

Research and Development Project by the German Federal Environmental Agency (UBA)

Register on Uses of Chemical Substances In the Framework of the New European Chemicals Policy

Berlin, May 21, 2003

Objective

The project aims to work out proposals on the practical implementation of certain elements in REACH¹, related to information on the use of new and existing substances placed on the market. The project is meant to contribute to the European implementation process, once the new strategy has been laid down in legislation.

Background

The Commission's strategy makes manufacturers, importers and professional users of chemicals responsible for assessing their properties, and the type and conditions of their use. This applies equally to substances placed on the market for the first time before 1981 (existing substances), or later (new substances). By this, the strategy aims to prevent and limit risks to human health and the environment and to allow for more informed choices on chemicals in the market.

A risk based assessment of chemicals requires information on i) substance properties and ii) exposure related data. While there is a comprehensive system in the EU to assess and classify the intrinsic properties of substances, the generation, processing, evaluation and dissemination of exposure related information will be a new element in the system².

Substances having "existed" in the market for a long time are often used in various applications, and these use patterns may also change over time, depending on market demands and innovation. Thus, any elements of REACH related to uses need to be i) flexible enough to reflect the market dynamics, ii) specific enough to address appropriate risk management measures and iii) broad enough to allow for open communication in the market.

REACH will include some standard information elements regarding the use of substances:

- In the technical registration dossier: Description of technological process of manufacture and intended uses; form in which the substance (including concentration ranges in preparations and articles) is made available to downstream users; guidance on safe use.
- In the *chemicals safety reports* by manufacturers and down stream users: Summary of risk management measures; definition of exposure scenarios (related to all intended uses and the conditions of use, including risk management measures); exposure estimation and risk characterisation for each scenario (see also "REACH registration" in figure 2).
- Report by downstream users to the European Central Agency (ECA), in case a substance is used in applications or under risk management measures not foreseen in the supplier's safety report (see also "DU's report" in figure 2).
- In the Agency's non-confidential data base: guidance on safe use; definition of intended use as far as described in the Safety Data Sheet.

These four core elements should be based on a common operational concept and should ensure sufficient transparency, accuracy, practicality and protection of business secrets at the same time.

¹ Registration, Evaluation and Authorisation of Chemical Substances

² The notification of new substances includes a definition of intended use, however these substances are mostly designed for a specific application and the use pattern is mostly less complex compared to the use patterns of existing substances.

Project Design

The project design allows for some flexibility to focus the work on particular steps in the implementation of REACH, depending on needs to be identified via communication with ECB, the German Federal Environmental Ministry and the relevant federal authorities in Germany (UBA, BAuA, BfR). Ongoing work on related issues shall be taken into account.

- Focus 1: Develop the REACH-component "Downstream User to Agency Report"³ as an element in the data system and in the evaluation work of the Agency. Such component may include: i) a simple information mechanism from down-stream-user to the Agency, ii) a mechanism to screen this information and to compare it with the data from registration (operated by the Agency), iii) a tool to support the down-stream user in identifying a suitable standard phrase for his particular use or iv) a feed back-mechanism from the Agency to the down-stream user to which extent refinement of exposure scenario, hazard assessment or risk assessment may be needed.
- Focus 2: Develop mechanisms for data transfer from the central system to national and regional authorities responsible for protection of human health and environment. Work out options to support regional authorities in their contribution to enforcement of the REACH system in Germany
- Focus 3: Develop a user friendly information system (EU or national) on the use of chemical substances, including tiered rules for data access, in order to make certain information available to the actors in the market, scientists, NGOs and other stakeholders outside the public authorities.

Independently of the focus of the project, two preparatory works shall be carried out in the first project phase, as a basis for the further steps:

1. Systematic compilation of the information needs related to the use of chemical substances, seen from the perspective of the various authorities, chemicals producers, other actors in the market, NGOs and others. Compilation of criteria based on which the rules for data access can be determined.
2. Proposals how to further develop the current system⁴ of main and industry categories, use categories and volume categories in a way that it will serve the information needs within REACH related to the uses and the expected exposure (see figure 1A/B).

Time-Lines and Milestones

The project work has started in September 2002 and is planned to be finished by April 2004. In the first project phase (till June 2003), the draft legislation will be analyzed and the views of relevant stakeholders (Germany and European level) investigated. A decision on the specific focus within the project will be taken by June 2003.

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³ Mechanism based on which down stream users inform the authorities on such uses or conditions of use, which are not covered in the chemicals safety report received from the supplier (**see also figure 2**)

⁴ as laid down in the current EU Technical Guidance Document (TGD) on Risk Assessment

*Figure 1A: Use Categories - Exposure Scenarios - Exposure Levels
Illustration of terms and their possible links to each other (as taken from
the EU TGD and draft building blocks of the new legislation)*

USE CATEGORIES

- **main category**
- **industry category**
- **use category by function**
- **use category by product type**

EXPOSURE SCENARIOS

based on ...

- **technical process**
- **risk management measures applied or recommended**
- **activities of workers or consumers, duration and frequency of exposure**
- **duration and frequency of emission to the environment**

PREDICTED EXPOSURE LEVELS

by ...

- **measured exposure data**
- **quantity of substance for each intended use**
- **degree of containment**
- **physico-chemical properties**
- **transformation products**
- **routes of human exposure**
- **pathways to the environment, environmental fate**

Figure 1B: Use Categories - Exposure Scenarios - Exposure Levels
Possible logical links among exposure related elements of REACH

¹⁾ Use Categories are the focus of the current project

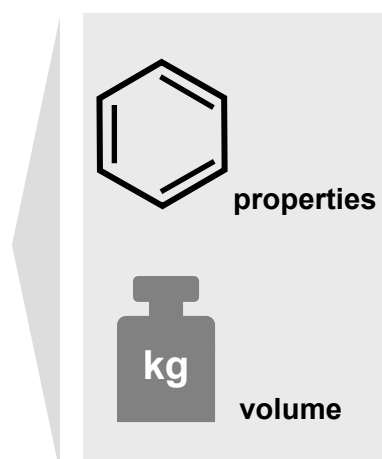
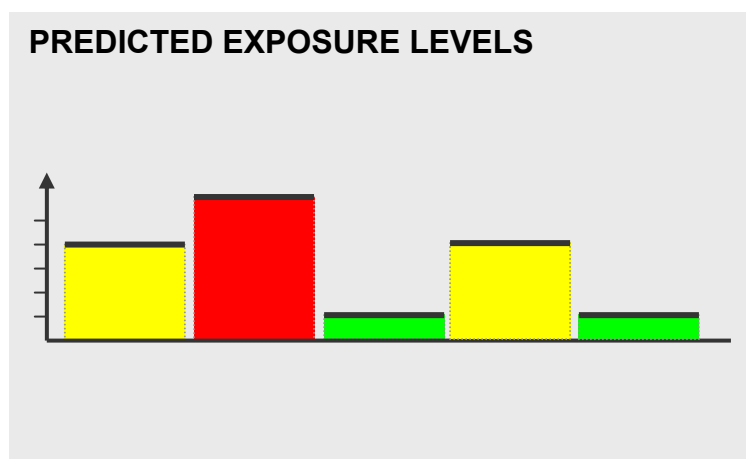
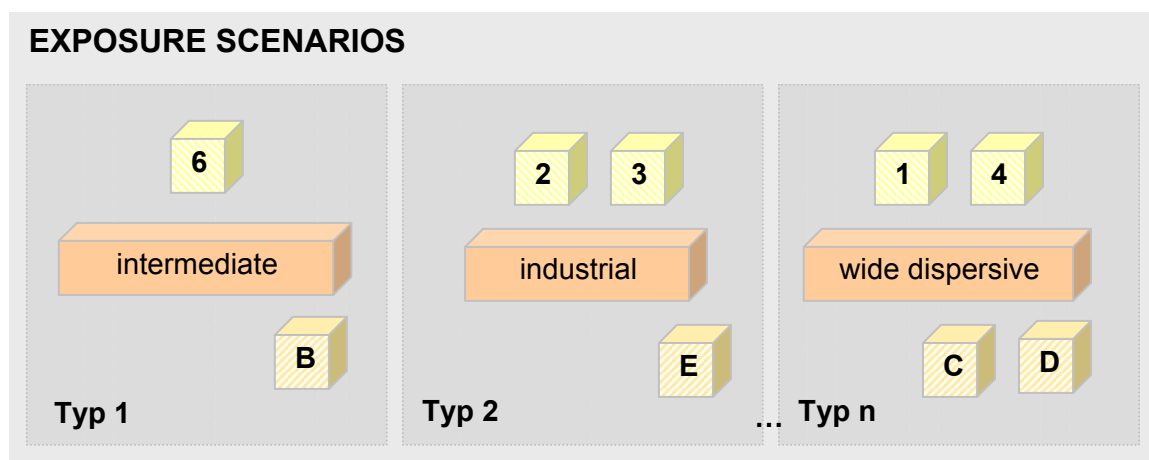
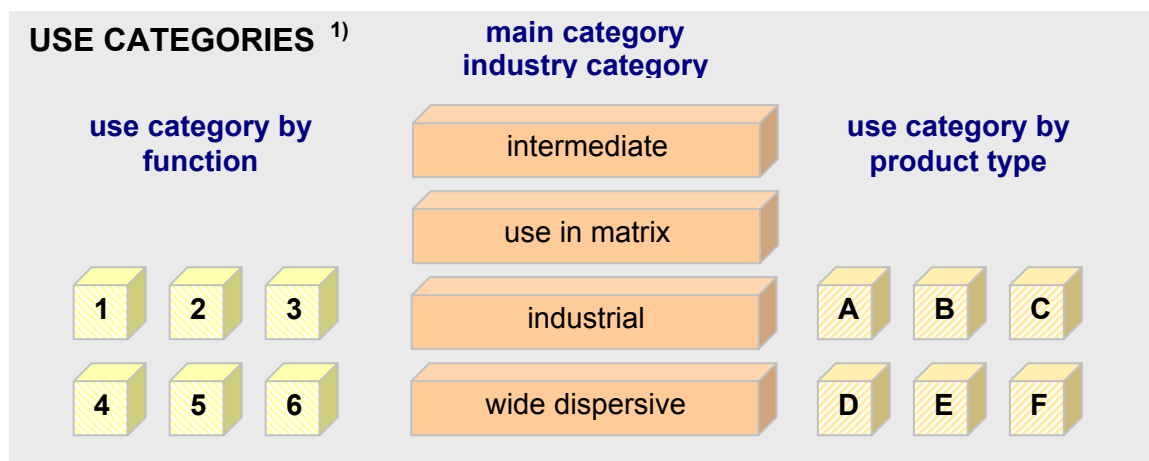


Figure 2: Use Related Information in the Producer Risk Assessment

