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REVIEW

- REACH and the safe use of chemicals
- Risk management under REACH
- Key priorities of NGOs on REACH
- Definitions of waste, recycling and recovery
- The UK Government's Ship Recycling Strategy
- Legislating e-waste management
- Exemptions under Article 5 (1) (b) RoHS Directive
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ARTICLES

REACH and the safe use of chemicals: definition and development of exposure scenarios

Dirk Bunke

1 Need for information on safe use of chemicals

Sustainable management of chemicals requires sufficient information on properties of substances and on the conditions of their safe use. Therefore, the so-called “**chemical safety assessment**” plays an important role in the registration procedure within the REACH proposal from October 2003. The chemical safety assessment aims to describe the potential effects of chemicals on human health in a structured way and the environment as well as the conditions which are necessary for their safe use.

One part of the chemical safety assessment is the **exposure assessment**. It consists of two elements: **development of exposure scenarios** and exposure estimation. Exposure scenarios describe the conditions of use and are themselves results of the chemical safety assessment.

Following the publication of the White Paper in 2001, discussion began on how to achieve a “workable” REACH. A plethora of recommendations were developed in order to make the registration more efficient without reducing quality in the course of this step.

The **grouping of “similar” uses and “similar” exposure situations** is one important possibility. Several approaches for such groupings have been developed in the interim. Some of these concepts supplement the exposure scenario approach of REACH, others intend to replace this concept. “**Categories**” is the common heading for different approaches (use categories, exposure categories, use- and exposure categories...). Until now no

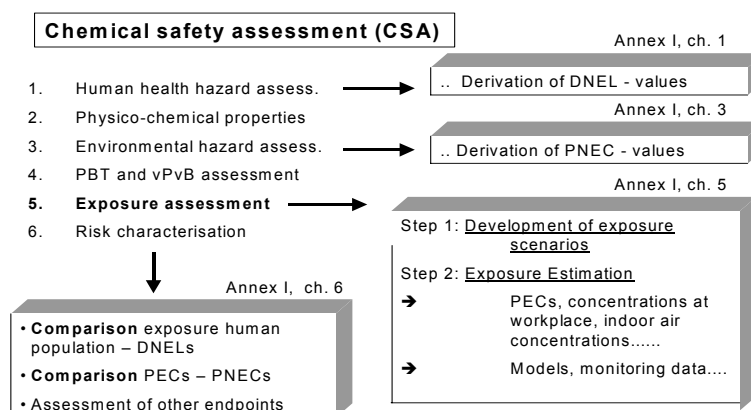
definition for an exposure category has come into being. In some cases, suggestions for “(use/exposure) categories” are part of even broader proposals regarding further elements of the REACH proposal. This makes the discussion of these concepts more complex and difficult.

This paper aims to give a short introduction to exposure assessment under REACH. It addresses key points of current discussion on exposure scenarios and exposure categories. Reference points are the REACH proposal from October 2003 (CEC 2003), experiences accrued in pilot trials on REACH, recent papers on several category approaches as well as the results of the workshop on the practical preparation for REACH in Arona, January 2005 (CEC 2005).

2 Chemical safety assessment according to REACH**2.1 Structure of the chemical safety assessment**

The chemical safety assessment is the tool used by industry to determine which risk management measures and which operational conditions are necessary for protecting human health and the environment (CEC 2005). The chemical safety assessment is comprised of six elements, including exposure assessment and risk characterisation (which only have to be carried out for a restricted number of substances, see chap.2).

Fig. 1 shows the structure of the chemical safety assessment and the position of the exposure assessment (step 5).



The objective of the **exposure assessment** shall be to make a quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. (REACH Annex I, Art. 55.0).

Exposure assessment begins after the hazard assessment has been completed (which aims to identify and evaluate the physicochemical hazards, the inherent substance properties which affect human health and the environment). Exposure assessment is a prerequisite for the risk characterisation step. In this step, the extent of exposure is compared with effect-related data¹ in order to decide whether there is cause for concern and what kind of risk reduction and risk management measures should be recommended.²

Exposure assessment under REACH entails two separate steps:

- Step 1: Development of exposure scenarios;
- Step 2: Estimation of exposure for each exposure scenario.

Exposure assessment aims to achieve predicted environmental concentrations (PEC-values) and values with regard to the exposure of human population.

2.2 Exposure scenarios: definition and description

Under REACH, the main element of the exposure part of the chemical safety report is the description of different **exposure scenarios**:³

“An exposure scenario is the set of conditions that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends others to control, exposures of humans and the environment.”

In order to do this, the registrant has to describe, if relevant, the following for the identified uses:

- processes involved in production, processing and use, including the physical form, during its lifecycle;
- risk management measures (by the manufacturer / importer / downstream users) and the waste management measures;
- activities and the exposure of workers and consumers which are exposed to the substance;

- emissions of the substance into the environment, including sewage treatment systems and dilution of the substance in the environment.

An exposure scenario can be understood as a picture describing the conditions of use of a substance; it provides the relevant information as to which kind of exposures occurs and makes recommendations on how to manage them.⁴

“The description of the conditions⁵ under which a substance can be used in a way that risks are adequately controlled, is called an exposure scenario.” (CEC 2005, p. 37).

Note: Exposure scenarios are a central element which is important not only for the registration, but also for information in the supply chain (Title IV), for downstream users (Title V), for evaluation (Title VI), authorisation (Title VII), restrictions (Title VIII) and enforcement (Title XIII). For an overview, see CEC 2005, p. 38f.

2.3 Who has to carry out the exposure assessment? Responsibilities and duties

Exposure assessment as part of the chemical safety report has to be undertaken first by the manufacturer/importer of a substance (whether the substance has to be registered; whether it is a dangerous substance with an annual production volume of > 10t/a).⁶

A downstream user only has to conduct his own chemical safety assessment (including the exposure assessment) when he uses a dangerous substance extraneous to the conditions described in an exposure scenario conveyed to him in a safety data sheet.

Instead of undertaking his own assessment, a downstream user can ask the supplier to provide him with exposure scenarios for his purposes. In this case, he should provide sufficient information so as to allow his supplier to prepare an exposure scenario for his use in the supplier's chemical safety assessment (REACH (CEC 2003), Art. 34,2).⁷

¹ Comparison of PEC/PNEC values, comparison of human exposure data with DNEL-values.

² Risk characterization of existing and newly-notified substances may include “risk estimation”, i.e. the quantification of the incidence and severity of adverse effects (TGD 2004, Part I, p. 7).

³ REACH, Annex I, chap. 0.6, p. 8, chap. 5.1, p. 15.

⁴ The exposure scenario itself does not contain estimations of emissions and exposure levels – these belong to the exposure estimation, the second step of exposure assessment.

⁵ Risk management measures and the related operational conditions

⁶ Under REACH, exposure assessment has to be undertaken for substances with a production volume of more than 10 t/a, if they meet the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or if they are assessed to be a PBT (persistent, bio accumulative, toxic substance) or vPvB (very persistent, very bio accumulative substance).

⁷ Downstream users have 12 months from receipt of the safety data sheet to perform the CSA (RIP 1, chap. 5.2, p.49).

2.4 Exposure scenarios as flexible elements

Annex I of the REACH proposal gives a clear definition of an exposure scenario. It is still undecided how detailed an exposure scenario should be. The given concept of exposure scenarios offers a large degree of flexibility. It is possible to develop exposure scenarios which encompass a broad range of applications.

“The level of detail required in describing an exposure scenario will vary substantially from case to case, depending on the use of the substance, its hazardous properties and the amount of information available to the manufacturer or importer. Exposure scenarios can describe the appropriate risk management measures for several individual uses of a substance. Single exposure scenarios may thereby cover large ranges of uses (REACH proposal (CEC 2003), Annex I, chap. 0.7, p. 8).

In addition, the possibility of using broad exposure scenarios and categories has already been mentioned in the RIP-1 document.

“Generic exposure scenarios and/or exposure categories can be developed by manufacturers and importers where appropriate”. (RIP-1, (CEC 2004), chap. 3.4.2.2, p. 30).

3 How is exposure assessment made workable? Experiences from pilot trials

Different pilot projects involving REACH demonstrated that a workable system and efficient implementation is crucial to the success of REACH. Several recommendations to improve the workability of the system (Bunke et al. 2002, Nover and Hippe 2004) have been developed.

Several elements of the registration process have been tested in the pilot trial of North-Rhine-Westphalia (ARGE 2004). It has been recommended that simplified procedures be developed for the exposure assessment and for the communication of exposure scenarios or exposure “categories” in the supply chains.

One overall conclusion drawn from the North Rhine-Westphalia project is to develop simple EU guidance documents (in addition to other aids and implementation tools) before the system starts. These should address, in particular, the development of standard exposure scenarios and exposure “categories” for various supply chains, in collaboration with substance producers, manufacturers of preparations and users of chemicals.

4 Use categories and exposure categories

The recommendation to group similar uses and similar exposure situations together and assess them

in unison was developed in several pilot trials on REACH. Several proposals have been made for systems of use and/or exposure categories in the interim:

- The German Federal Government recommended the development of a system of use and exposure categories, together with the IG BCE and the VCI (2003).
- The German Chemical Industry Association (VCI) developed a system of exposure categories, which is closely linked to far-reaching changes of the present REACH proposal. The VCI concept deploys a very broad system of exposure categories without branch-specific elements. Quantitative exposure assessments of identified uses by the manufacturer or importer of substances are not foreseen – in contrast to the present REACH proposal.
- A different system of use and exposure categories, which is closely linked to the exposure scenario concept of REACH, has been developed by the following national competent authorities of Germany: the Federal Environmental Agency (UBA), the Federal Institute for Risk Assessment (BfR) and the Federal Institute for Occupational Safety and Health (FIOSH). Quantitative exposure estimates and consideration of branch-specific elements are intrinsic to this system.

5 Recommendations

Exposure scenarios as described in Annex I of the REACH proposal are a helpful and necessary approach for the chemical safety assessment. The following recommendations are provided so that they can be developed into a successful tool applicable to different actors in the supply chains:

- **Standardisation:** There is concern that a myriad of complicated site-specific exposure scenarios would have to be generated. This is not required by REACH. It is possible to develop broad standard exposure scenarios, together with the actors of supply chains, which can encompass many individual applications of chemicals.
- **Use and exposure categories:** The REACH proposal is flexible enough to allow for the introduction of categories for similar uses and similar exposure situations within the exposure scenario concept. These categories should be developed. They have to be broad enough to cover typical applications, and detailed enough to reflect use and branch-specific exposure situations and to deliver the necessary transparency on the use of chemicals in general.
- **Responsibility:** Quantitative assessments of the expected exposure for identified uses (in a

standardised manner) belong to the responsibilities of manufacturers and importers. This responsibility should not be delegated to downstream users.

- **Standard assessments:** It cannot be expected that manufacturers (and importers) evaluate the whole range of individual uses of their chemicals. They should be able to perform and communicate exposure assessments for the identified uses of their chemicals under standard application conditions (as described in emission scenario documents or in the technical data sheets of the manufacturer).
- **Duty of the downstream users:** It remains an important task for downstream users to check whether their individual uses are covered by the exposure scenarios provided in the safety data sheets of their suppliers. In this respect, supporting tools are necessary, too.
- **Use of existing data:** Exposure assessment constitutes a crucial element of an appropriate risk assessment of chemicals. A slew of information on branch-specific emissions and exposures is available (e.g. in the OECD Emission Scenario Documents) which can be deployed to simplify these tasks.

6 Additional remarks

- A prototype of a standard exposure scenario has been developed for the textile finishing industry, together with actors of the textile chain of the NRW project (a project of the German Federal Environmental Agency, Berlin; contact: birgit.mueller@uba.de, ulrike.frank@oeko.de). Similar tools should be developed for other branches.
- A guidance tool for finding the proper emission scenario data (including stand-alone IT tools) is under development in the ESD Matrix Project of the German Federal Environmental Agency, Berlin (contact: silke.mueller@uba.de).

7 References

The general method of exposure assessment is described within the REACH proposal in Annex I (CEC 2003), chap. 5, pp. 15-17). Important explanations are provided in the RIP1- document (RIP-1 (CEC 2004), chap. 3.4.2.2, pp. 28-30). Further specific guidance on how to develop exposure scenarios and how to communicate these down the supply chain will be cultivated within the Reach Implementation Project (RIP) 3.2.⁸

The present state of discussion is documented in the report from the workshop held in Arona, January 2005 (CEC 2005, p. 7ff and p. 36ff). Guidance on finding existing exposure data and prototypes of standard exposure scenarios (including IT tools) as well as basic toolboxes for exposure assessments are in development.

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CEC 2005, Commission of the European Communities (CEC): *Planning for the operation of key elements of REACH: registration, evaluation and restrictions. Report of the workshop held under the auspices of the commission-working group on the practical preparations for REACH. Arona, 24th-25th January 2005. European Chemical Bureau, DG JRC, Institute for Health and Consumer Protection, Ispra 2005*

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Nover und Hippe 2004, Nover, H.; Hippe, D.: *Planspiel zur neuen EU-Chemikalienpolitik (REACH) in NRW. In: Friege, H. (Hrsg.), EU Chemikalienpolitik. Umweltwissenschaften und Schadstoff-Forschung (UWSF)*, 16 (2), 134 – 139, 2004

ARGE 2004, *Testing REACH in practice. Results of a Simulation in North Rhine-Westphalia (Germany)* <http://www.munlv.nrw.de/sites/arbetsbereiche/immission/chemiepolitik-nrw.htm>
<http://www.europa.nrw.de/themen/chemikalienpolitik/index.html>

Abstract

Safe management of chemical requires an assessment of their conditions of use. Exposure scenarios describe conditions of use and are a key element of the REACH proposal.

Standardised exposure scenarios can cover a broad range of applications – they are in line with the protection of confidential business information.

Grouping similar uses and similar exposure situations together (using "categories") should supplement the exposure scenario approach. Use categories and exposure categories have to be broad enough to encompass typical applications and detailed enough to reflect use- and branch-specific exposure situations as well as to deliver the necessary transparency on the use of chemicals in society.

Responsibility for the exposure assessment of identified uses should not be delegated by the manufacturer/importer to downstream users.

⁸ For an overview of the RIP-projects, see <http://ecb.jrc.it/REACH/>.

The Öko-Institut (Institut für angewandte Ökologie - Institute for Applied Ecology, a registered non-profit-association) was founded in 1977. Its founding was closely connected to the conflict over the building of the nuclear power plant in Wyhl (on the Rhine near the city of Freiburg, the seat of the Institute). The objective of the Institute was and is environmental research independent of government and industry, for the benefit of society. The results of our research are made available of the public.

The institute's mission is to analyse and evaluate current and future environmental problems, to point out risks, and to develop and implement problem-solving strategies and measures. In doing so, the Öko-Institut follows the guiding principle of sustainable development.

The institute's activities are organized in Divisions - Chemistry, Energy & Climate Protection, Genetic Engineering, Sustainable Products & Material Flows, Nuclear Engineering & Plant Safety, and Environmental Law.

The Environmental Law Division of the Öko-Institut:

The Environmental Law Division covers a broad spectrum of environmental law elaborating scientific studies for public and private clients, consulting governments and public authorities, participating in law drafting processes and mediating stakeholder dialogues. Lawyers of the Division work on international, EU and national environmental law, concentrating on waste management, emission control, energy and climate protection, nuclear, aviation and planning law.

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The University of Applied Sciences in Bingen was founded in 1897. It is a practiceorientated academic institution and runs courses in electrical engineering, computer science for engineering, mechanical engineering, business management for engineering, process engineering, biotechnology, agriculture, international agricultural trade and in environmental engineering.

The *Institute for Environmental Studies and Applied Research* (I.E.S.A.R.) was founded in 2003 as an integrated institution of the University of Applied Sciences of Bingen. I.E.S.A.R. carries out applied research projects and advisory services mainly in the areas of environmental law and economy, environmental management and international cooperation for development at the University of Applied Sciences and presents itself as an interdisciplinary institution.

The Institute fulfils its assignments particularly by:

- Undertaking projects in developing countries
- Realization of seminars in the areas of environment and development
- Research for European Institutions
- Advisory service for companies and know-how-transfer

Main areas of research:

- **European environmental policy**
 - Research on implementation of European law
 - Effectiveness of legal and economic instruments
 - European governance
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 - Know-how-transfer
- **Companies and environment**
 - Environmental management
 - Risk management

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The Society for Institutional Analysis was established in 1998. It is located at the University of Applied Sciences in Darmstadt and the University of Göttingen, both Germany.

The sofia research group aims to support regulatory choice at every level of public legislative bodies (EC, national or regional). It also analyses and improves the strategy of public and private organizations.

The sofia team is multidisciplinary: Lawyers and economists are collaborating with engineers as well as social and natural scientists. The theoretical basis is the interdisciplinary behaviour model of *homo oeconomicus institutionalis*, considering the formal (e.g. laws and contracts) and informal (e.g. rules of fairness) institutional context of individual behaviour.

The areas of research cover

- Product policy/REACH
- Land use strategies
- Role of standardization bodies
- Biodiversity and nature conservation
- Water and energy management
- Electronic public participation
- Economic opportunities deriving from environmental legislation
- Self responsibility

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- VolkswagenStiftung
- German Federal Ministry of Education and Research
- Hessian Ministry of Economics
- German Institute for Standardization (DIN)
- German Federal Environmental Agency (UBA)
- German Federal Agency for Nature Conservation (BfN)
- Federal Ministry of Consumer Protection, Food and Agriculture

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elni

In many countries lawyers are working on aspects of environmental law often with environmental initiatives and organisations or as legislators, but have limited contact with other lawyers abroad, although such contact and communication is vital for the successful and effective implementation of environmental law.

In 1990 a group of lawyers from various countries therefore decided to initiate the Environmental Law Network International (elni) to promote international communication and cooperation worldwide. Since then elni has grown to a network of about 350 individuals and organisations from throughout the world.

Since 2005 elni is a registered non-profit association under German Law.

elni coordinates a number of different activities:

Coordinating Bureau

The Coordinating Bureau was originally set up at and financed by the Öko-Institut in Darmstadt, Germany, a non-governmental, non-profit making research institute. The Bureau is currently hosted by the University of Applied Sciences in Bingen. The Bureau acts as an information centre where members can obtain information about others working in certain areas thus promoting the development of international projects and cooperation.

elni Review

The elni Coordinating Bureau produces and sends to each member the elni Review twice a year containing members' reports on projects, legal cases and developments in environmental law. elni therefore encourages its members to submit such articles to be published in the Review in order to allow the exchange and sharing of experiences with other members.

elni Conferences and Fora

elni conferences and Fora are a core element of the network. They provide scientific input and the possibility for discussion on a relevant subject of environmental law and policy for international experts. The aim is to bring together scientists, policy makers and young researchers, giving the opportunity to exchange views and information as well as developing new perspectives.

Publication Series

The elni publications series contains 12 volumes on different topics of environmental law.

- Environmental Law and Policy at the Turn to the 21st Century, Liber amicorum, Betty Gebers, Ormond/Führ/Barth (eds.) Lexxion 2006.
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Sadeleer/Roller/Dross, Europa Law Publishing 2005.

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- Dynamic International Regimes: Institutions of International Environmental Governance, Thomas Gehring; Peter Lang, 1994.
- Environmentally Sound Waste Management? Current Legal Situation and Practical Experience in Europe, Sander/ Küppers (eds.), P. Lang, 1993
- Licensing Procedures for Industrial Plants and the Influence of EC Directives, Gebers/Robensin (eds.), P. Lang, 1993.
- Civil Liability for Waste, v. Wil-mowsky/Roller, P. Lang 1992.
- Participation and Litigation Rights of Environmental Associations in Europe, Führ/ Roller (eds.), P. Lang, 1991.

elni Website: elni.org

The elni website at <http://www.elni.org> contains news about the network and an index of elni articles, gives an overview of elni activities, and informs about elni publications. Internships for young lawyers/law students at the Öko-Instituts environmental law division are also offered on the web.