EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH
AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and biocides

NOTICE TO BUSINESS OPERATORS IN THE FIELD OF

REGULATION (EU) NO 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL CONCERNING THE MAKING AVAILABLE ON THE MARKET AND USE OF 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 agreement establishes another date or the period is extended by the European Council in accordance with Article 50(3) of the Treaty on European Union, 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'.

In view of the considerable uncertainties, in particular concerning the content of a possible withdrawal agreement, all interested parties are reminded of certain legal repercussions stemming from currently applicable rules of Union law if the United Kingdom becomes a third country.

In particular, business operators should consider that, according to Union law, third countries cannot act as evaluting Member States or reference Member States[1].

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 e.g. 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 when the United Kingdom will leave 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 consider taking the relevant actions. For example, business operators may consider changing to another evaluating Member State.

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

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) will work with the Members States, EEA countries and Switzerland in order to establish a coordinated way forward for a timely communication, agreement and technical transfer of the file in case that 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 Commission Services and the European Chemicals Agency stand ready to provide further clarification to business operators and will provide series of Questions and Answers (Q&As) in relation to Biocidal Products Regulation (EU) No 528/2012 . They will be made publicly available on a dedicated page of (the Directorate-General for Health and Food Safety[2] and ECHA.

[2] https://ec.europa.eu/health/biocides/policy_en