

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>

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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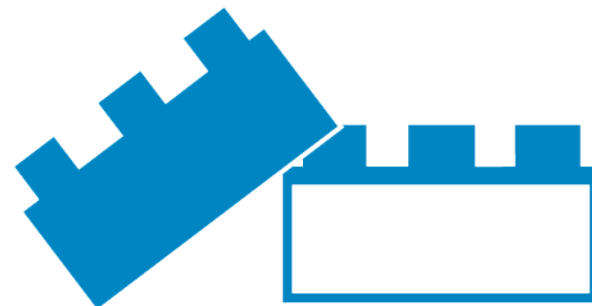
R4BP 3: making your life easier

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

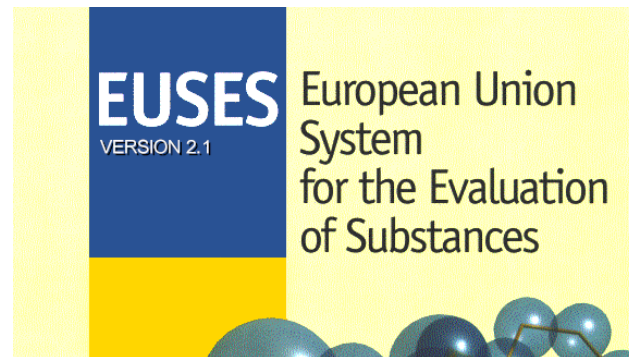


Guidance and user support

- 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

Reference: <https://ec.europa.eu/jrc/en/scientific-tool/european-union-system-evaluation-substances>

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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