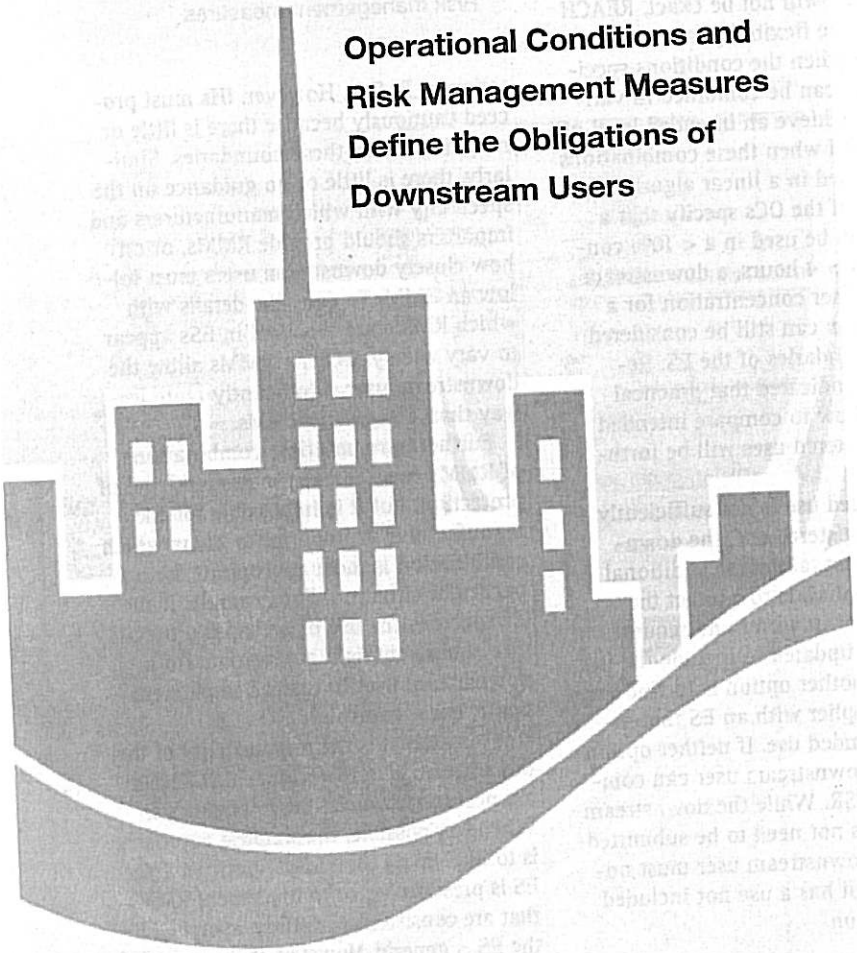
The Boundaries of REACH

Operational Conditions and Risk Management Measures Define the Obligations of Downstream Users



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REACH (Registration, Evaluation, Authorization and restriction of CHemical substances), the European Union's regulation on chemicals and their safe use, is fundamentally changing the way environmental and occupational hygiene is practiced. REACH impacts any company that puts products into the EU market, but especially impacts those that have manufacturing facilities in the region.

The parties responsible for putting REACH-regulated substances into European markets must, when certain criteria are met, develop quantitative hazard and exposure estimates and document, using a risk assessment, that the substances are safe for their registered uses. This information must be documented in a chemical safety report (CSR) and communicated to downstream users via exposure scenarios (ESs) as part of the extended safety data sheet (eSDS). REACH obligates downstream users subject to the regulation to follow the operational conditions (OCs) and risk management measures (RMMs) that are detailed in the ES. In aggregate, the OCs and RMMs define the conditions of use under which the substance can be safely used.

While the practicing industrial hygienist has an important role in the development of ESs, CSRs and eSDSs, this article focuses on their role in the downstream implementation of the conditions of use specified in the ES by the manufacturer or importer.

Exposure Scenario

In the context of REACH, an exposure scenario is a set of conditions that describes how a substance may be used so that the potential human exposure and environmental release are controlled to below acceptable limits. The use is therefore determined to be "safe." These conditions include both the OCs and RMMs.

OCs are the parameters that prevail during manufacture or use that might have an impact on exposure or release. These parameters include the physical form of the substance and process details such as amount, duration, frequency of use, and workplace dimensions. REACH guidance loosely defines a minimum set of OCs that should be included in every scenario. RMMs also impact exposure or release, but, in contrast to OCs, are purposely introduced during manufacture or use. RMMs primarily include engineering controls and personal protective equipment. Depending on the situation, a specific parameter can be either an OC or an RMM.

The requirements for an ES are spelled out in Section 5 of Annex I of the REACH regulation (EC 1907/2006) and focus on the OCs and RMMs. Additional details on the ES are found in the expansive set of guidance on information requirements and chemical safety assessment available on the European Chemical Agency's (ECHA) website (http://echa.europa.eu/). An ES should describe the uses and activities it covers (title sections), provide information on calculated

risks including exposure estimates and risk characterization ratios, and give advice on how to establish whether a use is within the boundaries of the ES.

In addition, ECHA guidance describes a building-block approach (also known as the contributing scenario approach) to authoring an ES. In general, the conditions relevant to the control of environmental releases are often facility-based, while those relevant to human exposure are often task-based. As a result, an ES will likely contain one set of conditions for controlling environmental releases and multiple sets of conditions for controlling human exposure.

Intended vs. Registered Uses

One of the more subjective and difficult decisions IHs need to make under REACH is determining whether their intended use of a substance has been registered by the manufacturer or importer. This determination can require extensive interpretation and professional judgment because the intended use is rarely an exact match with the description of a registered use in the ES.

The goal of this assessment is to establish that the intended and registered uses are sufficiently similar. The registered uses are described in the title section of the ES. Fundamental to this section is the concept of "use descriptors." The REACH use descriptor system is a set of five descriptor lists, which together briefly describe the use and serve as the ES's short title. The four substance-specific descriptor lists are:

- sector of use category (SU), which describes the sector of the economy the use is in;
- chemical product category (PC), which describes the type of products the use is in;
- process category (PROC), which describes the application techniques used; and
- article category (AC), which describes the type of articles into which the substance is eventually processed.

The fifth descriptor list is the environmental release category (ERC), which groups uses and activities with typical releases into the environment. Unfortunately, these descriptors, especially the PROC, can be interpreted broadly, so an understanding of the registered uses is often based on additional descriptive text provided by the ES author. Therefore, functional experience with the use descriptor system is essential in order for the IH to determine whether the intended use is sufficiently similar to the registered use. In addition, some of the use descriptors are assigned exposure characteristics and thus serve as input parameters to some of the available tier 1 exposure modeling tools for REACH. (Tier 1 models are the simplest and most conservative models and are often the first to be used. If safe use cannot be demonstrated using a tier 1 model, one option is to use a more complicated, but also more detailed and flexible, higher-tiered model.)

Because the fit between intended and registered uses will not be exact, REACH allows for some flexibility (also known as "scaling") when the conditions specified in the ES can be combined in various ways to achieve an intended level of protection, and when these combinations can be described in a linear algorithm. For example, if the OCs specify that a compound can be used in a < 10% concentration for > 4 hours, a downstream use with a higher concentration for a shorter duration can still be considered within the boundaries of the ES. Recently, ECHA indicated that practical guidance on how to compare intended uses with registered uses will be forthcoming.

If an intended use is not sufficiently similar to a registered use, the downstream user must take some additional actions. One option is to contact the manufacturer or importer and request that the ES be updated to include the intended use. Another option is to find an alternative supplier with an ES that includes the intended use. If neither option is possible, a downstream user can complete its own CSR. While the downstream user's CSR does not need to be submitted to ECHA, the downstream user must notify ECHA that it has a use not included in the registration.

Implementation

While scaling addresses the conditions of use as a whole, the guidance focuses primarily on the boundaries of the OCs. Nonetheless, there is flexibility, within reasonable boundaries, for the implementation of RMMs. However, IHs must proceed cautiously because there is little or no guidance on these boundaries. Similarly, there is little or no guidance on the specificity with which manufacturers and importers should provide RMMs, or on how closely downstream users must follow an RMM. To date, the details with which RMMs are specified in ESs appear to vary widely. Generic RMMs allow the downstream user significantly more leeway than do specific RMMs.

Furthermore, multiple combinations of RMMs can achieve the desired level of protection, but it is impossible for the manufacturer or importer to know which combination is most appropriate for a particular situation. For example, if the ES specifies the use of personal protective equipment, is it appropriate for a downstream user to instead implement engineering controls?

Ultimately it is the responsibility of the downstream user to decide which RMMs are necessary to meet their obligations. Whenever possible, the simplest approach is to implement the RMMs specified if the ES is prescriptive, or to implement RMMs that are consistent with those specified if the ES is generic. However, if the specified RMMs are not the best choice, IHs will have to decide how far they're willing to stretch the boundaries of the RMMs before asking the manufacturer or importer to expand them, or to complete their own chemical safety assessment. At a minimum, IHs should determine, via modeling,

The ABCs of REACH

A list of acronyms used in this article:

CSR
Chemical safety report

DNEL
Derived no effect level

ECHA
European Chemicals Agency

ES
Exposure scenario

eSDS
Extended safety data sheet

OCs
Operational conditions

RMMs
Risk management measures

measurement, or both, that an equivalent or higher level of protection is being provided. This decision should be sufficiently documented. Note, too, that when exposure measurements are used to support a decision under REACH, the data set is expected to be representative and robust.

Multiple ESs, Single Workplace

Compliance with a single ES can be complicated. But very few, if any, manufacturing processes include only one substance. If a manufacturing process includes two REACH substances, the intended use will have to be sufficiently similar to two independently registered uses.

Let's assume that the two sets of OCs are sufficiently similar. It is still possible that some RMMs are redundant, incompatible, or even contradictory, requiring the downstream user to determine whether a subset of the RMMs reasonably fits within the boundaries of the two ESs. If not, the user will need to either ask one or both manufacturers or importers to modify its ES or complete their own chemical safety assessment. Since the possibility of redundant, incompatible or contradictory RMMs increases with each additional ES, REACH compliance will take considerable effort for complicated manufacturing processes that need to comply with multiple ESs. And because of the staggered implementation of REACH, new eSDSs will continue to be made available for preregistered substances through 2018, and continuously for new substances and substances that cross new tonnage thresholds. This increases the likelihood that, after having conducted an assessment to meet one vendor's RMMs, a downstream user could receive a new eSDS with additional ESs, requiring a reassessment.

Coexistence of DNELs and OELs

DNELs (derived no effect levels) and OELs are quantitative estimates of "safe" levels for human exposure and are derived by applying safety factors to a no observable adverse effect level (NOAEL), a lowest observable adverse effect level (LOAEL), or another toxicological point of departure. However, the intended purpose of an OEL is to establish the acceptable limit of exposure in a workplace, while that of a DNEL is to establish the OCs and RMMs that define the safe use of a substance within a specific ES. As a result, the obligation of downstream users, under the EU Chemicals Directive, is to maintain exposures below the OEL. Under REACH, the obligation for the downstream user is to implement the OCs and RMMs specified by the manufacturer or importer.

The mandatory inclusion of both the applicable DNELs and the national OELs (for the EU member state in which the safety data sheet is being provided) in section 8.1 of the new EU eSDS may well cause confusion. When both a DNEL and a national OEL are provided for a substance, the OCs and RMMs must be implemented, but exposures must be controlled to below the national OEL. When no national OEL exists and only a DNEL is provided, the OCs and RMMs must be implemented. It is good practice to monitor the resulting exposures, but the DNEL is not the default limit for exposure control. When other, non-national OELs, such as the ACGIH® TLVs® or AIHA® WEELs, differ from the DNELs, IHs should consider whether these consensus limits are more robust than the limits set by the manufacturer or importer. Of particular concern are DNELs from multiple sources that can vary significantly from one another. If there are no national or consensus OELs, the DNELs may be a reasonable default limit for control, but IHs should understand their intended uses, limitations, and how they were derived.

As mentioned earlier, downstream users may deviate from the OC and RMM recommendations of the manufacturer or importer. In this case, users must develop their own ESs and demonstrate, by either modeling or a robust set of sampling data, that the anticipated exposure associated with the alternative OCs and RMMs is less than the DNEL. However, the role of the DNEL ends with the finalization of the ES. If there is a national OEL for the substance, the workplace limit will be the OEL and not the DNEL.

DNELs are not intended to be, or replace, OELs. Rather, they are part of the REACH assessment process designed to establish OCs and RMMs. They also conveniently fill a gap that exists due to the insufficient number of national and consensus OELs. However, DNELs are developed by the manufacturer or importer, and therefore may not have the scientific rigor or broad peer review of national and consensus OELs. The coexistence of DNELs and OELs in a workplace will not always be straightforward, so training on this topic should be provided to all affected individuals.

New Boundaries

Under REACH, the OCs and RMMs specified by the manufacturer or importer set a boundary around how a safe working environment can be established and maintained. These specifications can provide much-needed assistance to small- or medium-size enterprises that lack dedicated occupational health and safety resources. However, unless managed carefully, they can also limit a robust occupational health and safety program's ability to maintain a safe working environment in a responsive and cost effective manner.

To be effective members of a REACH compliance team, IHs must develop three skill sets. First, they must cultivate a thorough understanding and a functional expertise with obligations of REACH, the concept of an ES, and the details of OCs and RMMs. Second, they must add exposure assessment skills to their repertoire, including an understanding of both sampling/analytical and modeling techniques. And finally, they must foster the art and science of deciphering OCs and RMMs and developing exposure control strategies that fit within their boundaries.

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