

REACH – Understanding the Risk Assessment Process

Introduction

Across virtually every segment of society, we witness how chemicals have delivered significant benefits to society. However, those advancements have come in tandem with exposure to greater quantities of chemicals than at any other time in history.

Today, estimates show that 400,000 new chemical compounds are created worldwide each year. In the European Union (EU) and United States alone, the chemical industry is a \$3 trillion enterprise.

With the growing number of chemicals introduced into our environment comes greater potential for human exposure. Environmental regulatory agencies worldwide have implemented rigorous risk-assessment processes to determine our risk exposure to hazardous chemicals.

Today, we stand at a critical moment in chemical risk assessment, as the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) legislation in the EU shifts that responsibility to industry, which must demonstrate the safe use of substances across their life cycle. REACH also extends from chemicals used in industrial processes to those found in our day-to-day life, including cleaning products, clothing, electrical appliances and more. The following table illustrates the fundamental shift that needs to take place for the new REACH chemical management paradigm:

	General US Practice	Change Under REACH
Burden of Proof	Government shoulders the responsibility and not the Manufacturers or importers	Burden of Proof shifts towards the Manufacturers and importers
Risk Management for Chemicals	No formal Risk management process exists. This is done on a case-by-case basis and is relatively infrequent.	As Substances of Very High Concern (SVHC) are being identified, a risk management process is established based on hazard and exposure to chemicals.
Chemical Use Restriction	Chemical use restriction is voluntary with limited number of chemical restrictions on a case-by-case basis	Unsafe uses of chemicals restricted under REACH regulations.
Substances of Very High Concern (SVHC)	HPV initiative is strictly volume based. EPA has the hazardous chemicals list, but with limited or case-by-case restrictions.	A new list of SVHC chemicals has been established by the EU as part of the REACH. List will be expanded over time requiring active chemical inventory management.

CGI Environmental Solutions Group: REACH Change Management Framework (RCMF), Part 1

Starting with Risk Assessments

A risk assessment is a systematic approach to assessing potential health risks associated with exposure to known or potentially toxic agents. As the business of chemicals expanded, Environmental Health and Safety (EHS) professionals have gained the necessary skills to recognize, evaluate, control and communicate risk as we work in partnership to minimize human and environmental hazards.

Risk to chemical exposure can be defined as the function of exposure level (duration, concentration and route of exposure) and the toxicity of the chemical. Put more simply, the higher the toxicity or the exposure, the greater the risk. For most toxic chemicals in occupational and/or domestic environments, excessive exposure and inappropriate use of chemicals directly causes elevated risk levels.

A typical risk assessment process can be broken down into four components:

- **Hazard Identification:** Determines adverse health effects in humans and/or environment, caused by exposure to chemicals
- **Dose-response Assessment:** Measures the relationship between level of exposure (dose) and the effect on humans and the environment
- **Exposure Assessment:** Evaluates the potential chemical exposures to humans and the environment from the production, distribution, use, disposal and recycle of a chemical substance
- **Risk Characterization:** Integrates those identification and assessment results to determine the probability of adverse health and/or environmental effects.

Since we as a society do not have adequate resources to control all chemical hazards at zero-risk level, even if such a thing were possible, other factors must be considered in selecting risk management goals and techniques. That decision-making today is shaped in part by economics, technical feasibility, political pressures and public opinion.

To protect public health and environmental concern, many industrialized countries have enacted laws regulating the manufacturing and importing of chemicals. U.S. regulatory agencies, including the Occupational Safety and Health (OSHA), Environmental Protection Agency (EPA) and Food and Drug Administration (FDA), have standardized risk assessment processes. Now, the EU has taken another major step forward with REACH.

REACH

REACH came into effect on June 1, 2007 with a progressive implementation schedule. Both streamlining and improving the former legislative framework on chemicals in the EU, REACH replaces some 40 existing EU regulations and directives – placing more responsibility on industry to manage risks that chemicals may pose to human health and the environment.

What differentiates REACH is that it applies not only to industrial chemicals but to those used in everyday life, such as paints, cleaning products and more. The EU faces far more complexity in establishing accountability among manufacturers, distributors, importers and downstream users in the supply chain. The immediate result is that manufacturers and importers now must supply data on chemical properties; conduct testing on physicochemical, toxicology and ecotoxicology; and develop chemical safety assessments and implement risk management measures.

Risk assessments can be valuable in many ways, including evaluating exposure to chemicals associated with consumer products, occupational settings or specific contaminated sites. There also is the option to limit the scope to a single risk estimate, which is generally used for a highly exposed individual within a population (deterministic risk assessment), or expanded to risk estimates across the full distribution of the exposed population (such as probabilistic risk assessment).

Chemical Safety Assessment

The Chemical Safety Assessment (CSA) plays an integral role in enabling manufacturers and suppliers in REACH compliance. This activity is part of the overall risk-assessment process and constitutes a key element of the Chemical Safety Report (CSR).

The CSA is designed to assess and control risks arising from the manufacturing and/or use of a substance. REACH requires a CSA to be performed for all chemicals manufactured/formulated and imported at ≥ 10 tons per year.

The basic steps for conducting CSAs are the following:

- **Human Health Hazard Assessment:** Determines the substance's classification, labeling and derived no-effect levels (DNELs)
- **Physicochemical Hazard Assessment:** Determines the substance's classification, labeling and determination of potential effects to human health
- **Environmental Hazard Assessment:** Determines the substance's classification, labeling and derivation of predicted no-effect concentrations (PNECs)
- **Persistent, Bioaccumulative and Toxic (PBT) and Very Persistent and Very Bioaccumulative (vPvB) Assessment (or substances of similar concern):** Classifies data based on degradation, bioaccumulation and toxicity with regulatory criteria; if the substance meets criteria, it is considered as PBT/vPvB substance
- **Exposure Assessment:** Identifies relevant uses of the substance and resulting life cycle steps, including generation of exposure scenario(s); an exposure estimation of humans and the environmental compartments to the substance is performed from the conditions defined in the exposure scenarios
- **Risk Characterization:** Identifies if risks to humans and the environment arising from the manufacturing, importing and uses of a substance are adequately controlled

CSA is a full life cycle impact assessment process where chemical usage during formulation or production, storage, downstream usage and disposal must be identified and assessed. Resulting data are incorporated into the CSR and, where required, summarized in the Safety Data Sheet (SDS) that accompanies the substance through the supply chain.

If the CSA identifies the need for more information about a chemical, a testing proposal must be developed and submitted in the substance's technical dossier at registration. This proposal is evaluated as part of the dossier evaluation. No testing shall be conducted before a decision is taken. Until then, the risk management measures are put in place, taking into account the need for further information.

Risk Management Measures

The primary way to communicate Risk Management Measures (RMM) to downstream users is through Exposure Scenarios. RMM are the steps that workers, consumers, and the general public must take to ensure a particular chemical exposure is minimized. RMM come in two types, including:

- **Human Health (workers or consumers):** Details the type and effectiveness of single or combined options on exposure to be quantified and specifies the oral, inhalation and dermal routes of exposure
- **Environment:** Details the type and effectiveness of single or combined options to be quantified; specifies responses for wastewater, waste gas, protection of soil, water, air, environmental organisms and related issues

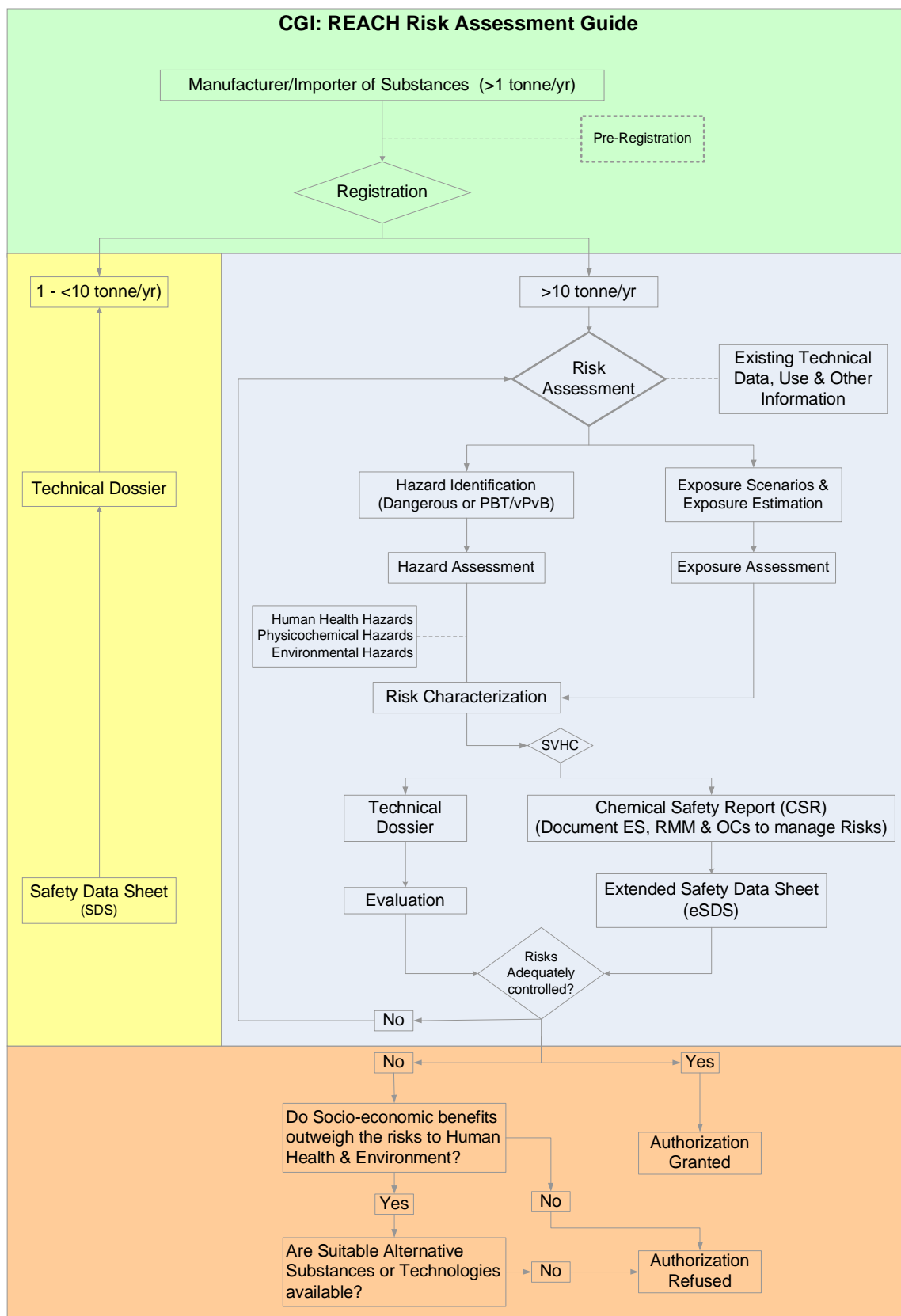
Operational Conditions of Use

Operational Conditions (OCs) of Use also serve as factors to minimize risk for the overall RMM strategy. OCs detail safe operating parameters, including:

- **Duration and frequency of use:** Specifies for workers, consumers and the environment (where relevant)
- **Physical form of substance or preparation and surface to volume ratio:** Details gas, liquid, powder, granules and massive solids and surface area per amount of article containing the substance (if applicable)
- **Concentration:** Specifies the substance on its own in a preparation or article
- **Amount used per time or activity:** Specifies for workers, consumers and the environment (where relevant)
- **Other relevant operational conditions of use:**
 - Temperature, pH, capacity of receiving environment (e.g. water flow in sewage/river; room volume x ventilation rate)
 - Wear and tear with regard to articles (if applicable); conditions related to service-life-time of articles (if applicable)

REACH Risk Assessment Guide

The accompanying flowchart below is a distilled and simplified version for the REACH risk assessment process. The guide provides a good high-level framework for EHS professionals for initiating REACH-specific risk assessment as they move forward with compliance initiatives.



Implications of REACH Moving Forward

REACH legislation has changed the way business is going to be conducted in the EU. As a result of this change US manufacturers and importers, if they want to continue doing business in the EU, will be forced to go through a range of adjustments in the following areas:

Adjustment of Business Processes to Manage Change

The following table provides a high-level framework to highlight the potential change in EHS processes moving forward. These changes will impact other existing business/operational processes. A concerted effort will have to be made to synchronize efforts across various functions within each organization to understand and map out REACH legislative implications.

	General US Practice	Change Under REACH
New Chemical Review and Assessment	Government conducts the review. If no decision is made within 90 days, the manufacture of the chemical may proceed with manufacturing the chemical.	Assessments will be conducted by Industry, not government. The information will be reviewed by the European Chemicals Agency for authorization
Existing Chemical Review and Assessment	High Production Volume (HPV) Chemicals Initiative requires hazard assessment data for ≥ 1 million pounds (~500 tonnes) .	REACH establishes a formalized process for prioritization and assessment of chemicals
Environmental Toxicity	Environmental safety is based on effluent and waste data.	Environmental toxicity data is required.
Dangerous Goods Classification and Labeling	The GHS classification is not implemented yet. If implemented, will lead to possible differences in classification and labeling with the current EPA system.	REACH has comprehensively adopted the Globally Harmonized System (GHS) for chemical classification and labeling requirements.
Risk Management Measures (RMM)	Isolation/Reduction Engineering Controls or Administrative Control for Workers.	Manufacturers and importers including downstream users must put RMM in place for workers, consumers and general public for minimizing chemical exposures.
MSDS	Standard format based on ANSI Recommendations	Approved CRS, CSA protocol for creating eMSDS
Exposure Limits	PELs – OSHA RELs – NIOSH OELs – Industry	REACH will generate new OELs for customers, workers, and consumers. Exposure Limits management will require change management initiatives.

CGI Environmental Solutions Group: REACH Change Management Framework (RCMF) – Part 2

Undertaking New Risk Assessment Process

REACH legislation is going to force EHS professionals to start looking at the risk assessment process from a new set of lenses. REACH hazard prioritization will require new CSAs. All CSAs will have to be documented in CSRs. These assessments, in turn, will require RMM strategy recommendations and OC guidelines for appropriate preventive and protective measures such as engineering controls, use of appropriate personal protective equipment, etc.

Expanding the Roles and Responsibilities of EHS Professionals

REACH is also likely to expand the role of the EHS professionals as they will not only have to look at the use, handling, storage and disposal of the chemicals within their own organization, but also for downstream users. EHS professional responsibilities will expand beyond their immediate employers and customers to downstream users. In addition, as safety data sheets are updated and standardized across the EU, EHS professionals in the US will find themselves increasingly involved in reviewing and updating their systems for health surveillance, hygiene, personal protective equipment and other occupational health safeguards to ensure conformance of control measures with a broader set of standards.

Integrating Technology and Data Management Systems

REACH is also going to push organizations to collect, track, and report more chemical data than ever before. Organizations will be forced to revisit their workflows and their IT systems to ensure their processes and technology is updated to accommodate these changes. In addition to registering substances and their approved uses through European Chemicals Agency's (ECHA) IUCLID5 system, companies also will need to tie those registered uses back to finished products so that safe uses can be communicated on the Extended Safety Data Sheet (eSDS).

Conclusion

Chemicals are here to stay. REACH regulations are now in effect. EHS professionals who have historically dealt with myriad risk assessment approaches will now have to come on a common platform to standardize their methodologies to conform to REACH requirements. Apart from understanding the REACH specific risk assessment methodology, EHS professional will now play a critical role in full chemical life cycle advocacy where the impact of chemical usage during formulation or production, storage, downstream usage and disposal will have to be documented and communicated to understand overall business risk implications.

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