The Biocidal Products Regulation

Regulatory update from the Commission

1 September 2016
ECHA Biocides Stakeholders' Day

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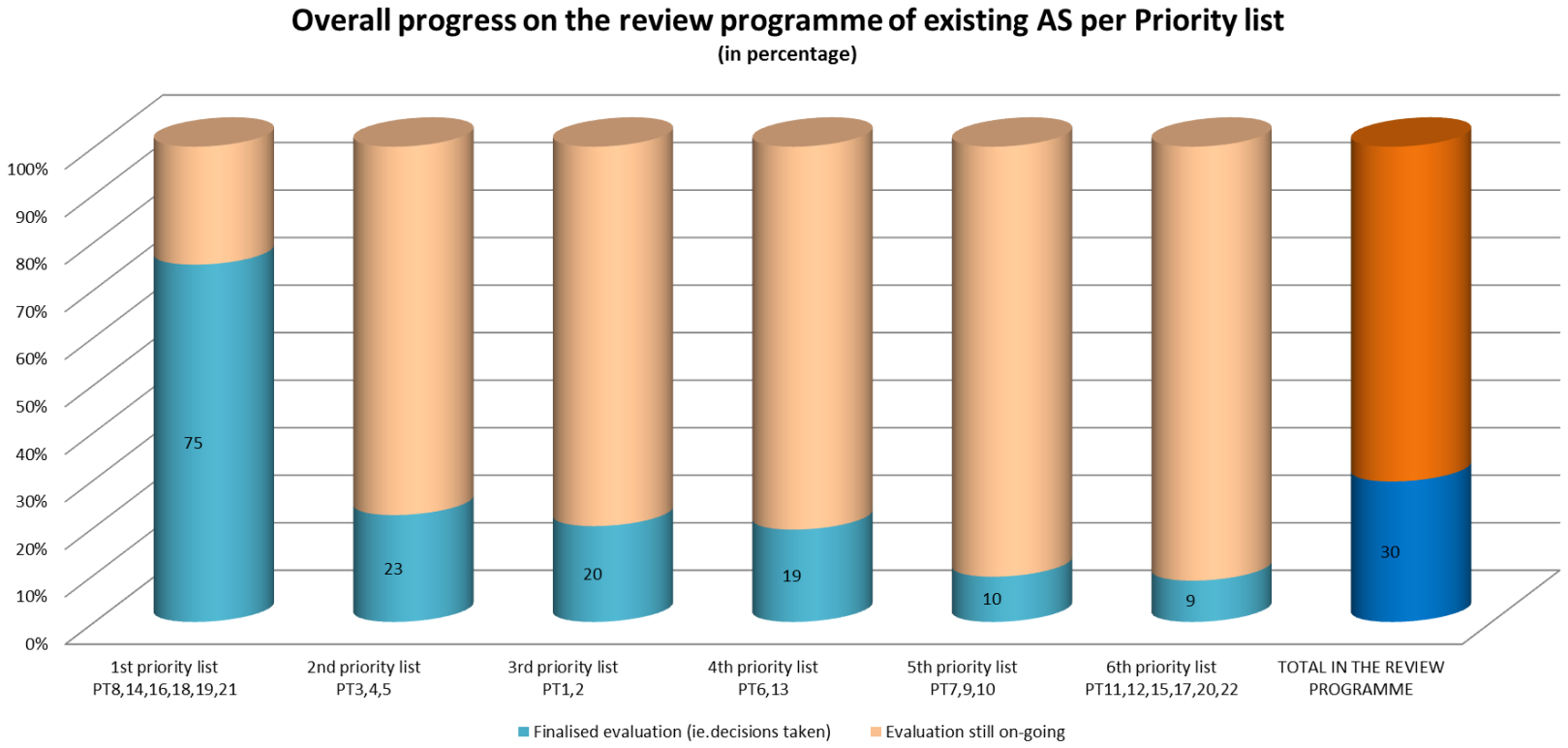
Introduction

- 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)



Review programme

- **Minimum 50 ECHA opinions and COM decisions per year**
- **Priorities in the Review Programme Regulation (EU) No 1062/2014 depending on product-types (cf. Annex III) :**

Product-types	Time limits for MS to submit the assessment report to ECHA	Time limits for ECHA (BPC) to start the preparation of the opinion
8, 14, 16, 18, 19 and 21	31.12.2015	31.3.2016
3, 4 and 5	31.12.2016	31.3.2017
1 and 2	31.12.2018	31.3.2019
6 and 13	31.12.2019	31.3.2020
7, 9 and10	31.12.2020	31.3.2021
11, 12, 15, 17, 20 and 22	31.12.2022	30.9.2023

- **Dates = Deadlines**
- **High priority : 1st and 2nd 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

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

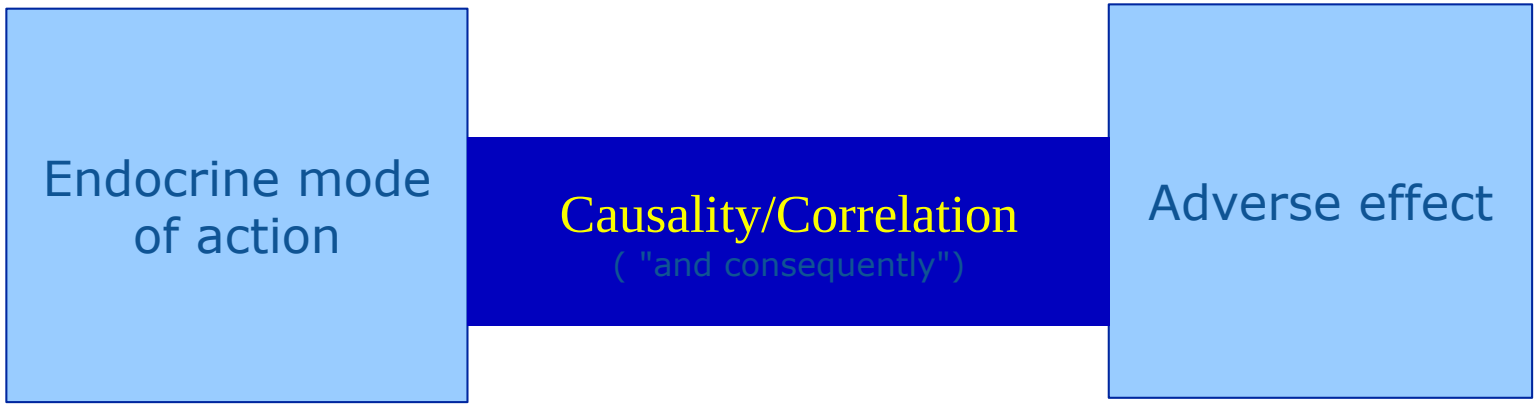
Endocrine disruptors

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:**



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

Biocidal active substance approved

110 active substances

ED working programme

Other policy developments

- Enforcement
- MRLs
- ECHA budget

ECHA's resources

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 :

http://ec.europa.eu/health/biocides/policy/index_en.htm

https://circabc.europa.eu/w/browse/e947a950-8032-4df9-a3f0-f61eefd3d81b

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ECHA website & Helpdesk on Biocides :

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