EUROPEAN COMMISSION
DIRECTORATE-GENERAL ENVIRONMENT
DIRECTORATE-GENERAL FOR INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES

Brussels, 26 February 2019

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES IN THE FIELD OF CHEMICALS REGULATION UNDER REACH

The United Kingdom submitted on 29 March 2017 the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. This means that as from 30 March 2019, 00:00h (CET) ('the withdrawal date')[1] the United Kingdom will be a 'third country'.[2]

Preparing for the withdrawal is not just a matter for EU and national authorities but also for private parties.

In view of the uncertainties surrounding the ratification of the Withdrawal Agreement, all interested parties, and especially economic operators, are reminded of legal repercussions, which need to be considered when the United Kingdom becomes a third country.[3]

Subject to the transition period provided for in the Withdrawal Agreement,[4] as of the withdrawal date, Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency,[5] will no longer apply to the United Kingdom. This has in particular the following consequences:

---

1 In accordance with Article 50(3) of the Treaty on European Union, the European Council, in agreement with the United Kingdom, may unanimously decide that the Treaties cease to apply at a later date.

2 A third country is a country not member of the EU.

3 This notice complements the comprehensive information provided by the European Chemicals Agency (ECHA) in respect of the withdrawal of the United Kingdom: https://echa.europa.eu/uk-withdrawal-from-the-eu

4 Cf. Part four of the *Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community* (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.CI.2019.066.01.0001.01.ENG&toc=OJ:C:2019:066I:TOC)

5 OJ L 396, 30.12.2006, p. 1.

1. REGISTRATION

1.1. Registrations held by a registrant (manufacturer/producer, importer or Only Representative) established in the United Kingdom

According to Article 5 of Regulation (EC) No 1907/2006, as a general rule, substances on their own, in mixtures or in articles manufactured or placed on the EU market in quantities of 1 tonne or more per year have to be registered with the European Chemicals Agency (ECHA). The registrant has to be established in the EU (Article 3(4), (9) and (11) of Regulation (EC) No 1907/2006). Where a manufacturer/producer is established in a third country, that manufacturer/producer may appoint a person acting as his "Only Representative" (Article 8 of Regulation (EC) No 1907/2006). The Only Representative has to comply with the requirements set out in Article 8(2) of Regulation (EC) No 1907/2006, in particular as regards the keeping available of information with regard to quantities and supply of the registered substances.

As of the withdrawal date, a registration held by a registrant (manufacturer/producer, importer or Only Representative) established in the United Kingdom is no longer valid in the EU.

Therefore, manufacturers/producers established in the United Kingdom should:

- transfer the registration to a manufacturer or importer in the EU-27; or
- appoint an Only Representative in the EU-27 as registrant for the substance.

ECHA has published detailed guidance on how to transfer a registration prior to the withdrawal of the United Kingdom.[6]

Manufacturers/producers established in a third country and using an Only Representative established in the United Kingdom should transfer the registration to an Only Representative in the EU-27.

Importers established in the United Kingdom and supplying substances, mixtures or articles to the EU-27 should take steps to ensure that the manufacturer/producer in the third country from which they are importing appoint an Only Representative in the EU-27 as registrant for the substance.

1.2. Relevance for downstream users in the EU-27

According to Article 5 of Regulation (EC) No 1907/2006, a downstream user may only use a substance or mixture in quantities of 1 tonne or more per year that has been registered in accordance with that Regulation.

6 https://echa.europa.eu/documents/10162/13552/how_to_transfer_uk_reach_registrations_en.pdf/1fb443ce-79de-6596-aae5-3f1033f1a5fb

Moreover, as of the withdrawal date, a substance not registered in accordance with Regulation (EC) No 1907/2006 can no longer be imported into the EU-27 in quantities of 1 tonne or more per year.

Therefore, downstream users should assess whether the substance used is registered by a registrant established in the EU-27. Where this is not the case, the downstream user should:

- adapt the supply chain accordingly (i.e. identify an alternative supplier);
- contact the registrant to ensure that the registrant plans to appoint an Only Representative; or
- register the substance in the capacity of importer or Only Representative appointed by the UK registrant.

ECHA has published a list of all substances solely registered by legal entities established in the United Kingdom.[7]

1.3. Joint submissions/lead registrant

Articles 11 and 19 of Regulation (EC) No 1907/2006 require the joint submission of a registration, with a Lead Registrant.

As set out in section 1.1 of this notice, as of the withdrawal date, the registration by a person established in the United Kingdom becomes invalid. If this person was the Lead Registrant, the steps set out above (section 1.1.) should be taken. If that Lead Registrant does not intend to take these steps, one of the other members of the joint submissions should take over the role of the Lead Registrant.

2. AUTHORISATION

2.1. Authorisation holders and authorisation applicants established in the United Kingdom

According to Article 56(1) of Regulation (EC) No 1907/2006, the use and placing on the market of substances listed in Annex XIV to that Regulation require an authorisation by the Commission to be placed on the market or used.

According to Article 62(2) in conjunction with Article 3(9), (11) and (13) of Regulation (EC) No 1907/2006, the applicant for an authorisation and the authorisation holder have to be established in the EU.

As of the withdrawal date, an application for an authorisation submitted by, or an authorisation held by a person established in the United Kingdom is no longer valid in the EU.

[7] https://echa.europa.eu/advice-to-companies

Where the application for authorisation or authorisation decision covers uses by actors downstream in the applicant's/authorisation holder's supply chain in accordance with Article 56(2) of Regulation (EC) No 1907/2006, the end of validity of the application/authorisation will also affect those operators established in the EU-27 who will no longer be covered by the application/authorisation.

There are no adopted authorisation decisions falling under this scenario.

Regarding pending authorisation applications falling under this scenario, in order to ensure that the downstream users are covered by the application, the UK-based applicant should ensure that:

- the application is transferred before the withdrawal date to a legal entity established in the EU-27. Such a transfer must be the result of a change of legal entity (for example, as the result of a merger, a split or an asset sale), and the person to whom the application is transferred must qualify as manufacturer, importer or downstream user of the substances within the scope of the application for authorisation; or

- the application is transferred to an Only Representative established in the EU-27 with effect on the withdrawal date.

The applicant has to notify ECHA of the legal entity change before the withdrawal date.

2.2. Relevance for downstream users in the EU-27

According to Article 56(2) of Regulation (EC) No 1907/2006, the authorisation may encompass the downstream use of a substance.

Therefore, downstream users subject to authorisation should assess whether the applicant for authorisation covering their use is established in the United Kingdom.

In this case, the downstream user should contact the applicant for authorisation in order to ensure that the latter takes the steps set out under section 2.1 of this notice. Alternatively, where the application for authorisation covering the downstream user's use is a joint application with other EU-27 legal entities, the downstream user may get the substance supplied from an EU-based co-applicant.

The dedicated "Brexit-website" of ECHA (https://echa.europa.eu/uk-withdrawal-from-the-eu) as well as the Commission website on Chemicals (http://ec.europa.eu/environment/chemicals/reach/reach_en.htm) provide additional information. These pages will be updated with further information, where necessary.

European Commission
Directorate-General environment
Directorate-General for internal market, industry, entrepreneurship and SMEs