

Communication of uses

Introduction

One key aspect of REACH is to improve communication in the supply chain. An increased amount of available information will ensure Downstream Users (DUs) of substances and mixtures have some assurance that how they use those chemicals is appropriate. It will also ensure that suppliers of chemicals do not propose uses that are not fit for purpose.

This short guide aims to provide some background as to why such communication is important. Once the reasons are understood, the level of information passed through the supply chain can be measured according to its relevance for understanding and controlling risk. A simple rule is that for low hazard substances, generic use information will probably suffice, but for substances of greater hazard, especially those of very high concern (SVHCs), considerable detail for exposure may be necessary. Conversely, substances with high exposure may need additional data, but for those with low exposure less comprehensive information may suffice.

Exposure in relation to risk assessment

The fundamental purpose of REACH is to improve protection of human health and the environment from the risks of chemicals. This aim is achieved by identifying those chemicals on the market, assessing their hazards and judging the risks to humans and the environment by considering the potential exposure. Risk management measures (RMM) need to be determined, and part of this may be to recommend uses only to certain sectors of the market. For example, RMM may suggest supply only to industrial settings and not to allow supply to the general public.

The RMM determined from the Chemical Safety Assessment (CSA) need to be communicated to the customer through the Safety Data Sheet (SDS). The SDS remains the key communication tool for the supply chain and is supported by other documents (the Chemical Safety Report (CSR) and Exposure Scenarios (ES)). If any of the sources of hazard or exposure data or the CSR itself are incomplete, the SDS may fail to provide sufficient information. The SDS must be written with the recipients in mind: risk management must be appropriate to their uses, for example if supplying in 5-litre containers to the professional building trade, recommendations for disposal may be very different than if providing in tankers to the chemical industry.

Understanding the scenarios for use is therefore an essential part of the risk assessment and communication process; the only way to know if the assessment and communication is appropriate is to understand from the user how the chemical is used.

Exposure Assessment

The term “Exposure Scenario” (ES) is part of the new REACH terminology and, although it is only a formal registration requirement for hazardous substances, the concept of the ES should be part of every risk assessment, whether for regulatory submission or as part of a well-constructed SDS. The ES needs to include details of exposure to workers, the general public and the environment that are specific to expected use patterns of the substance or mixture. Generic scenarios can be used (e.g. lubricants, paints, chemical intermediates) and, although these should be suitably comprehensive to cover generic exposure events, they may need to be more site-specific for hazardous substances that are of concern.

It is accepted that suppliers cannot know every detail of use by their customer and likewise, customers, or Downstream Users, may not want to divulge their specific uses to suppliers. If the DU does not give details of use to their supplier, there is a chance that the registration will not cover that application. However, it is possible for DUs to prepare their own ES and subsequent CSR. This provision in REACH may be especially applicable to substances that are being used in novel, innovative and therefore commercially sensitive applications.

Gathering exposure data

Determining “exposure” to chemicals is a complicated process. However, the guidance for REACH does strongly recommend that effort to determine exposure (and risk) is concentrated on areas where there is an apparent concern. Therefore, for non-hazardous substances, the effort to be given to determine exposure needs not be as great as the effort necessary for substances of concern.

Guidance documents for exposure and risk assessment models, such as EUSES¹ and the ECETOC² TRA (Targeted Risk Assessment) provide “default” exposures. Exposure estimates for workers, consumers and the environment can be modelled and estimated in this way using defaults that give unrealistic high levels of exposure, but do act as an approximate “worst case” scenario for risk management.

However, do remember that these models are only tools and do not provide definitive answers; they need to be used in conjunction with scientific assessment and common sense. There are limitations as well in terms of the class of substances. Models work with organic substances that are not surface active and are not mixed isomers or mixed molecular weights. However, they provide a good starting point for “Tier 1” risk assessments.

Customer communication

Even if using models for worker, environmental or consumer exposure, it is essential that the use of the substance is understood. Communication between the supplier and customer is crucial for this, but there are limits to what must be communicated. For example, a potential registrant is not required by REACH to ask customers for use information, and customers are not under any obligation to inform their supplier of their applications.



It makes good commercial sense for suppliers to help their customers; if a customer is known to need a chemical for a particular use, then it needs registration for that use and exposure needs to be assessed. However, if the customer has a confidential use for the substance (for example, not wanting to tell their supplier that there is a market open that the supplier was unaware of), then the responsibility for consider exposure and risk passed to the customer.

Questions for customers: communication

A balance should be struck between asking too many or too few questions when trying to obtain sufficient information to make an adequate exposure and risk assessment. The danger is that complicated or poorly drafted questionnaires or letters may receive no response from customers. Towards the end of 2009, when many manufacturers and importers were working towards the first registration deadline of 30 November 2010, response rates were as low as 5% for some questionnaires sent by registrants to DUs.

It is recommended that the first level of communication should be for the registrant to inform that customer what they plan to consider in the registration; most suppliers should have a reasonable idea about what their substances can be used for and in what sector of business.

Experience to date has shown a higher level of compliance from DUs when asked to list “additional” uses not already covered. This approach also makes good sense for the registrant as someone (or perhaps an expensive software package) will be needed to process the response from the DUs.

In terms of the information to put on the communication, it is agreed that it is best to use the Use Descriptor System found in Chapter R.12 of ECHA’s guidance on information requirements.

Use Descriptor System

As a minimum level of communication regarding use and processes, the use descriptor codes³ can be followed. This system breaks down use information into three main categories that covers processes (activities), product categories, and industry sectors that a chemical could be supplied to and the user can communicate the relevant use or industry codes. Further descriptors can be used to cover environmental release (Chapter R.16)

These category types are described below, but it is strongly recommended that the official guidance, which we feel is very good, is consulted to gain a full understanding of how to use the system.

| | |
|---------|--------------------------------|
| SU code | Sector of Use |
| PC | Product Category |
| PROC | Process Category |
| ERC | Environmental Release Category |
| AC | Article Category |

The tables from the guidance document should be consulted and it is possible to identify most sectors of use, preparation categories and process types using these codes, but sometimes the “Other” category will be needed.

The potential exposure to consumers needs to be described within this system. If only supplied as a substance or preparation for industrial use with no onward supply in products to the consumer, this must be stated.

For hazardous substances, or for uses that are not representative of default exposures provided by models and other sources of information, more details may be required from the customers and the downstream users. Downstream users should volunteer such information to their supplier if it is thought that the use may be outside “normal” expected applications.

If the substance is hazardous to health, but not dangerous for the environment, then the environmental exposure assessment is less critical, and vice versa. Guidelines for risk assessment suggest that registrants should concentrate effort on where there is considered to be a risk.

Second tier exposure data gathering

In the case of substances of concern (hazardous) where generic default exposure parameters result in unacceptable levels of risk, it may be necessary to refine the data gathering process with more site-specific information; these details would include the following types or input, but it is not necessary to supply such information in the cases of low hazard materials:

- Annual amount used per site (kg / year): the amount of substance received and used on site. Material shipped onwards without opening of containers need not be included.
- Activity days per site (days / year) relating to the substance; for example, if it takes 3 days to blend, package and clean equipment and this takes place once a month, then activity days are simply $12 \times 3 = 36$. This information is important for worker assessment and to consider the number of days when discharge or accidental loss to the environment could take place.
- Amount of substance used (either as supplied or in mixtures) per worker per day (kg/day). This amount may be a simple division of quantity received by the number of days use and the number of workers typically involved.
- Duration and frequency of exposure per day at workplace [for one worker] hours / day: if simply turning a valve on and off on an automated packaging plant, exposure will be minutes, if any at all, but if cleaning equipment, it may take several hours. Painters, for example, will have a high hourly rate of exposure to paint.
- Process condition: includes temperatures, pressure, closed equipment etc. Initially, include any useful information that helps improve understanding of the process. Detailed information on production and mixing methods are not required and do not ask for (or give away) commercially sensitive information relating to methods of manufacture or use.
- Releases to air, water and waste before risk management: these need to be considered if known. Numerical release would be good if known, but models and default figures will



probably have to be used. However, it would help the registrant to know roughly if exposure can occur.

- Quantity to be used by consumers / general public: although generally necessary to apply defaults found in exposure estimation models, estimates can be made for certain types of material. For example, it may be possible to estimate “typical” exposure to interior paints based on the number of times the average person decorates their house.

From considering the above examples, it is clear that beyond the use of chemicals by a few specialist customers, making realistic exposure estimates is difficult and generic assessments or models will need to be used. Many industry groups have developed generic exposure scenarios (GES) to help.

Conclusions: further specific information

The use descriptor system and defaults in environmental, worker or consumer exposure models may provide sufficient information efficiently in many cases, but for high-hazardous substance or those potentially of very high concern, the generic and sometimes vague information derived from the models or descriptor system are not enough. In these cases, it will be necessary to investigate use patterns more thoroughly.

Need further help?

If you need help understanding the impact of REACH on your business, you can get advice by emailing our Helpdesk at enquiries@reachready.co.uk or calling +44 (0) 207 901 1444.

If your customers or suppliers need help, get them to sign up to REACHReady's Gold service at <http://www.reachready.co.uk/> and let us help them too!

REACHReady References

¹http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/euses

²<http://www.ecetoc.org/tra>

³ [R_12_ECHA_guidance](#)