The Biocidal Products Regulation

Key Commission Issues & Next Steps

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Steptoe Seminar
Product Defense for REACH & Biocides
Annual Chemicals Regulation Seminar

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Introduction

- Substance approval
- In-situ generated active substances
- Article 95
- Product authorisation
- Treated articles
- Implementing legislation and guidance documents

Approval of active substances

- Review Regulation
  - Taking over of non-supported nanomaterial forms of existing active substances, of QUATs, of AS/PT combinations in part 2 of Annex II, of PT re-definitions of former food and feed derogation
  - Be aware of deadlines
- BPC opinions
  - Need to establish exclusion and substitution criteria before BPC
  - Discussion on treated articles provisions
- In-situ generated active substances
  - Clarification now available

In-situ generated active substances

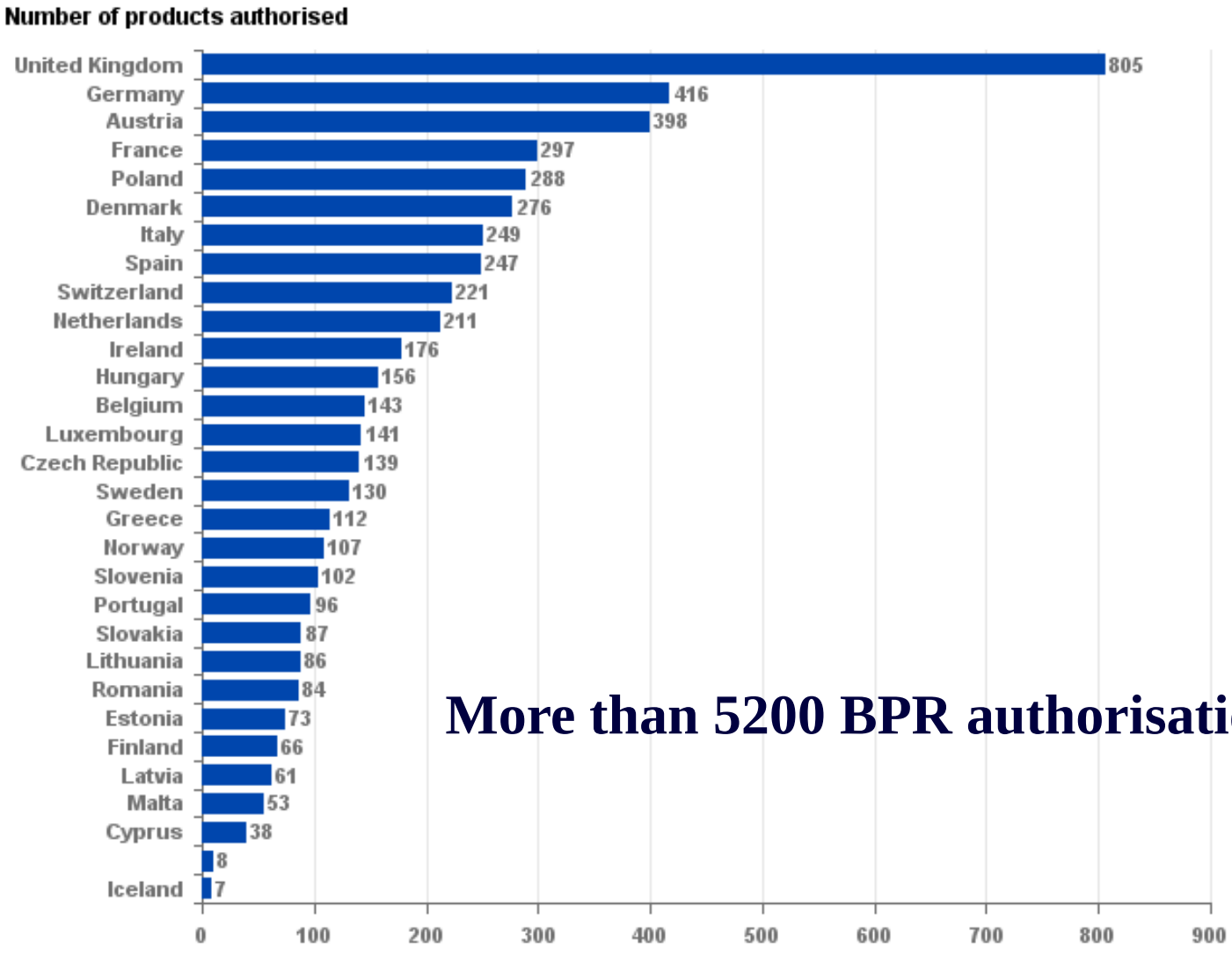
- Clarification on what is included in the review programme and what is not.
- For what is not, list is not exhaustive and two options:
  - Article 13 of the Review Programme Regulation
  - Article 93 of the BPR
- Case of specific substances such as ozone, nitrogen or hydroxylradicals remains to be addressed
- For product authorisation, any company can be authorisation holder (supplier of precursors, manufacturer of devices, the user generating the active substance).

Article 95

- 1 September 2015 deadline
- Practical guides for SMEs
  - Data sharing
  - Letters of access
  - Consortium
- Active involvement to help companies
  - Active chlorine
  - Silver
  - Ozone
- Discussion with MSs on enforcement

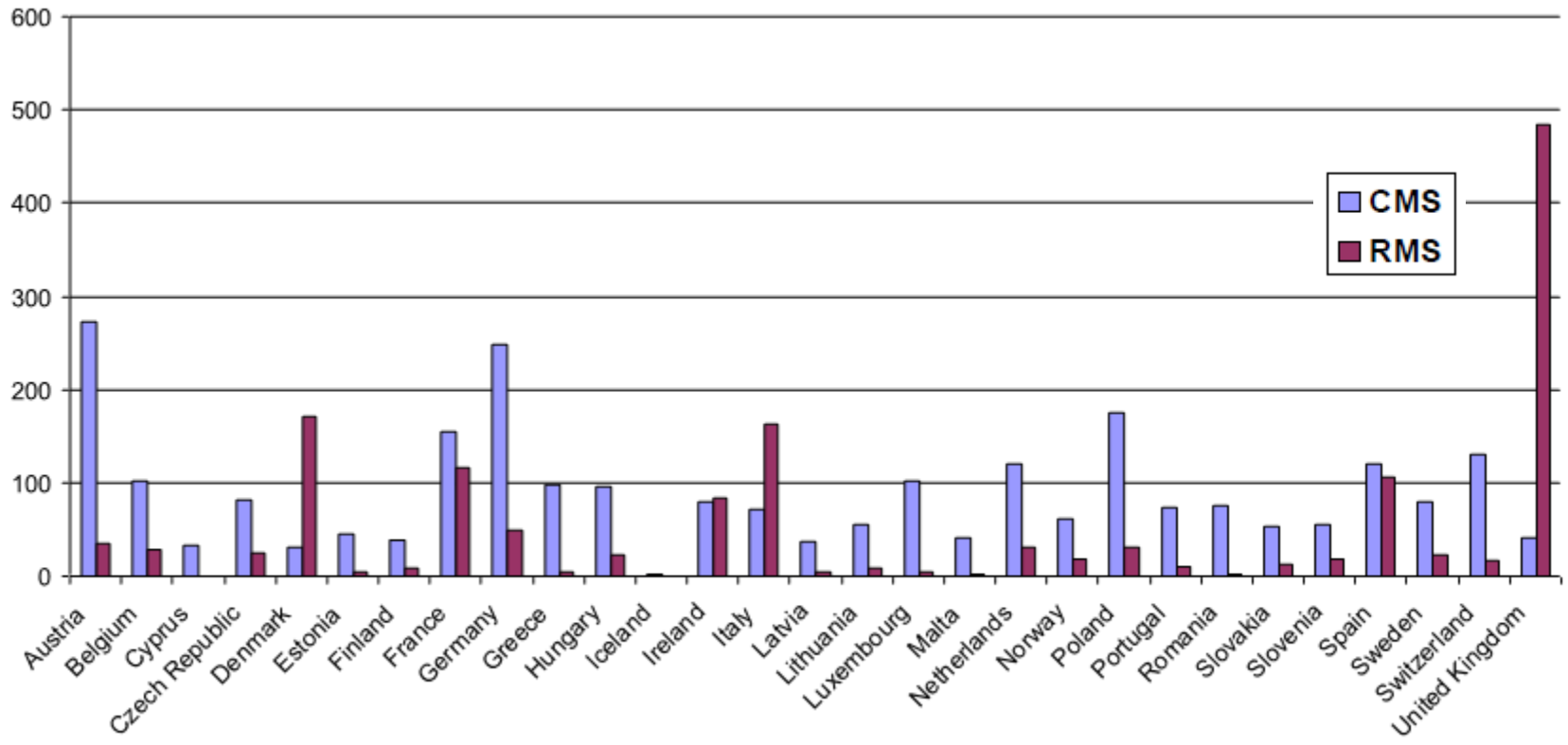
Product authorisations

- More than 5200 authorisations granted in accordance with the BPR
- Very few mutual recognition disagreements
- First product authorised through the simplified procedure
- Applications for Union authorisations expected in 2015
- Additional concepts to facilitate product authorisations
  - Same biocidal product
  - Biocidal products family
  - Consortium



More than 5200 BPR authorisations

Authorisations granted per MS



Revised guidance on Treated Articles

- Clarification on the use of biocides in earlier steps of production chain. Treated article if:
  - The biocidal active substance remains in the treated article, and
  - The biocidal active substance still has an intentional biocidal effect in the final product
  - Example: leather treated with a fungicide which gives a lasting protection from fungal decay even after it has been incorporated in shoes, bags, furniture etc.

Revised guidance on Treated Articles

- Clarification on complex articles of which only parts have been treated.
  - Such complex articles are considered treated articles if the biocidal treatment of one or several components/materials still has an intended biocidal effect in the finished complex article
  - Example: increasing the overall durability of the complex article by protecting a particularly vulnerable component from microbial/fungal decay.

Concluding remarks

- Article 95
- MRLs, SMLs and residual contents
- Renewal of rodenticides
- Sustainable use
- Communication on budget and ECHA fees review

Implementing legislation and guidance documents

Implementing legislation

- ✓ **Regulation on changes to product authorisation :** Reg. (EU) No 354/2013 of 18th April 2013
- ✓ **Regulation authorisation of same biocidal products :** Reg. (EU) No 414/2013 of 6th May 2013
- ✓ **Regulation on fees to ECHA :** Reg. (EU) No 564/2013 of 18th June 2013
- ✓ **Regulation on the extension of duration of review programme to 2024 :** Reg. (EU) No 736/2013 of 17th May 2013
- ✓ **Regulation on the modification on data requirements (proof of technical equivalence in BP applications) :** Reg. (EU) No 837/2013 of 25th June 2013
- ✓ **Regulation on the procedures for the inclusion of active substances into Annex I of the BPR :** Reg. (EU) No 88/2014 of 31st January 2014
- ✓ **Regulation on the procedures for the renewal of authorisations by mutual recognition :** Reg. (EU) No 492/2014 of 7th March 2014
- ✓ **Regulation on the organisation of the review programme of active substances (to replace Reg. (EU) 1451/2007) :** Reg. (EU) No 1062/2014 of 4th August 2014

Commission guidance

- **Work on guidance documents or proposals on various topics :**
  - ***Management of nanomaterials:***

    https://circabc.europa.eu/w/browse/f2d79b34-2f5a-4bb4-97e8-b982c9def765
  - ***Fees payable to Member States*:**

    https://circabc.europa.eu/w/browse/b5c900a2-ef66-4a46-996d-00d5a29aee9a
  - ***Similar conditions of use, for the Union authorisation* :**

    https://circabc.europa.eu/w/browse/2ac21f0f-d790-4667-9358-1bcd0db0b35e
  - ***Treated articles:***

    https://circabc.europa.eu/w/browse/d7363efd-d8fb-43e6-8036-5bcc5e87bf22
  - ***Comparative assessment :***

    https://circabc.europa.eu/w/browse/d309607f-f75b-46e7-acc4-1653cadcaf7e
  - ***Management of in situ generated active substances:***

    https://circabc.europa.eu/w/browse/67bab047-23bc-4edb-a11f-819cb5a5f2da

Thank you for your attention!

For further information:

Commission website on biocides:

http://ec.europa.eu/environment/biocides/

CIRCABC public space on biocides:

https://circabc.europa.eu/w/browse/85cf24d4-e4d3-4b34-b59d-7a69394d0942

ECHA website & Helpdesk on Biocides:

http://echa.europa.eu/regulations/biocidal-products-regulation