

Exposure scenarios for REACH – why should the user care?

Hans Marquart¹, senior researcher, 030-6944733, Hans.Marquart@TNO.nl, Mat Jongen², senior researcher, Rianda Gerritsen¹, researcher, Roy Veldhof¹, researcher, Doeke van der Schaaf¹, project manager. ¹TNO Quality of Life, Food & Chemical Risk Analysis. PO Box 360, 3700 AJ Zeist, The Netherlands, ²TNO Quality of Life, Arbomanagement, PO Box 718, 2130 AS Hoofddorp, The Netherlands.

Background

REACH

REACH is the new European chemicals legislation (Registration, Evaluation and Authorisation of Chemicals). It requires registration of substances by manufacturers and importers (registrants). The hazards of the substance need to be described in a Chemical Safety Report based on data that are dependent on the volume that a company manufactures or imports. When a substance is dangerous, this report should include Exposure Scenarios for the whole life cycle of dangerous substances. An Exposure Scenario is a description of how a substance should be used safely. Authorities can evaluate the submitted dossier and the substance and an authorization will be needed for substances that are very dangerous. The Exposure Scenario is the basis for:

- estimating the exposure and thereby the risk (with available hazard data);
- communication on the method of safe use to the user.

Downstream users in REACH

Downstream users in principle do not have to register substances or make a Chemical Safety Report (CSR). However, they are obliged to use a dangerous substance in accordance with the Exposure Scenarios provided by the registrants as an appendix to the safety data sheet (SDS). If their use is different from the described Exposure Scenarios, they can provide information to the supplier of the product on how they use their product, and have the supplier incorporate it an Exposure Scenario or they can decide to draft their own Exposure Scenario. Therefore, the downstream users are stakeholders in the development of Exposure Scenarios.

This presentation explores how such Exposure Scenarios are made and why downstream users of chemical products should care about this.

Methods

REACH Implementation Project 3.2-1

REACH Implementation Projects are done under auspices of the European Chemicals Bureau to assist in implementation of the REACH legislation. Scoping and further development of the concept of Exposure Scenarios was the goal of one of these projects (RIP 3.2-1). The project evaluated potential methods to develop Exposure Scenarios and use them in assessment of exposure levels and suggested what the content and format for the appendix to the (SDS) could be.

SPORT

The European Strategic Partnership On REACH Testing (SPORT) tested some of elements of REACH, including the interaction between registrants and users of substances. Eight subprojects were done by industry groups and authorities, facilitated by consultants, for different (groups of) substances. Testing of the CSR and of SDS containing information supposed to be in line with REACH was part of some of the subprojects.

VAS_t-REACH

In a separate Dutch study as part of the VAS_t-programme, Exposure Scenarios were described “top-down” and “bottom-up” in collaboration with the paint industry and the car body repair painting shops. Information and tools that were generally available to registrants, e.g. the ECETOC Targeted Risk Assessment Tool, were used top-down in accordance with the results of RIP 3.2-1. Workplace visits to gather more information from the downstream users were used bottom-up. Representatives of the downstream users were asked for feedback on the resulting Exposure Scenarios.

Results

RIP 3.2-1

The development of an Exposure Scenario starts with a description of the use situation. This should include all relevant information on determinants of exposure, including at least use category, operational characteristics, such as type and duration of activities, product characteristics and use rates. Very important is the description of risk management measures implemented and (where possible) their effect on exposure. Conservative tools for exposure assessment are used in a first iteration of Exposure Scenario building. Other tools provide guidance for risk management measures, based on the use and the hazard of the substances, through some form of “risk banding”. These are however less suitable for quantitative exposure assessment. It was concluded that tools are needed for REACH that include the following functionalities:

- generic broad assessments with limited information needs
- supporting the identification of exposure relevant activities/processes based on the use of a substance (described by a (useful) categorisation system) or – for downstream users - based on observations at the workplace
- basic structure of unit operations / standard scenarios
- direct link to a quantitative exposure assessment tool
- more advanced tool(s) considering more detailed information on the substance or preparation, on the processes/activities and on RMMs.

SPORT

Registrants often don't know exactly how their substance is used and what controls are used downstream. Product chains can be very complex, preventing direct contacts between registrants and (end-)users. An example of a complex product chain from one of the SPORT subprojects is presented in Figure 1.

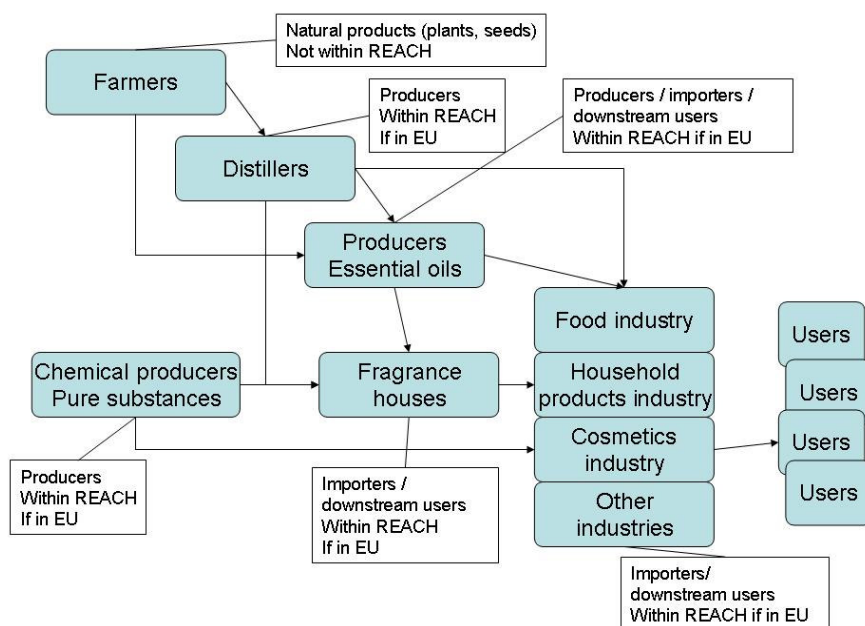


Figure 1. Example of a complex product chain

SPORT showed that there is a clear lack of suitable tools to quickly and transparently derive Exposure Scenarios. Generally, exposure assessment was done using methods that are presently used for assessing exposure to priority existing substances. Some of the tools mentioned in RIP 3.2-1 were tested, but the results were often not easily acceptable to the authorities that played the role of evaluators. The safety data sheets sent to downstream users did generally not contain a specific appendix with Exposure Scenarios. Feedback from downstream users suggested that these rather traditional SDS's did not provide useful information for them to guide them towards "safe use".

VAS_t-REACH

Exposure Scenarios have been made "top-down", with information generally available to producers and importers. The ECETOC TRA tool, which according to RIP 3.2 could be the basis of a useful tool under REACH, provided that it was modified and improved, was used as the tool for this purpose. Information available in the form of "Best Available Techniques" or similar documents formed the basis of the use descriptions for "bottom-up" scenarios. A reality check and completion of the Exposure Scenarios has been done using workplace visits. This leads to the following results.

- Reasonably detailed descriptions of processes, tasks and exposure controls, such as Best Available Techniques, are available at downstream user branches. These descriptions fit with the language and understanding of downstream users. A flow diagram of the process is a useful start (see figure 2).
- Working according to "Best Available Techniques" is not necessarily everyday practice in workplaces.
- Duration and frequency of tasks and amounts of products used are important aspects often not described in "Best Available Techniques" and similar documents. They are expected to be needed in an Exposure Scenario for REACH.

- Information on task duration is generally available. Information on frequency of tasks is less easily available. Gathering of information on amounts of products used needs substantial effort at companies to derive the information from files.
- There is not much easily available (exposure) data at downstream users to allow exposure assessment based for all relevant combinations of substances, processes, conditions and control measures. Confidentiality issues can furthermore hamper the exchange of relevant information within a branch.
 - Generic tools, such as EASE and ECETOC TRA can be used to estimate exposure levels and develop Exposure Scenarios “top-down” with only very limited specific information. However, they are broad and therefore:
 - lead to Exposure Scenarios that may not be understandable or recognisable to downstream users;
 - are inherently conservative;
 - may overestimate risks for several situations within the broad scope and/or;
 - may lead to unwarranted requirements for extensive controls for several situations within the broad scope.
 - The downstream user branches feel that working according to proper Exposure Scenarios under REACH should be accepted by authorities as proof of sufficient control of exposure.

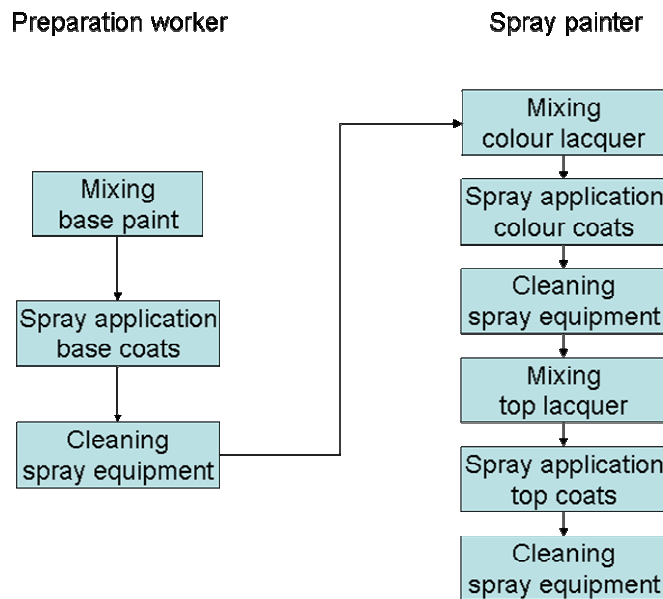


Figure 2. General process steps car body repair painting

A general finding is that “top-down” development of Exposure Scenarios focuses on exposure assessment and leads to rather broad and conservative scenarios. “Bottom-up” development of Exposure Scenarios focuses more on description of the process and risk management measures and is more specific and detailed, but may not generate sufficient information on exposure to do a proper exposure assessment (see figure 3).

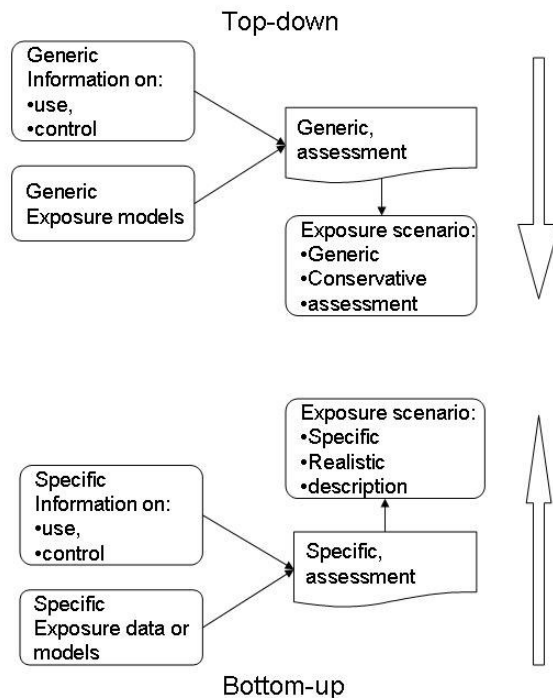


Figure 3. Top-down versus bottom-up development of Exposure Scenarios

In some cases, e.g. for car body repair painting, the whole process of a downstream user branch can be captured in one Exposure Scenario. In other cases there is substantial variability in the processes and risk management measures, related partially to the exact type of work done. For example, a paint factory producing tons of white wall paints may have much more automated and closed processes for material transfer, than a paint factory producing many different specialty paints in batches. A method to efficiently develop exposure descriptions for such a branch is being developed. This method uses a matrix of process steps and options related to technology, conditions and risk management measures in these process steps. Groups of companies can use this method to describe their exposure situation by following the process steps and choosing the relevant options. This concept of an “Exposure Scenario Builder” is welcomed by several industry branches and will be further developed in the future (figure 4).

Conclusions

Manufacturers have a lack of detailed knowledge on downstream use. They will often use generic assessment tools that are not yet suitable for quick and transparent assessment of worker exposure. The resulting Exposure Scenarios often do not fit the downstream user situation very well. These “top-down” Exposure Scenarios are generally broad (because of the tools used) and conservative. They will therefore often propose risk management measures that are aimed at a (very) worst case subset of the situations they are supposed to describe. The downstream users must then spend money on (unnecessary) controls or make their own scenario to show that their use is safe. Furthermore, the result of such

“top-down” approaches is not easily understandable to the downstream users, leading to difficulties for the downstream users in checking whether or not their situation already is in accordance with the Exposure Scenarios. If Exposure Scenarios are very conservative and overestimate risks substantially, the registrant can also decide to no longer sell this substance for this purpose.

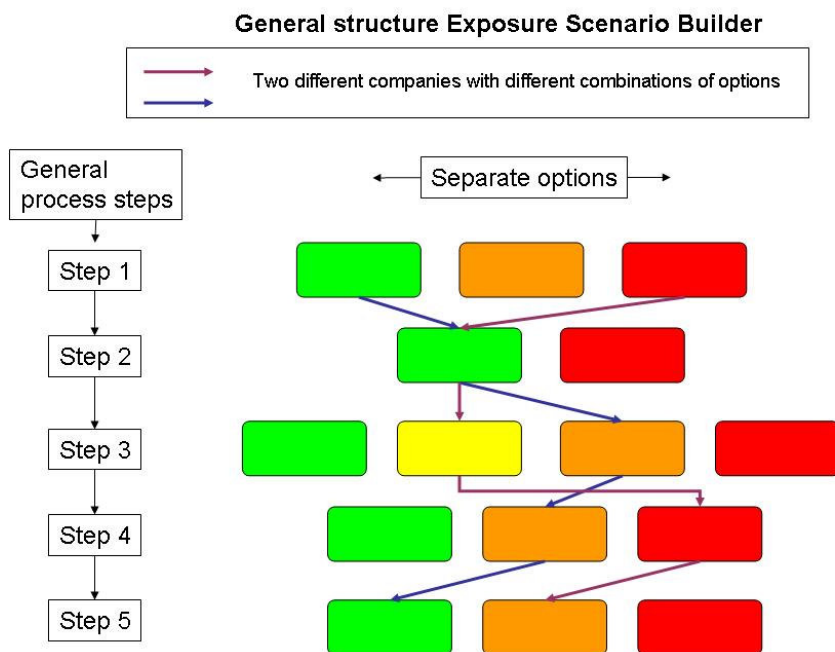


Figure 4. General set-up of an Exposure Scenario Builder; low exposure options are green, high exposure options are red

“Bottom-up”, good descriptions of use and controls by downstream users can be made. However, exposure data for the described situations are lacking or difficult to obtain. A combination of advanced tools and knowledge from downstream users is needed for useful exposure scenarios and appropriate exposure estimates. Such an approach is possible in cooperation with downstream users, but needs tackling of issues such as confidentiality.

Because of the potential difficulties that downstream users face when they need to work with “top-down” Exposure Scenarios, it is in their best interest to be pro-active. To prevent a multitude of different Exposure Scenarios, that are hardly understandable and do not fit their situation, coming from several suppliers, a concerted action by downstream user branches will be needed. These branches are the real experts on their own exposure situation and can use their knowledge to assist in developing useful realistic Exposure Scenarios. Several European branch organizations are already active in developing (partial) Exposure Scenarios. The concept of the Exposure Scenario Builder can be developed in these actions into a very useful tool. The project RIP 3.2-2 will further develop some of these concepts. To allow proper estimation of exposure levels in relation to Exposure Scenarios, TNO works together with other international groups to develop an advanced exposure assessment tool.