Brexit preparedness: actions taken by the Commission

Biocides Stakeholders Day

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Raising awareness

Notice to business operators + Q&A document published on 13/09/2017: https://ec.europa.eu/health/biocides/biocidal_products_en

Regular updates in the CA meetings to keep stakeholder organisations informed

European Commission

Calling for capacity building

UK has played an important role in the biocides EU regulatory network

Need to maintain the EU capacity to efficiently implement the BPR

Letter from the Commissioner to Ministers:

- Need to anticipate and prepare well in advance
- Call for Member State's capacity to absorb some additional work
- Opportunity to reinforce existing technical and regulatory networks and develop further expertise

Reassigning the role of the UK (1)

- 6 'Technical Seminars EU-27' back to back with CA meetings (from November 2017 to September 2018)
- Discussions focussing on finding a new eCA/refMS for different procedures: AS in the Review Programme; AS outside the review programme; renewals of AS; renewal of BPs (PTs 8 & 18); on-going applications for UA & MR-P
- This included checking with UK state of play of the evaluations (constructive cooperation)
- 100% success for AS / lower for Biocidal Products ("orphans")

European Commission

Reassigning the role of the UK (2)

- Evaluation of existing AS/PT combinations in the review programme is attributed by law to "a Member State"
- Need to re-attribute the AS/PT combinations currently under evaluation by the UK to an EU-27 MS, EEA country or Switzerland
- Some criteria:
  - ❑ Interest indicated by other MS
  - ❑ Synergies with similar AS/PT combinations under assessment by the new eCA,
  - ❑ Current workload
  - ❑ population size, etc…

Reassigning the role of the UK (2)

Outcome: draft delegated act amending Regulation 1062/2014 (CA-Sept18-Doc.3.2.a & b), available at https://circabc.europa.eu/w/browse/66c9ce91-170e-4435-8d26-7d62ad2f7a9c

Public consultation ("feedback mechanism") from 14/09 to 12/10 (2 contributions), available at https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2018-2382032_en

Adoption expected in November 2018

Followed by the scrutiny period by Council and European Parliament: 2 (+2) months

Publication in the OJ

Communicating to applicants

Informing via R4BP the relevant applicants or authorisation holders

Procedure	Nb of communications
On-going AS approvals in the Review Programme	48
On-going AS approvals outside the Review Programme	11
On-going AS renewals	1
Future AS renewals	21
Total AS	81
Renewal PT8/PT18 products with 1 cMS	58
Renewal PT8/PT18 products with volunteers	24
Total renewal PT8/PT18 products	82
Mutual recognition in parallel with 1 cMS	8
Mutual recognition in parallel with volunteers	13
Total Mutual recognition in parallel	21
Union authorisations	8
Total by COM	**184**

ECHA will contact the applicants for "orphan cases"

European Commission

Some reminders… (1/3)

- Holders established in the UK for authorisations granted by EU-27 /EEA countries or Switzerland: notify in due time new authorisation holder established in the EU/EEA/CH before 29/03/19
- Applicants for on-going applications: check with the UK the progress made with your application and if unlikely to be concluded before 29 March 2019, or at least:
  - For MR-P: the UK has entered in R4BP the agreed SPC and PAR)
  - For UA: ECHA has sent to COM the BPC opinion (including the SPC and PAR)

Some reminders… (2/3)

- In case a shift to new eCA/refMS is needed: contact the new eCA/refMS in order to further discuss any aspects affected by this change (and keep the UK CA involved).
- Applicants for on-going 'orphan' applications: find a new eCA/refMS… otherwise your application might be terminated and you would need to submit a new application.
  - ❑ If this were to happen, the legal status of your existing product is safeguarded by the original application if the second application is submitted before 29/03/19.

Some reminders… (3/3)

Applicants/holders under the simplified authorisation (SA) procedure:

- After 29/03/19 the simplified authorisation granted by the UK and the respective notifications in EU-27/EEA/CH cease to be valid.
  As a result you can no longer make the notified products available on the market nor used
- Before 29/03/19, you have to:
  - Obtain a new simplified authorisation from an EU-27 Member State, an EEA country or Switzerland **AND**
  - Notify the other relevant EU-27 Member States, EEA countries or Switzerland

Thank you for your attention

For further information:

Commission website:

https://ec.europa.eu/health/biocides/overview_en

https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a

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European Commission