Updates from the European Commission

Congrès Biocides, 30 September-1 October

Lyon

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Outline

Active substances

- Review Programme developments
- Endocrine disruptors: Commission report on experience from application of scientific criteria

Biocidal products

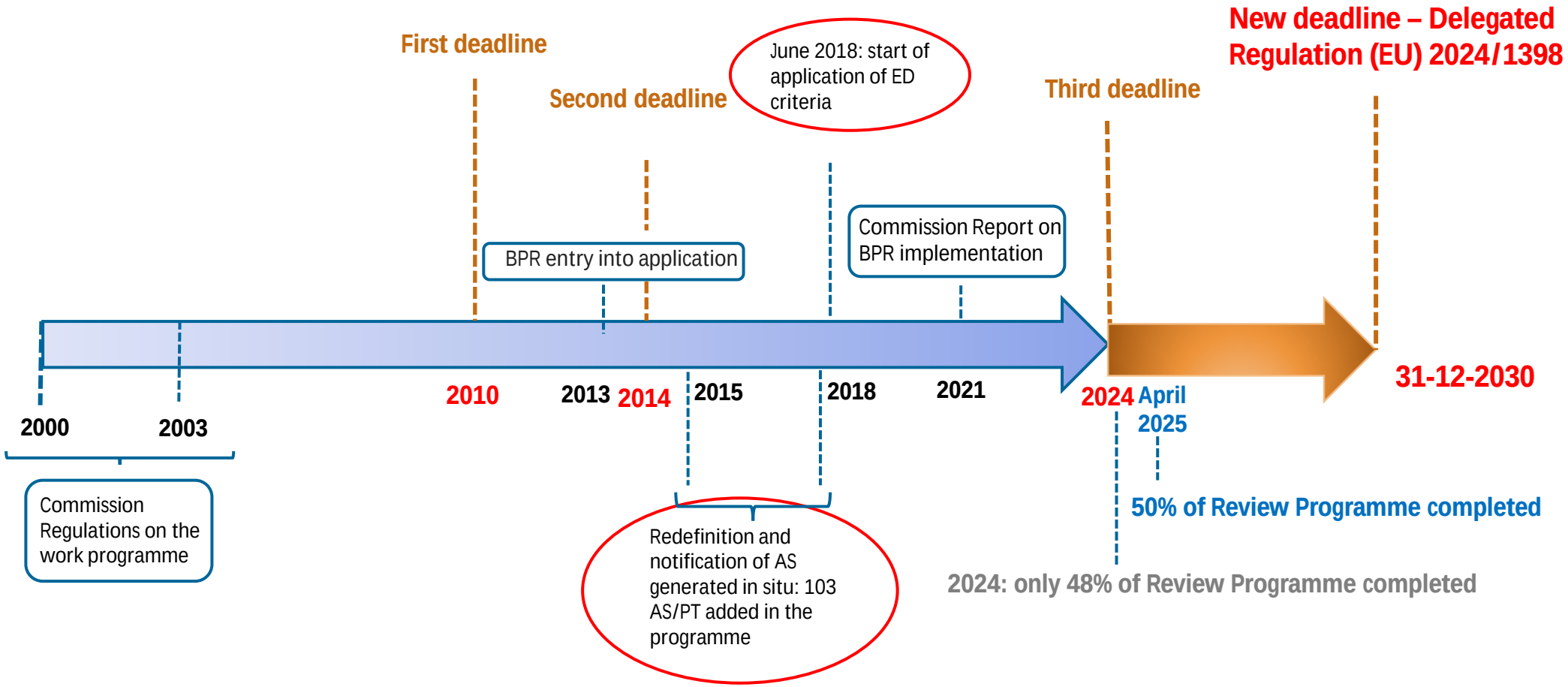
- Ten years of Union authorisation: experience so far
- Revision of rules for procedures concerning biocidal products: same BPs, mutual recognition and changes

Simplification Omnibus Food and Feed

BPR Evaluation

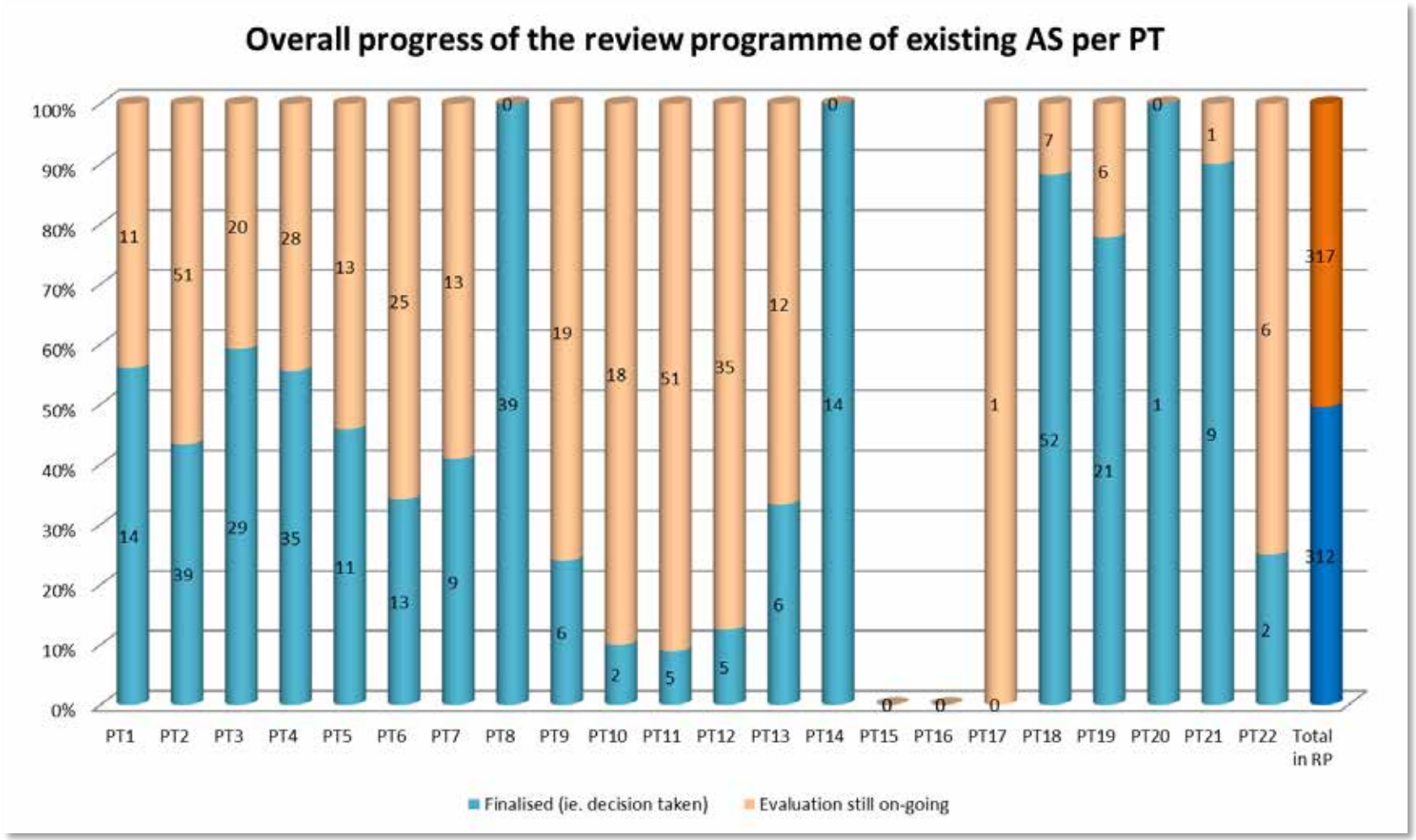
Implementation Dialogue

Review Programme: timeline



European Commission

Review Programme: progress so far



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Review Programme: developments

- Commission Delegated Regulation (EU) 2024/1398 of 14 March 2024: amended Article 89(1) of the BPR to extend the deadline of the Review Programme to **31 December 2030**

- Slow progress with the execution of the Review Programme to examine existing active substances – already highlighted in the first Commission report on the implementation of the BPR (June 2021)
  - systemic lack of resources in Member States
  - delays from applicants in providing required data
  - complexity of evaluation work, also related to the application of criteria to assess endocrine disrupting properties (since 2018)

  - One action to increase resources: grants awarded by the Commission for 2023-2028 to 9 Member States: € 6.8 million dedicated to biocides work (out of the joint € 10 million project covering biocides and plant protection products)

Review Programme: actions agreed with MSs

Ø Agreements reached with Member States in the Biocides Competent Authorities meetings (CA meetings) on actions to accelerate progress

- MSs to request by end-June 2024 missing data to assess ED properties
- Applicants to provide those data by end-2026

Possible way forward when data are missing to assess ED properties and the active substance meets other exclusion criteria

- Prioritise backlog reports
- Prioritise Review Programme evaluations over renewal evaluations

New guidance and updates of existing guidance agreed after 1 January 2024 not to be applied to evaluations of Review Programme substances

Review Programme: amendment of the Review Regulation

- Amendment of Regulation (EU) 1062/2014 (Review Regulation) under preparation
- Main amendments proposed:
  - changes related to joining or replacing participants by mutual agreement
  - removal of taking-over mechanism (in case of withdrawal of participants) >> removal of provisions on substances eligible for inclusion in the Review Programme
  - stricter rules for submission of missing data
  - removal of timelines provided for in Annex III (as obsolete) >> working along the priority lists

Most of the agreements reached at CA meetings can be implemented in the framework of the current Review Regulation (before an amendment is adopted)

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Endocrine disruptors

- Scientific criteria for endocrine-disrupting properties for biocides (and pesticides) applicable since 2018

  Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

- Joint EFSA/ECHA ED Guidance published in 2018, training for Member States provided by ECHA and EFSA

- Member States, EFSA and ECHA are applying the criteria since 2018 to all active substance dossiers (including those in the review programme)

- Clarification of data requirements: Commission Delegated Regulation 2021/525 amending Annexes II and III to the BPR >> setting data requirements for determining ED properties of biocidal active substances and biocidal products

Endocrine disruptors

Ø ED assessment*

- ongoing for **171** active substances
- completed for **54** active substances

  - **8** AS identified as ED for human health and non-target organisms: *cholecalciferol, DBNPA, cyanamide, propiconazole, iodine, PVP-iodine, medetomidine, zineb*
  - **17** AS identified as not being ED for both human health and non-target organisms
  - **8** AS identified as not being ED for human health, but inconclusive determination for non-target organisms
  - **21** AS inconclusive ED determination for both human health and non-target organisms

*data as of January 2025

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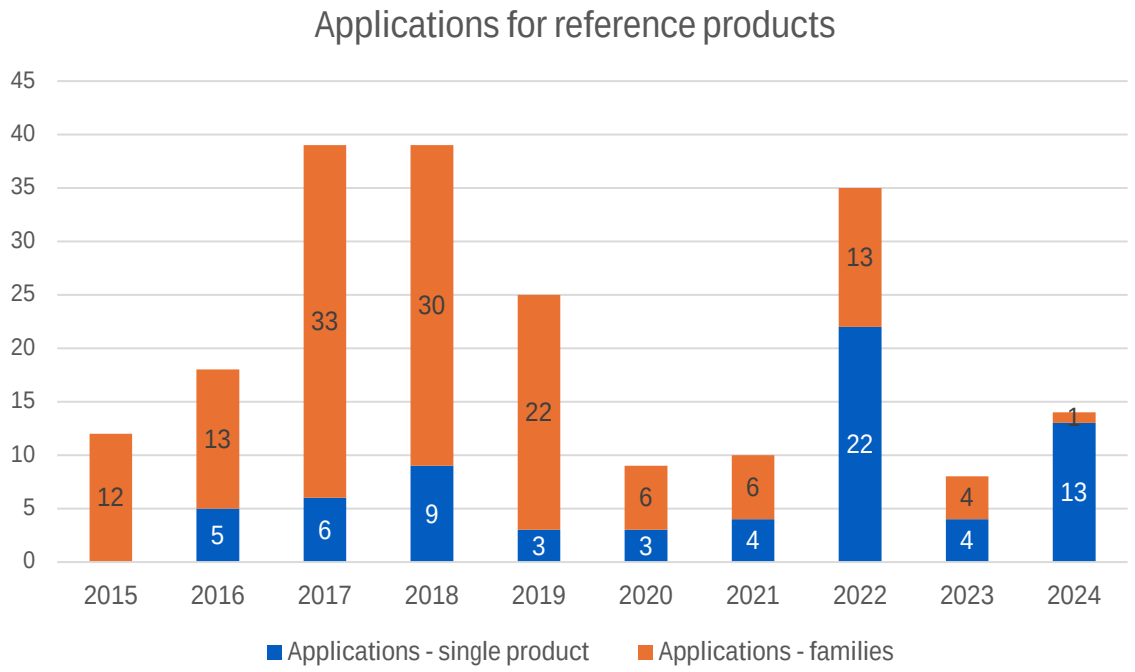
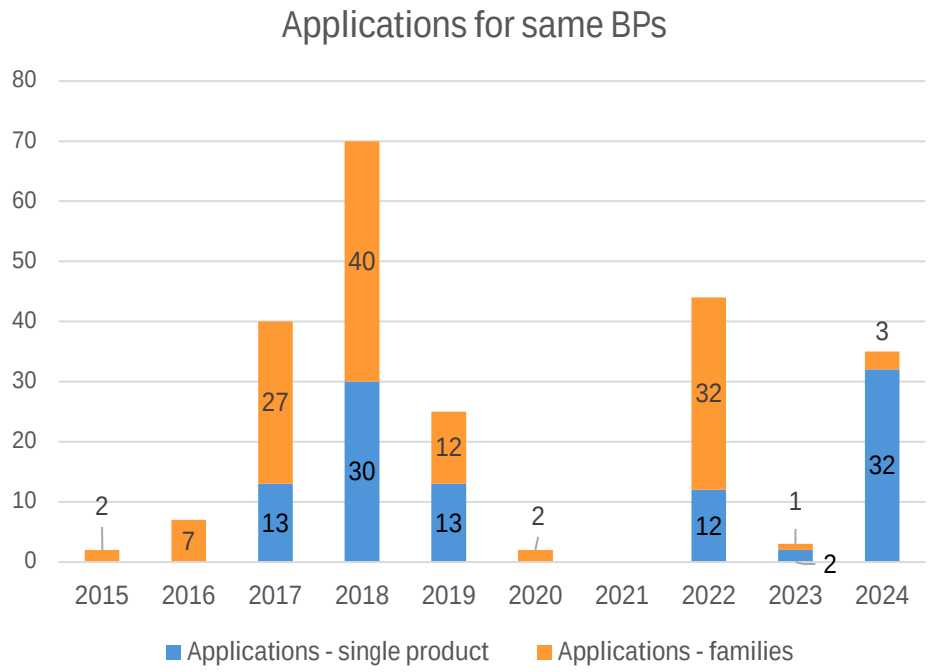
Ten years of Union authorisation: experience so far

- First applications for Union authorisation - submitted in September 2015
- So far, overall, 437 applications have been submitted (209 concerning reference products (single products and families) and 228 concerning same BPs (single products and families)





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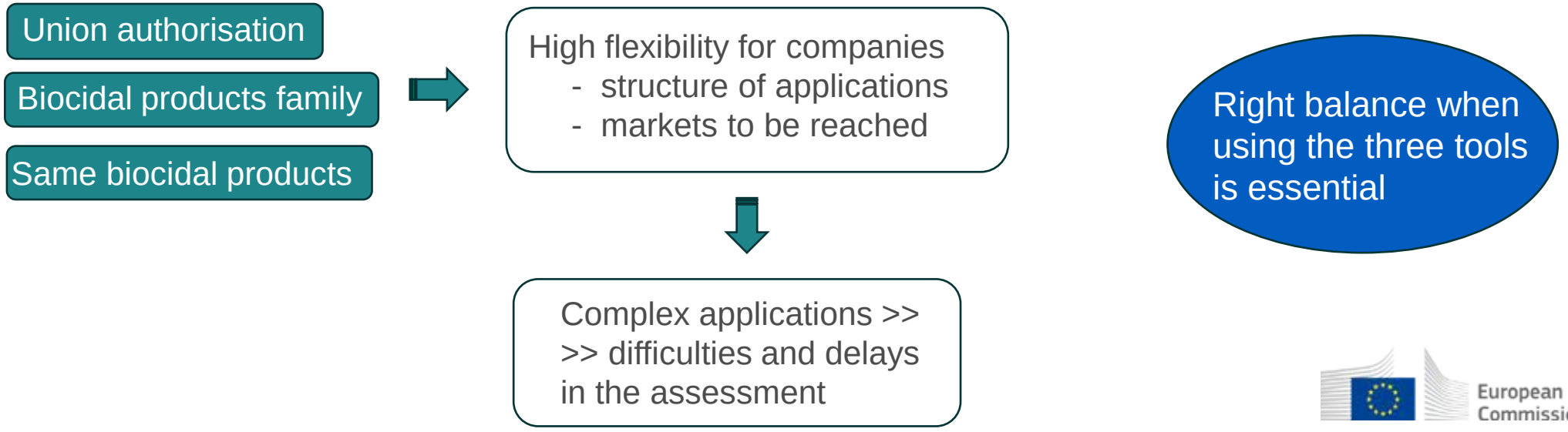
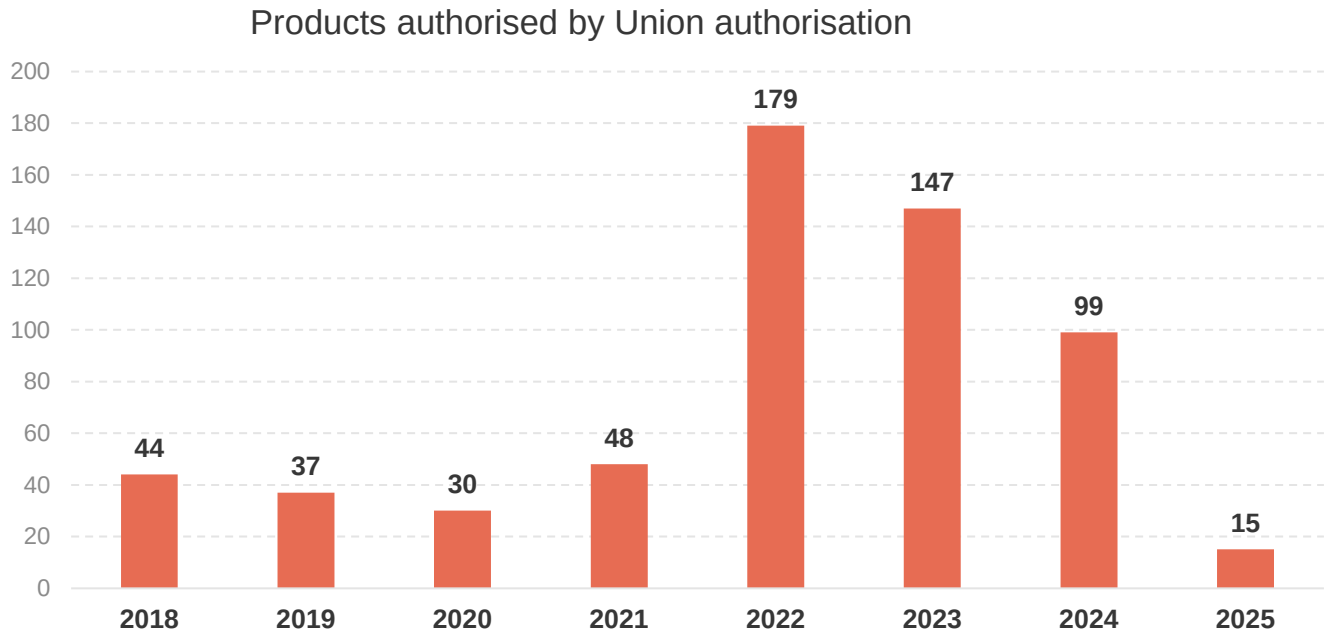
Ten years of Union authorisation: experience so far

ü The option of Union authorisation appears to be appealing to companies
- 216 companies have so far submitted a Union authorisation (approx. 12% SMEs)
- 61 companies are holders of a Union authorisation

ü Used often together with the biocidal product family and same biocidal product concepts
- almost 70% of applications concern biocidal products families
- more than half of the applications concern same biocidal products



Ten years of Union authorisation: experience so far



- ü First Union authorisations – granted in 2018
- ü So far, approx. 600 products have been authorised by Union authroisation (as single products, or as products belonging to biocidal products families)

European Commission

Ten years of Union authorisation: experience so far

Ø Successes

- § harmonisation achieved for products authorised by this procedure (similar conditions of use) >> the concept reached the purpose it was conceived for

- § reduction of administrative burden for companies: same result (access to entire EU market) could be obtained by national authorisation + mutual recognition in parallel, but advantages of UA:
  - single application submitted
  - access to entire EU market once authorisation is granted, avoiding delays related to mutual recognition (authorisation by concerned Member States)

Ten years of Union authorisation: experience so far

- Challenges
  - size of applications / large biocidal products families
    - need to split families >> submission of additional applications
    - complex assessment, very likely to result in delays
  - insufficient resources in Member States >> difficulties for applicants to find Member Sates willing to act as evaluating competent authority (eCA). Only 13 Member States have acted as eCAs so far
  - quality of SPCs, especially consistency between linguistic versions
    - SPC is part of the authorisation granted by the Commission >> annex to the Implementing Regulation granting the authorisation – publication in the Official Journal

» Applicants to consider carefully all aspects of the applications «
Completeness and consistency are key

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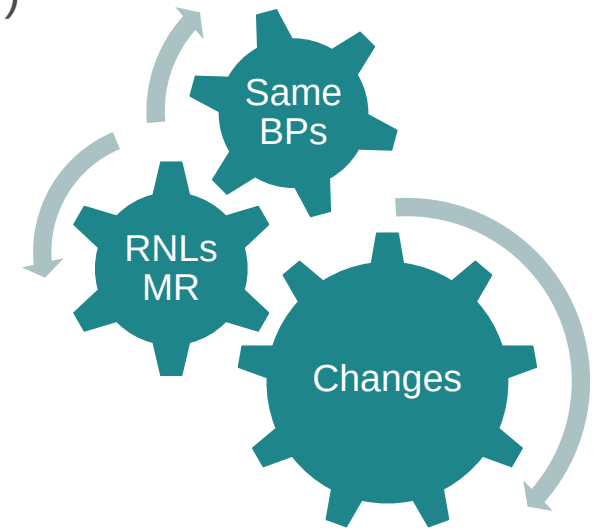
Revision of rules for procedures concerning biocidal products

The Commission is finalising the work on updating some procedures related to product authorisation

- New Regulation on Same Biocidal Products, repealing Implementing Regulation (EU) No 414/2013 (‘Same BP Regulation’)
- New Regulation on renewal of authorisations subject to mutual recognition, repealing Commission Delegated Regulation (EU) 492/2014 (‘Renewal Regulation’)
- New Regulation on changes of biocidal products, repealing Commission Implementing Regulation (EU) No 354/2013 (‘Changes Regulation’)



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Revision of rules for procedures concerning biocidal products: main changes proposed

- New Implementing Regulation on Same Biocidal Products

  - restricting the scope of differences allowed between reference product and same product so that same BPs can be authorised and renewed (no longer all information that can be subject to an administrative change, but only specific elements in Article 22(2))

  - setting out a simplified authorisation procedure for same biocidal products

  - laying down procedure and common principles for the renewal of authorisations of same biocidal products via national, Union and simplified procedure and in cases where the reference product was subject to mutual recognition

  - proposed start of application: 1 June 2026 (or later)

Revision of rules for procedures concerning biocidal products: main changes proposed

- New Regulation on renewal of authorisations subject to mutual recognition ('Renewal Regulation')
  - clarify the scope of renewals under mutual recognition – only differences allowed in terms and conditions are the ones referred to in Article 22(2), points (a), (d) and (f) of the BPR
  - interaction with Article 37 of the BPR: authorisations to which Art 37 derogations were applied are not eligible for grouped renewal
  - period of grace and referral of disagreements to the Coordination Group will be harmonised with the ones set out in the BPR
  - proposed start of application: 1 June 2026 (or later)

Revision of rules for procedures concerning biocidal products: main changes proposed

- New Changes Regulation
  - Revision and update of the annex proving the classification of changes, in light of experience
  - Clarification of provisions on
    - grouping of changes
    - content of applications
    - changes to authorisations granted through the simplified procedure
  - Discussion on the interplay between procedures for changes and renewal of applications

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Food and feed safety – simplification omnibus

- Call for evidence: Food and feed safety – simplification omnibus

16 September 2025 - 14 October 2025 (midnight Brussels time)

*The initiative proposes **targeted simplification measures** in several areas including authorisation and renewal procedures for biocidal products in order to address specific issues already identified, ahead of the full evaluation of the Regulation, scheduled to begin in 2025. These measures aim to **reduce administrative burden** for economic operators and national competent authorities, allowing them to focus resources on completing the review programme of existing active substances. The Commission **is also examining whether amending the expiry date of all data protection for existing active substances** could achieve a more balanced approach between the rights of review programme participants and those of other stakeholders.*

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BPR Evaluation

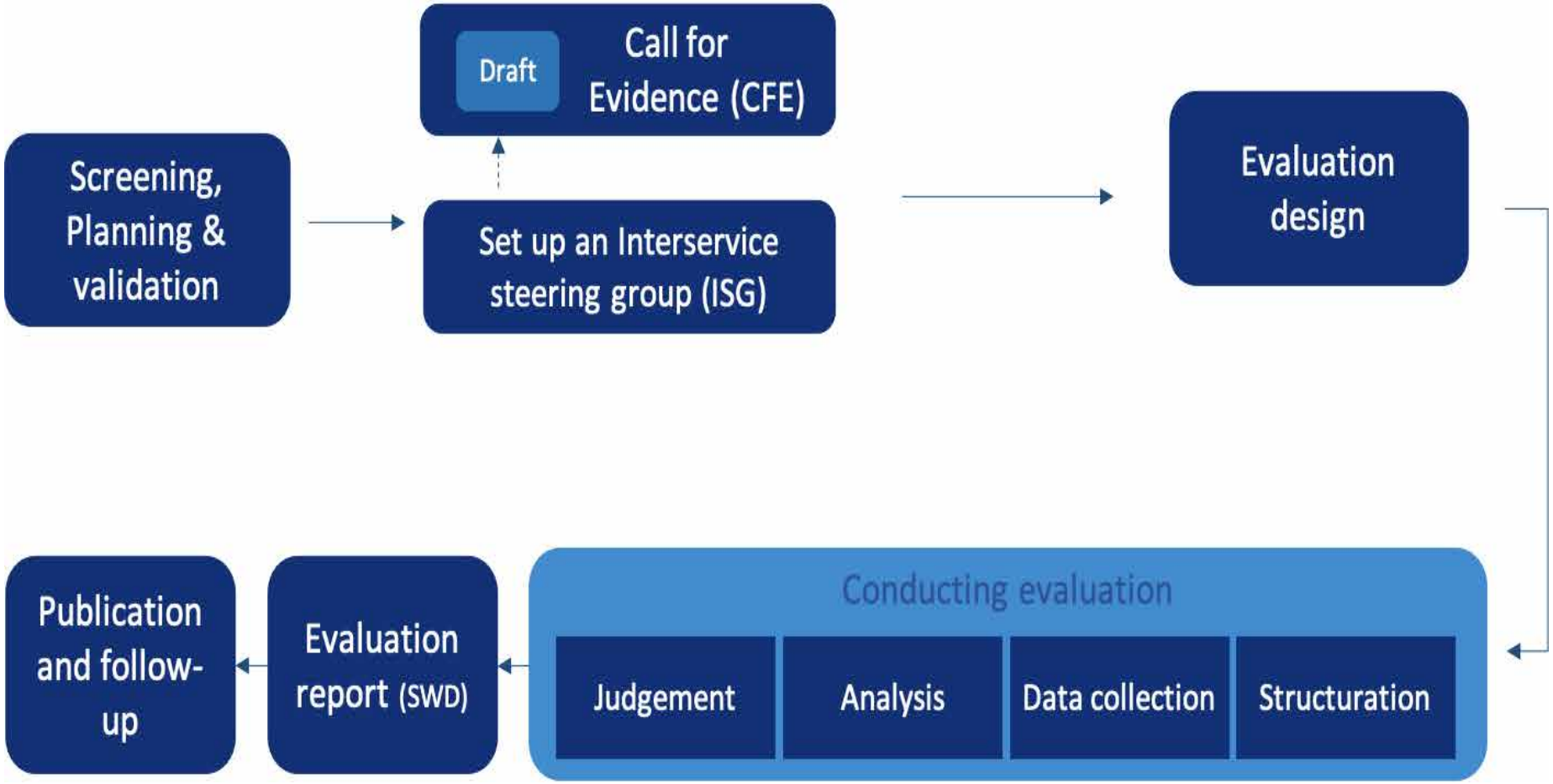
Implementation Dialogue

BPR Evaluation

Evaluation is an evidence-based assessment of the extent to which an intervention (the BPR) is

- relevant to the current and emerging needs
- effective in fulfilling the expectations and meetings its objectives
- efficient in terms of cost-effectiveness and proportionality and of actual costs and benefits
- coherent internally (how the various components of the same EU intervention operate together to achieve its objectives) and externally (with other EU interventions or international agreements); and
- it has added value - i.e. produces results beyond what would have been achieved by Member States acting alone.

BPR Evaluation. Main steps



BPR Evaluation
The Importance of Stakeholder Consultation

- Evidence-based policy making

Consultation strategy is a key requirement for each evaluation

Call for evidence - including 12-week internet-based public consultation

To be complemented by other consultation activities, targeted consultations (seminars, workshops, interviews, questionnaires…)

BPR Evaluation. Call for evidence

- Call for evidence document (3-4 pages): describes an initiative and (where applicable) a public consultation questionnaire. Invitation to:
  - Provide feedback on CfE – stakeholders expresses general views document, not based on specific questions
  - Respond to public consultation: formal process of collecting stakeholder input/views based on specific questions or background documents
- Member States are invited to participate
- All EU languages, open for 12 weeks in ‘have your say’ portal

Have your say - Public Consultations and Feedback

BPR Evaluation Report

- A key deliverable process that should:
  - Present the conclusions of the evaluation in a way in a useful way that can serve as a basis for future policy development
  - Tell an evidence- based story of the EU intervention
  - Respond to the issues raised in the call for evidence

Commission Staff Working Document. Written by DG SANTE, it might be reviewed by the Regulatory Scrutiny Board (RSB)

BPR Evluation. Publication

- To be published:
  - ü Call for evidence- Have your say
  - ü Consultation synopsis report
  - ü Contractor’s final report
  - ü Opinion from the RSB if applicable
  - ü Evaluation report
- Webpage with information on the BPR evaluation will be created

BPR Evaluation. Indicative timeline

- Call for Evidence and Public consultation
  - Publication - October 2025
  - End feedback - January 2026
- Evaluation study: February 2026-February 2027
- Evaluation (Staff Working Document) published in spring 2027

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Implementation Dialogue on Biocides

- In line with the ‘mission letters’ from the Commission President to all Commissioners, every Commissioner will organise at least two Implementation Dialogues with stakeholders each year

- Consultation tool at the political level, aiming to seek feedback from stakeholders to facilitate the implementation of EU policies and the simplification of EU rules

- The Biocidal Products Regulation was chosen as topic of the first dialogue of Commissioner Várhelyi, that took place on 15 July 2025 in Brussels

    - the dialogue can provide useful input to the evaluation of the BPR (that will start soon)
    - while the BPR evaluation will analyse in detail all aspects of the BPR, the Implementation Dialogue is a first opportunity to provide stakeholders’ views on the implementation of the Regulation

Implementation Dialogue on Biocides

Main elements emerging from the dialogue:

- ü Broad consensus on the need to have a clear, stable and predictable regulatory framework and to reduce the delays that affect approval and authorisation processes, in particular to complete the review programme of existing active substances

- ü Most participants acknowledged the importance of the ambitious goals set by the Biocidal Products Regulation to ensure a high level of safety for humans, animals and the environment

- ü Long time-to-market for both active substances and products, coupled with high regulatory costs and complex procedures were identified as main factors that stifle innovation in the biocides sector

Implementation Dialogue on Biocides

- Obstacles in bringing active substances and biocidal products to the EU market:
  - substantial delays in the approval and authorisation processes >> unpredictable timelines
  - high costs of data generation
  - changes to technical guidance and inconsistent interpretation and application of technical guidance and data requirements
  - rules on data protection, which is needed to protect investments by companies
- Obstacles to proper implementation of the BPR identified by non-industry stakeholders:
  - huge delay in the execution of the review programme and delay by applicants in providing data
  - insufficient reliance on non-animal and computational methods for data generation
  - Improper implementation of a regulatory framework that is in itself strong

Implementation Dialogue on Biocides

- Recommendations for simplification and improved implementation:
  - limit updates of technical guidance
  - ensure consistent interpretation by Member States of guidance and data requirements
  - stricter approach towards applicants that do not provide requested data on time
  - reconsider the use of the hazard-based approach for defining exclusion or substitution criteria and implement a risk-based approach
  - ensure appropriate data protection (Article 95(5))

Commissioner Várhelyi reassured that the issues raised will be considered in the context of the upcoming evaluation of the BPR and that possible solutions for the issues raised in relation to data protection could be considered in a forthcoming simplification package.

Web links

Implementation Dialogue on Biocides

Commission webpage on Implementation Dialogues

Keep in touch

https://ec.europa.eu/health/biocides/overview_en (DG SANTE Biocides website)

Email: SANTE-BIOCIDES@ec.europa.eu

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

ECHA website https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr

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Thank you

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