

Guidance for Downstream Users

Introduction

Many Downstream Users (DUs) are concerned about continuity of supply to ensure the stability of their businesses. Our helpdesk receives enquiries from such companies wanting to know what they should be doing to ensure compliance with REACH and in order to protect their business. We have prepared this short guide to help DUs understand the registration process and how it might affect them, and also to help manufacturers and importers understand how they can support their customers and allay some of their fears.

Uses and Downstream User rights

The legal text gives DUs the right to inform their suppliers of their supply chain's uses (Article 37(2)). In doing so, they are asking for their suppliers to consider those applications for inclusion in the registration dossier as "identified uses".

Many of our subscribers ask whether registrants are obliged to include a use unless it poses unreasonable risk to human health or the environment. This situation is often important for small DUs, and those with niche applications. Our understanding is that a supplier may choose not to support a use if it does not make commercial sense. In this situation the supplier needs to stop selling for that use. REACH does not oblige companies to include all uses communicated to them as either "identified uses" or "uses advised against"; REACH is as much a business issue as a regulatory matter, and companies may take business decisions against supporting some uses. Inevitably, the commercial decision not to support a use can have consequences on the business of the Downstream User.

Note that if a supplier cannot include the use in the registration due to human health or environmental risks they are obliged to inform both the DU and ECHA of the reasons without delay. This use is considered as "advised against", and the DU needs either to stop or to demonstrate through assessment that the use is indeed safe.

For registered substances, the DU's request needs to be given to the supplier at least one month before the next supply of the substance, be it alone or in a mixture.

Helping your supplier to assess uses

Suppliers need to have enough information to allow them to consider uses. In making a use known, a DU needs to provide sufficient intelligence to assess exposure. Experience from 2010 registrations shows that reporting uses only by means of combinations of the use descriptor codes may not provide all the information the registrant needs for an assessment. The Operational Conditions and



typical Risk Management Measures applied by the DU should also be communicated: if you want to encourage your supplier to identify your use, give them the information they need to assess it!

Phase-in registration deadline issues

The final phase in registration deadline was in May 2018 therefore, all manufactures and importers who are manufacturing or importing more than 1 tonne of substance per year need to have a registration in place before they can supply DUs.

This means that if your supplier missed the final deadline, they must not supply to you until they have a valid registration in place.

Consequences of uses not being included

DUs whose uses are not supported by their suppliers may find they are unable to source their substance or mixture from those suppliers. They may need to change their use patterns to fit those covered by the registration, or to assess those uses themselves. DUs whose use is not covered in the registration may need to inform ECHA and they may need to prepare their own Chemical Safety Report. They may need to find alternative supply routes, possibly even becoming importers and themselves and submitting a registration. And of course, existing suppliers may well lose contracts!

Exemptions from the Downstream User Chemical Safety Report

Even if your use is not included in your upstream supply chain's registration there are situations when you as a DU do not need to prepare their own Chemical Safety Report (CSR). If one or more of the following criteria apply, then a DU CSR is not required:

- ✓ The substance or mixture does not need a safety data sheet (substance is non-hazardous);
- ✓ The supplier is not required to prepare a CSR for the substance;
- ✓ The DU uses the substance or mixture at less than 1 tonne per year;
- ✓ The substance is present in a mixture below certain concentration limits (see Article 14(2));
- ✓ The DU alters their use pattern to fit the exposure scenarios covered by the registration;
- ✓ The use is under Product and Process Orientated Research and Development (PPORD) and the risks to human health and the environment are adequately controlled.

Updating SDS, preparing a DU CSR, notifying ECHA of uses

Once a substance is registered, the registrant will receive a registration number. Any safety data sheet (SDS) for this substance must then be updated to include the registration number and exposure scenarios for the identified uses; this obligation applies to each actor in the supply chain and not just the registrant.

If a DU is required to prepare their own CSR they must do so within 12 months of receiving that registration number on the SDS.



If a DU is required to report information on their use to ECHA, they must do so before starting the use or continuing with an existing use before the next instance of use, and also within 6 months of receiving the registration number on the SDS. Note that even if a DU CSR is not required because the substance/mixture is used at less than 1 tonne per year, notification to ECHA is still required.

Contingency planning

Managing REACH involves working with your supply chain to ensure continuity of supply and compliance, as well as planning for if and when things going wrong. Establishing a contingency strategy should be part of your Business Continuity Plan and will ensure your company copes with business continuity hurdles.

Practical methods to ensure business continuity will vary between sectors and indeed companies. Some of the following tips may help to get you started:

- ✓ Establish and maintain good relationships and communication routes with your supply chain;
- ✓ Negotiate with your supplier to include your uses;
- ✓ Feasibility of changing your use patterns to fit those covered by the registration;
- ✓ Is your own DU CSR required, or does an exemption apply?
- ✓ If a DU CSR is required, can you do it in-house or do you need some help?
(Consider our Matchmaker service if you need support
<http://www.reachready.co.uk/reachmatchmaker.php>)
- ✓ Do you have secondary suppliers, or can you source your materials from suppliers who already, or intend to, cover your uses?

Further help

Are you still concerned about your obligations and options, or about business continuity in light of your supplier's registration? Come along to one of our Downstream Users workshops and get more detailed guidance. For more information and a booking form, see our training page http://www.reachready.co.uk/services_training.php.

As a gold subscriber you can also speak to one of our experts about your obligations and a compliance plan. Please contact our Helpdesk at enquiries@reachready.co.uk or on +44 (0) 207 901 1444 with details of your enquiry.