Leading the way

Challenges for 2018 REACH lead registrants

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For the May 2018 REACH registration deadline, there will be many more SMEs and smaller Siefs than for the previous registration deadlines. At the same time, less information will be available on the substances being registered. It is evident that some will have to become lead registrants, meaning a big responsibility to lead the joint registration work and ultimately submit the dossier in time, before the deadline. Awareness of REACH obligations, registration costs, Sief work and lack of internal resources have been identified by SMEs as areas of concern.

A significant challenge

The management of the whole lead registration project requires expertise and knowledge from various areas, such as chemistry, toxicology, environmental science, economy, regulatory issues, IT and finance. The tasks of a lead registration include, among others, data mining and information collection, Iuclid dataset population, hazard assessment of chemicals, exposure assessment for human health and the environment, risk characterisation, Sief communication, drafting of agreements, clarifying copyright issues, negotiations for read-across data and so on. Furthermore, a lead registrant needs to be in contact with outside consultants, data holders, testing labs and even competitors. This means that particular expertise and knowhow is required from the lead to accomplish all necessary steps of the work.

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Cooperation

The major challenge of the Sief work is cooperating with other companies, as the law restricts them from working together. However, this cooperation between competitors is obligatory according to REACH. Thus, companies have to agree with their co-registrants how to work and communicate within the Sief. It is recommended that they communicate early on and regularly. The lead registrant should prepare an agreement to lay down principles of cooperation. If there are few members, and no newcomers are expected, it is possible to decide upon working without such an agreement, but this is not recommended.

If it is agreed that one member takes a prominent role or to appoint a consultant, this work should typically be compensated by the other members. The lead registrant needs to seek agreement on fair and transparent cost sharing. New challenges to calculating the letter of access (LoA) costs are set out in a new data sharing Regulation that entered into force on the 26 January. The Regulation requires the lead registrant to share detailed cost information with the (potential) co-registrants. This means that the lead needs to itemise all data, and non-study (management), costs related to a specific study. Furthermore, they need to have a cost sharing model which includes a reimbursement mechanism and future expenditure.

Risk of rejection

Identifying a substance is the central task in the REACH registration process and a prerequisite for successful registration. The lead registrant needs to characterise the substance by chemical analysis to determine its composition and type (monoconstituent, multiconstituent or UVCB). Clear identification poses a

challenge, especially in the case of substances of unknown or variable composition, complex reaction products or biological materials (UVCB substances). Thus, it is recommended that companies seek to establish the identity of their substance as soon as possible.

The lead registrant has to prepare the substance identity profile (SIP), where this is clearly defined. The data should be as detailed as possible, but also generic enough to be accepted by all interested registrants in the Sief.

Furthermore, the unambiguous identification of a substance enables data sharing by potential registrants and data holders, and prevents the duplication of testing on animals and unnecessary costs.

Testing

All available data should be collected in the registration dossier, including on the substance, its intrinsic properties, on manufacturing and uses, and on the related emissions and exposures.

To fulfil the information requirements, the lead may use its own studies, ask for data from the Sief members, use that from literature, investigate read-across possibilities and study waiver justifications. If studies are requested from data holders outside the Sief for a similar substance, the lead registrant should identify the data owner of this study, determine intellectual property rights (IPRs) and obtain access to the data, where relevant. They should be aware that the negotiations with the data owner may take longer than expected.

If available data is limited and of a poor quality, the lead registrant will most likely need to allow time to generate new data at competent laboratories. The companies should plan their testing programmes early because laboratory capacity may run out the closer to the registration deadline.

If vertebrate studies are needed, it is advised to allow up to six-nine months to complete these tests, typically required for ten-100 tonne substances.

When planning the testing programme, try to prepare an intelligent strategy because it is not necessary to test every substance for every endpoint. Registrants may group substances based on certain properties, and then use a read-across approach within the group.

Iuclid 6

This summer, version six of Iuclid will be released. It will have many improvements, including a streamlined structure in all sections. It also follows the OECD harmonised templates more closely. The 2016 release is linked to a wider update of Echa's

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IT tools with new versions of REACH-IT and Chesar. When the new version of REACH-IT is available, all dossiers submitted to the agency will have to be created in the Iuclid 6 format. So registrants need to prepare their organisation's IT for these changes and familiarise themselves with these new updated programmes.

Preparation

A chemical safety report (CSR) must be prepared if a ten-100 tonnes dossier is submitted, either by the lead or by each co-registrant that needs it. Furthermore, if the substance is hazardous, an exposure assessment has to be conducted. The most challenging part of the CSR is section nine (exposure assessment) and section ten (risk characterisation). Lead registrants have found the preparation of the CSR a time-consuming challenge to date, and many were rushed to meet previous deadlines. As a result of the low quality, they will need to be updated in good time to comply with all relevant requirements.

After dossier submission, the lead should inform co-registrants of LoA availability and the costs entailed. The new data sharing Regulation will pose challenges to the lead registrant in calculating LoA costs as they will have an obligation to provide (potential) co-registrants with a breakdown on request.

Keeping up to date

The lead has a legal obligation to update the submitted dossier, when new information on hazards or uses becomes available. Echa may examine any registration to verify if the information given by registrants is compliant with the legal requirements. Thus, it is recommended to take a proactive approach and not to wait for potential compliance checks by the agency.

Take-away messages

» If there is no lead registrant for a substance critical to your business, consider taking up that role yourself. You may also think about commissioning a consultant to conduct the work for you. In the long term, it might be more cost-effective to outsource, at least some of the work, to ensure that it is done correctly. But, if you decide to take the lead role, you need to try to anticipate the work expected, based on the steps of the registration process and agree on how to organise cooperation within the Sief.

» 2018 lead registrants must be aware that the lead registration dossier needs to be submitted at least two months before the last REACH registration deadline (31 May 2018), to give member registrants ample time to submit their own co-registrant dossiers.

» Joint submission is mandatory for all registrants of the same substance. This means that, since the release of the updated REACH-IT system last month, individual registrations – those registrations not part of a joint submission – cannot be submitted.

» If your company is affected by the 2018 REACH deadline, make sure that you have or acquire adequate resources because the last registration deadline is only two years away.