

Current Views on Supply Chain Communication under REACH

The European Solvent Industry Group (ESIG) acknowledges the ongoing developments to improve the utility of Human Health Exposure Scenarios/safe use communication in the supply chain. ESIG remains committed to this aim and to reviewing its approach in the light of these new developments.

At the same time, ESIG considers that the concept, structure and relevance of the Generic Exposure Scenarios remain valid and need to be kept aligned with parallel regulatory approaches such as sector use maps.

Background

Registration of substances under REACH that are classified and sold at greater than 10 tonnes requires that an exposure assessment is carried out for human health and the environment. This assessment is required to cover all the identified uses of the substance throughout the supply chain with any measures identified for the demonstration of safe use communicated via Exposure Scenarios in an Annex to the Safety Data Sheet (SDS).

Early in the REACH process, ESIG started to reach out to its downstream users (DU) by addressing them directly about their uses and collecting the answers. However, the responses received were frequently different in wording, not always conclusive and, in the end, often referred to similar uses. As a next step, the collected uses from over 15 different DU groups were brought together (under the umbrella of ESVOC) into Generic Exposure Scenarios (GES) allowing, for example, a registrant or formulator to identify and describe, for instance, a “coating scenario” regardless of any sectoral jargon.

This GES approach was adopted by Cefic as the preferred approach for the implementation of Chemical Safety Assessments for commodity chemicals¹ including the development of supporting guidance² and excel templates for use in its implementation³. It was extensively shared with stakeholders via ESIG/ESVOC workshops during development and interested parties at many of the Cefic REACH Implementation Workshops (RIW) and via the European Network on Exposure Scenario (ENES) meetings and ECHA engagement opportunities prior to ENES.

¹ Guidance on ES Development and Supply Chain Communication, Cefic, March 2009

² Developing Generic Exposure Scenarios under REACH, Cefic, July 2009

³ Generic Exposure Scenario (GES) CSA Template – Liquids, Cefic, May 2013 & Generic Exposure Scenario (GES) CSA Template Solids, Cefic, May 2013



[A peer reviewed article](#) was published in the Annals of Worker Exposure and Health (previously the Annals of Occupational Hygiene) in 2011⁴.

GES were developed in close liaison with the main DU Sector groups to ensure that safe use conditions applied when needed to demonstrate safe use reflect reality and are described in a manner relevant to the DUs and communicated in a consistent form by suppliers and their intermediaries e.g. formulators. This approach has worked since 2010. The adoption of the approach has enabled large numbers of uses to be registered and evaluated in an efficient and concise fashion, with no substantive issues having been raised by DU sectors. Where a sector flagged a slightly different or additional use – for example following the revision to the R12 Use Descriptors – then the necessary adaptations to the GESs were made.

Developments

As REACH developed, it became clear that the GES approach was not being consistently applied by all sectors. This can have several reasons, such as CSAs/dossiers being developed without proper regard for available Use Maps or supply chain communication. On the one hand, some DU sectors or companies might not have responded to manufacturers' requests for such information or, on the other hand, unrealistic RMMs or condition of use are communicated.

The poor consistency poses a real problem for the formulators and their downstream users. Formulators, in preparing SDSs for their mixtures, are required to take account of the safe use measures they receive via incoming substance Exposure Scenarios. Formulators have found this challenging, as the information they receive from different suppliers is not always in a consistent format, and some of it can contain safe use advice that is not realistic for the actual conditions of use. Currently many formulators are managing their compliance with REACH by forwarding on the substance ES for each component in a mixture attached to the mixture SDS rather than adjusting the ES by 'scaling' or carrying out a DU CSA. This is not at all helpful for the end users, who are left to interpret what is relevant safe use for themselves.

In a response to this, the Sector Use Map concept has been developed. It includes templates that allow Downstream Users to communicate up the supply chain to REACH registrants about the conditions under which typical end-uses take place, including SWEDs, SpERCs, SCEDs. Data from these templates can be taken directly into the ECHA Chesar (Chemical Safety Assessment) tool for processing.

In addition, formulators and their downstream users seek to communicate about the safe conditions of use down the supply chain in a consistent way, which is trying to be achieved with a so-called SUMI (Safe Use of Mixture Information sheet) attached to the mixtures SDS for end users. At the same time, DU associations are trying to fix existing operating conditions in SWEDs. The concentration is product related and the only flexible parameter, as it is seen as too complicated to change other parameters.

⁴ Generic Exposure Scenarios: Their Development, Application, and Interpretation under REACH. Ann Occup Hyg (2011) 55 (5): 451-464



Challenges

It has become apparent that there is an expectation from many DU sectors that the Use Maps they are now generating should be taken 'as is' into the Registrants Chemical Safety Assessments, so that Exposure Scenarios are sector-specific. This **undermines the generic nature of the GES, which seek to consolidate similar uses from across sectors into a few overall use titles**. Among the many advantages this brings is the fact that the risks from similar uses across different sectors are addressed consistently (rather than at the DU level), in addition to confidential uses being capable of being addressed in a generic way, e.g. a solvent used for the specific purpose of cleaning contact lenses can be included in the GES title 'Use in cleaning agents', without any mention of the specific application.

In a few cases, downstream user scenarios are even more general than the GES.

Another issue is the different expectations. For a formulator the basic question is: Up to which concentration is it safe to use? Whereas for the registrants a product stewardship view prevails: How can you use a substance /formulation safely?

What comes out of an ES, which presets conditions and allows only changes in concentration, is not the same as 'safe use'. It is just a set of recommended conditions of use that could fail to deliver effective safe use (for example by choosing to control risk through Operational Conditions rather than reliable RMMs) or even lead to restrictions when formulators might be tempted to just swap one substance with another, if a concentration is not "safe". This would lead to delisting of substances and hence distortion of the market, encouraged by what can be considered an illegitimate regulatory development.

So far, only a few sectors have published their use maps on the ECHA website, whereas an overview kept for many years by Cefic lists 30 different sectors. A large number of end uses are not covered by a sector or in sectors for which no use maps are being set up. So far it remains unclear how formulators will deal with Exposure Scenarios from such substances.

Way Forward

The Sector Use Maps now being developed provide a useful resource to verify the content of the ESIG GES. In addition, ESIG is in the process of revising the GES templates in such a way that they can be imported into Chesar as per the Sector Use Maps.

A supplier driven initiative that maps the different DU approaches can be a powerful resource to be put on ENES website. Therefore, ESIG is adding the available SWEDs to its overview table, which is then to be published on the website. This way, the GESs remain generic whilst continuing to reflect the key characteristics of DU uses. It also enables DUs to maintain certain distinctions between sectors – for example titles might be different but if the nature of the exposure is the same, SWED/use map naming can be matched to GES titles. A translation table or similar can cover and link wording differences in SWEDs.

ESIG will continue to monitor and engage with ECHA and the solvents supply chain to keep abreast of and influence developments in REACH exposure assessment and safe use communication in the supply chain

