



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH
AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and biocides

QUESTIONS AND ANSWERS RELATED TO THE UNITED KINGDOM'S WITHDRAWAL FROM THE EUROPEAN UNION WITH REGARD TO THE BIOCIDES SECTOR

On 13 September 2017, the European Commission published a Notice to business operators in the field of Regulation (EU) No 528/2012¹ of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (the BPR), stating: “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 this regard, business operators involved in activities falling under the scope of the BPR (i.e. activities related to biocidal active substances, biocidal products or treated articles) are reminded that preparing for the withdrawal is not just a matter for European and national authorities, but also for private parties.

Business operators should consider that, according to Union law, third countries cannot act as evaluating Member States or reference Member States. 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.

This list of Questions and Answers (Q&A pairs) has been drafted by the Commission services in consultation with ECHA, which aims at addressing the above mentioned consequences. The list of Q&A pairs will be a living document, which will be further updated and complemented when necessary.

¹ OJ L 167, 27.6.2012, p. 1.

1. What if my company is established in the UK and it is the holder of a product authorisation in another Member State or for Union authorisation?

According to Article 3(1)(p) of the BPR the authorisation holder must be established in the Union. Through the EEA Agreement² and the Mutual Recognition Agreement with Switzerland³, an authorisation holder can also be established in Norway, Iceland, Liechtenstein or Switzerland.

The authorisation holder will therefore need to transfer the authorisation to a new holder established in the Union, EEA countries or Switzerland. This amendment of the existing authorisations can be done by an administrative change requiring prior notification before implementation (see point 3 in section 1 of Title I in the Annex to Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products).

2. What if my company is listed in accordance with Article 95 and it is established in the UK?

According to Article 95(1) and (2) of the BPR, substance or product suppliers listed in the Article 95 list must be established within the Union. Therefore, a representative established within the Union (or EEA countries or Switzerland) should be appointed and communicated to ECHA⁴ in due time, so that the information on the list is updated before the date when the UK will leave the Union ("the withdrawal date" hereinafter).

3. My non-EU company is listed in accordance with Article 95 together with my EU representative; What if my EU representative is established in the UK?

According to Article 95(1) and (2) of the BPR, substance or product suppliers listed in the Article 95 list must be established within the Union. Therefore, a new representative established within the Union (or EEA countries or Switzerland) should be appointed and communicated to ECHA in due time, so that the information on the list is updated before the date the withdrawal date.

4. What if the manufacturing site of my active substance is located in the UK?

The BPR does not set any specific requirement regarding the location of the manufacturing site(s) of active substances. Therefore, the manufacturing can take place in third countries and no action needs to be taken in this respect. However, shipments to the EU of this active substance will be, as of the withdrawal date, importations which has consequences from the viewpoint of other sectorial legislation (e.g. customs).

5. What if the manufacturing site of my biocidal product is located in the UK?

The BPR does not set any specific requirement regarding the location of the manufacturing site(s) of biocidal products. Therefore, the manufacturing of biocidal products can take place

² OJ L 154, 22.5.2014, p. 22-23.

³ OJ L 171, 2.7.2015, p. 25-46.

⁴ See "requests for corrections" through this [link](#).

in third countries and no action needs to be taken in this respect by authorisation holders. However, shipments to the EU of this biocidal product will be, as of the withdrawal date, importations, which has consequences from the viewpoint of other sectorial legislation (e.g. customs)

6. What if the manufacturing site of my treated articles is located in the UK?

The BPR does not set any specific requirement regarding the location of the manufacturing site(s) of treated articles, which can be manufactured in third countries. Treated articles manufactured in third countries can be placed on the EU market if they meet the conditions of the BPR, in particular Articles 58 and 94. However, shipments to the EU of this treated article will be, as of the withdrawal date, importations which has consequences from the viewpoint of other sectorial legislation (e.g. customs).

7. What if the UK is acting as evaluating Competent Authority (eCA) or reference Member State (refMS) in any of my on-going regulatory procedures (e.g. active substance approval, renewal of an active substance approval, Union authorisation, simplified authorisation procedure, mutual recognition in parallel, renewal of product authorisations under Commission Delegated Regulation (EU) No 492/2014⁵ or applications for minor or major changes under Commission Implementing Regulation (EU) No 354/2013⁶)?

According to the BPR, the role of eCA/refMS is attributed to (the Competent Authority of) a Member State. Through the EEA Agreement and the Mutual Recognition Agreement with Switzerland, this is extended to include also Norway, Iceland, Liechtenstein and Switzerland.

Concerning those on-going procedures for which the UK is currently acting as eCA/refMS, 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 or reference Member State. The Commission Services and the European Chemicals Agency 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 1062/2014⁷).

8. What if my company is considering submitting now a new application for which the UK could be the eCA/refMS?

Until the withdrawal date, the UK remains a member of the European Union, with all the rights and obligations that derive from membership. Thus, the UK can still be chosen as

⁵ OJ L 139, 14.5.2014, p. 1.

⁶ OJ L 109, 19.4.2013, p. 4.

⁷ OJ L 294, 10.10.2014, p. 1.

eCA/refMS. However, on account of the current scenario and uncertainties as well as the expected timelines of the relevant regulatory procedure, 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 UK will leave the Union, applicants may choose by preference another eCA/refMS in order to avoid the procedure referred to in question 7 above (i.e. change to another eCA/refMS at a later stage).

9. What if the UK was the eCA for the first approval of my active substance and now my company needs to submit an application for renewal of the approval? Can my company choose another competent authority as eCA?

Yes. Article 13(3) of the BPR does not require that the eCA for the first approval shall be the eCA for the renewal, although it is usually recommended with the view that this can help streamlining the process. Article 13(3) requires that, when submitting the application for renewal, the applicant shall indicate the name of the competent authority that it proposes to evaluate the application for renewal and provide written confirmation that that competent authority agrees to do so. The Commission Services will work with Member States, EEA countries and Switzerland in order to establish a coordinated way forward to provide clear indications to prospective applicants.

10. What if the UK was my refMS for a MR procedure and now I need to submit an application for a change or renewal of my product authorisation? Can my company choose another competent authority as refMS?

Yes. Both Commission Implementing Regulation (EU) No 354/2013 and Commission Delegated Regulation (EU) No 492/2014 allows the authorisation holder to choose another refMS for the change or the renewal procedure, respectively. The applicant shall submit within the application written confirmation that the new competent authority agrees to be refMS.