Brexit
Impact on Biocides

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Pesticide Control Division
5th December 2018
Overview of Timelines

<table>
<thead>
<tr>
<th>Membership</th>
<th>Transition</th>
<th>Future Relations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acquis</td>
<td>Acquis + Full Alignment No decision making No trade agreements</td>
<td>Provisions of Agreement</td>
</tr>
<tr>
<td>Membership</td>
<td>Transition</td>
<td>Future Relations</td>
</tr>
<tr>
<td>TEU Negotiation and ratification of Withdrawal Agreement by Council and EP</td>
<td>Withdrawal Agreement + transitional arrangements + outline of the framework for future relations</td>
<td>Agreement depends on ratification by EU-27 Member States (mixed agreement)</td>
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<tr>
<td>Negotiations of future relations only possible with a “third country”</td>
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EU-27 Position
UK Parliament...11\textsuperscript{th} December?
What about Biocides Regulation (EU) No 528/2012?
Impact – many questions

• Effect on active substances (a.s.)?
• Effect on products (b.p.)?
• Effect on a.s. and b.p. suppliers (Art.95)?
• Effect on case owners?
• Effect on Authorisation Holders (A.H.)?
• Effect on Letters of Access (L.o.A.)?
• Effect on data protection?
• And so on…..
What is certain?

- What is certain come 29th March 2019?
- UK can no longer act as an eCA
- Applies to both active substances & products
- EU-27, EEA and CH have to carry more work
- eCAs have to increase capacity
- Inevitable delay in MS evaluations
- Potential loss of some products to IE market
- There is still time to act
Preparation

• 7 Brexit Technical Seminars
• Search for new eCA for a.s.
• Change to Review Programme – existing a.s.
• Search for new eCA for a.s. renewal
• Search for alternative eCAs for products
• First authorisations and renewals
Active substances

• Applicant is UK based? **Still OK.**
• Manufacturer is UK based? **OK.**
• Will ECHA refuse UK companies right to refer to vertebrate test/study? **No outright refusal.**
• Will a.s. studies retain data protection? **Yes.**
• Status of approved a.s. (UK refMS)? **OK.**
• Art.95 listed supplier is UK based? **Not OK.**
• L.o.A. to data from UK company? **OK.**
• UK a.s. evaluation ongoing? **Not OK.**
Product Notifications

• Registration under Article 89 transitional phase
• Brexit impact come 29/3?
• Art.95 listed supplier is UK based? Not OK.
• Can the notification holder be UK based? Yes*
• Can the label be an IE-UK dual label? Yes*

* The understanding of the IE CA would be yes, but await confirmation from EU COM.
Product Authorisations

- Authorisation under the BPR
- Brexit impact come 29/3?
- Art.95 listed supplier is UK based? Not OK.
- AH is UK based? Not OK. EU-27, EEA AH base.
- Can the label be an IE-UK dual label? Yes*
- UK company information on the label? Yes*
- L.o.A. to data from UK company? OK.
- UK evaluation ongoing? Not OK.

* The understanding of the IE CA would be yes, but await confirmation from EU COM.
Specific type of BPR Authorisations

- Brexit impact come 29/3?
- National Authorisations
- Mutual Recognitions (Sequence & Parallel)
- Union Authorisations
- Simplified Authorisations and notifications
- Same Biocidal Products
- Changes (minor/major/admin) to authorisations
National Autorisations

• Assets and ongoing cases in UK on 29/3/?
Mutual Recognitions - Parallel

• Available agreed SPC/PAR or Authorised 29/3
Mutual Recognitions - Parallel

• SPC/PAR will not be agreed by 29/3. Need new refMS.
Mutual Recognitions - Sequence

• Agreed SPC (Evaluate & Decide step) by 29/3?
Mutual Recognitions - Sequence

- No agreed SPC (in MSCA accept or Validate steps) by 29/3?
Union Authorisation

• Granted before 29/3, but need new eCA for RNL and Change
Union Authorisation

- Not likely to be granted before 29/3, need new eCA
Union Authorisation

• BPC Opinion adopted before 29/3
Renewal products

• UK reference will not be completed before 29/3. Need to find new refMS.
Simplified procedure

• If UK was the refMS, need new refMS to authorise before 29/3 and new notifications
Same Biocidal Products

• Remain unaffected by 29/3. Standalone auths.
IT Tools – R4BP3 & SPC

• Brexit impact come 29/3?
• Access to R4BP3 - UK CA? Restrictions.
• Access to their data – UK companies? Yes.
• UK company submit applications via R4BP3? Yes, but note ‘case owner’ and ‘AH’ difference
• ECHA Dissemination website
Useful Resources

• ECHA Q & A
  https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/topic/theukswithdrawalfromtheeu

• EU COM Q & A

• UK Gov. Biocide page
Conclusions & take home message

• Making the uncomfortable comfortable
• Check status of your a.s./products
• Check AH location
• Check Art.95 supplier listing
• Consider a new refMS if necessary
• Consider market area for future submissions
• There is still time to act
• Contact your CA for further information
Thank you!

Contact:

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