Brexit: what happens when the UK is zRMS

On 29 March 2019 at midnight, the United Kingdom (UK) will leave the European Union. Until that time the UK can act as a Zonal Rapporteur Member Stateⁱ (zRMS). In case of Art. 33 applications, if the core assessment and authorisation are issued in the UK before the date of Brexit, the Commission has ruled that the Concerned Member State (CMS) has up to 120 days after the date of Brexit to decide on the product authorisation on their territory.

When the UK did not come to a conclusion/final decision before the date of Brexit, there are two options:

- The application was not submitted yet or the UK did not start the assessment: Applicants are
 asked to indicate to the zonal secretariat which zRMS they preferⁱⁱ. The zonal secretariat and
 the Central Zone Steering Committee (CZSC) will allocate a fall-back zRMS directly after the
 date of Brexit.
- The UK has started the assessment already, but did not issue the authorization before the date of Brexit. In that case the CZSC will coordinate that the dossier and evaluations of aspects completely finalized by UK will be handed over to a fall-back zRMS. It will depend on the fall-back zRMS to what degree this evaluation will be reviewed or even adopted for the core assessment. Partly finalized aspects will not be handed over by UK, meaning that these aspects will be completely evaluated by the fall-back zRMS or that the fall-back zRMS could wait until UK has finalized its assessment (which should be checked by the applicant with the fall-back zRMS). In case transfer of documents is needed this happens directly after the date of Brexit. The fall-back zRMS may individually contact the UK to make practical appointments. The fall-back zRMS is responsible for the decision.

The applicant will need to submit a new application to the fall-back zRMS, and fees will be charged depending on the MS and the status of the dossier.

As the Brexit will result in a higher workload for the Member States it is expected that the timelines for Plant Protection Products applications will be prolonged.

ⁱ Where Zonal Rapporteur Member State is stated, also Interzonal Rapporteur Member State is meant.

ii Please send to post@ctgb.nl, and state 'zonal secretariat' in the subject.