How to cope with current lead registration maintenance challenges

Sami Vesikansa, REACH Manager at REACHLaw, looks at the continuing challenges of REACH compliance

ALTHOUGH THE LAST REACH registration deadline passed on 31 May 2018, requirements related to registrations and other obligations under the Regulation remain unchanged. All registrants have an ongoing duty to follow up and monitor regulatory developments of the substance. The main challenges for lead registrants (LRs) will be related to the financial and legal management of the joint submissions on any dossier update activities requested by the authorities.

Keeping up to date

Now that the ten-year transitional period is over, the 15,000 or so companies who completed their registrations are responsible on their own initiative to update their dossiers with new relevant information and to submit it to the European Chemicals Agency (ECHA) according to REACH Article 22. The need for updates may arise due to new information emerging on the risks of a substance to human health and/or the environment, an increase in the production volume or new uses of the substance.

This usually affects all registrants of a given substance but it is a particular burden on LRs, as they conducted the chemical safety assessment and have access to the original data and study reports. To comply with the obligations of REACH, LRs should schedule regular literature searches, the outcome of which should be included in a dossier update.

ECHA is expected to put forward further measures in order to improve the quality of registration dossiers submitted by the companies. As a result of these, an update of the dossier may be required. When compliance checks apply to the joint part of the dossier, LRs need to involve member registrants in discussion, get their feedback and coordinate the response. Often, additional testing or arguments are requested. LRs are recommended to take a proactive approach and not wait for potential compliance checks by ECHA.

Further regulatory actions

The European Commission, ECHA and member states have committed to having all substances of very high concern (SVHCs) identified by 2020. The intention is to assess potential substances that are carcinogenic, mutagenic or reprotoxic (CMR), persistent, bioaccumulative and toxic (PBT), or very persistent, very bioaccumulative (vPvB), plus endocrine disruptors and sensitisers.

The criteria to define whether a SVHC is relevant are based on screening the registration dossiers as a first step and risk management option assessment (RMOA), which identifies the best regulatory option to manage the risk as a second

step. After the screening process, the shortlisted substances might be selected for further regulatory action – for example, harmonised classification and labelling, inclusion in the candidate list, restriction or substance evaluation.

If a substance is added to the candidate list, it becomes a candidate for possible inclusion in the authorisation list. If this eventually happens, a company needs to apply for authorisation. If the substance is added to the restriction list, its manufacture, placing on the market or use may be limited or banned. Thus, registrants are advised to monitor possible regulatory actions on their substances by following screening processes via ECHA's web pages.

SIEF & consortium management

After the initial registration of a substance, LRs must carry out a number of continuous and *ad hoc* tasks to maintain the registration and respond to requests from authorities, such as ECHA or member states, or other registrants. This implies that the companies need to check their REACH-IT and substance information exchange forum (SIEF) mailboxes regularly and be ready to react to any correspondence following registration.

To address these tasks in a timely manner, registrants are required to keep in place permanent multi-disciplinary regulatory support functions to respond to the unpredictable requests. The workload is significantly heavier for companies acting as LRs, as they are required to deal with all enquiries from potential co-registrants and are responsible for the information submitted jointly.

LRs should have a permanent mechanism to welcome newcomers to join the registration and to continue the communication between member registrants if a new registrant joins. This means that the LR or consortium manager should maintain letter of access (LoA) sales and data access services, and also establish a well-organised process to allow proper management of this kind of requests.

Legal & financial obligations

According to the implementing regulation on data sharing, potential registrants are entitled to ask for a full breakdown of the LoA costs prior to purchase. This implies that the LR should have detailed documentation in place to prove the transparency required.

In most cases, lead dossiers require ongoing financial management, involving the recalculation of LoA costs, reimbursing registrants and planning financial management for keeping dossiers up to date in subsequent years. As the SIEFs' legal

obligations ceased on 1 June 2018, consortia and LRs are advised to replace SIEF-based contracts with 'cooperation contracts'.

The LR should prepare a contract laying down principles of future cooperation. This should take into account, for example, financial compensation in case new studies need to be purchased, new data need to be generated or dossier update activities need to be performed upon substance evaluation by the authorities.

What about Brexit?

At the time of writing, the UK was still due to leave the EU on 29 March, though the situation remained highly fluid and unpredictable. In the event that the UK does cease to be a member of the EU, a UK-based company can no longer be a REACH registrant and any registration previously carried by this company will therefore be regarded as non-existent, unless a transition period, is in the end, mutually agreed and ratified.

Over 1,100 substances were registered only by UK companies, so immediate action is needed from these registrants to maintain their REACH compliance. In order to continue supplying EU-27-based customers on the basis of the current registrations as a manufacturer or formulator, they need to appoint an only representative (OR) within the EU-27. Another option is to move their legal entity and manufacturing activity to the EU-27. ECHA had a Brexit window open from 12 to 29 March to facilitate all this.

Companies will need to notify this change in REACH-IT immediately ahead of the UK's withdrawal by transferring the registrations to the new OR. After the successful transfer of the registrations in REACH-IT, the legal entity change successor is expected to submit a dossier update to comply with Article 22, to ensure that the dossier reflects its new role as an OR. Accordingly, non-EU companies who are currently with UK-based ORs need to change to an EU-27-based OR to maintain their REACH compliance. ●

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