



Cefic position regarding chemicals regulatory cooperation after Brexit

Introduction

Europe's chemical industry is a global leader. We deliver the every-day practical solutions to accelerate Europe's industrial renaissance. Yet we, as many others, rely on an integrated single market throughout Europe, one that operates across borders, without discrimination. We are at the start of the production process, so any disruption of trade flows will reverberate throughout the entire industrial value chain.

The chemical industry has taken note of the idea advanced in Theresa May's Mansion House speech of 2 March for the UK to remain part of EU agencies, including ECHA, possibly in the form of Associate Membership. The draft Withdrawal Agreement and the guidelines for the negotiations of the future EU-UK relationship do not provide for this possibility.

With a focus on ensuring protection of human health and the environment in Europe from risks associated with chemicals, REACH is fast becoming an international reference standard in chemicals management. Establishing a separate and most likely different UK regulatory regime would take years to achieve, and at significant cost jeopardising a decade's worth of investment into safe chemicals management by government and industry, which should serve as a global example rather than segregate into fragments. A continued partnership between the UK and ECHA would focus administration, scientific work and related costs under REACH, as well as assuring continuity of supply to key customer industries such as aerospace, automotive and pharmaceuticals, all of whom rely upon access to chemicals from both sides of the channel.

This paper analyses the REACH related consequences of the UK becoming a third country after Brexit for companies and of the exclusion of the UK from participation in ECHA.

REACH related consequences for industry and customer industries

The impact to businesses both in the UK and EU-27 should not be underestimated. The UK chemical industry represents about 7% of total EU-28 sales. EU-27 export to the UK reached 22.6 billion EUR in 2016, about 4.5% of total EU-27 sales, while imports from the UK totalled 19.3 billion EUR.

Many EU based downstream users are currently relying on the 10,000 plus REACH registrations submitted by their UK suppliers. Without UK's participation in EU REACH these EU based companies will become importers and consequently need to complete their own registration or rely on an EU-based only representative appointed by their UK supplier, thereby risking losing the supply of a REACH registered substance. Similarly, UK downstream users importing chemicals from their EU suppliers without currently having any REACH related obligations may become importers now with new registration duties under UK REACH. Both scenarios will create significant disruption in supply chains as no import can take place until registration is complete – a process which can take several months to complete.

Beyond registrations similar disruptions are expected for existing REACH authorisation holders and their related supply chains (e.g. component manufacturers, chemical formulators) who will no longer be able to rely upon authorisations granted to UK based companies. At the same time there is a possibility of having to repeat the authorisation processes under the future UK regulation before being able to legally supply into the UK. Duplication of regulations and its associated costs will hamper the competitiveness of both, the EU-27 and the UK.

Following Brexit, EU-27 sales to the UK will have to comply with the relevant UK legislation, which is at this stage unknown.

UK's contribution in delivering chemical safety

To date the UK's participation in the implementation of REACH and related product policy regulations can be summarized as follows:

- UK companies are currently considered "EU legal entities" under REACH. Registrations or authorisations submitted under REACH allow companies to manufacture, import and trade chemicals within the EU. With the UK no longer participating in EU REACH, UK registrations and authorisations will no longer be recognised under REACH as they belong to "third country" entities outside the EU/EEA.
- Over 10,000 registrations have been submitted by the UK accounting for over 5,000 substances. This makes UK companies the second highest contributor to the number of REACH registrations, behind German companies.¹
- Between 2012 and 2018, UK is one of the top three member states assessing chemicals under the REACH substance evaluation process to alleviate a concern, behind Germany and France.
- UK is undertaking the highest number of evaluations for active substances and authorisations for biocidal products under the Biocidal Product Regulations.
- UK has been a major contributor to the inventory of harmonized classifications and according to the current state of the registry of intentions is one of the top five member states to be submitting over 50 dossiers for a European harmonised classification and labelling for chemical substances.
- UK also actively participates in several ECHA committees such as the Risk Assessment Committee (RAC), the Socio Economic Analysis Committee (SEAC), Biocidal Product Committee (BPC) as well as the Forum of Enforcement and related projects.

Industry position

Duplication of regulations, and its associated costs, should be avoided through securing regulatory alignment and continued collaboration with the relevant EU agencies such as ECHA. It is in the industry's interest, that existing data and registration dossiers can be leveraged in order to avoid duplication of work and associated costs.

- a) REACH registrations, authorisations, notifications and approvals remain in effect

It is our understanding that the draft withdrawal agreement TF50 (2018) 35 stipulates that during the transition phase (Art. 121 and following) Union law, including REACH and the CLP, remain applicable to and in the UK. Cefic urges the legislators of both negotiation partners to endorse this provision with high priority.

¹ Source: <https://echa.europa.eu/registration-statistics-infograph#>

In case of a no-deal scenario the chemical industry and their customers have to ask ECHA for support, in order to avoid compliance gaps and resulting disruption in the value chains of the affected chemicals. This may include

- adaptation of measures proposed by the Directors Contact Group like acceptance of preliminary registrations if a lead registrant for a substance is based in the UK
- information of Substance Exchange and Information Fora (SIEFs) if their lead registrant is located in the EU.

In addition, Cefic supports the continued grandfathering (continued validity) of existing and approved (by ECHA) registrations and authorizations, minimising the regulatory barrier for the sector in moving chemicals to its key downstream customer industries across Europe. Indeed, the free trade of these products should be guaranteed under the same current conditions and this should apply until the authorisation has to be renewed or the registration updated.

- b) Alignment of a future UK chemicals law to REACH, the Classification, Packaging and Labelling and the Biocidal Product Regulation.

REACH/CLP

- Alignment of GHS classification (including guidance documents and harmonised classification) and labelling between UK and EU.
- The process for registering new substances to remain the same as it is now i.e. registering it with ECHA.
- Registration requirements remain the same for new substances.
- Test methods, including read-across, aligned with the EU.
- Level playing field regarding authorisation: The UK should adopt REACH rules on authorisation. Formal mutual consultations regarding Annex XIV entries.
- Data protection rules identical to those provided under REACH.

Biocidal Product Regulation

- Alignment of a future UK BPR legislation to the existing EU BPR regulation.
- Acceptance of active substance evaluations
- Acknowledgment of European manufacturers as a listed source for the supply of active substances to the UK. No additional UK entity necessary – i.e. in an Only Representative type of function.
- Mutual recognition of Biocidal products.
- Union Authorisation of Biocidal products.
- No additional restrictions or requirements on placing treated articles on the market.

As a general request, the UK and EU should use the same IT tools for notifications as well as for authorisation of active biocide and crop protection substances.

- c) Involvement of UK Competent Authorities in EU Agencies

Industry would encourage both EU and UK negotiators to consider the following elements as a basis for the UK's continued participation in EU REACH. This would represent the most effective way for businesses to continue trading efficiently across borders without jeopardising the significant progress Europe has made over the last decade in chemical safety.

Recognising and appreciating the expertise and contributions of UK competent authorities to the regulatory processes:

- provide the UK competent authority with full access to EU Agencies data bases. The access to the ECHA database should avoid that EU companies exporting to the UK have to resubmit the same data already present in the ECHA database;
- allow for the participation of UK Competent Authority in the ECHA bodies; while the Withdrawal Agreement foresees that this participation does not include decision-making powers and that current assignments of dossiers to the UK competent authorities are transferred to competent authorities of other member states, Cefic would prefer a close involvement of the UK into activities of EU agencies considering that this would maintain the current pace of the processes, contain costs and avoid double work;
- allow for the UK competent authority to continue their work on assessments, approvals and authorisations which they will have led and which are ongoing on the day before the date of entry into force of the Withdrawal Agreement.

In considering the above elements, Cefic recommends a bilateral agreement between the EU and the UK that allows continued participation of UK authorities as well as UK businesses in the implementation of the regulations (REACH, CLP, PIC and Biocidal Products Regulation) administered by the Agency. This scenario would represent the most effective way to ensure companies can continue to efficiently trade across borders and their operations are not disrupted by Brexit.

Considering the EU's efforts to promote REACH as the preferred chemicals management system the argument that other third countries are not involved in REACH either does not fly. Whereas Canada, Korea and Japan can comply with REACH as third countries, the UK is fully in the REACH system. Establishing a separate UK agency would take years to achieve, and at significant cost threaten to waste a decade's worth of investment into chemical safety by government and industry. A continued partnership between the UK and ECHA would avoid duplicate testing and related costs under REACH, as well as assuring continuity of supply to key customer industries such as aerospace, automotive and pharmaceuticals, all of whom rely upon access to chemicals from both sides of the channel.