Upcoming developments

Biocides Stakeholders’ Day

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Main points

1. Core work
2. New hurdles
3. Progressing together
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Active substances approval

Review Programme

• Still 70% of active substance and product-type combinations to be assessed
• ~40 opinions foreseen in 2018 (like 2016 & 2017)

New active substances

• 10 opinions foreseen in 2018

In situ generated and Articles 93 and 94 active substances

• 30-45 applications expected
Union authorisations: ramping up

- Towards **70** applications by end 2017

- Same biocidal products also growing: over **30** applications by end 2017

- First **2** Biocidal Products Committee opinions in December 2017

- **18** Biocidal Products Committee opinions foreseen in 2018
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Foreseen impact of endocrine disruptor criteria

- New data needed to assess ED properties: what and when?
- Active substances: delays – *several years*?
- Authorisation of biocidal products: how to deal with co-formulants?
- Already approved active substances: a specific review programme or waiting for renewal?
- Increased workload and impact on resources
Brexit: uncertain consequences

- UK as evaluating authority (active substances and Union authorisations)
- UK as ref Member State for mutual recognition in parallel
- UK companies operating in the EU
- Future situation in UK for UK and EU companies

Many uncertainties: depends on the negotiations and the political choices of the UK government

Check new Q&As: [https://echa.europa.eu/uk-withdrawal-from-the-eu](https://echa.europa.eu/uk-withdrawal-from-the-eu)
Need for clarifying product families

- Note for guidance by Commission (2014)
- Topics that need to be further clarified
- Very complex families
- Issues for applicants and for Member States
- Coordination group working party starts
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R4BP 3: making your life easier

- Enhancing the workflows
- Refining summary of product characteristics comparison
- Improving the user interface
- Increasing the performance
- Preparing for Brexit
Guidance and user support

• Updating guidance on the technical equivalence

• More guidance for products:
  • Efficacy
  • Human exposure
  • Environmental exposure

• Translation of frequent sentences for summary of product characteristics - covering further product types: 6, 7, 9, 10, 11, 12, 13
EUSES

Tool for harmonised environmental exposure assessment

• Upgrading the current version
• Consulting the users
• Preparing for a sustainable future

Making data available

- Dissemination of product authorisations with summary of product characteristics (SPC)
- Advanced searches
- Improving dissemination of active substances
- Get your SPCs ready!
Conclusions

• Starting the 5th year of the BPR
  • Some new hurdles
  • Some processes with limited experience
  • Resources under pressure

• Positive expectations for the future
  • Union authorisation is developing
  • More experience gained by all
  • Improving further support and cooperation
Your feedback is important
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