The Biocidal Products Regulation

Upcoming Regulatory and Policy Developments

1 September 2015
ECHA Biocides Stakeholders' Day

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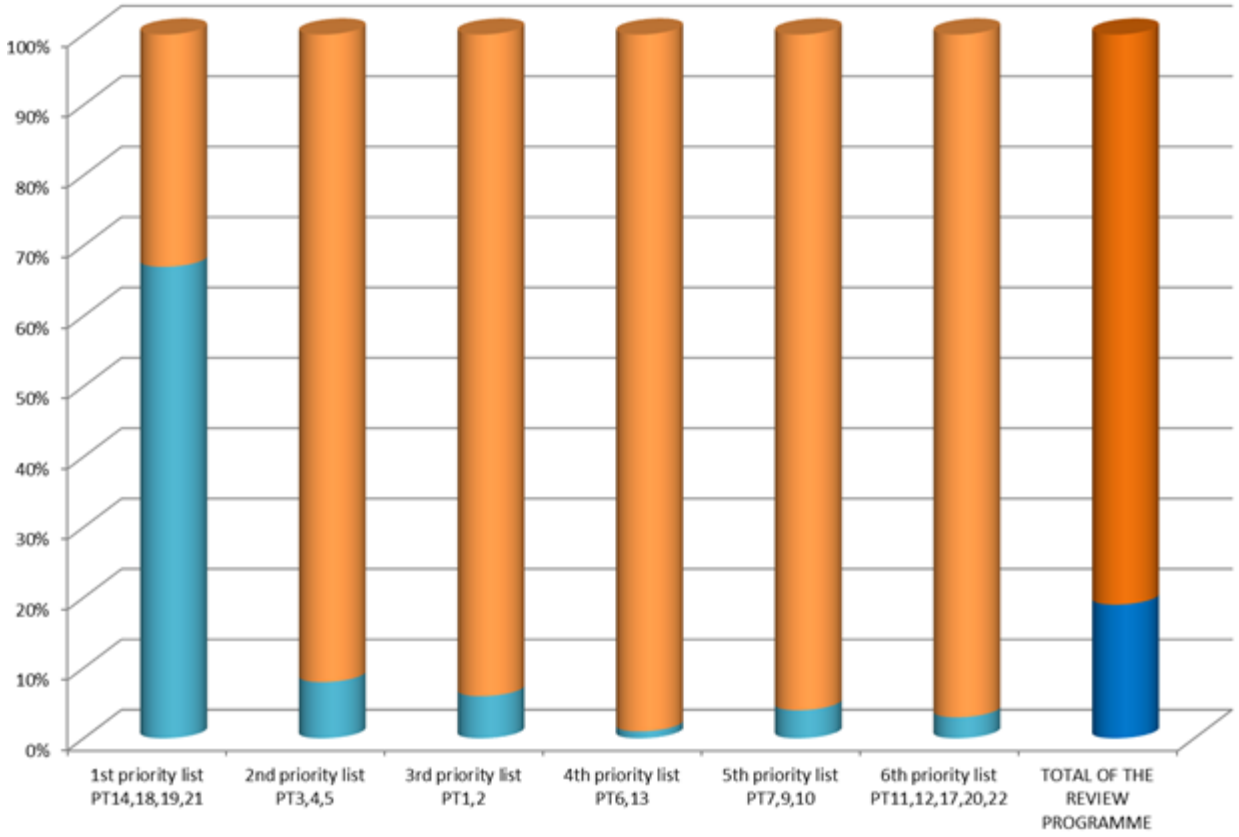
Introduction

- Substance approval
  - Review programme
  - In-situ generated active substances
  - Article 95
- Product authorisation
- Treated Articles
- Sustainable Use
- Policy developments
  - MRLs and SMLs
  - Enforcement
  - Review of ECHA Fee Regulation

Review programme for existing active substances

Progress on the review programme

On 1September 2015 : 20% of finalised evaluations (i.e. decisions adopted)



Review programme Regulation

- Taking over of non-supported active substances
  - nanomaterial forms of existing active substances
  - QUATs
  - PT re-definitions
  - Former food and feed derogation
  - AS/PT combinations in part 2 of Annex II
- Be aware of deadlines (30 October 2015)
- Corrigendum adopted and published (http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:JOL_2015_198_R_0014)

In-situ generated active substances

- Clarification on management of in situ generated active substances.
- Two important options for what is not currently supported:
  - Article 13 of the Review Programme Regulation
    - Deadline for notifying interest to take over: **26 April 2016**.
    - Upon notification, two years for submission of dossier
  - Article 93 of the BPR
    - submissions of applications by **1 September 2016**.
- Clarification on ozone
- To be addressed:
  - Cases of specific substances such hydroxylradicals
  - Article 95 implementation

Article 95

- 1 September 2015 deadline
- Practical guides for SMEs
  - Data sharing
  - Letters of access
  - Consortium
- Active involvement to help companies (Active chlorine, silver, ethanol, ozone)
- Discussion with MSs on enforcement
- Templates for self-declaration form and letter of confirmation of supply (https://circabc.europa.eu/w/browse/a9559435-0302-4a9f-96ee-75de835b81e4**)**

Authorisation of biocidal products

Product authorisations

- ca. 5000 authorisations granted in accordance with the BPR
- Very few mutual recognition disagreements
- First product authorised through the simplified procedure
- First applications for Union authorisations submitted
- Additional concepts to facilitate product authorisations
  - Same biocidal product
  - Biocidal products family
  - Consortium

Treated Articles

Treated articles

- Guidance on treated articles
- Main issues
  - Labelling requirements
  - Enforcement
- Deadline of 1 September 2016 for substances used to treat articles or incorporated in articles in third countries and not supported or approved in the EU.

Sustainable use of biocides

Sustainable use of biocides

- Report to EP and Council, by July 2015, on contribution of BPR to sustainable use of biocides.
- Gained attention and visibility last years (e.g. NGOs, EP), strong call for action from some MS (DE, DK, BE…) but expected to be of lower priority for most MS
- Thrust of report
  - Priority is the implementation, enforcement and control of an already very challenging piece of legislation
  - Review programme and product authorisation are the priorities

Policy developments

- Amendment of same biocidal product Regulation
- Enforcement
- MRLs, SMLs and residual contents
- ECHA budget
  - Study on appropriateness and impact of existing fee model for the BPR and its possible revision
  - Revision of fees payable to ECHA
  - Communication ECHA's budget for biocides related activites for the period 2017-2020

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