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REACH related issues in the future relationship between the EU-27 and the United Kingdom

Introduction

Following the UK's departure from the European Union on 31st January 2020, both sides are now engaged in the future-relationship negotiations during the transition period. A priority in these negotiations is the conclusion of a trade agreement that will be the core of the future economic relationship.

In 2018 bilateral EU27 – UK chemicals trade amounted to about €46 billion. With the UK chemical industry representing 6% of total EU28 sales and UK exports to the EU27 representing about 60% of UK sales in 2018, both sides are important markets to each other with highly integrated supply chains in the chemical sector and downstream.

Thus, the preferred option of the European chemical industry is a strong future partnership comprising a deep and comprehensive free trade agreement. While noting the challenges ahead, including the timing of the negotiations, this agreement should secure, at the minimum, frictionless trade and placing on the market of chemicals while ensuring the highest degree of regulatory cooperation between the UK and the EU27.

One of the key issues for our industry is regulatory cooperation. The chemical industry seeks an agreement that recognises the economic and environmental logic of remaining closely connected with regard to the REACH regulation, addressing the safe use of chemicals and their placement on the market. The UK and EU's negotiating approaches indicate that the two parties intend to form separate legal orders. The EU mandate suggests for a framework for voluntary regulatory cooperation in areas of Union interest, including exchange of information and sharing of best practice. Similarly, the UK mandate more specifically calls for cooperation on chemicals to be included in an annex to the future free trade agreement. To ensure high levels of protection for the environment, human and animal health and to support UK and EU businesses to meet the separate regulatory requirements of the two markets, the UK proposes to agree on data and information sharing mechanisms, in line with the relevant provisions set out in UK and EU regulation and existing third-country mechanisms. In addition, a commitment to develop a memorandum of understanding to enhance cooperation further, similar to those that the European Chemicals Agency has agreed with Australia and Canada, is suggested.

Consequences of separate REACH regulatory regimes without a comprehensive regulatory cooperation agreement

Due to the highly interconnected nature of chemicals supply chains, the outcome of the negotiations will have important implications for both manufacturers and users of chemicals both in the UK and in the EU27/EEA countries. EU-REACH would stop applying to the UK from 1 January 2021 and through the EU (Withdrawal) Act, the UK Government has converted REACH into UK law. This approach means that equivalent regulatory requirements to manufacture and import chemical products in the UK will apply

once the transition ends but specified in a separate regulatory framework. Registration, evaluation, authorisation and restrictions will remain key elements of a UK REACH scheme.

Withdrawal of the UK from the EU-REACH system risks triggering substantial disruption on chemicals flowing both ways adding costs, complexity and burden for business on both sides (e.g. re-registration/re-authorisation of substances with its associated costs and extensive timelines). In case of two separate legislative systems, EU27/EEA sales to the UK will have to comply with UK REACH registration requirements under almost identical conditions as those under EU-REACH and within extremely tight and challenging timescales (2 years). Further, it should be noted, that most chemical products are mixtures of several substances and suppliers of chemical products therefore have to ensure that all substances, including the ones they purchase, are duly registered under the respective legislation, a costly process that could risk a number of products being no longer available to the UK market.

The balance of this cost is not one-sided and this additional administrative and financial burden will negatively impact both suppliers from the EU, if choosing to appoint an Only Representative, along with chemical product users in the UK, acting as importers.

Similarly, once the UK leaves the EU REACH regime, EU27/EEA businesses relying on REACH registrations from UK suppliers will become *importers* under EU REACH and subject to registration requirements, unless they can purchase the substance from suppliers in the EU27/EEA who have a REACH registration or are covered by EU27/EEA-based ORs appointed by UK companies. Again, the risk is that a number of substances will no longer be available for EU market.

The immediate cost is expected to be over £1 billion in addition to the existing cost of EU REACH which is estimated at 10 billion euros, with no additional environmental benefit and potentially forcing duplicate testing including animal studies, if non-obligatory data-sharing between EU and UK companies cannot be successfully achieved. We believe duplicating data requirements on chemicals does nothing towards improving chemicals safety and would only bring long term costs and burden to businesses and regulators and would completely disregard and undermine the 3Rs principle (**R**eplacement, **R**efinement and **R**eduction of Animals in Research). The approach below sets out a pathway that would enable building on the existing efforts enabling the European chemical industry to thrive and continue delivering many of the solutions essential for environmental, social and economic performance. It would also enable both UK and EU downstream users to continue sourcing from a wider portfolio market, reducing the risk of supply-chain disruption whilst reducing the cost and resource requirements for businesses across Europe.

Proposed approach to minimize disruption to business and keep costs, bureaucracy, technical barriers to trade and animal welfare concerns to a minimum whilst maintain high levels of protection:

Agreement on data and information sharing for chemicals under existing EU regulation

Negotiating a partnership that is significantly closer than that one envisaged by existing regulatory cooperation agreements between ECHA and some non-EU countries is of vital importance. Existing cooperation agreements between ECHA and non-EU countries generally entail sharing best practice, exchanging views in experiences in implementing their respective regulations and scientific knowledge in relation to risk assessment of chemicals. The agreements between ECHA, Australia and Canada relate to

the use of data for the purposes of classification and labelling (under GHS) or in connection with the relevant local notification schemes where the chemical itself is listed, but – unlike REACH - there is no nominative listing (company by company). Usually for a substance that is inventory listed, there is no need to register, and hence no need to generate or obtain additional data. Signing an agreement similar to those ECHA currently has with Australia and Canada would not overcome issues companies will face in duplicating registration requirements as well as the need for data and intellectual property rights under both UK and EU REACH.

In terms of existing provisions under EU law, Article 120 of REACH foresees the potential scenario of an agreement on sharing information held by the Agency with non-EU authorities, providing its purpose is cooperation on the implementation or management of legislation concerning chemicals and the third party protects the confidential information as mutually agreed.

Also, Article 24 of REACH foresees a mechanism to acknowledge existing notifications under Directive 67/548 (“Dangerous Substance Directive”) and allows to accept them in place of registrations. Translating this mechanism to the situation under BREXIT would imply that current REACH registration would be acknowledged as being valid under UK REACH as well. Where necessary, designated ORs could notify UK competent authorities about the existence of REACH registration numbers ensuring that confidential business information in the value chain are not disclosed downstream in the value chain. This mechanism may require that ECHA verifies the information provided by the notifier.

As the intention of the UK government is to require individual registrations for substances and to continue to monitor and evaluate chemicals in the UK, we believe these options should be explored during the negotiations as basis for future cooperation on chemicals management across Europe and in order to leverage available data for the purpose of chemicals management to the extent possible.

Cooperation agreement

As a minimum, cooperation between the UK and EU should be based on the following areas:

- A work programme enabling sharing results of chemical assessments between the UK authority and ECHA with the aim to share knowledge on hazards and risk assessment of chemicals.
- Joint collaboration between the UK and the EU under the REACH evaluation process avoiding two parallel separate reviews of the same chemicals, limiting further animal studies and providing a consistent basis for decision making on chemicals.
- Establishing the disclosure of data between the relevant competent authorities in the UK and EU27 including confidential business information according to REACH Article 120 in order to assess chemicals from a comparable and consistent dataset.
- Regular meetings and exchange of information in the context of future technical and scientific cooperation.
- Information exchange on matters of common interest such as emerging risks from chemicals.
- Sharing operations or implementation experiences to strengthen enforcement and regulator capacity.
- Agreement on mutual acceptance of study-data generated based on well accepted guidelines and standards like GLP.

The registration of existing chemicals has already been carried out in the EU with a decade of REACH implementation by collecting and generating a myriad of data on the properties of chemicals and performing risk assessment as required by the legislation. We believe an agreement between the UK

authority and the EU on sharing information related to registration dossiers could also justify a review of the proposed UK REACH legislation. Going forward and building on the existing progress of the REACH objectives, the UK could focus on prioritising and addressing chemicals of most concern. In order to do so, the UK would have data available by means of the disclosure mechanism as allowed by Article 120 thus respecting the overarching principle ‘no data, no market’ of the REACH regulation. It is understood that substances entering the UK market as substances which have not been registered under REACH will have to provide the set of data required by UK REACH. In terms of priorities, with an agreement on cooperation in place, the UK could consider a simple UK notification scheme to confirm chemicals on the UK market have already been registered under EU REACH. As described above, this notification may require verification by ECHA.

This model would acknowledge the level of work and expense already made with respect to EU-REACH and focus future efforts on prioritizing and addressing chemicals of most concern by allowing those companies who deal in REACH registered supply-chains.

Advantages to this system would include:

- The level of human and environmental protection is not lowered, compared to EU standard, because data would be available to the UK competent authorities for scrutiny and further substance regulation. If anything, this regulatory mechanism could be regarded as a higher level compared to a UK-registration scheme, as we expect EU dossiers to be generally larger volume and therefore supported by a more comprehensive dataset.
- The UK would be regulating chemicals from the same and a more comprehensive dataset and would therefore minimize divergence in managing chemicals across Europe.
- The UK authority would still be able to regulate certain chemicals of national concern, separate to the EU if considered appropriate. This would also be in line with OECD’s guiding principles and international best practices to consider within prioritisation schemes**. UK and EU chemical users can continue to source from a wider portfolio/supplier market and not be restricted to those substances/suppliers registered under a UK-REACH
- Animal welfare, the removal of potential repetition of vertebrate studies.
- Reduction in cost & resource requirements for both the UK authority and UK chemical users.
- Reduction of supply-chain disruption compared to a fully stand-alone UK registration scheme

Smoothly planned transition

The timing to negotiate a deal is short and considering the importance for the sector of a good and organized transition, we urge the negotiators to put chemical cooperation high on the agenda.

Whatever shape the future relationship may eventually take, first and foremost we are urging negotiators to ensure that the regulatory systems of the EU-27 and the UK remain highly aligned and go beyond existing cooperation agreements between ECHA and some non-EU countries. In our view, this will not only allow for continuity and consistency for companies and regulatory bodies operating on both sides of the Channel, but also ensure a framework for the continued development and implementation of high health, safety and environmental standards in a level playing field.

** Article 120: Cooperation with third countries and international organisations*

Notwithstanding Articles 118 and 119, information received by the Agency under this Regulation may be disclosed to any government or national authority of a third country or an international organisation in accordance with an agreement concluded between the Community and the third party concerned under Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals (³¹) or under Article 181a(3) of the Treaty, provided that both the following conditions are met:

(a) the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation;

(b) the third party protects the confidential information as mutually agreed

*** [http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono\(2019\)34&doclanguage=en](http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2019)34&doclanguage=en)*