because of differences in production and use.

The European Chemicals Agency (ECHA) has developed a series of guidance documents on how to conduct exposure and risk assessment which is titled “Guidance on information requirements and Chemical Safety Assessment”. Details on exposure in occupational settings is given in part R.14 “Occupational exposure assessment”, while direct exposure as consumers is thoroughly described in part R.15 “Consumer exposure assessment”. In contrast to this, apart from the relevant release assessment section, humans exposed indirectly via the environment is only briefly touched upon in part R.16 “Environmental exposure assessment”. The exposure routes considered in the evaluation of indirect exposure to humans via the environment in the ECHA R.16 guidance is illustrated in figure 1.

Figure 1 (reproduced from ECHA R.16 guidance): Illustration of exposure routes considered in the evaluation of indirect exposure to humans via the environment



Due to the complexity in assessment of exposure to humans indirectly via the environment and lack of details in the guidance documents on how to perform this, the Nordic Exposure Group (NEXPO) received funding from the Nordic Chemical Group (NKG) within The Nordic Council of Ministers, to organise a workshop on this topic. ECHA contributed by organising one of the sessions of the workshop. Expert speakers were invited and asked to address topics covering exposure assessment requirements in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) processes, IT tools, and available data in the form of publications and databases. REACH exposure assessment experts from REACH competent authorities in the Nordic Countries were invited to participate in the workshop, and received reimbursement from the Nordic Chemicals Group (NKG). Also members of the REACH Exposure Expert Group (REEG) were invited to participate, but without reimbursement.

The overall aim of the workshop was to make a compilation of recommendations to better assess human exposure to chemicals via the environment, and to identify knowledge and data gaps.

Summary of presentations

As an introduction to the workshop two examples illustrating the complexity and difficulties in assessing exposure of humans via the environment were presented. The first example was an application for authorisation under the REACH regulation for a use of diarsenic trioxide, while the second was a REACH restriction proposal to ban five phenylmercury compounds. In addition to these examples, the exposure assessment described in a restriction proposal on cadmium in artist paints was presented in the end of the workshop. Together these three examples highlighted relevant challenges and the frequent need for refinements in assessments of exposure to humans via the environment.

The workshop programme was divided in two main sessions; an ECHA session (organised by ECHA) on estimation of release and exposure and refinement of the assessment, and a session on databases and real data. The complete workshop programme and abstracts of all presentations are given in Appendix C. A summary of important aspects from the presentations is given below.

ECHA session

As described in the ECHA R.16 guidance, indirect exposure of humans via the environment comprises exposure from air, food and drinking water. However, it was highlighted that also inadvertent ingestion of soil and dust, in particular for children, may be relevant indirect exposure pathways.

The REACH processes for which exposure assessments, including exposure to humans via the environment, are relevant to conduct, comprise registration, substance evaluation, authorisation and restriction. For these processes, exposure assessments are conducted by the industry or competent authorities.

Risk assessment of indirect exposure via the environment consists of several elements: Hazard assessment, describing the environmental contributing exposure scenario, estimating the release, exposure assessment, and a risk characterisation.

It was highlighted that the first and main step to conduct a realistic exposure assessment is the release estimation. The release estimations - expressed as release rates – are the main input parameters for estimating exposure levels in water, air and soil, which in turn is crucial for obtaining realistic concentrations in food, drinking water and outdoor air. The formula for estimating release rates is simply multiplying the amount used with a release factor. However, in many cases obtaining accurate information on use is challenging, and information on relevant release factors may be even more limited. The release factor will amongst others depend on the operational conditions and implemented risk management measures. As for the exposure assessment, also release estimations may be carried out at different levels. The roughest and usually the most conservative estimates are obtained using Environmental Release Categories (ERCs) as default, while more sector-specific estimations can be carried out using Specific Environmental Release Categories (SPERCs) (https://echa.europa.eu/documents/10162/15669641/sperc_factsheet_guidance_en.pdf/4c94f0fb-07dd-4e9f-842a-3f21a63bd3fe). SPERCs are developed by sector organisations. Release estimates may be relevant both on a regional and on a local scale, and on the local scale measured releases are preferred. The role of formal or informal independent review of the reliability of SPERCs was discussed. ERCs are the default approach to estimating releases in the Chemical Safety Assessment and Reporting tool (Chesar) used for REACH registrations, whilst SPERCs may be imported into the tool which was developed by ECHA (<https://chesar.echa.europa.eu/>).

Exposure assessments are usually carried out using a tiered approach, starting with a rough estimate (Tier 1) with many default values aiming at obtaining a worst case scenario. The lower tier approach is often conducted by using the tool EUSES.

The European Union System for the Evaluation of Substances" (EUSES) (<https://ec.europa.eu/jrc/en/scientific-tool/european-union-system-evaluation-substances>) is the default tool for assessing indirect exposure to humans via the environment in Chesar (ECHA R.16 Guidance). . EUSES is generally considered to only be applicable for screening purposes as it in most cases reflects a worst-case scenario. EUSES is not intended to be used for site specific assessments. ECHA R.16 guidance notes that whilst EUSES should be interpreted as a helpful tool for decision making (particularly to identify critical exposure routes) resulting exposure estimates should not be considered as a prediction of the human exposure actually occurring at some place or time,. Further, the applicability domain of EUSES is limited to neutral organic compounds, but with specific modifications a broader range of compounds can be assessed. The last update of EUSES was done in 2004. However, the National Institute for Public Health and the Environment in the Netherlands (RIVM), have suggested improvement options for EUSES. The latest one, an ECHA funded project, is "Identification and preliminary analysis of update needs for EUSES" (https://echa.europa.eu/documents/10162/13630/echa_2014_253_euses_report_en.pdf). These update needs include among others to expand the applicability of the tool to cover more chemicals such as per- and polyfluoroalkyl substances. Updates of bioconcentration factors (BCFs) and biomagnification factors (BMFs), including the addition of compound specific BCFs and BMFs, would be helpful. Further, updates on plant uptake, use of empirical data when available, and addition of purification factors would be beneficial for improving assessments using EUSES. The SimpleBox and the SimpleTreat models form the so called "environmental distribution" part of EUSES. New versions of these models have been published, and are addressing some of the identified needs for improvements. Recently, ECHA has taken on the responsibility for EUSES and it is expected that an updating will start in the near future. The improvements above, along with other identified needs, will help in conducting more accurate exposure assessments of humans via the environment.

Depending on the purpose of the assessment, and in case safe use cannot be demonstrated in tier 1 EUSES assessments, refinement may be carried out for the relevant route/pathways and (sub)populations. This refinement may include higher tier approaches such as simple refinement using probabilistic approaches or more advanced refinement by using complex exposure models like MERLIN-Expo (<https://merlin-expo.eu/>), inclusion of monitoring data or a full site-specific assessment. The level of refinement depends on which REACH process the assessment is conducted in relation to (for example registration or restriction), but also whether the chemical of interest is a threshold substance or a non-threshold substance, i.e. a substance for which no safe threshold has been identified. In the latter case, rather than a classical quantitative risk assessment, a qualitative assessment or impact assessment may be carried out. And, as no safe threshold is defined, there is a need to refine the assessment as much as possible, and then evaluate whether or not the benefit of use to society outweigh the risks.

Databases and real data

One of the possible refinements in exposure assessments is to make use of real data e.g. measured concentrations. An extensive amount of real data is available in reports and published papers, but it can be challenging to retrieve the information, especially when the information is not presented in scientific journals. Currently the Norwegian Environment Agency is managing a database called "Vannmiljø" featuring water related monitoring data from Norway. However, to provide data access to other environmental data more easily, the database is presently being retooled to include also this information. On the European level, the Dutch Ministry of Infrastructure and Environment (I&M) in cooperation with the RIVM, requested IVAM UvA BV (IVAM) to identify exposure databases that are

useful when conducting exposure assessments. In this report, IVAM identified 69 databases of which 44 databases contain exposure relevant data that could be useful for conducting exposure assessments. The Information Platform for Chemical Monitoring (IPCHEM) (<https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html>) is seen as a useful tool in the future.

The European Food Safety Authority (EFSA) gather an extensive amount of data on food consumption and occurrence of various environmental pollutants (like concentrations of chemicals) in foods and beverages. When performing a refined assessment of exposure to humans via the environment, these databases may be highly relevant. Data on food consumption is publically available on internet (<http://www.efsa.europa.eu/en/food-consumption/comprehensive-database>), while the occurrence data is presently not. EFSA has also gathered a summary of their human health hazard assessments in a chemical hazards database called OpenFoodTox (<https://www.efsa.europa.eu/en/data/chemical-hazards-data>), which might be a relevant source of information. However, there are several issues to be aware of. The database on food consumption includes information from dietary surveys conducted in different ways, this may hamper the comparability between countries. EFSA uses FoodEx to divide the foods and drinks into categories. One of the present challenges is to obtain consumption data, which is categorized according to the FoodEx system. To partly overcome these two problems, members of EFSA's Advisory Forum support the establishment of a pan-European food consumption survey (<https://www.efsa.europa.eu/en/press/news/100212>). Another uncertainty to be aware of is that occurrence data is usually reported for raw foods, while the consumption data is presented as for consumption. Further, EFSA receives data on occurrence from various sources which have conducted analyses for different purposes (e.g. surveillance or targeted analyses at hot spots) and the quantification limits vary. This may have a large impact on the exposure assessment.

Drinking water may be a significant source for indirect exposure to humans via the environment. When risk assessing chemicals in drinking water, the exposure assessment can be performed via intake calculations, biomonitoring or toxicokinetic modelling. The area of risk assessment of drinking water may be good for cooperation between various national and European authority sectors. This could also be the case for activities under the Water framework directive (WFD) producing monitoring data, even if WFD targets a limited number of substances. Data obtained from monitoring carried out in relation to WFD can be useful when conducting an exposure assessment of humans via the environment. The principles used within REACH are taken into account in the substance prioritisation process within the WFD. REACH and WFD are somewhat linked, but it is unclear if and how REACH takes information from the WFD into account.

In models such as EUSES, default plant uptake values are defined and used to estimate transfer of a chemical from the environment to the food chain. More advanced and crop-specific models for uptake of chemicals by plants are available. However, empirical data demonstrate that at least in simple models default values may be highly inaccurate, as both physicochemical properties of the chemical and plant specific properties affect plant uptake of chemicals. Thus, an important refinement would be to use empirical data on plant uptake. It is also important to keep in mind that reuse of sludge as a fertiliser on agricultural land may have an impact on the concentrations of chemicals in plants, as in the example with cadmium. This source (i.e. sludge) is often not taken into account when performing exposure assessments.

Concentrations of chemicals in outdoor air may provide insight into trends and use of chemicals as air has a short response time to releases. Also for estimations of exposure from outdoor air real data may be useful. A database on background concentrations from national monitoring programs of persistent organic pollutants (POPs) and heavy metals is a source of such publically available data

(<http://ebas.nilu.no/>). Use of research models such as the Cozmoman model in combination with measured data might also be helpful to understand exposure through outdoor air.

In addition to performing intake estimations, exposure assessments may be carried out using human biomonitoring data. Further, back-calculation of intakes based on human biomonitoring data using physiologically based pharmacokinetic modelling (PBPK) may also be used. For persistent compounds, human biomonitoring data reflects an integrated exposure over time comprising various sources and pathways. However, adequate collection of biological specimen can be resource-intensive. Further, human biomonitoring does not give any information on the relative importance of different routes and sources of exposure (exposure pathways), which may be an important drawback if it is of importance to distinguish between consumer exposure and exposure of humans via the environment. Thus, if possible, both intake estimations, human biomonitoring and modelling should be considered in order to obtain a picture as complete as possible.

One important source of human biomonitoring data is the European Human Biomonitoring Initiative (HBM4EU), which aims to harmonize the human biomonitoring activities within Europe. The human biomonitoring data will be publically available at the Information Platform for Chemical Monitoring (IPCHEM) (<https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html>), which may be very helpful and an important data source when performing exposure assessments.

Overall, effective communication between authorities is important to make use of all available information and to avoid duplicate work.

Discussion points

During the workshop plenty of time was set aside for discussions. Parts of the discussion was held in plenum, while for the remaining part the group was divided in two, encouraging more workshop participants to contribute. At the end of the workshop the discussion was summarised in plenum.

The following topics were discussed, and a brief summary is presented. Further, the main outcome resulted in a set of recommendations described below.

1. What are the main obstacles when conducting an exposure assessment for humans exposed indirectly via the environment and the uncertainties in these, and hence the main area for improvement? Which measures could be taken?

The participants agreed that it is challenging to conduct an exposure assessment for humans exposed indirectly via the environment, and in particular when refined assessments are needed. REACH registrations and the chemical safety assessments/reports often do not contain exposure assessments for humans exposed indirectly via the environment, and the registration dossiers often lack information needed to develop this assessment. It can be challenging to retrieve relevant information from the literature, and information on where such data may be found is not described in the guidance documents. Many participants find that the ECHA guidance document R.16 limits the demand for this assessment more than the legislation itself¹. Also the guidance document is not very useful when refined assessment of exposure to humans indirectly via the environment is needed. Finally it was stressed that this sector of exposure assessment has no clear ownership between exposure experts in REACH, and may sometimes fall between environmental exposure and consumer exposure. This may be due to the fact that indirect exposure to humans via the environment only in a few cases is the driver in the risk assessment. However, in some cases it is the main driver.

2. Is there a need for extending the section on Humans exposed indirectly via the environment in guidance R.16? Which topics would be relevant to include? Would it be helpful to divide this section in sub sections for the different REACH processes?

The participants agreed that there is a need for further guidance on indirect exposure assessment, and this is further described in the recommendation below. The guidance should include a description of all sources of information as well as description of methods and models for the exposure assessment, including refinement of the release and exposure estimates. The importance of describing the risk on an individual level as well as on a population level was underlined. The pros and cons of dividing the guidance in subsections for the different REACH processes were discussed, but no conclusion was made.

¹ ECHA Guidance R.16: **Particular considerations (ii): scope of exposure assessment for indirect exposure of humans**

An assessment of indirect exposure of humans via the environment is generally only conducted if:

- the tonnage is >1 000 t/y or
- the tonnage is >100 t/Y and the substance is classified as STOT RE8 1; or as a carcinogen or mutagen (any category); or as toxic to reproduction (categories 1A or 1B).
- as a carcinogen or mutagen (any category); or
- as toxic to reproduction (categories 1A or 1B).

3. Is there a need for more collaboration and exchange of information between European authorities on this topic?

The participants agreed that there is a need for expanding the exchange of information between European authorities, and that information on other relevant ongoing or completed assessments is crucial. Information on such assessments is available on several webpages, for instance ECHA's search for chemicals (<https://echa.europa.eu/home>) and EFSA's OpenFoodTox (<https://www.efsa.europa.eu/en/data/chemical-hazards-data>). However, a more efficient way to obtain information is through the OECD eChemPortal (<https://www.echemportal.org/echemportal/index.action>), which includes links to chemical hazard and risk information prepared for government chemical review programmes at national, regional and international levels.

4. How can human biomonitoring data contribute to assessment of indirect exposure to humans via the environment?

The participants agreed that human biomonitoring data is useful when conducting an exposure assessment for humans exposed indirectly via the environment, and should be used whenever feasible and available. Human biomonitoring data can be considered complementary to data on external exposure. The importance of data availability - e.g. via IPCHEM - was stressed.

Recommendations

1. There is a need for extending the section on Humans exposed indirectly via the environment in guidance R.16. An alternative is to prepare a separate practical guide with the relevant information. In the following both are called guidance documents. The specific needs are:
 - To further explain the important differences between approaching the exposure assessment and risk characterisation for a threshold substance compared to a non-threshold substance, specifically to highlight when refinements to default approaches are needed to avoid overestimating potential risks via the environment
 - A flow chart describing possible refinements when conducting exposure assessments
 - A more thorough description of what kind of refinements may be relevant, and in particular how to make use of real data
 - Highlight the usefulness of human biomonitoring data, particularly in combination with PBPK modelling for back-calculation of intake, when conducting exposure assessments
 - Cross references to other relevant REACH guidance documents
 - A list of relevant exposure models and tools available, as well as their applicability and limitations
 - A link to a webpage describing databases which include real data
 - A list of relevant web pages where information on other relevant ongoing or completed assessments are described. One such web page is the OECD eChemPortal (<https://www.echemportal.org/echemportal/index.action>) - a worldwide source of information about chemicals from authorities and international organisations
 - Good examples of exposure assessments, (for instance from relevant REACH restrictions and authorisations from opinions published by the Scientific Committee on Consumer Safety (SCCS) or EFSA) and where to find them
 - More emphasis on exposure from dust and soil, particularly for children
 - Emphasise that children breath, eat and drink more per kg body weight compared to adults and thus have higher indirect exposures via the environment
2. The generic "food basket" which is described in the ECHAR.16 guidance and used in EUSES should be considered updated, to reflect a more realistic but, still conservative, food consumption estimate. The extensive information on food consumption gathered by EFSA could be used as a basis for this.
3. A discussion on possible mechanisms for evaluating the quality and reliability of SPERCs once they have been developed
4. EUSES needs to be updated to tackle a broader range of compounds.
5. A training course giving an overview of the updated version of EUSES should be provided by ECHA.
6. The collaboration between European authorities or committees dealing with topics relevant for exposure assessments should be extended. Examples of such authorities are ECHA, RAC, EFSA and SCCS.
7. It would be useful to establish a forum, which could help giving feedback on assessments of exposure to humans via the environment. This applies in particular to proposals for restriction.

List of helpful references and webpages

Useful documents and web pages

ECHA: Search for chemicals field: <https://echa.europa.eu/home>

ECHA Guidance on Information Requirements and Chemical Safety Assessment

<https://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

See especially ECHA guidance R.16 (scroll down the page)

ECHA website on Chemical Safety Report/Exposure Scenario Roadmap

<https://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap>

OECD eChemPortal:

<https://www.echemportal.org/echemportal/index.action>

European Commission: Common guidelines on practical arrangements for the sharing of scientific data between the scientific committees and panels of European agencies and the scientific committees of the commission.

<http://www.efsa.europa.eu/sites/default/files/assets/ecsharingdataguidelines.pdf>

EFSA. Overview of existing methodologies for the estimation of non-dietary exposure to chemicals from the use of consumer products and via the environment.

<http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2016.4525/epdf>

EFSA news on plans for pan-European food consumption survey

<https://www.efsa.europa.eu/en/press/news/100212>

SPERC Factsheet Guidance Document

https://echa.europa.eu/documents/10162/15669641/sperc_factsheet_guidance_en.pdf/4c94f0fb-07dd-4e9f-842a-3f21a63bd3fe

OECD guidance: GUIDANCE DOCUMENT FOR EXPOSURE ASSESSMENT BASED ON ENVIRONMENTAL MONITORING

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2013\)7&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2013)7&doclanguage=en)

OECD report: DESCRIPTIONS OF EXISTING MODELS AND TOOLS USED FOR EXPOSURE ASSESSMENT Results of OECD Survey

[http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO\(2012\)37&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2012)37&doclanguage=en)

RIVM Report: Identification and preliminary analysis of update needs for EUSES

https://echa.europa.eu/documents/10162/13630/echa_2014_253_euses_report_en.pdf

Krop H., Krystek P. 2016. Exposure information - available databases for the exposure assessment for regulatory purposes. IVAM UvA BV (not available on web)

Databases

Information Platform for Chemical Monitoring (IPCHEM)

<https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html>

The EFSA Comprehensive European Food Consumption Database.

<http://www.efsa.europa.eu/en/food-consumption/comprehensive-database>

Substances in Products in the Nordic Countries (SPIN database)

<http://spin2000.net/>

The Norwegian Vannmiljø database:

<http://vanmiljo.miljodirektoratet.no/>

Norman network; EMPODAT database

<http://www.norman-network.net/empodat/>

EMEP database

<http://ebas.nilu.no/>

Models

European Union System for the Evaluation of Substances (EUSES)

<https://ec.europa.eu/jrc/en/scientific-tool/european-union-system-evaluation-substances>

Chemical Safety Assessment and Reporting tool (CHESAR)

<https://chesar.echa.europa.eu/>

MERLIN-Expo

<https://merlin-expo.eu/>

The Cozmoman model

Breivik et al. 2010 Environ Int 36: 85-91

<http://www.sciencedirect.com/science/article/pii/S0160412009002128?via%3Dihub>

Other useful links

The HBM4EU project:

<https://www.hbm4eu.eu/>

**Invitation to
Workshop on human exposure to chemicals via the environment**

Starts: Tuesday 26 September at 11 AM (with lunch)

Ends: Wednesday 27 September at 4 PM

Venue: The Norwegian Environment Agency

Grensesvingen 7

Oslo, Norway

To the Nordic REACH Competent Authorities,

The Nordic Exposure Group (NEXPO) cordially invites your REACH exposure assessment experts to a workshop on assessment of human exposure to chemicals via the environment. The workshop is funded by the Nordic Chemicals Group (NKG).

In the workshop exposure assessment issues and challenges will be discussed. Humans are directly exposed to chemicals in occupational settings and as consumers, but in addition to this comes the indirect exposure received via the environment as contaminants in air, food and drinking water. It is challenging to assess this exposure and little guidance is available. Therefore, NEXPO appreciates the support from ECHA, and the cooperation in organizing one of the sessions of the workshop.

The aim of the workshop is to make a compilation of recommendations to better assess human exposure to chemicals via the environment, and to identify knowledge and data gaps. Expert speakers will address exposure assessment requirements in REACH processes, IT tools, and available data in form of publications and databases.

The program for the workshop is attached.

Date, location and how to get there

The workshop will start on Tuesday 26 September at 11 AM with a light lunch in the lobby and end on Wednesday 27 September at 4 PM. We urge potential participants to stay for the whole workshop.

The location for the meeting is the conference center of the Norwegian Environment Agency, Grensesvingen 7, Oslo, Norway. The agency is situated in Helsfyr which is a public transportation hub (metro and bus). Eastbound metro lines 1, 2, 3, and 4 stop at the Helsfyr station. The northern exit to Fyrstikktorget leads you to our door (see details below).

Upon arrival in the Oslo airport at Gardermoen, the SAS airport express bus leaves from platform 11 (on your right hand side when you exit the arrival hall) every 20 minutes (00, 20, 40' past the hours). It stops right by our office, as do many other local buses. The bus from the airport takes about 30

minutes. You can buy a single or round-trip-ticket with credit card. NB! Please note that the stop called Helsfyr comes very quickly after two other stops named Ulven and Teisen. Leaving the bus at Helsfyr you pass a grocery shop named Kiwi and Copy Cat on your right and Nord café on your left. Walk straight ahead and cross at a street light in Grensesvingen. Then you will be looking at our building which has Brick Lane Café in the ground floor. It takes about 5 minutes to walk from the bus to the agency.

It is also possible to take the airport express train from the airport to the city center and the metro up to Helsfyr, but the bus is usually more convenient.

Reimbursement

The workshop is funded by The Nordic Chemical Group. This means that we will reimburse the travelling expenses for the following number of participants from the Nordic REACH CAs:

Five participants from each of these countries: Denmark, Finland and Sweden. Two participants from Iceland.

Norwegian participants will not receive reimbursement.

The maximum seats in the conference hall is 50.

Hotel accomodation

Please note that we have reserved 20 rooms between 26 and 27 September at a nearby hotel (Hotel Scandic Helsfyr, Strømsveien 108) and we will organise the bookings and pick up the bill for these rooms, so you only need reimbursement for the travelling expenses. We expect that the reimbursed participants will stay in this hotel. The hotel is situated in short walking distance from the venue.

Social dinner Tuesday 26 September

A social dinner at own expense will be organised in a restaurant not far from the venue. We encourage all to sign up for the dinner.

Registration to the meeting

Please register for the meeting **by 20 August** at the latest by sending an e-mail to:

Senior Adviser Marianne van der Hagen at marianne.vanderhagen@miljodir.no.

In your registration, please remember to:

- 1) register for the workshop (both days preferably),*
- 2) indicate your need of a hotel room from 26-27 Sept, and*
- 3) sign up for the social dinner on 26 Sept. If you have any allergies or special dietary needs, please let us know for planning of lunches and dinner*

We will get back to you shortly to confirm your place in the workshop and the hotel room.

Contact

Should you have any questions about the workshop, please do not hesitate to contact:

Marianne van der Hagen, T +47 984 54 889 or email marianne.vanderhagen@miljodir.no

Sjur Andersen, T +47 976 38 506 or email sjur.andersen@miljodir.no

Line Småstuen Haug (Senior scientist and consultant at the workshop project), T +47 21 07 65 49
line.Smastuen.Haug@fhi.no

- or your national NEXPO member!

NEXPO member	Country	E-mail address
Alexandra Stewart	SE	Alexandra.Stewart@kemi.se
Margareta Warholm	SE	margareta.warholm@kemi.se
Stellan Fischer	SE	Stellan.Fischer@kemi.se
Lena Höglund	DK	lemah@mst.dk
Björn Gunnlaugsson	IS	bjorngunn@umhverfisstofnun.is
Ísak Sigurjón Bragason	IS	isak.bragason@ust.is
Jouni Räisänen	FI	Jouni.Raisanen@tukes.fi
Jukka Mehtonen	FI	Jukka.Mehtonen@ymparisto.fi
Marianne Moilanen	FI	Marianne.Moilanen@tukes.fi
Abdulqadir Suleiman	NO	abdulqadir.suleiman@arbeidstilsynet.no
Sjur Andersen	NO	sjur.andersen@miljodir.no
Marianne van der Hagen	NO	marianne.vanderhagen@miljodir.no

Welcome to Oslo!

Kind regards,

Heidi Morka

Fejl! Ukendt betegnelse for dokumentegenskab.

Appendix B: Workshop programme

Time slot	Title	Presenter
Tuesday 26 Sept		
<i>11.00-12.00</i>	<i>Standing lunch in the lobby outside the conference hall Østmarka</i>	
Introduction		Host
12.00-12.15	Welcome/tour the table	Heidi Morka, NO
12.15-12.30	Examples illustrating over- and/or under estimations based on the current approach for assessing exposure of man via environment	Marianne van der Hagen, NO
12.30-14.30	ECHA session	Chair: Peter Simpson, ECHA
12:30 – 13:00	Introduction to indirect exposure assessment under REACH	Peter Simpson , ECHA
13:00 – 13:30	Estimating releases of chemicals to the environment under REACH	Stefano Frattini, ECHA
13:30 – 14:00	Introduction to EUSES and its role in the assessment of indirect exposure to humans via the environment	Joost Bakker , RIVM
14:00 – 14:30	Refining indirect exposure assessments to improve their usefulness for socio-economic impact assessment: site-specific and generic approaches	Frederik Verdonck, ARCHE
<i>14.30-14.50</i>	<i>Coffee break</i>	
14.50-16.30	Data bases and real data	Chair: Margareta Warholm SE
14.50-15.10	Inventory of databases on consumer and environmental exposure	Marius Gudbrandsen, Norwegian Environment Agency
15.10-15.45	EFSA databases on food consumption and contaminant levels in the diet	Andrea Altieri, EFSA
15:45-16:30	Discussion	Moderator Line Småstuen Haug
<i>19.00</i>	<i>Social event: Dinner at restaurant, at own expense, Walking tour to the restaurant</i>	Host

Time slot	Title	Presenter
Wednesday 27 Sept		
9.00-12.00	Real data	Chair: Sjur Andersen NO
9.00-9.10	Summary of 1 st day	Sjur Andersen
9.10-9.30	Contamination of drinking water	Anders Glynn, the National Food Agency, Sweden
9.30-9.50	Contaminant levels in fish and link between REACH and WFD	Jukka Mehtonen, Finnish Environment Institute
9.50-10.10	Plant uptake	Trine Eggen, The Norwegian Institute for Agricultural and Environmental Research
10.10-10.30	The European Human Biomonitoring Initiative - HBM4EU	Cathrine Thomsen, Norwegian Institute of Public Health
<i>10.30-11.00</i>	<i>Coffee break</i>	
11.00-11.20	Stationary sampling of ambient air in Europe	Knut Breivik, Norwegian Institute for Air Research
11.20-11.40	Cadmium in food (vegetables, crops) - estimation of contributions from cadmium in fertilizers and deposition.	Helena Parkman, Keml
11.40-12.00	Summary of presentations on real data	Line Småstuen Haug to organise
<i>12.00-13.00</i>	<i>Lunch in the cantina of the Norwegian Environment Agency</i>	
13.00-16.00	Discussion and recommendations	Chair: Line Småstuen Haug, NO
13.00-13.45	Discussion in groups - topic 1 Practical questions for CAs	
13.45-14.30	Discussion in groups - topic 2 Practical questions for CAs	
<i>14.30-15.00</i>	<i>Coffee break</i>	
15.00-16.00	Summary of discussion and recommendations for future guidance and activities	

ECHA session

ECHA session	Title	Presenter	Notes/Ideas
12:30 – 13:00 25 mins ~5 mins questions	Introduction to indirect exposure assessment under REACH.	Peter Simpson, ECHA	<p>Presentation to address:</p> <ul style="list-style-type: none"> • Details of the REACH processes that address indirect exposure of humans via the environment, including: <ul style="list-style-type: none"> ◦ underpinning concepts of use, release, exposure), ◦ available guidance ◦ examples from relevant processes (restriction and authorisation). • Short discussion on 'representativeness' of data (but not much) • Specific Issues surrounding the interface between risk assessment and impact assessment (most-likely vs worst-case assessments),
13:00 – 13:30 20 mins ~5 mins response ~5 mins questions	Estimating releases of chemicals to the environment under REACH	Stefano Frattini, ECHA	<p>Presentation to address:</p> <ul style="list-style-type: none"> • How releases to the environment are estimated from industrial uses, including: <ul style="list-style-type: none"> ◦ ERCs, ◦ spERCs, ◦ Other documentation (e.g.) OECD emission scenarios, measured data <p>RESPONSE: FREDERIK (as an expert practitioner) – to cover practical difficulties encountered by assessors as they estimate releases</p>
13:30 – 14:00 20 mins ~5 mins response ~5 mins questions	Introduction to the EUSES and its role in the assessment of indirect exposure to humans via the environment	Joost Bakker, RIVM	<p>Presentation to address:</p> <p>Introduction to EUSES, including its strengths and weaknesses. To also cover areas identified for improvement.</p> <p>RESPONSE: PETE (in the context of RAC/SEAC evaluation of AfA) – to focus on issues due to the application of EUSES as a site-specific assessment tool in applications for authorisation</p>
14:00 – 14:30 20 mins ~5 mins response ~5 mins questions	Refining indirect exposure assessments to improve their usefulness for socio-economic impact assessment: site-specific and generic approaches	Frederik Verdonck, Arche	<p>To cover approaches such as site-specific dispersion modelling, representativeness of data in generic assessments. EUSES+ and MvE decision framework (being developed by Eurometaux); illustrated with examples from Eurometaux workshop</p> <p>RESPONSE: STEFANO</p>

Appendix C: Abstracts

Examples illustrating overestimation and underestimation based on the current approach for assessing exposure of man via environment

Marianne van der Hagen, Norwegian Environment Agency

Example 1, Authorisation: Boliden's smelter Kokkola, located on the west-coast of Finland, is the second largest zinc smelter in Europe. The main part of the zinc concentrate comes from Boliden's own mines, but concentrates are also purchased from other mining companies.

During the production process zinc is extracted to meet the most demanding customer needs. The total amount of zinc products in the portfolio is about 40, containing both pure zinc and tailored products for certain customers and customer segments.

In 2014 Boliden Kokkola applied for authorisation of diarsenic trioxide, which is included in REACH Annex XIV due to its carcinogenic properties. In the application the applicant had made a risk assessment based on the reference dose-response relationship developed by RAC and an exposure assessment based on EUSES 2.1. The exposure estimate for humans exposed indirectly via the environment was refined by using national data for food consumption and monitoring data for emission and air pollution. The resulting exposure assessment corresponded to a risk level in humans in the order of 10^{-4} .

Example 2, Restriction: In 2010 Norway submitted a proposal for a restriction to ban five phenylmercury compounds. These substances are mainly used in the production of polyurethane coatings, adhesives, sealants and elastomers. There is a widely recognised need to further reduce mercury emissions at EU and global level. The life-cycle of the phenylmercury compounds leads to a release of mercury to the environment corresponding to around 4% of the total European mercury emissions.

The main exposure via environment may be through food in which the phenylmercury compounds' transformation products (me-Hg) may be found. Especially methylmercury containing seafood has a marked impact on total mercury concentration in the human brain. Available data did not allow for quantification of the contribution from these particular compounds to the total intake of methylmercury because of other sources as well. The restriction enters into force on 10 October 2017.

Introduction to indirect exposure assessment under REACH.

Peter Simpson, ECHA

The REACH Regulation is intended to ensure a high level of protection of human health and the environment from the manufacture and use of chemicals in the EU. This high level of protection extends to addressing risks to human health that occur in the general population as a result of 'indirect exposure to humans via the environment'. Indirect exposure is most regulatory assessed in terms of concentrations in air (inhalation), water and, but indirect exposure can also occur through the inadvertent consumption or soil and dusts.

An assessment of indirect exposure to humans via the environment is usually undertaken by industry as part of the 'Registration' of a substance required under REACH and is also performed as part of an application for an 'Authorisation' of a substance of very high concern (SVHC). Risks to humans via indirect exposure can also result in proposals for the 'Restriction' on the use or placing on the market

of a substance. For example, ECHA's scientific committees are currently considering a restriction on the use of lead-based stabilisers in PVC based on the risks to the general population via indirect exposure.

Assessments of indirect exposure via the environment typically comprise the following elements: (1) a 'hazard assessment' that identifies safe-thresholds for the substance in human populations or dose-response relationships for non-threshold substances e.g. certain carcinogens, (2) an 'exposure scenario' that describes the conditions of use of the substance and any accompanying risk management measures that are applied; (3) an estimates of 'releases' to environmental compartments that occur from the use, and (4) an 'exposure estimate', which includes an assessment of the amounts of chemical consumed by humans and, finally, (5) a 'risk characterisation' that determines if exposures in human populations are safe or if they are associated with a potential for harm.

The importance of robust assessment of the risks posed to humans via indirect exposure have been highlighted in recent applications for authorisation for non-threshold substances (carcinogens), where a large part of the risks associated with the use were estimated to be in the general population surrounding industrial sites, rather than workers. In these cases it is critical that assessments of indirect exposure are reliable and realistic as Authorisation can only be granted where the *benefits of the use (to society) outweigh the risks*. As such refinements to default approaches are likely to be necessary.

Estimating releases of chemicals to the environment under REACH

Stefano Frattini, ECHA

Release estimation is the first and key step for the environmental exposure assessment, including the humans exposed via environment, and subsequent risk characterisation. Releases from a site (generic or specific) or from widespread uses need to be carefully estimated and justified; moreover, operational conditions (e.g. amount of substances used per day, whether water is used in the process or in cleaning activities) and risk management measures (e.g. on site air treatment unit) linked to the release estimation need to be specified in the exposure scenario.

Releases to environment (water, air, soil) depend on the amount of the used substance and the release factor. There are several ways to estimate the release factor. ERC (Environmental Release Categories) release factors is the default method, considered to give conservative estimation; it can be used as first tier assessment in absence of more specific information. The SpERC (Specific Environmental Release Categories) are developed by industry sector organisations and reflect typical release estimation within the sectors; SpERCs contains release factors, justifications, operational conditions and risk management associated to those releases. Release factors might also be derived from reliable literature, such as Emission Scenario Documents developed by OECD. Finally, releases can also be measured at the site; in such a case, the reference to the measures taken (e.g. concentrations, flow rates) and methods for release estimation (e.g. max value, 90th percentile) should be provided by registrants / applicants.

The presentation will go through the different methods, supporting them with real examples. Special focus will be given to the SpERC development, which is considered crucial in the long term prospective in providing reliable release estimation for the relevant life cycle stage (formulation, industrial use, widespread uses) of the substance.

Exposure assessment for man via the environment in the EUSES model

Joost Bakker, RIVM

The European Union System for the Evaluation of Substances (EUSES) has been used extensively in the past in the evaluation of new and existing substances. It is merely an implementation of the Technical Guidance document for new and existing substances. EUSES is still being used in the risk assessment of chemicals in the context of REACH as such and as (environmental distribution) part of the CHESAR model. EUSES also includes the assessment of indirect exposure to humans via the environment.

EUSES was primarily developed for screening purposes, identifying critical exposure pathways. Its applicability domain is limited to neutral organic compounds. Although, with some work arounds it can be used as well for other kinds of chemicals such as metals and ionic compounds by applying chemical specific partition coefficients as input. Furthermore, the model is not intended to be used for site-specific assessments, it uses generic environments as a basis. EUSES has not recently been updated, the latest version dates back to 2004. As a result, specific issues for certain types of chemicals are not addressed properly using the model.

Obviously there are needs for updating and the improvement of EUSES, that have been identified over the recent years. An overview of the needs has been reported by ECHA and within the OSIRIS project. In the meantime, new versions of SimpleBox and the SimpleTreat model that form the environmental distribution part of EUSES are published addressing some of the identified improvement needs making the models suitable for the assessment of for instance ionized compounds. In addition, a specific version was developed geared to nano-particles.

The presentation will provide an introduction to the EUSES model, its strengths, weaknesses and options for improvement, with a specific focus on the exposure of man via the environment. Furthermore, the role of the EUSES model and CHESAR in the context of applications for authorisation under REACH will be touched on.

Refining indirect exposure assessments: site-specific and generic approaches

Frederik Verdonck, ARCHE

Under REACH, a high level of protection of human health is advocated and includes addressing risks to human health that occur in the general population as a result of 'indirect exposure of chemicals to humans via the environment'. In a risk or safety assessment context (typically under registration), worst-case assumptions are used to overestimate exposure and risk. Refinements are only needed in case safe use cannot be demonstrated. However, in impact assessment context (typically done as part of socio-economic analysis under authorisation), refinements are more often needed to ensure to estimate exposure and risk as realistically as possible.

Refining indirect exposure assessments can be efficiently conducted in a tiered approach. Lower tier approaches include generic EUSES modelling and probabilistic approaches. Higher tier approaches include the use of more complex exposure models like MERLIN-Expo, the use of monitoring data and/or full site-specific assessments. Ambient monitoring data in the local environment around sites can supplement exposure modelling. An assessor moves to the next tier by considering only the dominant route(s) or food pathways and/or the most relevant populations (adult/child) and/or the local or regional scale.

[Inventory of databases on occupational, consumer and environmental exposure And "Retooling Vannmiljø "](#)

Marius Gudbrandsen, Norwegian Environment Agency

A large number of exposure databases are available to help regulators and scientists assess the potential exposure for workers, consumers or the environment. A recent study commissioned by the Netherlands found and listed these along with descriptions of their content. The list will likely prove very useful to regulators and scientists. Unfortunately, scrutiny of the databases reveals that they are often targeted for specialized audiences and applications and are difficult to assess systematically. The Commission initiative IPChem could potentially be helpful in future attempts for a comprehensive monitoring database.

"Retooling Vannmiljø"

The Norwegian database Vannmiljø is being retooled from its current state as a database exclusively featuring water related monitoring data (sediment, fish, water etc) to also encompass all other environmental data performed by the Norwegian Environment Agency. The Norwegian monitoring programs produce a large amount of data, and includes measurements of emerging environmental contaminants. Also, results from chemical analysis of products-enforcement activities will be incorporated in the database. This is initiated to enable better dissemination and access to data.

[EFSA databases on food consumption and contaminant levels in the diet](#)

Altieri Andrea, EFSA

The accuracy of any international exposure assessment will ultimately depend on the precision in the two calculation inputs – chemical concentration and food consumption. Food consumption and chemical concentration data are therefore required, as far as possible, for each country. Data from individual dietary surveys are understood to more closely reflect actual consumption and are therefore preferred for the assessment of dietary exposure within the risk assessment process. However, national dietary surveys currently present important differences with respect to a number of parameters affecting the level of detail and the accuracy of the collected data, such as: the dietary assessment method (24-hour recall or dietary record), the number of days per subject, the sampling design and the quantification of portion sizes. Different consumption patterns between countries can simply be induced by the survey methodology and direct country-to-country comparisons is therefore not advisable. Depending on the purpose of the exposure assessment chemical concentration data can originate from different sources, e.g. analytical determinations from monitoring and surveillance programs, legislated limits, usage levels as reported by food manufacturers, etc. The representativeness of the data will vary according to the measurement method, whether it is based on estimated levels or actual analytical results, the sampling strategy and the market coverage. Chemical concentration data from different countries are often pooled to derive international summary representative concentrations for use in multi-national dietary exposure calculations. By doing this it is assumed that it is a global market and concentrations from commodities sampled in one country are representative of the others.

Exposure assessment of chemicals in drinking water

Anders Glynn, Department of Risk and Benefit Assessment, Swedish Food Agency, Uppsala, Sweden

Exposure assessment is a fundamental part of drinking water risk assessment, and exposure assessment can be performed in several ways and for several purposes. The main options are (1) intake calculations, (2) biomonitoring, and (3) toxicokinetic modelling. (1) Intake calculations are commonly used in cases when there is a need for a quick risk assessment for rapid risk management/communication. In these cases the calculated intake is compared with a health-based guidance value (HGV), for non-genotoxic substances often a tolerable intake, if available. As a default an intake above the HGV is regarded as being of health concern. For genotoxic compounds the margin of exposure (MOE) approach may be used. This approach is, according to the European Food Safety Authority (EFSA 2005), useful in assessing the safety of genotoxic and carcinogenic chemicals at very low levels. Use of the MOE can support risk managers in defining possible risk management options to ensure that exposure to such substances is as low as possible. In this case the intake of the chemical in question is compared with the BMDL10 from an animal study regarded as the critical effect.. MOE does not quantify risk but indicates a level of health concern. (2) In certain cases biomonitoring is useful for attaining a more comprehensive exposure assessment, for instance in cases of exposure to chemicals with very long half-lives. The concentration in tissues, usually blood, from exposed individuals give a good estimate of total exposure to the chemical from all sources. The biomonitoring results can be used to assess the contribution of the drinking water exposure to the total exposure. Background biomonitoring reference values, if available, can be used for comparison. Alternatively “control individuals” with no drinking water exposure, may be included in the exposure study. Biomonitoring can also be used in the follow-up of results of risk management measures to reduce exposure, by measuring samples taken both before and after risk management action. Finally, (3) simple toxicokinetic modeling may be useful in risk assessment for estimating concentrations of the chemical in blood from intake data, and vice versa. Examples of the usefulness of different methods of exposure assessment will be given.

References

EFSA. 2005. Opinion of the Scientific Committee on a request from EFSA related to a harmonized approach from risk assessment of substances which are both genotoxic and carcinogenic. EFSA J 282, 1-31.

Contaminant levels in fish and link between REACH and WFD

Jukka Mehtonen, Finnish Environment Institute (SYKE) Centre for Sustainable Production and Consumption, Contaminants Unit

Monitoring

Monitoring produces information for risk assessment of contaminants. Monitoring information supports decision making on risk reduction measures. Monitoring results show if the current control measures are sufficiently efficient or if further measures are needed.

PFAS are found everywhere in fish in Finland. PBDEs exceed always the WFD Environmental Quality Standard (EQS) in fish both in inland waters and sea area. Mercury exceed often and PFOS seldom the EQS in inland waters, but usually not in sea area. Dioxins exceed often the EQS in fish in sea area but not in inland waters. HBCD, HCB and HCB levels in fish do not exceed the EQS in Finland.

Linking REACH and Water Framework Directive (WFD)

REACH & WFD are linked with each other at least to some extent. WFD chemicals (i.e. priority substances) are mainly restricted within REACH and e.g. biocide/plant protection legislation. WFD utilizes REACH risk assessment principles and take REACH into account in substance prioritization process. Nevertheless, they pose to some extent different scope; WFD focuses on protection of aquatic environment and human health. REACH e.g. collects more widely chemical information, targets much broader number of chemicals than WFD and set restrictions. REACH and WFD pose different competent authorities (at least in some countries) that may lead to situation that authorities focuses their resources only to their "own piece of legislation". Effective co-operation and interaction is needed among different authorities and duplicating work is to be avoided!

How about Best Available Techniques Reference Document (BREFs) developed under Industrial Emission Directive (IED)? The "BAT conclusions" is a document containing the parts of a BAT reference document laying down the conclusions on best available techniques. According to Article 14(3) of the IED, BAT conclusions shall be the reference for setting the permit conditions to installations covered by the IED. Chemicals should be more thoroughly added into BREFs!

Challenges and research needs

- Contaminant monitoring should take into account topical and pending information needs of REACH!
- More accurate information on use and emissions
- Data on "new" compounds, incl. GES or other threshold values suitable in Finnish conditions
- etc.

Plant uptake

Trine Eggen, Norwegian Institute of Bioeconomy (NIBIO)

The uptake and translocation of foreign compounds varies highly between compounds. Properties like e.g. charge (neutral, cationic, anionic), hydrophobicity, water solubility and volatilization influences on uptake pathway and rate. In addition, uptake and allocation in plants differ highly between species. Triethyl-chloro-phosphate (TECP) and tris(1-chloro-2-propyl) phosphate (TCPP), which have relative similar structure and physico-chemical properties, have shown unexpected uptake and translocation pattern in plant uptake experiments.

Several different generic plant uptake models for organic chemicals have been made. The models vary widely in their structure, complexity and in input requirements ranging from regression-based simple steady-state equations relating a plant BCF for a single chemical parameter to complex and parameter-intensive dynamic models with several compartments (e.g. root, stem, foliage, fruit compartments) and uptake both from soil and air. Different crop-specific models have been developed by Stefan Trapp and co-workers at DTU. Trapp has also developed a plant uptake and transport model for ionic chemicals.

Understanding plant uptake processes of contaminants and developing realistic plant uptake models is an important step in estimating transfer from environment to food chain, and thus, necessary in order to perform a reliable risk assessment. Emerging contaminants are new substances found or expected to be found in the environment and which may have potential toxic effects, but yet not regulated due to lack of persistent, toxicity and bioaccumulation data. Emerging contaminants cover a wide range of properties and, unlike many legacy organic hydrophobic contaminants (e.g. Persistent

Organic Pollutants, POPs), many of these new compounds tend to be more polar and water-soluble, but are still persistent in the environment. Emerging contaminants also include bioactive compounds such as pharmaceuticals, which should have special high attention.

The presentation will focus on organic contaminants, plant uptake and plant uptake models, and point at lack of knowledge.

The European Human Biomonitoring Initiative - HBM4EU

Cathrine Thomsen, Norwegian Institute of Public Health

A major hurdle in reliable risk assessment and management of chemicals is the lack of harmonised information at European level concerning the exposure of citizens to chemicals.

The HBM4EU project will use human biomonitoring (HBM) to assess human exposure to chemicals; to better understand the associated health impacts; and to improve chemical risk assessment. HBM supports the assessment of human exposure to chemicals by measuring chemicals, their metabolites or markers of subsequent health effects in body fluids or tissues. HBM4EU will draw on existing scientific excellence and build capacities to establish a European Human Biomonitoring Platform, with the aim of harmonizing human biomonitoring activities in our 26 partner countries. This platform will deliver comparable, European data on human exposure to chemicals and mixtures of chemicals, as a scientific basis for policy making to improve chemical safety. Both new and existing HBM data will be made available at the European Commission's Information Platform for Chemical Monitoring (IPChem). We will assess the potential health impacts of chemical exposures in different age groups and across genders, as well as exploring the impact of factors such as socio-economic status, lifestyle, diet and environmental conditions. We will also investigate the effects of exposure to mixtures of chemicals, and will use cutting edge technologies to search for emerging substances in human matrices that may serve as early warnings of future concern.

HBM4EU partners will establish a dialogue with policy makers to ensure that our results can be used to support the development of policies, to evaluate existing policies and to design measures to reduce exposure to toxic chemicals. Our results will inform the safe management of chemicals and so protect human health in Europe.

Stationary sampling of ambient air in Europe

Knut Breivik, NILU – Norwegian Institute for Air Research

Beyond direct inhalation, the atmosphere has been shown to represent a key pathway for chemical entry via other parts of the physical environment as well as the human food-chain. Air monitoring data is therefore important for a complete understanding of human exposure to airborne chemicals. Such data are furthermore required for attempts to understand and evaluate relationships between emission sources and atmospheric concentrations - and thereby an integrated aspect of overall source-exposure relationships. In this talk, an introduction to existing databases on chemicals in ambient air will be given. The focus will highlight monitoring data and databases for selected persistent organic pollutants (POPs) and heavy metals in European background air. Using organic contaminants as examples, the merit and limitations of different techniques to measure spatial and temporal trends of chemicals in air and deposition will be discussed in terms of exposure relevance. Finally, opportunities of combining air monitoring data with exposure models to understand and predict human exposure via the environment will be assessed.

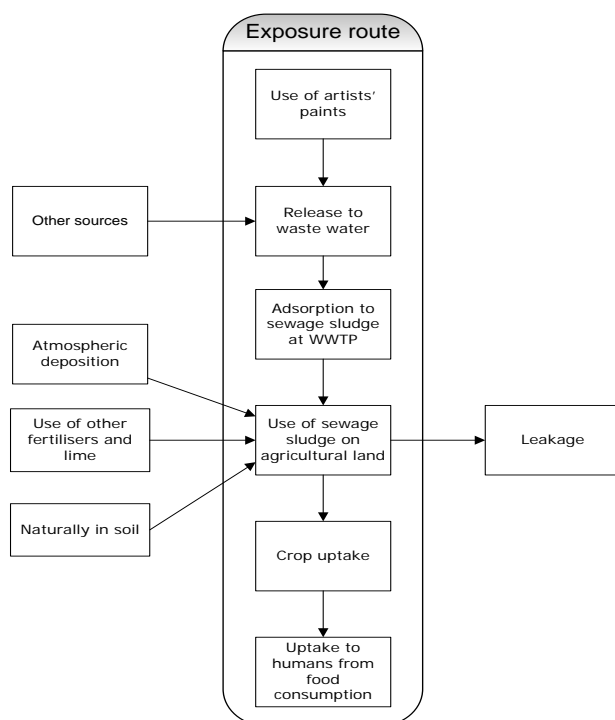
Cadmium in food (vegetables, crops) - estimation of contributions from cadmium in fertilizers and deposition

Helena Parkman, Swedish Chemicals Agency

In 2012, EFSA concluded that children and adults at the 95th percentile exposure level for Europeans could exceed health-based guidance values. This conclusion was drawn from detailed individual food consumption data, data on cadmium in food, and a tolerable weekly intake of cadmium based on toxicological data on kidney failure. Since then, new research have indicated other effects, e.g. on bone, at lower exposure levels. Food is the dominating source of human exposure to cadmium in the non-smoking general population. Food consumed in larger quantities has the greatest impact on dietary exposure to cadmium, e.g. grains and grain products (27%), vegetables and vegetable products (16%) and starchy roots and tubers (13%). Since these food categories get their cadmium content from the soil in which they are grown, one measure to reduce exposure to cadmium is to reduce the input of cadmium to soil.

The main sources of cadmium to arable soil are deposition, different types of fertilizers and other products used in agriculture, such as lime.

Sludge is used as fertilizer in several European countries, and cadmium in artists' paint is one source of cadmium in sludge. Therefore Sweden proposed restrictions on cadmium in artists' paint in EU, but this was not supported by the EU community, motivated by the low contribution that this source had to the total exposure in the very long term scenario that was used. In this talk I will use cadmium in artists' paint as an example of an indirect exposure of cadmium via food and explain how we did our exposure estimates and which assumptions we made in the restriction proposal.



Appendix D: List of participants

Name	Affiliation
Karolin Ask Björnberg	Swedish Chemicals Agency
Alexandra Stewart	Swedish Chemicals Agency
Amrit Kaur Sakhi	Norwegian Institute of Public Health
Anders Glynn	National Food Agency, Sweden
Andrea Altieri	European Food Safety Authority, EFSA
Cathrine Thomsen	Norwegian Institute of Public Health
Cécile Blom	Norwegian Environment agency
Cecilia Westöö	Swedish Chemicals Agency
Christine Bjørge	Norwegian Environment agency
Daniel Sättler*	UBA (The German Environment Agency)
Eva Haug	Norwegian Environment agency
Frederik Verdonck	ARCHE Consulting
Heidi Morka	Norwegian Environment agency
Helena Parkman	Swedish Chemicals Agency
Ingunn Correll Myhre	Norwegian Environment agency
Jarkko Loikkanen	Finnish Safety and Chemicals Agency (Tukes)
Joost Bakker	RIVM (The Dutch National Institute for Public Health and the Environment)
Jukka Mehtonen	Finnish Environment Institute
Knut Breivik	Norwegian Institute of Air Research
Lea Stine Tobiassen	Danish Environmental Protection Agency (DEPA)
Linda Reierson	Norwegian Environment agency
Line Småstuen Haug	Norwegian Institute of Public Health
Margareta Warholm	Swedish Chemicals Agency
Marianne Moilanen	Finnish Safety and Chemicals Agency (Tukes)
Marianne van der Hagen	Norwegian Environment agency
Marius Gudbrandsen	Norwegian Environment agency

Panu Rantakokko	the National Institute for Welfare and Health (THL)
Peter Simpson	ECHA (European Chemicals Agency)
Rebecca Henricsson	Swedish Chemicals Agency
Sara Martin	Environment Agency UK
Sjur Andersen	Norwegian Environment agency
Stefano Frattini	ECHA (European Chemicals Agency)
Stellan Fischer	Swedish Chemicals Agency
Stine Husa	Norwegian Environment agency
Trine Eggen	The Norwegian Institute for Agricultural and Environmental Research