

Use and exposure categories - an essential pre-requisite for the workability of REACH

September 22, 2005

Chemicals safety through targeted information and assessment

We and our environment are composed of chemical substances; they surround us everywhere, whether in sweaters, as ingredients in food or as coatings on our cars. What has to be borne in mind for ruling out damage to health and the environment when handling substances? Under which conditions one can come into contact with a substance and how can its effect be assessed? For this purpose, certain information about the use of substances is needed.

The introduction of use and exposure categories is one of the indispensable pre-requisites to make REACH workable at all. Use and exposure categories provide specific information tailored to the various user groups about what has to be borne in mind when the substances are used. Thereby, the assessment of substances, as required from manufacturers and importers according to the REACH-draft, is significantly simplified while retaining the objectives of REACH.

The assessment and communication dilemma under REACH

REACH requires from the manufacturer or importer, who is obliged to register, for substances beyond 10 t/a, which fulfil the criteria for classification as dangerous according to Directive 67/548/EEC, or which are PBT- or vPvB-substances, an assessment of the identified uses (documented in the so-called Chemical Safety Report) by means of exposure scenarios¹. For this purpose, a hazard evaluation, an exposure assessment and a risk characterization must be carried out. For marketed substances, the exposure scenarios incl. risk management measures have to be passed onto customers as an Annex to the Safety Data Sheet for uses assessed as safe. The exposure estimation however, is rather complex especially if no measured data are available.

In reality the following problems arise, which have been confirmed by the SPORT² project:

- Customers often do not pass on details on exposure and use to the manufacturer/importer. On one hand the necessary contacts do not exist since wholesale and foreign trade is an actor in-between for various reasons. On the other hand, the conditions of use and exposure often comprise confidential

¹ cf. REACH-terminology; application of a substance for a rather specific use.

² Strategic Partnership on REACH Testing, a pilot trial with eight substances finished in the middle of this year. Commission, industry and member states were the active partners. Industry compiled substances' registrations according to the proposal of the Commission as of October 29, 2003.

business know-how. Therefore, the intensive exchange of information between customer and supplier obliged to register, regarding exposure, i.e. kind and conditions of use, as intended under REACH, does not take place in reality.

- Therefore, the manufacturer/importer has to assess exposure conservatively as a precaution, which then may induce overly high requirements for risk reduction measures.
- Neither manufacturers/importers can elaborate and pass on the information on the many and detailed exposure scenarios nor can customers manage it.
- Too detailed exposure scenarios are particularly problematic for customers. They on one hand require high own expertise for assessing whether the own use is covered by the exposure scenarios. On the other hand, the customer is forced to pass on information, necessary for the assessment, onto the supplier.
- Due to the often large number of users with different applications per substance, an analysis, documentation and communication of each individual use is impossible without structuring by categories.

Use and exposure categories offer a way out of this dilemma. Communication along the supply chain can thereby be structured and simplified. Confidential information has no longer to be passed on. The testing efforts beyond the necessary basic information can be focussed depending on the use and the exposure-related risk. In the majority of cases, the assessment by use and exposure categories is sufficient. Consideration of individual cases is only required, where categorisation does not enable for achieving the objective.

Exposure categories are thus at the beginning of what may be needed within a multistage consideration:

- In a first step, the manufacturer/importer divides uses very generally into industrial, commercial or private ones. Then the relevant routes of uptake for humans, routes of emission into the environment, and duration and frequency of exposure are determined in the form of categories. Limit values to be observed for safe use are given for these categories. In the same time, general measures are determined, which enable to comply with these limit values. Starting from the general measures and respective conditions, individual measures such as ventilation, application method, protective clothing etc. adjusted to the customer's special situation are developed. A practical example is given in the Annex.
- If the user cannot meet the limit values given in the first step or cannot assess their observance, he must describe his situation more exactly in a second step. In this respect, he can use more finely structured categories for his branch or involve the manufacturer/importer.
- Only the third step corresponds to an individual consideration as it is intended generally by the current REACH-draft. Here for example the measurement of emission values on-site can become necessary in order to account for a special risk and to develop adequate management measures.

Conclusion: Use and exposure categories make REACH workable

According to the REACH draft, formal requirements on information have to be met for the registration of chemical substances depending on the amount to be produced or imported without a differentiation being made according to the actual risk (possibility, intensity and duration of contact). This involves very intensive and unnecessary efforts particularly for substances with many different areas of application. In many cases, particularly for small and medium enterprises, confidential information and business secrets are affected although for a risk assessment their transmission is not necessary.

Registration of substances and transmission of data on substances on the basis of use and exposure categories focus the efforts on the actually given risks. Use and exposure categories render REACH workable, confidential business information is safeguarded.

Advantages:

Use and exposure categories

- ⇒ simplify communication in the supply chain. General categories are considered instead of many substance-related individual scenarios.
- ⇒ alleviate the evaluation of exposure for downstream users. His scope of action is not restricted more than necessary; the protection objective is not compromised.
- ⇒ have the advantage that the manufacturer/importer can on the basis of his risk assessment define a range (and not a single situation), where the safe use of a substance is safeguarded.
- ⇒ prevent that confidential information has to be passed on.
- ⇒ can provide for the targeted use of test resources. The effect of substances is investigated particularly rigorously where an exposure is given.
- ⇒ avoid numerous unnecessary animal studies.

Example solvent “Unisolv”

The solvent Unisolv is a component in automotive coatings. Different contact scenarios for this substance are possible: The criteria for private car owners who repair a scratch on the coating of their car by means of a spray coating containing Unisolv once in three years must be different from those for coaters who coat automobiles every day or for the manufacturer of substances who uses many tons of the solvent in his production. Although end users may come into contact with Unisolv only sporadically, it has to be assumed that he is not experienced in using chemical substances, that he doesn't obtain any instruction and doesn't take any protection measures. In contrast to a professional user, he is not protected by a hermetically sealed production plant and doesn't dispose of a special spray booth with air exhaustion.

In order to assess possible contacts with a substance such as Unisolv, situation-related as well as substance-related factors must be taken into account.

Situation-related factors

Forms of contact (humans):

General: inhalation, skin contact or swallowing by misuse.

Example Unisolv: the solvent Unisolv being highly volatile, contact by inhalation is to be borne in mind in particular.

Forms of contact (environment):

General: emission to air, soil and water.

Example Unisolv: the solvent Unisolv being highly volatile, the air as a potentially affected area is particularly important here.

Duration/frequency of contact:

General: here, a differentiation can be made between short-term and permanent contact since: whether and to which extent health and the environment are affected depends apart from the concentration vitally on the duration of contact.

Example Unisolv: the professional coater is generally exposed for many hours each day to the solvent Unisolv, the private car owner only rarely and for a short period.

Application conditions:

General: industrial, commercial or private use.

Example Unisolv: Unisolv is used by chemical companies and processors (industrial production of coating intermediates or coatings), in paint shops (commercial use) and by end consumers (private use).

Substance-related factors

Every chemical substance has its own specific material properties, such as e. g. flammability, boiling point, solubility in water, (eco-) toxicity and skin irritation.

The most important properties for the assessment of Unisolv:

Physico-chemical properties	- liquid
	- flammable
	- poorly soluble in water
	- highly volatile
Toxicological properties	- irritating to the skin
	- harmful
Ecotoxicological properties	- dangerous for aquatic organisms
	- readily biodegradable

Use and exposure categories for Unisolv

The situation-related factors can be presented as a matrix of general use and exposure categories. Any substance with its special material properties and uses can be comprehensively considered on the basis of this matrix. If adequately handled, not each category is relevant. In the case of Unisolv oral intake would be restricted to accidents or misuse.

The matrix of use and exposure conditions is suitable for providing each user with the specific safety information decisive for his use. In the categories relevant for their customers, manufacturers/importers of intermediates and end products supply information on possible restrictions of use, as well as limit values and measures to achieve these limit values. Example categories for Unisolv are:

- **Industrial use – long-term respiratory contact**

With regard to the material properties "flammability" and "volatility", a closed system should be used in order to rule out contact. On the basis of the toxicological properties, a limit value can be derived that can be observed by a closed system.

- **Industrial use – short-term respiratory contact**

Permitted with reservations (limit value to be given), measures: inhalation protection

- **Commercial use – long-term respiratory contact**

Permitted with reservations (limit value to be given), measures: continuous air exhaustion, closed spray booths, etc.

- **Private use – short-term respiratory contact**

Permitted with reservations (limit value to be specified for the manufacturer of the end product), measures: safety advice like "use outdoors", product to be supplied in small packages, etc.