Safety Guideline SG-C-0-0-4

REACH – ADVICE CONCERNING THE DUTIES FOR DOWNSTREAM USERS OF CHEMICALS

Abstract
This Safety Guideline is intended to provide practical advice concerning the steps to be taken if you use hazardous substances which have been registered under REACH1.

DOCUMENTATION

Reference documents:

Further reading:
- Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- Guidance Fact sheet – Guidance for downstream users :
- The Candidate List of Substances of Very High Concern (SVHC) for Authorization: https://echa.europa.eu/candidate-list-table

TRACEABILITY

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<table>
<thead>
<tr>
<th>Rev. No.</th>
<th>Date</th>
<th>Description of Changes</th>
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<tbody>
<tr>
<td>2</td>
<td>30/05/2017</td>
<td>Under Further Reading and in text, removal of reference to Directive 67/548, replaced by Regulation no. 1272/2008 and update hyperlink to candidate list. Chapter 3, update of numbers of substances on the candidate and authorization list. Removal of obsolete hyperlink to authorization list.</td>
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1 Registration, Evaluation, Authorisation and restriction of CHEmicals.
1 INTRODUCTION

Under REACH, chemicals that are manufactured or imported into the EU need to be registered with the European Chemical Agency (ECHA) in Helsinki. REACH is intended to provide improved information on the hazards of chemicals and how to use them safely. This information will be passed down the supply chain by chemical manufacturers and importers through improved Safety Data Sheets (often called ‘extended Safety Data Sheets’, eSDS) compiled in line with the requirements of Commission Regulation (EU) 453/2010.

This Safety Guideline is intended to provide practical advice concerning your duties if you are a user of hazardous substances which have been registered, i.e. if you are a ‘Downstream User’2 as defined by REACH.

If you are such a Downstream User your suppliers will start to provide you with the new, extended safety data sheets. The new eSDS should include:

- The REACH Registration number, RN (section 1.1 of eSDS);
- The main identified use of the substance and uses which are advised against (section 1.2 of eSDS);
- E-mail address of competent person (section 1.3 of eSDS);
- New threshold values of the exposure levels for human health and the environment that should not be exceeded3 (section 8 of eSDS);
- One or more exposure scenarios, as an annex or attachment4.

Exposure scenarios should have a standard structure:

- Short title;
- Processes and activities covered;
- Duration and frequency of use;
- Amounts used over a given period/activity;
- Other operational conditions (e.g. temperature);
- Risk Management Measures (e.g. local exhaust ventilation, ppe);
- Predicted exposure;
- Advice to downstream users on how to check whether or not they work within the boundaries.

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2 Downstream User – someone who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities.

3 DNELs = Derived No Effects Levels and PNECs = Predicted No Effects Concentrations

4 Exposure scenarios must be prepared if more than 10 tonnes per year of a substance subject to registration is manufactured or imported, and the substance is classified as dangerous or is regarded as PBT/vPvB (see section 3).
2 WHAT DO YOU NEED TO DO?

From the moment you receive an eSDS with a registration number you need to take the following steps:

1. Check whether your uses are covered in section 1.2 of the safety data sheet and in the exposure scenarios, if attached;
2. If your uses are covered, compare the conditions of safe use described in the exposure scenarios with the actual conditions of use;

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Ensure you are working within the conditions set out in the exposure scenario. The level of worker protection for your use must be equivalent or stricter, resulting in lower exposure.

If you use a different combination of operational conditions and risk management measures, it may be possible to use Scaling\(^5\) to demonstrate that you achieve the same level of safety.

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In terms of deadline, you have, from the moment you receive an extended safety data sheet:

- 12 months to implement the measures described in the eSDS.

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Downstream users must communicate “new” information on the hazardous properties of substances to their suppliers. For example, acute health effects observed at the workplace for which information has not been communicated to you by your supplier and which is not available in public data bases or literature.

You must also inform the HSE Unit: Jonathan.Gulley@cern.ch

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You must also perform/review your chemical risk assessment\(^6\) to ensure the risk management measures included in the exposure scenario are taken account of.

You should inform your supplier of any risk management measures in the exposure scenario which you consider to be inappropriate.

You must also inform the HSE Unit: Jonathan.Gulley@cern.ch

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3. If your use or your conditions of use are not covered you must either:
   i. Ask your supplier, in writing, to include your use in their chemical safety report and to provide you with a revised exposure scenario (need to share information with supplier on the operational conditions you employ);
   ii. Adapt your activity to the conditions of safe use as described in the exposure scenarios;
   iii. Find another supplier who can provide an exposure scenario covering your use;
   iv. Use another substance.

If none of the above are possible, you must carry out your own Chemical Safety Assessment.

In terms of deadline, you have, from the moment you receive an extended safety data sheet:

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\(^5\) Scaling is only possible for the parameters specified by the supplier and only in accordance with his scaling instruments.

\(^6\) As required by the Safety Regulation on Chemical agents (SR-C, Ref. 1)
12 months to carry out your own chemical safety assessment and prepare your own downstream user chemical safety report (including eSDS, with attached exposure scenarios). See exemptions below;

A Chemical Safety Report is not required if:
- an SDS is not required (e.g. if the chemical is not classified as hazardous); or
- the registered tonnage for the substance is < 10 tonnes; or
- you use < 1 tonne of the substance per year.

You still need to identify and apply appropriate risk management measures.

3 OTHER ACTIONS

It is important to ask questions of all your suppliers to know what stage they are at in registering the chemicals that they supply to you. In particular, for the use of unusual chemicals which are critical for CERN activities, you should ask to be informed of any which will not be registered at a future date and therefore will no longer be supplied, or to potential changes in formulations which will effect you. There may also be increases in cost. You may need to find an alternative supplier or even re-design a process.

You should always order chemicals manufactured outside of the EU through an EU supplier (importer) or through an ‘Only Representative’ appointed by a non-EU supplier. This is to ensure that you will not be considered as an importer of chemicals but rather as a downstream user.

A further objective of REACH is to phase-out substances which are extremely hazardous or dangerous for human health and/or the environment, from consumer and industrial products. Under REACH, such substances are termed Substances of Very High Concern (SVHC) and fall into one of the following categories:
- carcinogenic, mutagenic or toxic to reproduction (CMR) substances of of category 1a or 1b in accordance with EU regulation (EC) No 1272/2008;
- persistent, bio-accumulative and toxic (PBT) substances in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- very persistent and bio-accumulative (vPvB) in accordance with the criteria set out in Annex XIII of the REACH Regulation;
- substances which can seriously and / or irreversibly damage the environment or human health, and substances which have endocrine disrupting properties.

A list of such substances, called the Candidate List of Substances of Very High Concern (SVHC) has been established and is regularly updated. Some substances from the candidate list will be prioritized for authorization and be included in Annex XIV of REACH ("SVHC authorization list"). Those substances on the authorization list will not be allowed to be used, placed on the market or imported into the EU after a set date unless an Authorization is granted.

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7 A legal person established in the Community to fulfill, on behalf of a manufacturer or supplier outside the EU, the obligations on importers regarding the registration of substances. The only representative shall also comply with all other obligations of importers under REACH.
As of the date of publication of this guideline, there are:

- 173 substances on the SVHC candidate list; and
- 31 substances on the SVHC authorization list.

You should be aware of whether or not you use any SVHC by checking the Candidate List periodically (see link under ‘Further Reading’). If you do use substances which appear on the Candidate List you should consider using alternative chemicals to avoid future supply problems.

4 DEADLINES FOR REGISTRATION

For information, the deadlines for registration by the manufacturer, importer or an ‘only representative’ depend on the quantity of the chemical concerned that is manufactured or imported into the EU, as shown in the table below.

<table>
<thead>
<tr>
<th>REACH Deadlines</th>
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<td>1 June 2007</td>
<td>REACH comes into force</td>
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<td>1 December 2010</td>
<td>End of the registration period for:</td>
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<td>CMR (cat 1 and 2) ≥ 1 t/y</td>
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<td>R50/53 (environmentally hazardous) ≥ 100 t/y</td>
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