

EU REACH: how's life after the Registration deadlines?

The registration deadlines for pre-registered “phase-in” chemical substances under the European Union’s (EU) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation presented for the chemicals industry a wide range of demanding tasks requiring substantial expertise from scientists, consultants, lawyers, and others. The transitional phase of REACH ended on 31 May 2018, and companies of all shapes and sizes are now engaged in a wide range of ongoing compliance activities. This column addresses certain important REACH-related activities being undertaken by numerous entities in the ongoing post-deadline era, and provides comments on their significance.

Dossier Updates

REACH Article 22 requires companies to update registration dossiers “without undue delay” in case of a change in the registrant’s status or identity, changes in substance composition, changes in annual quantities, new identified uses or uses advised against, new information regarding risks of a substance, and changes in classification and labelling. REACH registrants face obligations for continuous engagement, and the European Chemicals Agency (ECHA) evaluates closely whether registration dossiers are REACH-compliant. Following relief from the demands of the deadlines, chemical companies are devoting increased resources towards ensuring that necessary dossier updates are performed timely.

This is great news from a chemical safety standpoint as better information on chemicals facilitates their safer regulatory management.

Management of dossier and substance evaluation

In accordance with REACH Title VI, ECHA performs compliance checks for registration dossiers. A significant proportion of submitted registration dossiers are considered non-compliant by ECHA due to invalid read-across arguments, illegitimate “opt-outs,” or incompleteness. ECHA requires updates for non-compliant dossiers to bring them into compliance with REACH requirements, and these updates oftentimes require additional testing to be performed. ECHA is keen on ensuring compliance of registration dossiers, and many companies that registered phase-in substances are actively following ECHA’s dossier evaluation process and performing necessary updates. These efforts can be

challenging for chemical companies and consultancies due to limited resources, ECHA’s short timeframes for response, and the need to coordinate with co-registrants.

Substance evaluation is also an important matter for REACH registrants. Member States are evaluating chemical substances under the Community Rolling Action Plan (CoRAP), which currently lists 375 substances. Member States are evaluating several important chemicals in 2019, and product stewardship teams are following closely these measures due to their potentially significant commercial repercussions (e.g., identification as a substance of very high concern, restrictions). Many entities are busy, in 2019, due to substance evaluation-related needs for suitable correspondence with Competent Authorities and completion of additional testing.

The ongoing efforts of regulatory authorities and industry in the evaluation procedures improve chemicals management and contribute importantly towards Europe’s achievement of its ambitious goals pertaining to environmental, health and safety.

Cost reconciliation, new Co-registrations, ECHA decisions, and legal updates

Many Lead Registrants (LR) are currently performing cost reconciliation for substances registered ahead of the final registration deadline, including hiring external accountants, ensuring fair and transparent cost distribution, and issuing reimbursements to co-registrants. Due to Implementing Regulation (EU) 2016/9 and recent case law, non-discrimination in cost sharing under REACH is better than ever. Managing data compensation equitably under REACH is more difficult for LRs than previously, and the robust rules are keeping industry occupied. In addition, LRs are now assisting post-2018 Letter of Access requesters in completing their registrations.

Due to ECHA’s seemingly insurmountable workload for the final registration deadline, decisions on certain matters were delayed. ECHA is currently issuing decisions for ongoing contentious issues such as LR disputes, and these decisions require prompt action and coordination by LRs and co-registrants (e.g., forming one registration in accordance with the “One Substance, One Registration” principle). As Substance Information Exchange Forums (SIEF) became non-operational on 1 June 2018, many attorneys have completed modifications to LRs’ “SIEF Agreements” to support compliance. Lawyers continue to negotiate contracts facilitating substance co-registrations to ensure the state of the art is reflected in these documents.

These activities support the proper functioning of REACH and advance its crucial goals.

Brexit preparation

Numerous companies have, this year, followed Brexit-related developments and implemented programs for post-Brexit REACH compliance. While a detailed discussion on these measures is beyond the scope of this article, it is clear that well-informed and comprehensive plans will support post-Brexit market access across Europe.

Discussion

Life after the deadlines remains busy and interesting in the EU REACH space. The transitional years under REACH were vital in gathering information on chemicals and developing a solid foundation for achievement of the regulation's goals. The end of the registration deadlines marks the start of a new chapter under REACH, rather than the end of the REACH era. REACH compliance activities are expected to continue for many years to come, and that is a positive sign for chemical safety in Europe.

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Catalyst opens new History Makers gallery!

On Friday 17th May, Catalyst was thrilled to officially open the Baker Gallery, a new exhibition which celebrates the work of local chemist Dr Harry Baker, a pioneer in the development of chlorine production at the Castner Kellner factory in Runcorn, on the site now owned by INOVYN.

The gallery has been funded by AIM BiffaAward under a scheme called History Makers which enables museums to recognise remarkable people that helped to shape our world.

Guests at the opening included members of the Baker Family, Chris Tane CEO of Inovyn, members of AIM, invited guests and year 5 pupils from Weston Point Community Primary School who worked with the designer of the gallery to research the life and work of Harry Baker. They produced a newspaper which was given away at the event and created a song which they performed at the opening ceremony.

Dr Diana Leitch, Chair of Trustees and Acting Director of Catalyst said "It's almost 3 years ago that we had a dream

to create a gallery dedicated to a local history maker and we hope that when you see the gallery you will understand its significance. Catalyst is very much about the past, present and the future, and the future is the young people that we inspire.

We chose to work with Weston Point Community Primary School particularly because they are right next door to where Harry Baker worked from 1897 for the rest of his career, and where 122 years on, chlorine is still produced today, which is incredibly important."

Emma Chaplin, Director of AIM, the Association of Independent Museums, said "It is fair to say that most of us had not heard of Harry Baker when we received the application from Catalyst but we were blown away by the passion and the huge connection to the site and the community. You've set the bar really high for other History Makers and from our point of view, it's great that we can showcase you to other museums across the country and that BiffaAward can show how landfill tax money is being invested, so, incredibly well done for making such a difference."

You can find out more about Catalyst by visiting the website at www.catalyst.org.uk

