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**QUESTIONS AND ANSWERS RELATED TO THE UNITED KINGDOM'S WITHDRAWAL FROM
THE EUROPEAN UNION WITH REGARD TO PLANT PROTECTION PRODUCTS AND
PESTICIDES RESIDUES**

On 23 January 2018, the European Commission services published a "*Notice to stakeholders – withdrawal of the United Kingdom and EU rules on plant protection products*".¹

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. The new text introduced in this version of Q&As "Rev2" is indicated by the word "NEW".

This list of Q&As addresses a situation where the United Kingdom becomes a third country on 30 March 2019 ("the withdrawal date") without a withdrawal agreement and hence without a transition period provided for in the draft Withdrawal Agreement.²

GENERAL

1. What if my company is established in the United Kingdom and it is the holder of a PPP authorisation in a Member State?

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market³ ("the PPP Regulation") does not require applicants for authorisations for plant protection products ("PPP") and authorisation holders to be established in the European Union. Therefore, no action needs to be taken in this respect.

2. What if my company is an applicant for approval of a substance, or for the setting/modification/deletion/review of a MRL and it is established in the United Kingdom?

¹ This notice replaced the notice of 26 September 2017.

² Cf. Part four of the draft *Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community*, as agreed at negotiator's level on 14 November 2018 (https://ec.europa.eu/commission/publications/draft-agreement-withdrawal-uk-eu-agreed-negotiators-level-14-november-2018-including-text-article-132_en)

³ OJ L 309, 24.11.2009, p. 1.

The PPP Regulation and Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC⁴ ("the MRL Regulation") do not require applicants for approval of active substances and applicants for MRLs to be established in the European Union. Therefore, no action needs to be taken in this respect.

3. What if the manufacturing site of my active substance is located in the United Kingdom?

The PPP Regulation and MRL Regulation do not set any specific requirement regarding the location of the manufacturing site(s) of active substances, which can be manufactured in third countries. Therefore, no action needs to be taken in this respect. However, after the withdrawal date the substance will be imported from a third country and will be subject to any applicable EU law in this respect (e.g. administrative formalities linked to the introduction into the customs territory of the EU).

4. What if the manufacturing site of my PPP product is located in the United Kingdom?

The PPP Regulation and MRL Regulation does not set any specific requirement regarding the location of the manufacturing site(s) of PPP products, which can be manufactured in third countries. Therefore, no action needs to be taken in this respect by authorisation holders. However, PPP will be imported from a third country and will be subject to any applicable EU law in this respect (e.g. administrative formalities linked to the introduction into the customs territory of the EU).

NEW APPLICATIONS

5. What if my company is considering submitting a new application for an active substance for which the United Kingdom could be the rapporteur Member State (RMS)? What if my company wishes to apply for an amendment to the approval of an active substance under Article 7 of the PPP Regulation for which the United Kingdom has been the RMS?

Until the withdrawal date, the United Kingdom remains a member of the European Union, with all the rights and obligations that derive from its membership, including the principle of sincere cooperation which states that the Union and all its Member States shall assist each other in carrying out the Treaty. Thus, the United Kingdom can still be chosen as RMS. However, as of the withdrawal date, the United Kingdom can no longer act as a RMS. This also applies if a withdrawal agreement is concluded: during the transition period, the United Kingdom cannot act as RMS.⁵ Applicants should take this into account when choosing the RMS: Choosing the United Kingdom means that the file would need to be handed over to another Member State taking up the role as RMS before the withdrawal date.

⁴ OJ L 70, 16.3.2005, p.1.

⁵ See Article 128(6) of the draft Withdrawal Agreement.

6. What if my company is considering submitting a new application for a PPP or for MRLs for which the United Kingdom could be the zonal rapporteur Member State (zRMS) or the Evaluating Member State (EMS)?

Until the withdrawal date, the United Kingdom remains a member of the European Union, with all the rights and obligations that derive from its membership, including the principle of sincere cooperation which states that the Union and all its Member States shall assist each other in carrying out the Treaty. Thus, the United Kingdom can still be chosen as zRMS or as Evaluating Member State for MRLs.

However, as of the withdrawal date, the United Kingdom can no longer act as a zRMS or as EMS. This also applies if a withdrawal agreement is concluded: during the transition period, the United Kingdom cannot act as zRMS or Evaluating Member State for MRLs.⁶ Applicants should take this into account.

In the context of an application for authorisation or renewal of authorisation of a PPP, the evaluation by the zRMS is considered completed, when the assessment pursuant to Article 36(1) or Article 43 of the PPP Regulation is made available to the concerned Member States within the same zone.

In the context of an application for MRLs, the evaluation by the EMS is considered completed, when the evaluation report is made available to the Commission pursuant to Article 9(1) of the MRL Regulation.

APPLICATIONS FOR RENEWAL OF THE APPROVAL OF AN ACTIVE SUBSTANCE

7. What if the United Kingdom was designated as RMS or Co-RMS under Commission Implementing Regulation (EU) No 686/2012 and my company needs to submit an application for renewal of the approval of an active substance?

Until the withdrawal date, the United Kingdom remains a member of the European Union, with all the rights and obligations that derive from membership, including the principle of sincere cooperation which states that the Union and all its Member States shall assist each other in carrying out the Treaty. Thus, the United Kingdom can still act as RMS or Co-RMS under the renewal procedure.

However, as of the withdrawal date, the United Kingdom can no longer act as a RMS or Co-RMS. This also applies if a withdrawal agreement is concluded: during the transition period, the United Kingdom cannot act as RMS or Co-RMS.⁷ An amendment to Commission Implementing Regulation (EU) No 686/2012 has been adopted by the Commission to this effect.⁸

⁶ See Article 128(6) of the draft Withdrawal Agreement.

⁷ See Article 128(6) of the draft Withdrawal Agreement.

⁸ Commission Regulation (EU) 2018/155 of 31 January 2018 amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of active substances, OJ L 29, 1.2.2018, p. 8.

ON-GOING ASSESSMENTS

8. What if the United Kingdom is RMS for the assessment of the application for approval of my substance or application for an amendment to the approval, or for the assessment of confirmatory information (Article 13(3) of the PPP Regulation), and my dossier is already submitted to the United Kingdom? What will happen with the on-going evaluation of my application for approval?

As of the withdrawal date, the United Kingdom can no longer act as a RMS. This also applies if a withdrawal agreement is concluded: during the transition period, the United Kingdom cannot act as RMS.⁹ While the draft Withdrawal Agreement provides for the transfer of files and documents relating to ongoing procedures,¹⁰ stakeholders are strongly advised to carefully monitor progress of on-going assessments. The Commission services are currently working with Member States and EEA countries in order to establish a coordinated way forward for a timely communication and technical transfer of the files concerned.

9. What if the United Kingdom was designated as RMS under Commission Implementing Regulation (EU) No 686/2012¹¹ and my supplementary dossier is already submitted to the United Kingdom? What will happen with the ongoing evaluation of my application for the renewal of approval?

As of the withdrawal date, the United Kingdom can no longer act as a RMS. This also applies if a withdrawal agreement is concluded: during the transition period, the United Kingdom cannot act as RMS.¹² The draft withdrawal agreement provides for the transfer of files and documents relating to ongoing procedures. (NEW) The Commission has adopted an amendment to Commission Implementing Regulation (EU) No 686/2012 to allocate the role of RMS to an EU-27 Member State.¹³ Commission services continue to assess whether additional re-allocations are necessary.

**10. Is the new RMS entitled to require fees or charges and if so, to what extent?
(NEW)**

The new RMS who has agreed to take over files from the UK is entitled, in accordance with Article 74 of the PPP Regulation and Article 42 of the MRL Regulation to recover costs of work carried out under these Regulations. The conditions set out in Article 74 of the PPP Regulation and Article 42 of the MRL Regulation apply.

⁹ See Article 128(6) of the draft Withdrawal Agreement.

¹⁰ See Article 44 of the draft Withdrawal Agreement.

¹¹ Commission Implementing Regulation (EU) No 686/2012 of 26 July 2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances whose approval expires by 31 December 2018 at the latest, OJ L 200, 27.7.2012, p. 5.

¹² See Article 128(6) of the draft Withdrawal Agreement.

¹³ Commission Implementing Regulation (EU) 2019/150 of 30 January 2019 amending Implementing Regulation (EU) No 686/2012 as regards the rapporteur Member State for the evaluation of the following active substances contained in plant protection products: deltamethrin, diflufenican, epoxiconazole, fluoxastrobin, prothioconazole and tebuconazole, OJ L 27, 31.1.2019, p. 23.

11. What if the United Kingdom is zRMS for the assessment of the application of an authorisation or the renewal of an authorisation for a PPP, or EMS for an application for a MRL? What will happen with the ongoing evaluation of my application for PPP authorisation or the MRL?

As of the withdrawal date, the United Kingdom can no longer act as a zRMS or EMS. This also applies if a withdrawal agreement is concluded: during the transition period, the United Kingdom cannot act as zRMS or EMS.¹⁴ Concerning procedures that are ongoing on the withdrawal date and for which the United Kingdom is acting as zRMS for the assessment of the application of an authorisation or the renewal of an authorisation for a PPP, or EMS for an application for a MRL, the zRMS or EMS will need to be changed.

For evaluations of PPP applications ongoing on the withdrawal date, the draft withdrawal agreement provides for the transfer of files and documents relating to ongoing procedures.¹⁵ The Commission Services work with Member States and the Zonal Steering Committees in order to establish a coordinated way forward for a timely communication and technical transfer of the file. Please see also Question 11 for more details regarding the granting of authorisations by other Member States for plant protection product assessed by the United Kingdom as zRMS.

For ongoing MRL applications, the new EMS will carry on with the evaluation in accordance with Article 8 of the MRL Regulation or, where that evaluation is considered completed by the United Kingdom before the withdrawal date (see Question 6), perform the assessment of supplementary information potentially requested by the European Food Safety Authority (EFSA) in accordance with Article 11(2) of the MRL Regulation.

CONCLUDED ASSESSMENTS

12. What if an EU Member State wants to make a decision on an authorisation for a PPP based on an assessment concluded by the United Kingdom before the withdrawal date?

Until the withdrawal date the United Kingdom may act as zRMS, whereas the other Member States act as Member States concerned (cMS).¹⁶ The zonal assessment process is a collaborative process involving also scrutiny of the application by all the cMS and established in a harmonised format (Article 36(1) of the PPP Regulation).

When the assessment by the United Kingdom is completed, i.e. made available to the other Member States in accordance with Article 36(1) of the PPP Regulation and the United Kingdom has issued its national authorisation before the withdrawal date, other Member States will have to decide, within 120 days, on

¹⁴ See Article 128(6) of the draft Withdrawal Agreement.

¹⁵ See Article 44 of the draft Withdrawal Agreement.

¹⁶ This system applies for the first authorisation of a plant protection product in one zone or, through the reference of Article 43(3) of the PPP Regulation, also for applications for renewals.

the application in accordance with Article 37(4) and 36(2) of the PPP Regulation on the basis of the assessment carried out and completed by the United Kingdom.

However, when the assessment by the United Kingdom is completed, i.e. made available to the other Member States in accordance with Article 36(1) of the PPP Regulation, but the United Kingdom has not issued its national authorisation prior to the withdrawal date, there is no authorisation granted prior to the withdrawal date, which (in addition to the assessment) is needed to trigger the 120-days deadline for the authorisation decision by a cMS (Article 37(4) of the PPP Regulation). Therefore, the authorisation that would have been issued by the original zRMS has to be substituted in that case by one of the cMS. This cMS will issue such authorisation on the basis of the assessment concluded by the United Kingdom. Business operators finding themselves in this situation will have to approach one or more of the cMS with the relevant request – cMS could then agree appropriate arrangements in the respective Zonal Steering Committee.

MUTUAL RECOGNITION OF AUTHORISATIONS

13. What if my company wishes to obtain after the United Kingdom withdrawal an authorisation in an EU Member State of the same zone or another zone by mutual recognition in accordance with Article 40 of the PPP Regulation on the basis of an authorisation that was granted by the United Kingdom?

As of the withdrawal date, an EU-27 Member State of the same zone or another zone (in accordance with Article 40(1)(b) and (c) of the PPP Regulation) can no longer recognise an authorisation which was issued by the United Kingdom. This also applies if a withdrawal agreement is concluded: during the transition period, the United Kingdom cannot be a reference Member State in the mutual recognition procedure.¹⁷ Business operators will need to (re-)apply for an authorisation based on an existing product authorisation in another EU-27 Member State.

However, where an authorisation by an EU-27 Member State has been granted under the mutual recognition procedure before the withdrawal date, this authorisation is not affected by the withdrawal of the United Kingdom.

PARALLEL TRADE PERMITS

14. Are parallel trade permits (Article 52 of the PPP Regulation) granted by an EU-27 Member State valid as of the withdrawal date for plant protection products of which the United Kingdom was the Member State of origin? (NEW)

Article 52 of the PPP Regulation provides for issuance of parallel trade permits for parallel trade between Member States. As of the withdrawal date, a parallel trade permit issued by an EU-27 Member State prior to the withdrawal date for a plant protection product of which the United Kingdom was the Member State of origin is no longer valid¹⁸. Plant protection products benefiting from such parallel trade permit can therefore no longer be placed on the market in the particular

¹⁷ See Article 128(6) of the draft Withdrawal Agreement.

¹⁸ A condition for granting a parallel trade permit under Article 52 is that it is granted to a product that is identical to a plant protection product authorised in an EU Member State (Member State of Origin).

Member State. This does not affect the possibility to use, in the EU-27 products purchased prior to the withdrawal date.