



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

On 26 September 2017, the European Commission published a Notice to business operators in the field of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market (PPP Regulation) and Regulation (EC) No 396/2005 on maximum residue levels of pesticides (MRL Regulation) 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 the 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 the European Union, all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET) (hereafter called 'withdrawal date'). The United Kingdom will then become a 'third country'.”

In this regard, business operators involved in the activities falling under the scope of the PPP Regulation and MRL Regulation are reminded of certain legal and operational consequences that need to be considered in a timely manner. Preparing for the consequences of the UK's withdrawal from the Union 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 rapporteur Member States (RMS), zonal rapporteur Member States (zRMS) or evaluating Member States for MRLs<sup>1</sup>.

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 UK will leave the Union, applicants may choose by preference another RMS, zRMS or evaluating Member State for MRL applications to carry out the evaluation.

This list of Questions and Answers (Q&A pairs) which has been drafted by the European Commission services, 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.

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<sup>1</sup> With the exception of contracting states of the European Economic Area ("EEA").

## **General**

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

The PPP Regulation does not require applicants for authorisations for 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 MRLs and it is established in the UK?**

The PPP Regulation and 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 UK?**

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 UK?**

The PPP 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 UK 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 UK has been the RMS?**

Until the withdrawal date, the UK 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 UK can still be chosen as RMS. However, on account of the current scenario and uncertainties as well as the expected time lines for the relevant regulatory procedure, applicants 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 Member State as RMS in

order to avoid the procedure referred to in point 8 below (i.e. change of RMS at a later stage).

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

Until the withdrawal date, the UK 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 UK can still be chosen as zRMS or as Evaluating Member State for MRLs.

However, on account of the current scenario and uncertainties as well as the expected time lines for the relevant regulatory procedure, applicants 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 Member State as zRMS or Evaluating Member State for MRLs in order to avoid the procedure referred to in points 9 and 10 below (i.e. change of zRMS or Evaluating Member State at a later stage).

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

**7. What if the UK 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 UK 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 UK can still be act as RMS under the renewal procedure.

Applications for renewal of approval must be sent by the deadline set under Article 15 of the PPP Regulation. For the moment, companies must also submit their applications to the RMS and co-RMS designated in Commission Implementing Regulation (EU) No 686/2012.

The Commission services have started discussing with all Member States in order to re-allocate some substances to a new RMS or co-RMS. Commission Implementing Regulation (EU) No 686/2012 will be amended accordingly.

## **On-going assessments:**

**8. What if UK is RMS for the assessment of the application for approval of my substance or application for an amendment to the approval and my dossier is already submitted to the UK? What will happen with the on-going evaluation of my application for approval?**

Concerning on-going procedures for which the UK is currently acting as RMS, 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. The RMS will need to be changed. The Commission Services will work with Members States and EEA countries 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.

**9. What if UK was designated as RMS under Commission Implementing Regulation (EU) No 686/2012 and my supplementary dossier is already submitted to the UK? What will happen with the ongoing evaluation of my application for the renewal of approval?**

Concerning those on-going procedures for which the UK is currently acting as RMS or co-RMS under the renewal procedure for active substances, business operators should carefully monitor their progress. The Commission Services will work with Members States and EEA countries in order to establish a coordinated way forward for a timely communication, agreement and technical transfer of the file in case a change of RMS or co-RMS is needed. Commission Implementing Regulation (EU) 686/2012 designating RMS and co-RMS will then be amended accordingly.

**10. What if UK is zRMS for the assessment of the application of an authorisation or the renewal of an authorisation for a PPP, or Evaluating Member State for an application for a MRL? What will happen with the ongoing evaluation of my application for PPP authorisation or the MRL?**

Concerning those on-going procedures for which the UK is currently acting as zRMS for the assessment of the application of an authorisation or the renewal of an authorisation for a PPP, or Evaluating Member State for an application for a MRL, 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. The zRMS or Evaluating Member State will need to be changed. The Commission Services will work with Members States and the Zonal Steering Committee 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.