Regulatory Impact Report

The impact of REACH on downstream users

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- Resetting a baseline for chemicals known to be in the market in Europe.
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Introduction

The EU’s REACH Regulation has been in the process of being implemented since 2007 and vast quantities of information have been disseminated about it. Even so, many companies are still, to varying degrees, unaware of how the Regulation actually works and how it will affect them.

Some believe that the whole process came to an end on 31 May 2018, when the last of three volume-based registration deadlines passed. This is not correct: obligations continue indefinitely. As has been stated many times, 2018 is not the end of REACH, or even the beginning of the end, only the end of the beginning.

REACH has important implications for those who use chemicals – just about every large manufacturing industry, in other words. ‘Downstream users’, as the Regulation defines them, did not have any registration requirements but they do have important obligations in communicating information about the use of chemicals back up the supply chain.

In addition, they are likely to be affected if any of the chemicals they use disappear from the market, either because no-one registered them in time, or if they are subject to any of the processes REACH uses to control chemicals deemed hazardous to human health and/or the environment.

Information has been perhaps the single biggest challenge of REACH. Many companies did not know – because often they did not really need to know, or because their immediate suppliers did not know either and/or did not have to tell them – exactly what chemicals went into the products they bought. Now they do. And they also have to communicate with suppliers more regularly and in more depth than ever before.

Many downstream sectors have now realised that REACH has significant consequences for business and have been helping their members with their compliance obligations. It is important that the entire supply chain is up to speed with the legal framework in all its complexity, not least because the regulatory emphasis is now shifting from information-gathering to enforcement.

This Regulatory Impact Report aims to help companies using chemicals within the purview of REACH to understand the basics of this complex and novel regulation, as well as their roles and compliance obligations, and what to watch out for. It includes an introduction, a deeper dive into the safe use obligations and authorisation provisions, some top tips and definitions of the law’s key terms, responsibilities and some statistics. There are also links to key sources of additional information.

Dr Andrew Warmington
Editor - Regulatory Impact Report

Who is Chemical Watch?

Chemical Watch provides the global business community with the facts and perspectives it needs to achieve safer chemicals in products.

With a team of expert journalists keeping you abreast of global policy and business trends, our ultimate goal is to help you meet your responsibilities under chemicals legislation worldwide, including regimes such as REACH, GHS and TSCA. We are not tied to any trade associations, governments or campaign groups, which means we are able to offer objective news and analysis for all sectors.

Alongside our authoritative news coverage, we also support your professional development with our intensive courses, premium webinars and eLearning offering. Together they provide you and your teams with the training you need to manage the risks of chemicals in the workplace, through the supply chain, and in products.

To find out more about Chemical Watch and our coverage of regulatory developments in your sector, feel free to have a look at our sector pages, or take a free trial to get full access to all our coverage for two weeks.
The impact of REACH on downstream users

The EU’s REACH Regulation imposes obligations on users, as well as manufacturers and importers

It is estimated that about 98% of manufactured products incorporate or rely on industrial chemicals. As such, almost every company making or selling products in the EU needs to be aware of REACH – the EU Regulation for the registration, evaluation, authorisation and restriction of chemicals.

However, many in the wider supply chain, downstream of chemical manufacture, may not fully comprehend their obligations under the legislation, and that its impact on business continuity can be significant. Companies using chemicals in the EU face three key threats to their business:

• substances are disappearing from the market as manufacturers and importers decide, for one reason or another, they are not worth registering under REACH – such substances are illegal under the ‘no data, no market’ provisions;

• risky chemicals identified under the Regulation are facing control measures and substitution; and

• there is an increased likelihood of enforcement action as authorities focus on safe use obligations – where downstream users have specific responsibilities.

To ensure continuity, savvy businesses need to know what chemicals are critical to their processes and products (see box ‘Creating an inventory’). They can then check the registration status, and, with a bit of research, the likelihood of further regulatory action. A good understanding of REACH, coupled with proper record-keeping and documentation of compliance efforts, should keep the inspectors happy.

“REACH defines a downstream user as "a natural or legal person established in the Community, other than the manufacturer or importer, who uses a substance either on its own or in a preparation, in the course of his industrial or professional activities"
Background

REACH has been in force since 2007. Its key aims are to protect human health and the environment, while enhancing competitiveness and innovation across the EU. Principally, it tackles the lack of knowledge that existed about the risks resulting from the use of tens of thousands of chemicals in commerce. The Regulation places the burden of proof on industry to supply the data on hazards and uses, assess risks and advise on safe use (see box ‘The elements of REACH’).

Under REACH, any company or individual in the EU or European Economic Area (EEA) that uses chemicals in its business is classified as a ‘downstream user’, even when chemicals are not the main element of its goods or services. Downstream users are mentioned over 120 times in the regulatory text.

The European Chemicals Agency (Echa), which is responsible for managing and carrying out technical, scientific and administrative aspects of the Regulation, has prepared numerous guidance documents to help downstream users, including a web page specifically for them and an interactive map of relevant information. EU member states also provide assistance through their national helpdesks. Chemical Watch has specific sector pages on its websites, as well as events and other relevant publications.

It is not just the obvious contenders, such as paint manufacturers and companies that develop cleaning agents, that are covered. REACH also impacts food processors, pharmaceutical companies, textile manufacturers, automobile, aerospace and electronics companies, among many others.

Downstream users can undertake a huge variety of activities and REACH imposes different obligations based on those activities, so careful assessment is required. There are four defined – and reasonably logical – downstream user categories and the distinctions between them are important:

- ‘formulators’, who produce formulations of chemicals for their customers – for example, paints, adhesives or detergents;
- ‘end users’, who directly use these formulations, such as construction or cleaning companies;
- ‘producers of articles’, who use them to manufacture goods, from cables to ziplock bags; and
- ‘refillers’, who transfer materials from one container to another.

Some companies may think they are downstream users when they are not. Distributors, retailers and consumers, for instance, are not considered downstream users. However, distributors, who only store and supply chemicals, do have obligations regarding information flow within the supply chain and retailers must fulfil obligations to respond to requests about substances of concern in products.

REACH is intended to complement and support existing EU environment, health and safety (EHS) legislation, and sector specific regulations (see box ‘EU sector-specific regulation interfacing with REACH’).

Downstream users should therefore comply with all the legal requirements in the markets where they operate. In general, if different pieces of legislation set different requirements, the more restrictive ones apply. Chemical Watch’s business stories and most sector trade groups can help on this topic.
Downstream user obligations -
a focus on safe use

First of all, downstream companies need to ensure the substances they use are legally permitted on the EU market – that is, they have a valid registration, if one is needed. For inspections, they should have documented evidence that their suppliers have registered the substance or that it is out of the scope of REACH.

Downstream users, whatever their role, have an obligation to support the safe use of chemicals, implementing advice from their suppliers and communicate relevant information to their customers and back up to suppliers if necessary.

Substance manufacturers and importers take the primary role in registering substances – being responsible for generating and collecting the hazard and use data, preparing chemical safety assessments (CSAs) and documenting that information in chemical safety reports (CSRs). However, downstream users are not secondary players in the roll-out of REACH. They are vital links in the compliance chain.

Exposure scenarios

The key tool to communicate safe use through the supply chain is the extended safety data sheet (eSDS). An eSDS is required for all hazardous substances registered under REACH in quantities over ten tonnes/year.

The word ‘extended’ refers to the exposure scenarios (ESs) from the substance’s CSR, which is part of the REACH registration dossier. This provides specific information on how to use a substance, or mixture containing it, safely, and how a business can protect its workers and customers and the wider environment.

EU sector-specific regulation interfacing
with REACH

- cosmetics Regulation;
- restriction of hazardous substance in electrical and electronic equipment Regulation (RoHS);
- toy safety Directive;
- medical devices Regulation;
- food contact Regulation;
- construction product Regulation;
- safer detergents Regulation; and
- biocidal products Regulation.

Downstream users have an obligation to ensure the descriptions in the eSDSs – including operational conditions and risk management measures – adequately match their uses. The advice should cover manufacturing and industrial, professional or consumer uses, and also the service life of any finished products and articles.

Businesses have to contact their supplier if the description of use is markedly different from the way a downstream user (or in some cases its customers) uses the product.

Appropriate measures

To check if the use of a substance or mixture is covered by an ES, a company needs to:

- gather information on how it will use the substance; and
- establish whether its actual use and conditions of use match the conditions described in the ESs.
If the use is covered, downstream users should make a record of the checks that established this, in case of inspections, and provide relevant information on safe use to their customers, if necessary. When the use is not covered, they have a number of options. They can:

• implement the conditions of use described in the ES;

• make their use known to their supplier and request an updated ES;

• substitute the chemical with a different substance for which an ES is not required or where one is available that covers the conditions of use, or find a supplier who provides the substance or mixture with a scenario that covers the use; or

• replace the process with one not requiring the substance.

Downstream users may also prepare their own CSR, if their use is outside the conditions described in the ES provided by the supplier. They have to report to Echa within six months if they intend to prepare a CSR, then they have 12 months to complete it. However, the CSR does not have to be submitted to the agency. Formulators also have to consider the foreseeable use of their mixtures by their customers.

To help these elements of REACH, an exchange network on ESs has been set up by Echa, member states and industry. The agency also provides comprehensive guidance on the preparation and submission of downstream CSAs.

### Chemical safety assessments - top tips

The CSR should be readily understandable as a stand-alone document and should include all the relevant information from the CSA, notably the principles applied in the hazard and exposure assessments, the assumptions made, the conclusions drawn and any uses advised against. In some cases, downstream users do not need to carry out a CSA. These are when:

• a SDS is not required for the substance – for example, because it is not classified as hazardous;

• a CSR is not required for the substance – for example, because the registered tonnage is below 10 tonnes/year;

• the substance is present in a mixture in a concentration below that for which a CSR is required (this is typically at classification limits and is set out in Article 14 (2) of REACH);

• use of the substance is less than 1 tonne/year; or

• use the substance falls under the product and process-oriented research and development (Ppord) provisions.

If either of the last two points apply, the downstream user must report this exemption to Echa. The situations where downstream user CSR exemptions apply, and where reporting is required, are summarised on Echa’s website.

A downstream user CSR undertaken in compliance with REACH does not fulfil obligations to undertake risk assessments under other national EHS legislation, which implement Directives such as the chemical agents Directive (CAD) and industrial emissions Directive (IED). However, assessments done under REACH and other EHS legislation can support each other.

### Classification differences and new information

Downstream users also have an obligation to report to Echa if their classification of a substance differs from that of any of their suppliers. However, reporting is not required if the downstream user employs the substance or mixture in a total quantity of less than one tonne/year.

There is also a legal obligation for downstream users to inform suppliers if the recommended risk management measures are inappropriate and whenever new information on hazards becomes available.
Beyond registration – the other impacts of REACH

Downstream users are affected by the other provisions of REACH, including those covering evaluation, restriction and authorisation. They should keep an eye on the substance evaluation process, which is an early flag that a substance may be of concern and face regulatory action.

Monitoring the so-called ‘Community Rolling Action Plan’ (Corap) work, and even the Public Activities Coordination Tool (Pact), provides an early warning. If a business-critical substance is placed on the Corap list, it would be advisable to get in touch with its registrants, who are the main contact point for the evaluators.

Businesses down the supply chain should also be aware of the growing trend to regulate ‘groups’ of chemicals with similar properties. For substances deemed to present unacceptable risks, REACH provides a number of options – either through a restriction, or the REACH candidate or authorisation lists.

Other risk management outcomes of substance evaluation include harmonised classification and labelling, under the classification, labelling and packaging (CLP) Regulation, or controls under occupational safety Directives or sector-specific Regulations, among others. Note that some substances have been deemed to be safe after substance evaluation.

Restriction and authorisation

Restricted substances under REACH are listed in Annex XVII. Companies manufacturing consumer products should note that REACH prohibits the sale of certain carcinogenic, mutagenic and reprotoxic (CMR) substances in consumer products through the restriction process. Recent examples include polycyclic aromatic hydrocarbons (PAHs), and carcinogens in textiles.

REACH also includes a mechanism to identify substances of very high concern (SVHCs). These are defined as substances with the following properties:

- CMR category 1A and 1B;
- persistent, bioaccumulative and toxic (PBT);
- very persistent and very bioaccumulative substances (vPvB); and
- identified on a case-by-case basis as having health and environmental effects that give rise to an equivalent level of concern to those above, for example endocrine disrupting chemicals and sensitisers.

Obligations exist to pass information on the presence of such substances in products as they pass through the supply chain (see next section).

The Regulation also includes provisions to place the most risky SVHCs on the authorisation list (Annex XIV). These substances cannot be placed on the market or used after a given date (the ‘sunset date’), unless an authorisation is granted for its specific use, or the use is exempted from authorisation.

The aim of authorisation is to properly control the risks stemming from these substances and progressively replace them with suitable, less hazardous alternatives or technologies, where these are economically and technically viable.

Complying with CLP

Downstream users who place substances or mixtures on the market must also classify the chemicals according to CLP. They may use the classification provided to them by their supplier or classify it themselves. If, however, they use a classification different to that of all of their suppliers, they need to report this to Echa.

When a substance or mixture is classified as hazardous, it must be labelled and packaged accordingly. Downstream users also have to communicate information regarding safe use to their own customers. This should normally be in the form of a SDS. This information needs to be updated immediately if:

- new information on risk management measures or hazards becomes available;
- an authorisation was granted or refused; or
- a restriction is imposed.

If a business supplies a substance down the supply chain, it has an obligation to inform its customers about conditions of safe use. They, in turn, are responsible for performing their own checks concerning their uses and conditions of use, based on the information provided by the supplier. When in doubt, seek out expert advice, as any mistake could be extremely costly.
If downstream users employ a substance that is on the authorisation list, they should first try to substitute it with a safer alternative. If they need to continue to use the substance, they or their supplier must apply for an authorisation for that use and additional obligations apply. There is some time pressure to make a decision as the authorisation application process takes time.

A company can use a substance subject to authorisation, provided it is in accordance with the conditions of an authorisation granted further up the supply chain. Downstream users must notify Echa within three months of the first supply of the authorised substance.

They can also decide to apply for authorisation for themselves and their customers’ uses. If a substance is subject to authorisation, this information should be communicated by the supplier. Echa provides lots of advice on applying for authorisation.

Communication on SVHCs

Downstream users need to inform their customers if an SVHC in a product is above a concentration of 0.1% w/w. There is no tonnage threshold for reporting. Since a European Court of Justice (ECJ) ruling in 2015, this concentration applies to all components within a complex article.

If downstream users produce or import an article containing an SVHC at above 0.1%, they must give sufficient information to allow recipients to use and dispose of it safely – and, as a minimum, the name of the substance. This information should be provided at the same time as its delivery.

In addition, if the substance is present in those articles in quantities totalling more than 1 tonne/year, the downstream user, including those importing, must notify Echa within six months, unless exposure can be excluded or the uses listed are registered.

If a company supplies products containing over 0.1% of an SVHC to consumers, it should be prepared to deliver that information within 45 days, if requested.

REACH compliance – top tips

Some of the key things downstream users can do to ensure they are REACH-compliant include the following:

- identify substances critical to your business, including substances in mixtures;
- check if the substances are already registered by searching the list on Echa’s website. Now that the final registration deadline has passed, downstream businesses will have a much clearer idea about which substances have been supported through REACH:
- check if the substances should be registered;
- certain types of substances, such as naturally occurring ones (not extracted chemically) or materials that are subject to registration or licensing under other legislative regimes, such as substances in food, have no registration obligations (if they are only used in those regimes);
- look for alternative suppliers if necessary. Companies that have registered the substance can be found on the Echa’s website.
- check that your uses are covered in the registration, particularly if you use a substance in an unusual way. Users of chemicals can inform suppliers of their uses so that they are covered in the registration. This helps to ensure your use is covered in the ESs you receive later on;
- if you operate within an organised sector, your trade body may have generated documents that describe typical uses and conditions of use that registrants can easily modify and save time;
- if no supplier intends to register a substance, consider importing it directly. If you import more than 1 tonne/year of a substance, you need to register it. Registration requirements are less comprehensive for quantities up to 10 tonnes/year;
- check out the guidance and other information specifically aimed at downstream users which is available on the website of the Downstream Users of Chemicals Coordination Group (Ducc) and for article makers the 60+ members of the Cross Industry Initiative have significant resources; and
- follow national REACH competent authorities activities, including inspections, and the EU-wide enforcement activities coordinated by the Echa Forum.
Communication in the supply chain

One of the biggest challenges faced by companies that use chemicals is obtaining information on substances from their suppliers – whether it is to check if substances are registered, or if materials and components contain SVHCs in quantities over 0.1% w/w. Initially, many companies downstream attempted to fulfil their obligations by sending letters or emails to their suppliers. Unfortunately it seems that, more often than not, those letters went unanswered.

While companies could switch from their current supplier to a more responsive one, that option is often not straightforward. Many companies have tried to build closer relationships in the supply chain, but, again, this might not be practical if those relationships span many hundreds, let alone thousands, of suppliers. Others have added obligations to contractual agreements, requiring suppliers to provide the information.

Business ownership
One compliance department at an agrochemical company found that engaging its own business was a good way to improve the information flow. It had been struggling to get confirmation that its suppliers were registering non-active, coformulant ingredients for the 2018 REACH deadline.

The compliance team raised the problem by highlighting that, if the ingredients were not registered, products could not be sold and that would cost much the same as the total value of its agchem sales in Europe. This sparked the attention of the CEO, who from the top ensured that solutions were found and executed. For the business, this meant going beyond one-way communication from customer to supplier.

The business itself sent emails to suppliers and then chased them up with telephone calls; the procurement department was trained in the regulation, so they could talk to suppliers and explain the needs. They discovered that one common reason that their emails went unanswered was because the recipient had no idea what they were about.

The approach was successful. Key to its success was the connection between regulatory compliance and the business.

Harmonised approach
For some article makers, the different approaches companies have taken have resulted in a complex web of information requirements for suppliers. This has highlighted the need for a harmonised system that shares information on which chemicals are in finished products.

Industry and the authorities are now taking action to address this. Representatives from several sectors have come together to discuss how to develop a solution for collecting and sharing material data for articles – including their chemical composition – across sectors.

Meanwhile, the EU’s Council of Ministers has called on the European Commission and Echa to implement measures to ensure that by 2030 substances of concern in materials – including those in imported articles – can be traced through the entire supply chain.
Here are some of the key points to remember for downstream companies that are likely to have responsibilities and obligations under REACH:

- With REACH registration complete and the focus increasingly on enforcement, it is important for the entire supply chain – especially downstream users – to be aware of the legal framework of the regulation;

- There are four defined types of downstream user: formulators, end users, producers of articles and refillers;

- Downstream users have some important obligations under REACH when it comes to communicating information about the use of chemicals back up the supply chain. REACH imposes different obligations depending on your activities, so careful assessment is required;

- Companies using chemicals in the EU face three key threats to their business as a result of REACH: substances disappearing from the market, chemicals identified as risky being subject to control measures, and an increased likelihood of enforcement action;

- Creating an inventory of the chemicals they deal with, and in what quantities, is a good first step for downstream users to take;

- Downstream users are vital links in the compliance chain and need to make sure a substance or mixture is legally permitted in the EU and communicate relevant information to their own customers and back up to suppliers if necessary;

- Downstream users should keep an eye on the substance evaluation process, in case substances are designated as being ‘of concern’ and could potentially face regulatory action;

- Downstream users should try to substitute substances on the REACH authorisation list with safer alternatives, or apply for authorisation for that use if this is not possible;

- Downstream users have requirements to inform members throughout the supply chain about any use of substances of very high concern (SVHCs).

If you are interested in tracking all the latest regulatory developments in your sector, take a look at our collection of sector pages on the Chemical Watch website. Additionally, if you’d like a more detailed understanding of what your business needs to do to comply with REACH, we run regular training courses on REACH compliance for downstream users.

For more information you can visit the downstream users page of the Echa website.

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