Ensuring Business and Supply Chain Continuity Through Compliance with REACH 2018

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Business through Science

Have you fully considered the obligations and implications of the final REACH registration deadline? Supply chain continuity may well be at risk for many products, but it is not too late to act.

Obligations and supply chain continuity

REACH obliges entities who manufacture or import substances in the European Union in quantities of greater than 1 tonne per annum (tpa) to submit a registration to the European Chemicals Agency (ECHA). A series of phased tonnage and classification-based deadlines were implemented to reduce the burden of generating the hazard and risk assessment on industry, however there is no obligation to inform supply chains or the regulator of a company's intention to register. Consequently, there is a possibility that some supply chains may start to unexpectedly dry up in mid-2018 if companies chose not to register or find that costs are prohibitive.

Only European manufacturers and importers, and only representatives acting on behalf of a non-EU manufacturer can register substances in Europe. Formulators and article manufacturers will need to ensure their upstream suppliers have taken the appropriate measures to ensure continuity of supply. Supply chains are invariably complex and as such, require careful consideration to identify obligations and potential impacts to minimise the risk of having to find another supplier, reformulate or remove the product from the market.

What are the risks and the mitigation options?

Most risks arise from lack of information, so for any substances critical to their operations, companies are advised to check on the registration status within their supply chains. The main risks and mitigation options are set out in the table below:

Status of product	Risk	How to mitigate
Non-EU supplier has pre-registered (via Only Representative) but not yet registered	Supplier may not go ahead with registration – if so, as of 1 June 2018 your company will be considered an importer and be liable for registration	Communicate with supplier and/or the Only Representative to obtain assurances.
EU supplier has pre-registered but not yet registered	If supplier does not go ahead with registration, product will no longer be available as of 1 June 2018	Communicate with supplier to obtain assurances.
Supplier claims exemption for a substance but cannot substantiate	If substance found to be not exempt, your company will be in non-compliance	Carry out exemption assessment based on information provided by the supplier.
Non-EU supplier not willing to disclose full ingredient breakdown	Your company is unable to assess its registration obligations due to lack of import volume information per substance – risk of non-compliance	Obtain compliance certificate from the Only Representative.
EU supplier not willing to disclose full ingredient breakdown	Risk that your company may be unknowingly purchasing non-compliant product	Obtain compliance certificate

Where supply is critical and where these mitigation options do not provide the required confidence that the product will be compliant with REACH post 1 June 2018, you may have to consider making a registration or finding an alternative supplier in order to secure supply chain continuity.

Key aspects to consider when making a registration

Lead or Joint?

REACH requires registrants to work together to submit one dataset per substance. If others are already preparing (or have submitted) a lead dossier for your substance, then joint registration is your route to compliance. The joint registrant is granted access to the data by purchasing a Letter of Access from the lead registrant, which in turn permits them to submit their joint registration dossier to ECHA. In the absence of a lead registrant, your company will need to take this role. The timescales for a lead registration are significantly longer than for a joint registration, and time and effort required to compile a lead registration dossier can vary significantly. For example, on-hazardous substances in the 1-10 tpa tonnage band only need a small amount of information to be submitted compared to a hazardous substance in the 10-100 tpa tonnage band.

Substance Identity

Sameness of substances is the basis for cost sharing of hazard data, and is verified through substance identity. There is often uncertainty over substance identity, particularly if a substance can be manufactured by a number of different processes, can be derived from various sources, or is a UVCB. Comparison of a detailed substance characterisation report with the lead registrant's Substance Identity Profile (SIP) will help establish which registration is most suitable to join. If it becomes apparent that you have pre-registered the wrong substance, this is not necessarily a problem because it is often possible to migrate to the correct submission at the time of registration.

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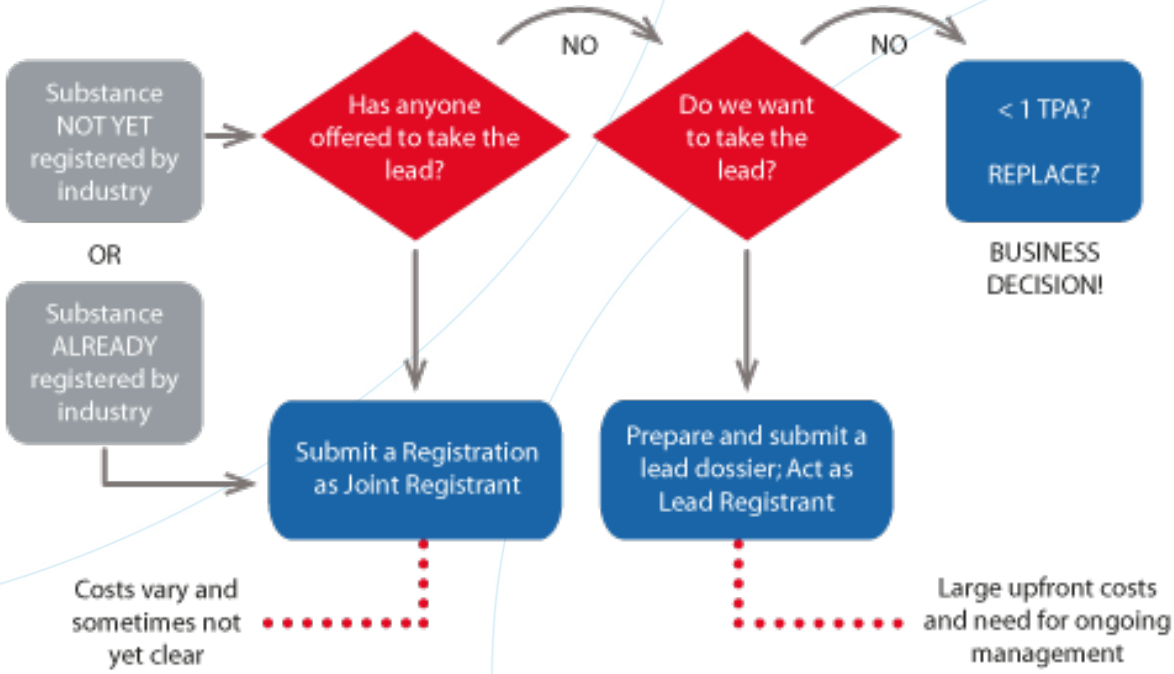

How does this affect Manufacturer/Importer and Processors?

To comply with the Inventory Reset companies must notify any chemicals that were manufactured, imported or processed during the ten years prior to enactment of the 2016 amendments, 21 June 2006 to 21 June 2016, to the EPA. This 10-year duration is known as the 'lookback period'.

Within this ruling there are two types of reporting. The first is known as 'Retrospective Reporting' applies to substances manufactured, imported or processed during the lookback period. There are varying deadlines for the notification, 180 days from implementation for manufacturers and importers (7 February 2018), and 420 days from implementation for processors (5 October 2018). Processors have an extended notification period to allow them to view the EPA's publication of the draft Inventory and to report only those substances listed as 'inactive'. The EPA originally proposed that processors could report on such substances within 360 days however this has now been extended to 420 days. Substances that are designated as inactive simply mean that they were not active in U.S. commerce during the lookback period, or were not notified as being active during this period. Processors can file a supplemental report during this 'extended submission period' in order for the EPA to redesignate the substance as 'active'. Moreover, processors can voluntarily report for the Retrospective reporting period.

The second type of reporting is known as 'Forward-looking reporting' and is intended for substances the EPA designate as 'inactive' that are to be reintroduced to U.S. commerce for non-exempt purposes. Importers, manufacturers and processors must notify the EPA with their intent to reactivate an inactive substance no more than 90 days before the anticipated date of activity, be it manufacturing, processing or importing such substance.

Reportable Information and Submission

Based on comments received by the EPA on the proposed rule, the EPA made many changes, including amending the type of data required in the final rule. As described in the Active-Inactive Requirements Rule, persons meeting the criteria must notify the EPA of general contact information, certification from the AO (Authorised Official, a U.S. based entity assigned by the notifying persons), the technical contact and finally chemical-specific data such as CAS/CA Index name or, if a substance is covered under Confidential Business Information (CBI), the TSCA Accession No. and generic name. Some additional information is required for Forward-looking reporting.
The final rule requires manufacturers and processors to report to the agency electronically, via the Central Data Exchange (CDX) by one of two bespoke forms, Notice of Activity (NOA) Form A for Retrospective reporting and NOA Form B for Forward-looking reporting. Persons subject to notification requirements are obliged to retain records of all provided information for up to 5 years after submission of such information. Furthermore, if chemical-specific data cannot be provided by the supplier, the EPA will accept joint submissions.

Exemptions from Reporting

There are a number of exemptions from reporting under the Inventory Reset Notification Rule, these largely align with those under the Chemical Data Reporting (CDR). These include those for R&D substances, naturally occurring chemicals, and impurities and byproducts with no commercial purpose. Exemptions to notification requirements can include substances within articles, certain polymers, and under certain conditions substances such as naturally-occurring materials, impurities and by products. Please note, there are some exceptions within these exemptions.
Importers of substances covered under an exemption, such as LVE or polymer exemption are obliged to notify such substances for the Inventory Reset if said substance(s) is listed on the Inventory or the confidential Inventory.

Data sharing costs and implications

Joint registration requires registrants to share the costs associated with generating the data, as well as those associated with technical and administrative activities relevant to their tonnage band. Since 2016, many aspects of the original REACH data sharing requirements have been clarified by Implementing Regulation (EU) 2016/9. This regulation confirmed that joint registrants don't have to accept or agree to the existing data-sharing agreement if they do not believe the costs to be 'fair, transparent and non-discriminatory'. Potential costs that could be difficult for the lead registrant to justify include excessive administration fees, risk premiums and annual inflation costs. If after a reasonable period of discussion between the lead and potential registrant a satisfactory justification for the costs cannot be provided, companies can submit a data sharing dispute to ECHA.

Service provider capacity

In the run up to REACH 2018, service providers are becoming increasingly stretched. From The REACH Centre's professional experience as a service provider and from working with contract research organisations, we know that delivery times are starting to draw out and submitting a successful registration may take longer than originally expected. Companies are therefore advised to start as soon as possible.

What next?

With the deadline less than a year away, and many aspects to consider, it is clear that having a robust action plan for each substance in place as soon as possible is essential. This requires information on registration status, hazard, substance identity and likely cost, so that business decisions can be made and priorities established.