Business impacts of not registering for REACH on time

The last deadline is looming and there are serious consequences to not meeting it by 31 May



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At the start of the year Echa was still expecting about 25,000 unique substances covered by some 60,000 registrations, to be submitted by the last REACH deadline of 31 May 2018, for substances in the 1-100 tonnes/year band. However, the numbers at that point were about 6,500 and 15,000 respectively, meaning there is a large gap to be filled during the remaining months.

This begs two questions. What will happen to the substances that are not registered by the deadline? And what will the business impact be on would-be registrants and downstream users?

From 1 June, the REACH Regulation will have reached a business-as-usual state where no further transitional schemes will apply for substances that require registration - that is, those manufactured in or imported into the EU and EEA at one tonne/year or more and not exempt from REACH or the registration requirement. Therefore, companies will have either:

- successfully registered their substances;
- 2. submitted registrations but, for whatever reason, had them rejected and not resubmitted them in time;
- had an additional extension granted by Echa to complement an inadequate submitted dossier; or
- not registered at all, due to negligence, wilful intent not to register or unawareness of the obligation.

Options available

This article will focus on cases two and four, looking at the business impact on the would-be registrant and the options available. The downstream user implications of not registering may actually have an even greater impact on businesses in the supply chain through obsolescence, but this will not be covered here.

What are the options when a registration that was submitted on time has been rejected due to the poor quality or noncompliance of the dossier? Where the failed registrant is a co-registrant, the obvious alternative is to reduce the volume of the substance to less than one tonne/year or simply cease to manufacture or import it, but this generally does not make business sense.

If the substance is in stock within the EU and EEA (at whatever volume), it can be used even if the stock is not registered, because it was presumably either manufactured in or imported into the EU and/or EEA before the applicable deadline. However, placing substances on the market in this way may encounter difficulties as well-informed downstream users will generally only accept registered substances after the deadline.

Although the substance will have been pre-registered, it will not be possible to simply resubmit it with a compliant dossier. The phase-in regime will have ended and substance information exchange forums (Siefs) disbanded, effectively making pre-registrations invalid.

Inquiry process

In practice, this means that any registrations submitted from 1 June 2018 onwards would first have to go through the inquiry procedure. Echa uses this process to verify substance identity and place the registrant in contact with the lead registrant (LR) of that substance.

Echa must accept an inquiry before a new registration can be submitted. There is no way around this requirement. Therefore, when preparing the inquiry dossier, the registrant should contact the LR or consortium and purchase access to the joint submission of the substance through a letter of access (LoA).

LoA negotiations may often prove timeconsuming and therefore it is recommended that you start them as soon as possible. Once access has been granted to the joint submission, Echa has accepted the inquiry and the registrant has prepared a compliant co-registration dossier, the registration can be submitted.

The agency will accept the dossier when the registration fee is paid and, once all the checks are made, it will issue a registration number as a decision. Only when this number is available can the manufacture and import of the substance and related business continue.

Where the failed registrant is an LR, the matter becomes even more complicated, especially if there are other co-registrants. This is because other Sief members cannot successfully submit their co-registrations if the LR dossier is rejected.

They will not have a valid registration for their substances until the LR has successfully resubmitted the lead dossier and passed at least the business rules check. Later, all All Echa's checks on the lead dossier must be successfull for the LR and co-registrants to have a valid registration for the substance in place.

Liability for failure

With failures of this magnitude, the LR may be liable towards the co-registrants, especially those that have bought a LoA and signed a Sief agreement. The LR's responsibilities in this case, would probably be determined on the applicable national civil or commercial law.

Therefore, coming back to the question of what options are available to the LR from

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a registration compliance perspective, the answer is: the same ones that are available to the co-registrant in the first case, except that the LR does not have to purchase a LoA.

Therefore, ahead of 31 May, LRs are strongly recommended to keep Sief members informed of progress in developing the lead registration dossier, whatever the circumstances. Being open with Sief members allows them, when there are problems, to vote to change the LR before the registration deadline. This gives them a chance of meeting it with a new, and hopefully better, LR. Although time is short, changing the lead may be the only option.

Based on information provided by the <u>Directors' Contact Group</u> (DCG), Echa can allow the new LR to submit an incomplete dossier (though passing the business rules is a must) with an extended time period given for delivering the complete dossier.

Echa determines the length of the extended deadline on a case-by-case basis. However, it is worth noting is that the registration number will only be issued once the complete dossier has passed all checks and is considered compliant. This may, in turn, have implications in the supply chain, where downstream users may be unsure of the REACH compliance status of the substance.

To conclude, the registrant can register substances after the final deadline, but that does not come without business implications. Therefore to avoid disruptions to business, make sure to register your substances for REACH on time.

The views expressed in this article are those of the expert author and are not necessarily shared by Chemical Watch

Summary: options for late registrants

If the volume is one tonne per year or more and the business does not wish to cease its commerce involving the substance, stop manufacture and/or import of the substance immediately and do the following:

1. For substances where a joint submission is available, contact the

LR or consortium for access to it (usually via LoA purchase). If not, you need to become the LR.

- 2. Submit an inquiry to Echa with information on the substance identify and await acceptance before submitting the registration dossier for the substance.
- Submit the required (co- or lead) registration dossier to Echa and pay the registration fee.
- 4. Await acceptance of registration dossier and issuance of a registration number, before continuing manufacture or import of the substance.

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