The Biocidal Products Regulation

Regulatory update from the Commission

1 September 2016
ECHA Biocides Stakeholders’ Day

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Introduction

- Substance approval
  - Review programme
  - In-situ generated active substances
- Product authorisation
- Treated Articles
- Endocrine disruptors
- Other policy developments
  - MRLs
  - Enforcement
  - ECHA budget
Review programme for existing active substances
Progress on the review programme

On August 2016: 30% of finalised evaluations (i.e. decisions adopted)

Overall progress on the review programme of existing AS per Priority list
(in percentage)

- 1st priority list: 75% finalised, 25% still ongoing
- 2nd priority list: 23% finalised, 77% still ongoing
- 3rd priority list: 20% finalised, 80% still ongoing
- 4th priority list: 19% finalised, 81% still ongoing
- 5th priority list: 10% finalised, 90% still ongoing
- 6th priority list: 9% finalised, 91% still ongoing
- TOTAL IN THE REVIEW PROGRAMME: 30% finalised, 70% still ongoing
**Review programme**

- Minimum 50 ECHA opinions and COM decisions per year

<table>
<thead>
<tr>
<th>Product-types</th>
<th>Time limits for MS to submit the assessment report to ECHA</th>
<th>Time limits for ECHA (BPC) to start the preparation of the opinion</th>
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<tbody>
<tr>
<td>3, 4 and 5</td>
<td>31.12.2016</td>
<td>31.3.2017</td>
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<td>1 and 2</td>
<td>31.12.2018</td>
<td>31.3.2019</td>
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<td>6 and 13</td>
<td>31.12.2019</td>
<td>31.3.2020</td>
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<td>7, 9 and 10</td>
<td>31.12.2020</td>
<td>31.3.2021</td>
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<td>11, 12, 15, 17, 20 and 22</td>
<td>31.12.2022</td>
<td>30.9.2023</td>
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- Dates = Deadlines
- High priority: 1\textsuperscript{st} and 2\textsuperscript{nd} lists
Approval of active substances

- Review Regulation
  - Draft delegated act to amend Annex II of the Review Regulation
- In-situ generated active substances
  - Art 13 of Review Regulation or Article 93 of BPR
- Guidance on data requirements for free radicals generated from ambient air or water
Authorisation of biocidal products
Product authorisations

- ca. 5700 authorisations granted in accordance with the BPD/BPR
- Few mutual recognition disagreements – good performance of the CG
- Monitoring of progress in Member States and reflection how to improve the performance of the system
- First products authorised through the simplified procedure
- Same biocidal products: amendment of the Regulation to address the needs of Industry, particularly SMEs
  - Need to amend IT tools – applicable as from October 2016
Product authorisations- Union authorisation

- 33 applications submitted (SBP = 7)
- Other pre-submission consultations initiated
  - Key to identify scope issues (e.g. hand disinfectants)
- Most applications are BPFs: practical implementation of the new concept of biocidal products family
- First Union authorisation to be granted in 2017
- COM to implement the administrative procedures
Renewal of anticoagulant rodenticides

- BPC opinions adopted at June BPC meeting.
- Article 5(2) "consultation" by mid-September → discussion at SCBP level (September – November)
- Commission decisions to be adopted towards the end of the year.
- Product authorisation renewal to follow in 2017 and to be completed by the end of 2017.
- Comparative assessment to be carried out at EU level.
- In parallel, implementation of the new classification of the active substances (9th ATP - CA-May16-Doc.4.1 – Final)
  - Still discussions on the applicability of the additivity principle to products containing two similar ASs below the SCL
Treated Articles
Beyond 1 March 2017, only articles treated with or intentionally incorporating active substances approved or under evaluation in the EU will be allowed on the EU market.

- Wide communication to all third countries delegations and missions to the EU and to WTO contact points.
Endocrine disruptors
Commission's 15th of June package

- Communication
  - Impact Assessment report (+ JRC methodology + contractor's report)
- Draft delegated act (BP)
- Draft implementing act (PPP) Communication
Criteria put forward:

- Contain the 3 elements of the 2002 WHO/IPCS definition of an endocrine disruptor:

  - Endocrine mode of action
  - **Causality/Correlation** ("and consequently")
  - Adverse effect
Next steps (Criteria):

- Draft delegated act for BPs
- PRAC measure for PPPs
- WTO notification (SPS/TBT)

Discussion in a group of experts of MS and adoption by the Commission for BPs + Discussion and vote in the Standing Committee (PRAC measure) for PPPs

Scrutiny

Implementation of the criteria after adoption without transitional period
Adoption of ED criteria

- 49 substances
- On-going procedure

- 110 active substances
- Biocidal active substance approved

ED working programme
Other policy developments

- Enforcement
- MRLs
- ECHA budget
Outcome of ECORYS study publicly available.

Main findings:
- Staff within the limits previously agreed
- Lower level of submissions for Union authorisations than originally expected
- Budgetary imbalance confirmed as a result
Way forward

- Staff and budget
  - 2017 draft budget responds to ECHA's needs in terms of staff and EU balancing contribution
- Amendment of Fee Regulation
  - Better Regulation Guidelines
  - Still under consideration
- Payment by instalments
  - Non-legislative measure easier to implement
  - Feasibility to be assessed by ECHA
Policy discussions on MRLs

- Interim approach
- Some substances covered by FCM, VMP or PPP legislation
- Default MRLs under PPP-legislation apply to substances formerly used as PPP
- For the others, proposal based on contaminants approach
  - Applicants to provide analytical methods for monitoring
  - Levels established, where necessary, based on monitoring data
Maximum Residue Limits (2)

- Threshold values for determining whether there is a need for a targeted monitoring programme
- Applicants to provide analytical methods.
- Competent authorities to monitor residues.
- Levels established, where necessary, based on monitoring data.
Thank you for your attention

For further information:
Commission website:

https://circabc.europa.eu/w/browse/e947a950-8032-4df9-a3f0-f61eefd3d81b
(Sante-Biocides@ec.europa.eu)

ECHA website & Helpdesk on Biocides: