ICDA
Irish Cosmetics, Detergent & Allied products Association
Ibec

Q&A – United Kingdom (UK) Exit from the European Union

Biocides

November 2018

1. **What effect will the withdrawal of the United Kingdom have with regard to active substances that were originally evaluated by the United Kingdom and subsequently approved by the European Commission?**

The withdrawal of the United Kingdom will not have any effect to the validity of the approval of these active substances. The approval of these active substances is a decision taken at EU level.

2. **My company is currently considering submitting an application concerning the making available on the market and use of biocidal products, for which the UK authorities could act as evaluating Competent Authority (eCA) or reference Member State (refMS). How should we proceed?**

Until the withdrawal date, the United Kingdom remains a member of the European Union, with all the rights and obligations that derive from membership. Thus, you may still choose the United Kingdom as eCA/refMS. However, as of the withdrawal date, the United Kingdom can no longer act as an eCA/refMS. This also applies if a withdrawal agreement is concluded since the United Kingdom cannot act as eCA/refMS during the transition period. Applicants should take this into account if considering the United Kingdom as their eCA/refMS as it also implies that the file would need to be handed over to another Member State taking up the role as eCA/refMS before the withdrawal date.

3. **The manufacturing site of the active substance/biocidal product that my EU27-based company is placing on the EU market is located in the United Kingdom. Do we need to be concerned about the withdrawal of the United Kingdom?**

The Regulations do not set any specific requirement regarding the location of the manufacturing site(s) of active substances or biocidal products. Therefore, manufacturing can take place in third countries. However from the withdrawal date, shipments to the EU of this active substance/biocidal product will be considered to be imports, which may have consequences from the viewpoint of other sectorial legislation – see REACH questions.

4. **My UK-based based supplier is listed as a supplier according to Article 95 of Regulation (EU) No 528/2012. With a view to the withdrawal of the United Kingdom, what do I need to do?**

According to Article 95(1) of Regulation (EU) No 528/2012, substance or product suppliers listed in the Article 95 list must be established within the European Union. You will need to contact your supplier to see if they intend to appoint a representative established within the Union (or the EEA countries or Switzerland) and communicate this to ECHA (by submitting a "request for correction" 15) in due time, so that the information on the list is updated before the withdrawal date. Otherwise, the UK supplier will be removed from the Article 95 list, and biocidal products from this source would no longer be allowed to be made available in the EU.

5. **Will an EU-27 Member State, still be able to issue a national authorisation for a biocidal product on the basis of the mutual recognition in sequence of a UK authorisation after the withdrawal date?**

No. This will no longer be possible.

6. **My company holds an authorisation issued by an EU-27 Member State prior to the UK withdrawal date on the basis of the mutual recognition of a UK authorisation. Will my authorisation in the EU-27 Member State be affected by the withdrawal of the United Kingdom?**

No. The national authorisation granted by each EU-27 Member State will remain valid in that EU-27 Member State.

7. **My company notified to a number of Member States under Article 27(1) of Regulation (EU) No 528/2012 a low risk biocidal product authorised in the United Kingdom via the simplified procedure. What effect would the withdrawal of the United Kingdom have on these notifications?**

As of the withdrawal date the authorisation granted by the United Kingdom ceases to be valid. Therefore, in accordance with Article 17(1) of Regulation (EU) No 528/2012, the products notified in the other Member States can no longer be made available on the market nor used. If you want to keep your product on the market of the notified Member States, your company will need to obtain a new authorisation of the product via the simplified procedure, from an EU-27 Member State, prior to the withdrawal of the United Kingdom and then you will have to notify the other relevant Member States, EEA countries or Switzerland.

Further information

https://echa.europa.eu/advice-to-companies-q-as/bpr

https://ec.europa.eu/info/sites/info/files/qa_biocides.pdf