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26 February 2019

NOTICE TO STAKEHOLDERS

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

Since 1 February 2020, the United Kingdom has withdrawn from the European Union and has become a ‘third country’.¹ The Withdrawal Agreement² provides for a transition period ending on 31 December 2020.³ Until that date, EU law in its entirety applies to and in the United Kingdom.⁴

During the transition period, the EU and the United Kingdom will negotiate an agreement on a new partnership, providing notably for a free trade area. However, it is not certain whether such an agreement will enter into force at the end of the transition period. In any event, such an agreement would create a relationship which in terms of market access conditions will be very different from the United Kingdom’s participation in the internal market,⁵ in the EU Customs Union, and in the VAT and excise duty area.

Therefore, all interested parties, and especially economic operators, are reminded of the legal situation as of the end of the transition period (Part A below). This notice also explains certain relevant separation provisions of the Withdrawal Agreement (Part B below), as well as the rules applicable to Northern Ireland as of the end of the transition period (Part C below).

Advice to stakeholders:

¹ A third country is a country not member of the EU.

² Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, OJ L 29, 31.1.2020, p. 7 (“Withdrawal Agreement”).

³ The transition period may, before 1 July 2020, be extended once for up to 1 or 2 years (Article 132(1) of the Withdrawal Agreement). The UK government has so far ruled out such an extension.

⁴ Subject to certain exceptions provided for in Article 127 of the Withdrawal Agreement, none of which is relevant in the context of this notice.

⁵ In particular, a free trade agreement does not provide for internal market concepts (in the area of goods and services) such as mutual recognition, the ‘country of origin principle’, and harmonisation. Nor does a free trade agreement remove customs formalities and controls, including those concerning the origin of goods and their input, as well as prohibitions and restrictions for imports and exports.

To address the consequences set out in this notice, manufacturers/producers established in a third country, including the United Kingdom, of 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, are in particular advised to:

- ensure registration is with a manufacturer or importer in the EU; or
- appoint an Only Representative in the EU as registrant for the substance.

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

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

A. LEGAL SITUATION AS OF THE END OF THE TRANSITION PERIOD

As of the end of the transition period, 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 Agency⁶ no longer applies in the United Kingdom.⁷ This has in particular the following consequences:

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.

⁶ OJ L 396, 30.12.2006, p. 1.

⁷ Regarding the applicability of Regulation (EC) No 1907/2006 to Northern Ireland, see Part C of this notice.

As of the end of the transition period, 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/formulators/producers established in the United Kingdom should:

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

ECHA has published detailed guidance on how to transfer a registration prior to the withdrawal of the United Kingdom.⁸

Manufacturers/formulators/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.

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

1.2. Relevance for downstream users in the EU

According to Article 5 in conjunction with Article 6(1) of Regulation (EC) No 1907/2006, a substance on its own or in a mixture may only be manufactured or placed on the market in quantities of 1 tonne or more per year if it has been registered in accordance with that Regulation.

The above means that, as of the end of the transition period, a substance not registered in accordance with Regulation (EC) No 1907/2006 can no longer be imported from the United Kingdom into the EU in quantities of 1 tonne or more per year.

Therefore, downstream users in the EU should assess whether the substance used is registered by a registrant established in the EU and whether their uses are covered by the registration. Where this is not the case, the downstream user should:

- adapt the supply chain accordingly (i.e. identify an alternative supplier) and, in case the downstream use(s) are not supported, report them together with a downstream user chemical safety report;
- contact the UK registrant to ensure that it plans to appoint an Only Representative; or

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

- 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.⁹

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 end of the transition period, 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, 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.

Therefore, as of the end of the transition period, 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.

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, as they will no longer be covered by the application/authorisation.

There are currently three adopted authorisation decisions falling under this scenario.

For those decisions as well as for pending authorisation applications falling under this scenario, in order to ensure that the downstream users are covered by the authorisation/application, the UK-based authorisation holder/applicant should ensure that:

⁹ <https://echa.europa.eu/advice-to-companies>

- the import activity/application is transferred before the end of the transition period to a legal entity established in the EU. 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
- if the authorisation holder/applicant is a manufacturer, it appoints an Only Representative established in the EU with effect at the end of the transition period.

The applicant has to notify ECHA of the legal entity change before the end of the transition period.

2.2. Relevance for downstream users in the EU

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

Therefore, downstream users in the EU 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 legal entities, the downstream user may get the substance supplied from an EU-based co-applicant.

B. RELEVANT SEPARATION PROVISIONS OF THE WITHDRAWAL AGREEMENT

Article 41 of the Withdrawal Agreement provides that an existing and individually identifiable good lawfully placed on the market in the EU or the United Kingdom before the end of the transition period may be further made available on the market of the EU or of the United Kingdom and circulate between these two markets until it reaches its end-user.

The economic operator relying on that provision bears the burden of proof of demonstrating on the basis of any relevant document that the good was placed on the market in the EU or the United Kingdom before the end of the transition period.¹⁰

For the purposes of these provisions, “placing on the market” means the first supply of a good for distribution, consumption or use on the market in the course of a commercial activity, whether in return or payment or free of charge.¹¹ ‘Supply’ means that ‘an existing and individually identifiable good, after the stage of manufacturing has taken place, is the subject matter of a written or verbal agreement between two or

¹⁰ Article 42 of the Withdrawal Agreement.

¹¹ Article 40(a) and (b) of the Withdrawal Agreement.

more legal or natural persons for the transfer of ownership, any other property right, or possession concerning the good in question, or is the subject matter of an offer to a legal or natural person or persons to conclude such an agreement.’¹²

C. APPLICABLE RULES IN NORTHERN IRELAND AFTER THE END OF THE TRANSITION PERIOD

As from the end of the transition period, the Protocol on Ireland/Northern Ireland (‘IE/Ni Protocol’) applies.¹³ The IE/Ni Protocol is subject to periodic consent of the Northern Ireland Legislative Assembly, the initial period of application extending to 4 years after the end of the transition period.¹⁴

The IE/Ni Protocol makes certain provisions of EU law applicable also to and in the United Kingdom in respect of Northern Ireland. It also provides that insofar as EU rules apply to and in the United Kingdom in respect of Northern Ireland, it is assimilated to a Member State.¹⁵

The IE/Ni Protocol provides that Regulation (EC) No 1907/2006 applies to and in the United Kingdom in respect of Northern Ireland.¹⁶

This means that, insofar as EU law made applicable by the IE/Ni Protocol to the United Kingdom in respect of Northern Ireland is concerned, references to the EU in Parts A and B of this Notice have to be understood as including Northern Ireland, whereas references to the United Kingdom have to be understood as referring only to Great Britain.

More specifically, this means *inter alia* the following:

a) Registrations:

- as a general rule, substances on their own, in mixtures or in articles manufactured or placed on the market in Northern Ireland in quantities of 1 tonne or more per year have to be registered with the European Chemicals Agency (ECHA); This also applies where the substance is shipped from Great Britain to Northern Ireland and placed on the market in Northern Ireland.
- a substance that is manufactured in Northern Ireland and shipped to the EU is not an imported substance for the purpose of registration requirements. A UK registrant established in Northern Ireland need not transfer the registration to a manufacturer or importer in the EU and need not appoint a person acting as his “Only Representative” in the EU;

¹² Article 40(c) of the Withdrawal Agreement.

¹³ Article 185 of the Withdrawal Agreement.

¹⁴ Article 18 of the IE/Ni Protocol.

¹⁵ Article 7(1) of the Withdrawal Agreement in combination with Article 13(1) of the IE/Ni Protocol.

¹⁶ Article 5(4) and section 23 of annex II to the IE/Ni Protocol.

- where the appointment of an Only Representative is possible, an Only Representative established in Northern Ireland will be considered to be an Only Representative in the EU (see above, section A.1);

b) Authorisations:

- the placing on the market and use in Northern Ireland of substances listed in Annex XIV to Regulation (EC) No 1907/2006 ('Annex XIV substances') is subject to the rules for authorisation under Regulation (EC) No 1907/2006; This also applies where the substance is shipped from Great Britain to Northern Ireland and placed on the market in Northern Ireland.
- Annex XIV substances manufactured or placed on the market in Northern Ireland require an authorisation under Regulation (EC) No 1907/2006;

However, the IE/Ni Protocol excludes the possibility for the United Kingdom in respect of Northern Ireland to

- participate in the decision-making and decision-shaping of the Union;¹⁷
- initiate objections, safeguard or arbitration procedures to the extent that they concern regulations, standards, assessments, registrations, certificates, approvals and authorisations issued or carried out by EU Member States;¹⁸
- act as leading authority for assessments, examinations and authorisations.¹⁹

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

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 Directorate-General for internal market, industry, entrepreneurship and SMEs

¹⁷ Where an information exchange or mutual consultation is necessary, this will take place in the joint consultative working group established by Article 15 of the IE/Ni Protocol.

¹⁸ Fifth subparagraph of Article 7(3) of the IE/Ni Protocol.

¹⁹ Article 13(6) of the IE/Ni Protocol.