



Brussels, 23 January 2018

NOTICE TO STAKEHOLDERS

WITHDRAWAL OF THE UNITED KINGDOM AND EU RULES ON BIOCIDAL PRODUCTS

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 unless the withdrawal agreement¹ establishes another date, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET) ("the withdrawal date"). The United Kingdom will then become a 'third country'.

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

In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, business operators involved in the activities falling under the scope of Regulation (EC) No 528/2012 concerning the making available on the market and use of biocidal products are reminded of certain legal repercussions stemming from currently applicable rules of Union law which need to be considered when the United Kingdom becomes a third country.

Subject to any transitional arrangement that may be contained in a possible withdrawal agreement, as of the withdrawal date, the EU rules in the field of biocidal products no longer apply to the United Kingdom. In particular, business operators should consider that, according to Union law, third countries cannot act as evaluating Member States or reference Member States².

Concerning **submissions of any new applications**, business operators should take into account the expected timelines of the different regulatory procedures in which the United Kingdom would be acting as, for example, evaluating Member State or reference Member State. Taking account of these uncertainties as well as the regulatory framework, business operators should consider taking the relevant actions. For example, where there is a risk that those procedures are not concluded by the date that the United Kingdom leaves the Union, applicants may choose by preference another evaluating Member State or reference Member State to carry out the evaluation.

Concerning those **on-going procedures** for which the United Kingdom is currently carrying out an evaluation, business operators should carefully monitor their progress. Where there are clear indications that the procedure will not be concluded by the withdrawal date, taking account of the uncertainties as well as the regulatory framework, business operators should

¹ Negotiations are ongoing with the United Kingdom with a view to reaching a withdrawal agreement.

² With the exception of contracting States of the European Economic Area ("EEA countries") and Switzerland.

consider taking the relevant actions. For example, business operators may consider changing to another evaluating Member State.

Business operators should also consider that, according to Union law :

- holders of product authorisations must be established within the Union (or EEA countries or Switzerland);
- active substance or product suppliers included in the list referred to in Article 95 of the Biocidal Products Regulation (EU) No 528/2012 must be established or have a representative established within the Union (or EEA countries or Switzerland).

The Commission services and the European Chemicals Agency (ECHA) are working with Members States, EEA countries and Switzerland to establish a coordinated way forward for the timely communication, agreement and technical transfer of the file in case change is needed. This will be particularly relevant for the review programme of existing active substances for which the United Kingdom was assigned as evaluating Member State by law (Commission Delegated Regulation (EU) No 1062/2014).

The website of the Commission on approval of active substances (https://ec.europa.eu/health/biocides/policy_en) provides general information concerning the approval of active substances as well as a series of Questions & Answers (Q&A) in relation to Biocidal Products Regulation (EU) No 528/2012 . This information is also available on the ECHA website.

These pages will be updated with further information and relevant Q&A, where necessary.

European Commission
Directorate-General for Health and Food Safety