REACH tasks beyond the final registration deadline

Registrants still have many obligations after 31 May

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The REACH Regulation always required more than just the registration of chemical substances. Where essential data is missing, it has to be generated. Moreover, REACH covers all uses of a substance and the data makes it possible to estimate human and environmental exposure specifically.

On that basis, an assessment of each substance and use will identify those that pose risks to man or the environment and will therefore potentially initiate further regulatory actions within the framework of REACH.

At the moment, most manufacturers and importers of chemical substances still talk about the challenge of registering phase-in substances by the end of May 2018. For some, this final registration deadline appears to be the end of REACH. Be assured, this is not the case.

The registration process for 'existing' substances that were already on the market before REACH and were pre-registered between June and December 2008, was - and still is - the REACH task with the highest workload for the chemicals industry. However, the only goal achieved on 1 June 2018 will be the creation of a database about chemical substances in the European Economic Area (EEA).

This will, indeed, be the largest database on chemical substance properties in the world. It will provide the basis for implementing one of the key goals of REACH stated in Article 1, "To ensure a high level of protection of human health and the environment". Hence, registration is just the beginning.

So, what will follow once all chemical substances marketed at above one tonne/year in the EEA are known to Echa? The Regulation itself also contains the 'E' for evaluation and the 'A' for authorisation. There are mechanisms to restrict certain uses of substances where it is not possible to exclude risks to human health or the environment.

Dossier and substance evaluation

Let's have a closer look at the evaluation of dossiers and substances. Of course, Echa has been evaluating dossiers and member states have been evaluating substances for several years already. The Community Rolling Action Plan (Corap) list of substances contained 337 entries as of 20 February 2018, and actions are already scheduled for 50 this year and 47 more in 2019.

On the dossier evaluation side, as the new executive director of Echa, Björn Hansen, wrote in February, the REACH Review in 2017 indicated that the overall performance has been good but there is still a need to be more efficient. Hence, there are already numerous chemical substances for which regulatory actions have already been triggered and the lists will continue to grow.

At the agency's most recent stakeholder day on 31 January, Christel Musset, director of registration, pointed out that the authorities will pay special attention to substances that are likely to have hazardous properties and also have the potential for significant exposure. These are the high priority substances for evaluation, but they will also focus on those where hazards and exposure potential are uncertain.

For this reason, Article 22 of the REACH Regulation should also be kept in mind. This obliges registrants to update their registration dossiers whenever new information becomes available, such as:

- changes in substance composition;
- changes in the annual quantities;
- new identified uses or uses advised against;
- new data on the risk of the substance; or
- changes in classification and labelling.

According to the agency, 67% of all dossiers have never been updated. The current update status of all dossiers is published on Echa's website. Very old dossiers have a higher probability of

getting picked for further evaluations, especially if the substance has widely dispersive uses in large quantities.

For this reason, companies are advised to check their dossiers for uses that might not be relevant any more. There should not be any widely dispersive use in the dossier if the substance is not used in such ways.

It is also advised to check read-across and quantitative structure-activity relationship (Qsar) justifications in a dossier, since this might also be a target that determines further regulatory action. In cases where justifications for the use of read-across or Qsars are insufficient or not conclusive, the agency may consider a dossier to be incomplete and request further actions.

In summary, a registration dossier is not a static piece of work; it needs continuous care. Although all the aforementioned activities are going on at the same time, the improvement of data quality in the registration database is a crucial factor in further actions, for example, the identification of substances of very high concern (SVHCs) and uses that pose a risk to man or the environment.

Article 57 lists properties that categorise such substances as subject to inclusion in the candidate list. Registrants should be aware that Article 57 (f) states that "substances … for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) … can also be included in the candidate list".

Continuing obligations

Once a substance is listed, there are obligations for all participants in the value chain. The presence of candidate substances at concentrations above 0.1% requires communication throughout the supply chain, and the use of safety data sheets (SDSs) for the substance itself and mixtures that contain it at above 0.1% and any final article, using similar declarations.

Substances on the candidate list may become subject to authorisation. In such cases, the registrant needs to decide whether the use of the substance is essential and go for an authorisation or if it can be substituted with less hazardous alternatives. Authorisation is a very complex, time- and money-consuming process without any guarantee of success.

Another function of REACH that is not reflected in its name is the restriction of specific uses of a substance. If the authorities consider that such uses are "not without risk", as defined by REACH, they can initiate a process to restrict that use. Registrants are advised to keep an eye on changes in Annex XVII, which lists all restrictions.

Finally, registrations are not the end. Substances that enter the EEA market for the first time at above one tonne/year need to be registered before they can be marketed. The determination as to whether a substance is indeed entirely new to the market is carried out by Echa.

If a manufacturer or importer intends to widen its product portfolio, an inquiry by Echa is necessary. Where the substance is already registered by other companies, the agency will inform the potential new registrant accordingly. By acquiring a letter of access (LoA), the registration process can be concluded.

Companies should be aware that Article 29, paragraph 3, points out that each Sief "shall be operational until 1 June 2018". Hence, the Sief that originally registered a substance may disband. This makes negotiations about a LoA and the compensation of co-registrants more complicated and all Sief members should think about keeping a Sief-like structure in place. The same might also be true for consortia formed for REACH registrations.

Companies remain responsible for the safe use of their chemical substances. Hence, there are tasks that must be continuously undertaken to ensure that the business stays compliant with REACH. Some tasks and questions that need to be considered are listed below.

Key tasks after the deadline

Firstly, check the status of your Siefs and consortia after 31 May. Will they still exist? If not, for how many substances has the company taken the lead registrant (LR) function? If a company wants to put one of your substances on the EEA market for the first time, Echa will communicate with the LR, who must then negotiate with existing and potential new registrants about the cost for the LoA. How this is going to work is currently unclear.

Keep an eye on the status of the registration dossiers. Are they up-to-date? The status includes keeping track of new data and literature that becomes available. Further, are there justifications for read-across and/or Qsars to be assessed? Are the uses accurate? Are uses of new clients covered? Check the chemical safety report and the SDSs, including its extensions, on a regular basis.

Importers of mixtures in particular may find that their products might change in composition, which may lead to different tasks. New components in a recipe may need to be registered, while a change in the concentrations of existing components may require an update of a dossier as soon as the threshold tonnages (one, ten, 100 or 1,000 tonnes/year) are passed.

Is the business about to market new substances? You need to check with Echa whether there are companies that have already registered them.

Keep track of your supply chain.
There may be suppliers who do not register all of their substances and take them off the market. Get in touch with yours to check whether they have registered or intend to. Is the supplier just selling his remaining stock and leaving the market afterwards? Check for alternative suppliers to prevent supply chain disruptions.

Are there substances in the portfolio that might become subject to further regulatory actions? Do you need to prepare to seek authorisation for the use of a substance or are there safer alternative substances that can be used?

Taking all this together it should become clear that REACH does not end after 31 May 2018, it has rather just begun. As Mr Hansen said in the Global Business Briefing in February: "After this year's registration deadline, REACH moves from a setting-up stage to total operation." So from 1 June 2018, let us see what is ahead of us instead of looking back.

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