

eSDS Use and Development: Meeting the Challenges
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Presenter biography

Antonio Riganelli is currently responsible for Hazard Communication in the EMEA region for The Dow Chemical Company. Accountable for the regional hazard communication strategy he is also ensuring that the local strategy is integrated with the global Hazard Communication Strategy of the Company.

Beyond his experience in Hazard Communication, Antonio worked in Dow Corning Europe S.A as the Product Safety and Regulatory Compliance Leader for new markets and geographies and several years with Selerant s.r.l. serving as a lead Consultant/Advisor to a number of companies in the process industry. He also served as an Appointed Professor at the University of Perugia, Italy. He has more than 30 publications in peer reviewed journals and is co-author of three books.

Presentation abstract

In the complex European product regulatory arena, the risk assessment consisting of Exposure Scenarios (ESs) is one of the pillars of the REACH Registration process which has represented a very challenging task for the chemical industry. According to the REACH Regulation, ESs have to be developed for classified registered substances manufactured or imported into the European territory in quantities over 10 tonnes/year.

Exposure Scenarios under REACH provide an integrated approach to controlling risks and form an integral part of the chemical safety assessment (CSA) and chemical safety report (CSR). When it comes to the exposure assessment part of these documents, REACH requires that information on exposure be translated into a verbiage which can be understood by downstream users. This is called ES for communication purposes and a Safety Data Sheet (SDS) with the ES appended is called an extended SDS, where "extended" stands for the extension represented by the ES that is attached to SDS.

The legislation requires that Exposure Scenario(s) be documented and communicated to the downstream users. However, the legislator did not adequately provide details on how this can be done. For example, no details on the format were provided except for the objectives below:

1. describe the use for which the Exposure Scenario is applicable,
2. specify under which conditions of use substances can be used safely. Therefore it is meant to provide information on the Operational conditions (OCs) and required Risk Management Measures (RMMs) that are important for safe handling,
3. document the key outcome parameters of the risk assessment to provide guidance to the user on how to apply the information in the Exposure Scenario.

In this work, we are going to present how Dow chemical has developed a fully integrated approach for the ES development with the SDS authoring process, both from a work process stand point and even more important from a system standpoint.