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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

On 23 January 2018, the European Commission services published a "*Notice to stakeholders – withdrawal of the United Kingdom and EU rules on biocidal products*".[1] This notice recalled the following:

"*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*[2] *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 States[3]."

This list of Questions and Answers (Q&A pairs) which has been drafted by the European Commission services aims at giving further guidance on the basis of the above-mentioned notice to stakeholders. The list of Q&A pairs will be further updated and complemented when necessary.

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1 This notice replaced the notice of 13 September 2017.

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

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

GENERAL

1. **My company is currently considering submitting an application under the Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products[4], 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 a eCA/refMS. This also applies if a withdrawal agreement is concluded since the United Kingdom cannot act as eCA/refMS during the transition period.[5] Applicants should take this into account when choosing 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.

2. **Currently, the United Kingdom is acting as evaluating Competent Authority (eCA) or reference Member State (refMS) in an on-going regulatory procedure related to my company (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 492/2014[6] or applications for minor or major changes under Commission Implementing Regulation (EU) No 354/2013[7]). What effect will the withdrawal of the United Kingdom have on the pending process?**

   According to Regulation (EU) No 528/2012, the role of evaluating Competent Authority (eCA) or reference Member State (refMS) is attributed to (the Competent Authority of) a Member State.[8]

   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[9].

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4 OJ L 167, 27.6.2012, p. 1.

5 See Article 123(6) of the draft Withdrawal Agreement, as agreed between the EU and the United Kingdom at negotiator's level, which is available here: https://ec.europa.eu/commission/sites/beta-political/files/draft_agreement_coloured.pdf

6 OJ L 139, 14.5.2014, p. 1.

7 OJ L 109, 19.4.2013, p. 4.

8 Through the EEA Agreement, as well as the Mutual Recognition Agreement with Switzerland, this is extended to further include Iceland, Liechtenstein, Norway, and Switzerland.

9 See Article 123(6) of the draft Withdrawal Agreement, as agreed between the EU and the United Kingdom at negotiator's level, which is available here: https://ec.europa.eu/commission/sites/beta-political/files/draft_agreement_coloured.pdf

Applicants in an ongoing procedure for which the United Kingdom is currently acting as eCA/refMS are advised to carefully monitor the UK authority's progress and to take the relevant actions. For example, if you see indications that the UK authority will not conclude the procedure by the withdrawal date, you may consider a transfer to another evaluating Member State.

The services of the European Commission and ECHA have been working with the EU-27 Member States, EEA countries and Switzerland to establish a coordinated approach to ensure a timely agreement and technical transfer of the file in case such a change is needed. The services of the European Commission and ECHA have already communicated some and will also communicate future transfers. This will be particularly relevant for the review programme of existing active substances for which the Commission Delegated Regulation (EU) No 1062/2014[10] assigned the United Kingdom as evaluating Member State (see more specific Q&A pairs below).

3. The manufacturing site of the active substance/biocidal product that my EU-27-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?

Regulation (EU) No 528/2012 does 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. Therefore, in this regards you will not need to take any action to continue complying with Regulation (EU) No 528/2012. However, shipments to the EU of this active substance/biocidal product will be, as of the withdrawal date, importations, which may have consequences from the viewpoint of other sectorial legislation (e.g. the Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals[11], EU customs legislation, etc.).

4. Will ECHA still grant UK-based companies a right to refer to tests or studies on vertebrates that were submitted to ECHA or to a competent authority in connection with a previous application under Regulation (EU) No 528/2012 or Directive 98/8/EC[12], also after the withdrawal of the United Kingdom?

The data sharing mechanism under Articles 62 and 63 of Regulation (EU) No 528/2012 will still be available to such companies, for the purposes of Regulation (EU) No 528/2012; for example, where a UK-based company intends to submit an application for active substance approval – and it requires vertebrate data for its application.

In this connection, it should be stressed that it is a legal obligation for companies to make an inquiry to ECHA in the case of vertebrate data (see Article 62(2)(a) of Regulation (EU) No 528/2012).

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10 OJ L 294, 10.10.2014, p. 1.

11 OJ L 201, 27.7.2012, p. 60.

12 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market, OJ L 123, 24.4.1998, p. 1.

5. **Will the substance or product-specific data owned by my UK-based company remain protected by the data protection rules of Regulation (EU) No 528/2012 after the withdrawal of the United Kingdom?**

   Yes. Data protection applies to all information submitted for the purposes of the Regulation (EU) No 528/2012 or its predecessor, Directive 98/8/EC, under the conditions set out in the Regulation (EU) No 528/2012.

ACTIVE SUBSTANCES

6. **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.

7. **My company needs to submit an application for renewal of an approval of our active substance for which the United Kingdom acted as the evaluating Competent Authority (eCA) during the first approval procedure. Considering that the United Kingdom can no longer, as of the withdrawal date, act as eCA, can my company choose another competent authority as eCA?**

   Yes. Article 13(3) of Regulation (EU) No 528/2012 does not require that the eCA for the first approval shall be the eCA for the renewal, although it is usually recommended as a means to streamline the process. The mentioned provision requires that, when you submit your application for renewal, you shall indicate the name of the competent authority that you propose for evaluating your application for renewal and provide written confirmation that that competent authority agrees to do so.

   The services of the European Commission have been working in a coordinated manner with EU-27 Members States, EEA countries and Switzerland in order to identify new eCAs for concerned active substances. The services of the European Commission have already informed the original participants in the review programme about the new eCAs. ECHA will also make this information publicly available in order to inform other prospective applicants (e.g. alternative suppliers).

8. **What effect does the withdrawal of the United Kingdom have with regard to applications for approval of active substances, either within or outside the review programme, that are currently being assessed by the United Kingdom?**

   As of the withdrawal date, the United Kingdom can no longer act as the eCA. This also applies if a withdrawal agreement is concluded since the United Kingdom cannot act as eCA/refMS during the transition period.[13]

[13] See Article 123(6) of the draft Withdrawal Agreement, as agreed between the EU and the United Kingdom at negotiator's level, which is available here: https://ec.europa.eu/commission/sites/beta-political/files/draft_agreement_coloured.pdf.

The services of the European Commission have been working in a coordinated manner with EU-27 Members States, EEA countries and Switzerland in order to identify new eCAs for concerned existing active substances. The European Commission will adopt and publish, before the withdrawal date, an amendment to the Review Programme Regulation[14] listing the existing active substances and the eCAs that will assess them. The name of the new eCAs has already been directly communicated to the participants in the review programme.

The services of the European Commission have also identified new eCAs for the assessment of pending applications for approval of those active substances that are not subject to the Review Programme Regulation (e.g. new active substances). The name of those eCAs has also been directly communicated to applicants and will be made known on the ECHA's website.

9. My UK-based company 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. Therefore, you will need 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.

10. I am a non-EU company and my EU representative for the purpose of Article 95 of Regulation (EU) No 528/2012 is established within the United Kingdom. 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. Therefore, you will need to appoint a new representative established within the Union (or EEA countries or Switzerland) and communicate this to ECHA (by means of a "request for correction"[16]) in due time, so that the information on the list is updated before the withdrawal date.

11. My EU-27-based company is listed under Article 95 of Regulation (EU) No 528/2012 as a supplier of a listed active substance for which we had purchased a letter of access (LoA) from a UK-based company. Will the withdrawal of the United Kingdom affect my company's listing under Article 95 of Regulation (EU) No 528/2012?

No. Data owners granting letters of access do not need to be EU-based.

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[14] The draft Delegated Regulation amending the Review programme Regulation has already been made publicly available through the "Better regulation" portal of the Commission at https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-2382032_en.

[15] https://echa.europa.eu/information-on-chemicals/active-substance-suppliers.

[16] https://echa.europa.eu/information-on-chemicals/active-substance-suppliers.

12. Will my UK-based company still be able to submit requests for active substance approval or inclusion of a substance on Annex I, after the withdrawal date?

Yes, third country entities can undertake such submissions. Contrary to the case of a product authorisation, applicants for the approval of an active substance or Annex I inclusion are not "holders"/"owners" of an approval and they do not need to be established in the EU. However, you will have to get the agreement of an eCA from an EU-27 Member State, EEA country or Switzerland for the evaluation of the application.

BIOCIDAL PRODUCTS

13. My UK-based company is the holder of a product authorisation in an EU-27 Member State or of a Union authorisation under Regulation (EU) No 528/2012. What effect will the withdrawal of the United Kingdom have on our authorisation?

According to Article 3(1)(p) of Regulation (EU) No 528/2012, an authorisation holder must be established within the European Union. By virtue of the EEA Agreement as well as the Mutual Recognition Agreement with Switzerland, an authorisation holder can also be established in Iceland, Liechtenstein, Norway or Switzerland.

You will therefore need to transfer the authorisation to a new holder established within an EU-27 Member State or one of the afore-mentioned countries before the withdrawal date. You can trigger the amendment of your existing authorisation by means of an administrative change requiring prior notification before implementation (see point 3 in section 1 of Title I of the Annex to Commission Implementing Regulation (EU) No 354/2013).

14. Will an EU-27 Member State, as of the withdrawal date, 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?

No. This will no longer be possible.

15. 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.

16. My company needs to apply for a change or renewal of a product authorisation granted in a mutual recognition procedure in which the United Kingdom acted as the reference Member State (refMS). Considering that, as of the withdrawal date, the United Kingdom can no longer act as refMS, 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 allow the authorisation holder to choose another refMS for the change as well as the renewal procedure.

You will, however, need to submit within the application a written confirmation that the new competent authority agrees to act as refMS.

The services of the European Commission and ECHA have been working in a coordinated manner with EU-27 Members States, EEA countries and Switzerland in order to identify new refMSs for some products of the product-types 8 and 18 for which authorisation holders had to apply for renewal before the end of 2018. The name of those refMSs has been directly communicated to the relevant holders.

17. What is the effect of the withdrawal of the United Kingdom on ongoing applications for mutual recognition in parallel for which the United Kingdom is the reference Member State?

As of the withdrawal date, the United Kingdom can no longer act as reference Member State. This also applies if a withdrawal agreement is concluded since the United Kingdom cannot act as eCA/refMS during the transition period[17].

Therefore, as set out in the Q&A pair No. 2, where the United Kingdom is currently acting as refMS, you are advised to carefully monitor the UK authority's progress and take the relevant actions. For example, if you see indications that the UK authority will not conclude the procedure by the withdrawal date, you may consider changing to another evaluating Member State. In this case, the new refMS will continue handling the relevant tasks referred to in Article 34 of the Regulation (EU) No 528/2012.

The services of the European Commission and ECHA have been working in a coordinated manner with EU-27 Members States, EEA countries and Switzerland in order to identify new refMSs for some on-going applications. The name of those refMSs has been directly communicated to the relevant applicants.

However, where no Member State takes over the role of refMS, there could be different consequences depending on the procedural stage at which the application is by the withdrawal date:

- Where the United Kingdom as refMS has entered, before the withdrawal date, the elements referred to in Article 34(5) of Regulation (EU) No 528/2012 in the Register for Biocidal Products (R4BP) (i.e. the agreed summary of biocidal product characteristics (SPC) and the final assessment report, together with any agreed terms or conditions imposed on the making available on the market or use of the biocidal product), the cMSs may proceed to grant the national product authorisation in accordance with Article 34(6) of Regulation (EU) No 528/2012.

- Where the current refMS (i.e. the United Kingdom) has not entered, before the withdrawal date, in R4BP the above-mentioned elements, the applicant will need to submit a new application for mutual recognition in parallel to a new refMS of his choice and to the relevant cMSs in accordance with Article 34(1) and (2) of Regulation (EU) No 528/2012, respectively.

[17] See Article 123(6) of the draft Withdrawal Agreement, as agreed between the EU and the United Kingdom at negotiator's level, which is available here: https://ec.europa.eu/commission/sites/beta-political/files/draft_agreement_coloured.pdf

18. What is the effect of the withdrawal of the United Kingdom on ongoing applications for Union authorisation for which the United Kingdom is the evaluating Competent Authority?

As of the withdrawal date, the United Kingdom can no longer act as evaluating Competent Authority (eCA). This also applies if a withdrawal agreement is concluded since the United Kingdom cannot act as eCA/refMS during the transition period.[18]

Therefore, where the United Kingdom is currently acting as eCA, you are advised to carefully monitor the UK authority's progress and take the relevant actions. For example, if you see indications that the UK authority will not conclude the procedure by the withdrawal date, you may consider changing to another eCA. In this case, the new eCA will continue handling the relevant tasks referred to in Article 44 of the Regulation (EU) No 528/2012.

The services of the European Commission and ECHA have been working in a coordinated manner with EU-27 Members States, EEA countries and Switzerland in order to identify new eCA for some on-going applications. The name of those eCAs has been directly communicated to the relevant applicants.

However, where no Member State takes over the role of eCA, there could be different consequences depending on the procedural stage at which the application is by the withdrawal date:

- Where the peer review phase referred to in Article 44(3) of Regulation (EU) No 528/2012 has been concluded before the withdrawal date (i.e. ECHA has submitted the relevant opinion to the Commission, which includes the agreed summary of biocidal product characteristics (SPC), the final assessment report and any agreed terms or conditions imposed on the making available on the market or use of the biocidal product), the Commission may proceed to grant the Union authorisation in accordance with Article 44(5) of Regulation (EU) No 528/2012.

- Where the peer review phase referred to in Article 44(3) of Regulation (EU) No 528/2012 has not been concluded before the withdrawal date (i.e. ECHA has not submitted the relevant opinion to the Commission), the applicant will need to submit a new application for Union authorisation in accordance with Article 43(1) of Regulation (EU) No 528/2012.

19. In case an application for mutual recognition in parallel or for Union authorisation is terminated and a new application has to be submitted, how would this affect the legal status of the existing products on the market with regard to Article 89(2) and (3) of Regulation (EU) No 528/2012?

With the submission of the initial application assessed by the United Kingdom the applicant fulfilled his legal obligation laid down in the second subparagraph of Article 89(3) of Regulation (EU) No 528/2012. As a consequence, the existing

[18] See Article 123(6) of the draft Withdrawal Agreement, as agreed between the EU and the United Kingdom at negotiator's level, which is available here: https://ec.europa.eu/commission/sites/beta-political/files/draft_agreement_coloured.pdf

product(s) currently benefit from the provisions in Article 89(2) of Regulation (EU) No 528/2012.

Therefore, the above-mentioned existing product(s) could continue being made available on the market and used in accordance with the provisions of Article 89(2) and (3) of Regulation (EU) No 528/2012 provided that the applicant submits a new application for mutual recognition in parallel (to a new refMS of his choice and to the same Member States concerned in accordance with Article 34(1) and (2) of Regulation (EU) No 528/2012, respectively) or a new application for Union authorisation in accordance with Article 43(1) of Regulation (EU) No 528/2012, before the withdrawal date.

20. My company handles a low risk biocidal product, authorised in the United Kingdom via the simplified procedure. May we notify the placing on the market of that product to EU-27 countries after the withdrawal of the United Kingdom?

No. After the withdrawal date the authorisation granted by the United Kingdom ceases to be valid with regard to Regulation (EU) No 528/2012. As a result, the right of the authorisation holder to make the product available on the market of the notified Member States pursuant to Article 27(1) of the Regulation (EU) No 528/2012 also ceases. Therefore, your company will need to obtain a new authorisation of the product via the simplified procedure from an EU-27 Member State, an EEA country or Switzerland prior to the withdrawal of the United Kingdom.

21. 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, an EEA country or Switzerland prior to the withdrawal of the United Kingdom, and then you will have to notify the other relevant Member States, EEA countries or Switzerland.

TREATED ARTICLES

22. The manufacturing site of a treated article that my EU-27-based company is placing on the EU market is located in the United Kingdom. Do we need to be concerned?

Regulation (EU) No 528/2012 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 Regulation (EU) No 528/2012, in particular its Articles 58 and 94. However, shipments to the EU of this treated article will be, as of the withdrawal date, importations, which may

have consequences from the viewpoint of other sectorial legislation (e.g. the Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals, EU customs legislation, etc.).

23. What will happen to a treated article that has been manufactured outside the EU and first imported into the United Kingdom before the withdrawal date, and made available on the EU-27 market after the withdrawal date?

Any treated article placed on the EU market is subject to the provisions of Regulation (EU) No 528/2012, in particular Articles 58 and 94. As of the withdrawal date, shipments from the United Kingdom to the EU of this treated article will be importations. If the treated article was placed on the UK market before UK withdrawal, it can be expected to be compliant with the Regulation (EU) No 528/2012 already, and there should be no specific consequences as regards to compliance with Regulation (EU) No 528/2012 (i.e. active substance approved in the EU-27, proper labelling information etc.).

IT ISSUES – REGISTER FOR BIOCIDAL PRODUCTS (R4BP)

24. Will my UK-based company still have an access and possibility to submit a dossier via the R4BP submission tool?

Yes. Companies based in third countries have access to R4PB for certain processes, e.g., active substance approval, notifications and submissions. Upon its withdrawal, the UK will become such a "third country".

25. Will my UK-based company's accounts in R4BP remain accessible as of the withdrawal date?

Yes, you will continue to have access, as non-EU companies to R4BP. UK-based companies will be able to perform the same actions allowed for non-EU companies (e.g. active substance approval submissions).

26. Will ECHA continue to grant my UK-based company access to all the information in its R4BP account after the withdrawal of the United Kingdom?

UK-based companies will still have access to their data in R4BP.

27. Can a UK-based company continue to submit applications via R4BP as of the withdrawal date?

A UK-based company can continue to act as a 'case owner' in R4BP. This means that it will be able, among other things, to submit applications/notifications and monitor the progress of a given case. For instance, UK-based companies can continue to request active substance approvals (or renewals of approval) after the withdrawal of the United Kingdom. However, it is worthwhile recalling here that a biocidal product authorisation can only be granted to an EU-based company.