



federal public service
**HEALTH, FOOD CHAIN SAFETY
AND ENVIRONMENT**

IMPACT OF THE **BREXIT** ON BIOCIDAL PRODUCTS

Biocidal Products Forum, 8 November 2018

Van Berlo Boris



BREXIT

What & when?

- ▶ The United Kingdom leaves the European Union.
- ▶ On 29 March 2019

How?

- ▶ Very unclear
- ▶ Retreat agreement with transition period?
- ▶ Or rather *no deal*?

BREXIT

What can we expect?

- ▶ UK becomes a “third country”.
- ▶ Is no longer eCA, reporter or rMS (not even during a possible transition period)
- ▶ Transfer of applications in progress to another EU-27 authority
- ▶ Transfer of all documents relating to those applications in progress to an EU-27 authority (through ECHA)

Direct consequence of Article 123(6) of the *Title on Transition*:
"During the transition period, the UK shall not act as leading authority for risk assessments, examinations, approvals and authorisation procedures provided for in Union law."

BREXIT

How to get prepared?

- ▶ EU level: technical seminars with EC, ECHA and EU-27
- ▶ BE biocidal products: scan of impact FPS HFCSE
- ▶ Stakeholders: scan of impact on BE BREXIT portal
 - ▶ <https://economie.fgov.be/en/brexit>
- ▶ Information provided: *awareness* and *preparedness*
 - ▶ Biocidal Products Forum
 - ▶ <https://www.health.belgium.be/en/engimpact-du-brexit-sur-le-secteur-des-biocides>
 - ▶ <https://echa.europa.eu/nl/advice-to-companies-q-as/bpr>
 - ▶ https://ec.europa.eu/health/sites/health/files/biocides/docs/brexit_note_en.pdf
 - ▶ https://ec.europa.eu/info/sites/info/files/qa_biocides.pdf
 - ▶ Information sessions (FPS Economy, Customs & Excises,...)

IMPACT ON BIOCIDAL PRODUCTS IN THE EU

Active substances (AS)

- ▶ 84 cases to be taken over (RP AS, new AS, renewals)
- ▶ BE takes 1 AS over for renewal (2020)
- ▶ RP: formal procedure, amendment (EU) n° 1062/2014
- ▶ For the rest: communication to APP by ECHA in R4BP3

Union authorisations (UA)

- ▶ 11 applications to be taken over (UA-APP and UA-BBP)
- ▶ BE takes 4 UA over (2 x UA-APP + 2 x UA-BBP)
- ▶ Cases to be transferred in R4BP3 on 29 March 2019

IMPACT ON BIOCIDAL PRODUCTS IN THE EU

National authorisations with mutual recognition

- ▶ 64 applications to be taken over (mainly PT8 & 18)
- ▶ BE does not take any application over for the moment.
- ▶ A large number has been redistributed (on a voluntary basis).
- ▶ Decision needed for the remaining *orphan cases*

Simplified procedure

- ▶ No application to be taken over
- ▶ Existing UK authorisations: to be submitted again to a new Member State
- ▶ New notifications in all the other Member States

IMPACT ON BIOCIDAL PRODUCTS IN THE EU

Fees

- ▶ New eCA/rMS can claim a fee.
- ▶ Preferably in proportion to the accomplished work
- ▶ Refund of fees paid to UK: bilaterally between applicant and UK
- ▶ Legal basis: amendment provided (EC) n° 1062/2014

ECHA IT

- ▶ Adaptations needed for the authorisation of *transfer cases/assets* (these are no new applications)
- ▶ Transfer on 29 March 2019

IMPACT ON BIOCIDAL PRODUCTS AT NATIONAL LEVEL

Existing authorisations/notifications

- ▶ Administrative review of existing authorisations/notifications with the present authorisation holder/notifier in UK for transfer to a new authorisation holder/notifier in the EU
 - ▶ Application required for administrative modification of APP
 - ▶ Application to be submitted on time (at the latest on 29 December 2018)
- ▶ Cancellation of existing authorisations/notifications with authorisation holder/notifier in UK if abovementioned application has not been submitted (on time)

IMPACT ON BIOCIDAL PRODUCTS AT NATIONAL LEVEL

Active substances in the future?

- ▶ Up to now, UK took care of the greatest part of applications for “new active substances”.
 - ▶ One can expect that in the future, BE will more often be asked to become an eCA.

Products in the future?

- ▶ Up to now, UK took care of ± 10 % of the overall product applications in the EU.
 - ▶ One can realistically expect that the workload will increase because of the Brexit.
- ▶ Applicants are free to choose their eCA/rMS.
 - ▶ Real increase is difficult to predict.

Thanks...