EU REACH Post-2018

Obligations and Activities

ReachCentrum SA

Turning our Chemical expertise into practical help for industry

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1. Introduction

According to the EU REACH Regulation, the 31st May 2018 is simply the deadline for the registration of substances manufactured in a specific tonnage band (1-100 tons/a); other obligations will remain unchanged after 2018. The activities that registrants should take into consideration after 31st May 2018 can be grouped as follows:

- On-going registrant activities
- Dossier maintenance activities
- Compliance and Evaluation activities
- Authorisation and Restriction activities
- Data access for use in other jurisdictions (not part of EU REACH)

This document provides a summary overview of the obligations that will remain after 31st May 2018. It also describes the likely activities that will be required of Consortia, Lead Registrants and Registrants.

ReachCentrum (www.reachcentrum.eu) is an ERM company. ERM is a global sustainability consultancy which has a European footprint with offices in the UK, and Europe. As part of the ERM team we are able to support single Clients or groups of clients with respect to a wide range of product stewardship aspects throughout the supply chain. Further information on our wider product stewardship services can be found at www.erm.com.

If you are interested in receiving a quotation for any of the services described in this document following the period end date of the current Consortium Management Services Agreement, or your Lead Registrant support agreement, please contact your ReachCentrum Consortium Manager.

2. On-going Registrant Activities

2.1 Letter of Access Sales and Data Access Management

LoAs sales (REACH registration dossiers)

Requests for LoAs will occur after 2018 registration deadline. Companies that have not registered prior to the deadline i.e. those who were unaware of the obligation or are new to the market in the EU for production, import or use, will be obliged to submit a registration dossier immediately. There is no 'pre-registration' grace period.

Additional LoAs also may be purchased by former Affiliates of Consortium Members or LoA buyers or in case of other relevant corporate changes (e.g. divestments) or a change in tonnage band.

ReachCentrum will be maintaining its current Reach LoA e-shop http://www.reachcentrum.eu/letters-of-access.html and support services (e.g. finance activities and LoAShop platform) for use by Clients.

Questions from (potential) LoA purchasers

Potential LoA buyers usually come with detailed questions concerning the substance and documents provided together with the LoA. ReachCentrum has established a well-organized process that allows proper management of this kind of requests and, depending on the Client, may be in a position to provide technical responses as well as process related responses.

According to the Implementing Regulation on Data Sharing, potential co-registrants are entitled to ask for a full breakdown of the LoA costs prior to purchase. ReachCentrum provides support to Lead Registrants in preparing financial statements that provide the transparency required.

Updates of LoA prices

It will be necessary to re-calculate the LoA price once the May 2018 deadline is past so that the costs for the registration are shared in a fair, transparent and in a non-discriminatory way between all co-registrants of the substance. This calculation will take into consideration the overall costs of the registration as well as the current number of co-registrants sharing these costs. It may also consider likely testing costs and requirements under the Evaluation phase. Where necessary reimbursements may be made to registrants or conversely registrants will be invoiced where there is an under-payment in relation to registration costs incurred.

It is envisaged that a proportion of Lead Dossiers may require on-going financial management beyond the May 2018 recalculation i.e. in subsequent years as the costs for the next phases of REACH (e.g. Evaluation activities) accumulate.

Our financial team is able to provide robust LoA calculations and can support Lead Registrants in the re-imbursement or invoicing stages.

2.2 Consortium Management and Lead Registrant Support

In a majority of cases the consortia activities will continue after the May 2018 deadline. ReachCentrum will continue to support consortia in activities including maintenance of communications between co-registrants and management of financial aspects including sharing of the costs with co-registrants and invoicing.

Third Party Technical Providers or CROs – contract and management

If further developments of the registration dossier are needed, identification and contracting of external technical service providers will be required. ReachCentrum is a specialist consortia management company and maintains a separation between its consortia activities and ERM. . In its consortium management role, ReachCentrum will identify potential technical partners (or CROs) and manage the request for proposal, quotation process and contracts for appointment. It is also noted that ReachCentrum is able to offer turn-key technical support through ERM companies if appropriate.

ReachCentrum has experienced consortia managers and in-house legal counsel who are able to deliver on these aspects.

Financial reporting

The ReachCentrum finance team can support the Lead Registrant or the consortium with respect to financial management and reporting and, cost sharing and invoicing.

Organization of meetings, communications with the consortium members

Day to day consortium management comprises preparation and organization of Steering Committee and Technical Committee meetings and preparation of communications to the consortium members on different topics.

Communication with the SIEF members

Communications with the other co-registrants may be needed from time to time. ReachCentrum may use IT systems such as LinkinSIEF™ to ensure that the communication is well done and archived for future reference.

SharePoint and Consortium page on ReachCentrum website

Visibility of the Consortium is important and will continue to be important after the 2018 registration deadline. ReachCentrum will continue to host consortia webpages on our website. In addition, we will continue to maintain and update the consortium SharePoint website that should be used for sharing the data and to keep the archives of the Consortium activities.

Acting as a Trustee for Consortium and SIEF Members

Information that is required and used for the purposes of EU REACH registration, including the registration intentions, is often confidential business information. As such it should not be shared by co-registrants. This kind of information should be correctly treated by a Trustee. For the past 11 years, since 2006, ReachCentrum has acted in the role of Trustee for EU REACH purposes and has proper procedures to ensure the correct treatment of confidential information.

Competition law compliance should also be maintained and it is crucial to ensure that Consortium Members do not interact directly with each other in contravention of EU competition law. In its capacity as an independent third party, and in its role of consortium manager, ReachCentrum is able to adopt appropriate procedures to ensure the compliance with competition law rules during calls or meetings.

Maintaining archives

Archives of consortium records, studies and financial information should be maintained after 2018 registration deadline. This information should be stored in a safe place and managed by an external third party independent from Consortium Members.

ReachCentrum maintains electronic and physical archive storage on behalf of clients and will continue offering this service in the future.

New Lead Registrant Support

It is not anticipated that there will be many new submissions of lead dossiers after the 2018 deadline. Nevertheless, this may happen in cases where:

- a new substance is introduced to the market;
- ECHA does not agree with substance identity, the SIEF may need to be split and a new separate lead dossier prepared and submitted;
- a pre-registered substance is registered after the 2018 registration deadline. In this case the registering entity will likely be the Lead Registrant and have lead registrant obligations; or
- new definitions of substances under REACH are described by the regulators.

3. Lead Dossier maintenance activities

Beyond May 2018 the Lead Registrant (and indeed the co-registrants) will have an on-going obligation to update the dossier when new information becomes available.

Continual dossier updates

According to the REACH Regulation and ECHA Guidance, each registrant is obliged to keep their dossier continuously updated. This implies that regular literature searches should be scheduled and implemented e.g. on an annual basis, the outcome of which, where relevant, should be included in a dossier update.

Upgrades into a new versions of IUCLID

It is noted that ECHA has continually evolved and developed its IUCLID software. To date, each new version has had new data requirements for REACH dossiers. When a dossier is updated, for example due to a literature search, it will be necessary to upgrade to the latest version of IUCLID and incorporate the new IUCLID requirements. .

4. Compliance and Evaluation activities

Dossier evaluation - compliance checks

ECHA is completing dossier compliance checks. Currently 30% of dossiers are being reviewed with a high percentage 'failing' due to poor substance identification, read-across arguments, and incomplete dossiers among other reasons. As an outcome of a compliance check, an update of the dossier may be required. Often additional testing or arguments are requested. The co-ordination of this work and the associated financial management on behalf of the Lead Registrant, and if applicable, the consortium, will be necessary.

Substance evaluation – CoRAP

ECHA is proceeding with substance evaluations. As an outcome of substance evaluation, an update of the dossier may be required and there may be a request for additional testing or argument. The co-ordination of this work and the financial management will be necessary.

Testing proposals

Under REACH Regulation, ECHA is obliged to verify and issue a decision on the testing proposals included in the registration dossiers. ECHA will give feedback in due time – for the 2018 substances the verification and feedback should be completed by 1 June 2022. By this time there should be a good overview of the likely approved testing proposals. Further activities will be required to implement the regulatory Decisions.

Proposals for harmonized classification

A substance may be the subject of a proposal for harmonized classification. The co-ordination of the work related to this process between co-registrants and the financial management of all the related activities will be necessary.

Advocacy activities

Very often when a substance is subject to an evaluation by the Authorities, a broad outreach to the EU Members States Competent Authorities can help the evaluation to progress more effectively from the registrants point of view. ReachCentrum has close heritage ties with CEFIC, different industry associations, ECHA and the Member States. As such ReachCentrum can support registrants with respect to advocacy.

5. Authorisation and Restriction activities

Inclusion on the candidate list and selection as SVHC

Where a substance is included on the SVHC candidate list, registrants may wish to try all routes at their disposal to avoid a move to SVHC listing. ReachCentrum has a good track record of developing strategies with member companies, co-ordinating the work required and providing support to the advocacy activities.

Support for the applications and re-applications for Authorisation

ReachCentrum has also provided support to companies seeking Authorisation in the event a substitute substance has not been identified. With ERM providing the technical input, we successfully supported a client for the use of TCE as a solvent for obtaining caprolactum oils. This was cited by ECHA as one of several exemplar applications due to its clarity of presentation and quality of the SEA. ReachCentrum's activities comprise support for advocacy activities, coordination of the joint efforts as well as communication with authorities and financial management of the process.

Restriction proposals

In the event of a substance becoming the subject of a restriction proposal, co-ordination of the process is needed as well as support in the cooperation with the authorities. In addition, cost sharing among Consortium Members and external co-registrants as well as downstream users may be implemented and require financial oversight.

Management of appeals

Where registrants do not agree with the decisions of the regulators, there is the possibility to file an appeal. The process is quite complex and usually lasts between one and three years. ReachCentrum can support the coordination of the preparation of the appeal documents and the overall management of the process and communication between co-registrants.

6. Data for Use in Other Jurisdictions

Ideally studies should not be repeated, specifically vertebrate studies, both from an ethical and legislative perspective. Therefore, if studies can be used to support other regulatory purposes then this should be facilitated. Equally under EU REACH there is an obligation to consider new data (of whatever origin), and if necessary complete an update of the dossier. It may therefore be expedient to share available data to reduce the likelihood of new data of potentially uncertain quality being generated.

Selling access to data/information for REACH or other regulatory purposes

Data sharing is not limited to EU REACH and BPR Regulation. Having completed tests for the purpose of EU REACH, these can be used for any other regulatory purpose where possible and required. In theory and practice it is possible to use the same study data for REACH like registration outside EU, and also for biocides (BPR) or cosmetics legislations in EU or other world jurisdictions. In addition, data from one substance can be used for read-across to other substances and used in REACH registration dossiers.

ReachCentrum can support Data Owners with respect to data sharing agreements and also has an online data brokerage platform to facilitate the transaction between data owner and a verified third party.

7. Brexit

Brexit will occur in March 2019, after the May 2018 registration. We are therefore not expecting a change in approach for UK companies with regards to the 2018 deadline. The relationships between the UK and Europe and its institutions such as ECHA have yet to be negotiated and established. ERM companies (ERM, JSC, ReachCentrum) have a pan-European UK platform and will be able to support Clients beyond March 2019.