An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine

5th PCD Biocides Symposium

Important updates on the BPR

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Dr. Mervyn Parr

Pesticide Registration & Controls Divisions
Department of Agriculture, Food & the Marine

Biocide Developments

- BPR Objectives
- Active Substances Updates
- Data Protection
- Biocidal Product Updates
- BPR Review (REFIT)
- Future

BPR Objectives

- Improve the functioning of biocidal products in the EU, while ensuring a high level of protection for humans and the environment
- Harmonise the market at the “Union level”
- Simplify approval of Active Substances and authorisation of biocidal products
- Introduce timelines for MS evaluations, opinion-forming, and decision-making
- Co-ordination under ECHA

Active Substances

Active Substance Overview

- ~350 AS/PT Combinations still under review
- Review Programme **(RP)** has been extended to 31st December 2030 Reg (1398/2024)

- Some AS's approvals in 2025 and 2026 (impact on transitional measures)
  - ✓ *ADBAC/BKC (C12-16) for PT2 01/07/2025*
  - ✓ *Pentapotassium bis(peroxymonosulphate) bis(sulphate) for PT2,3,4,5 01/07/2025*
  - ✓ *Prallethrin for PT18 01/03/2026*
  - ✓ *Polymeric betaine for PT8 01/06/2026*

- Application for renewal >550 days before expiry

- Full list of biocide AS's available on ECHA website:
- Information on biocides - ECHA (europa.eu)

Updates on Specific Active Substances

- Ethylene oxide
  - Commission non-approval decision was presented at Standing Committee meeting of March 2025
  - No sell out period – as Ethylene Oxide is outside the scope of BPR
- Rodenticide Active Substances (PT14)
  - Brodifacoum, Flocoumafen, Coumatetralyl, Chlorophacinone, Difethialone, Difenacoum, Bromadiolone and Alpha-Bromadiolone
  - Discussed and Opinions agreed at BPC-55 (May 2025)
  - Next Steps >> Commission >>> Discussion/Vote at SCBP
- Ethanol
  - Under review for PT 1, 2, 4 and 6
  - Currently in peer review phase (PT 1, 2, 4)
  - BPC opinion expected by end of 2025

Actions to speed up the Review Programme

- Prioritise Backlog Dossiers and RP Evaluations over Renewal Evaluations
- 125 renewal applications for renewal of AS's are expected from 2024-2026!
- Amendment of Regulation 1062/2014 (Review Regulation) is underway to try speed up the RP
- Possible changes to timelines which are now obsolete and stricter rules for submission of missing data
- One Substance One Assessement

One Substance One Assessment (1S1A)

- Chemicals Strategy for Sustainability launched in 2020 to address/achieve:
  - Consistency/harmonisation of regulatory outcomes with coherent terminology
  - Make decision-making faster & predictable
  - Interoperability and accessibility of data
  - Align methodologies
- One Substance One Assessment
  - *"The 'one substance, one assessment' approach aims to ensure that methodologies are made more coherent and to the extent possible harmonised."*

  Expectations
  - Regulatory processes alignment
  - Single, harmonised data package and mutual accessibility to necessary data
  - Same methodologies
  - Cooperation of experts and bodies (MS's, EFSA, ECHA, Commission)

Where are we now with 1S1A

- 5 Active substances (Tebuconazole, Etofenprox, Sulfuryl Fluoride,Deltamethrin, Dinotefuran) have had various levels of co-operation between EFSA, ECHA and evaluating Member States.
- Cypermethrin is currently being peer reviewed for 1S1A by MS's.
- Current regulatory approach is not fully designed for 1S1A
- Guidance documents and methodologies are developed separately – not a common platform for data sharing
- Strengthen co-operation between all stakeholders
- If successful, would have a positive impact on the progress of the review programme.

Data Protection

- Data protection on data for Active Substances and Products will end on 31st December 2025
- Article 64(1) – Use of data for subsequent applications

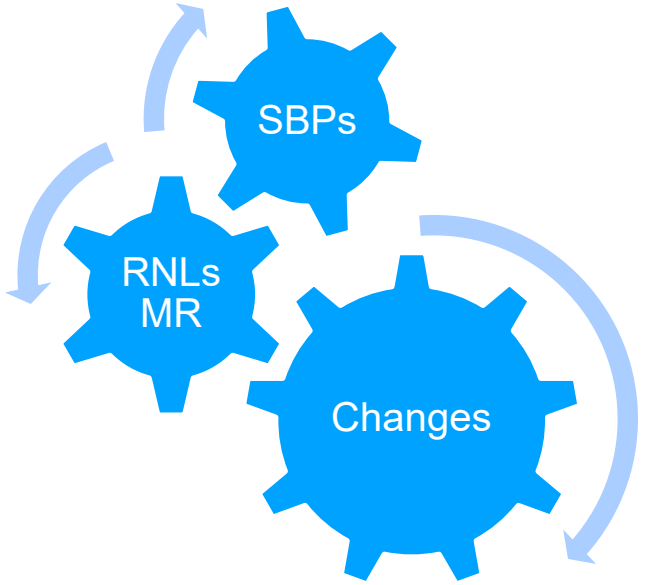
  - *'(1) Where the relevant data protection period according to Article 60 has expired in relation to an active substance, the receiving competent authority or the Agency may agree that a subsequent applicant for authorisation may refer to data provided by the first applicant in so far as the subsequent applicant can that the active substance is technically equivalent to the active substance for which the provide evidence data protection period has expired, including the degree of purity and the nature of any relevant impurities'*
  - *.. provide evidence that the biocidal product is the same as the one already authorised, or the differences between them are not significant in relation to the risk assessment and the active substance(s) in the biocidal product are technically equivalent to those in the biocidal product already authorised, including the degree of purity and the nature of any impurities.*

Biocidal Products




Revision of Rules for Procedures Concerning Biocidal Products

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



SAME BIOCIDAL PRODUCTS

- New Regulation on Same Biocidal Products
  - ✓ Clarifying the definition of a same biocidal product >> restricting the differences allowed (no longer information that can be subject to an administrative change, but only specific elements in Article 22(2))
  - ✓ Setting a procedure for renewals of same biocidal products/families (same BPs)- Union authorisation, national authorisation, mutual recognition and its combinations, simplified procedure
  - ✓ Coherence of procedures with the (new) definition – changes/amendments to same BPs
  - ✓ Addressing the renewal of same BPs having as reference products a product authorised under mutual recognition

Renewal of authorisations subject to mutual recognition

- New Regulation on renewal of authorisations subject to mutual recognition, repealing Regulation (EU) 492/2014 ('Renewal Regulation')
  - CA-Sept24-Doc.4.3.RNLs MR
  - Inclusion of rules for renewal of same BP authorisations subject to mutual recognition
  - Inclusion of provisions on minor and major changes in the context of the renewal of authorisation – specific time limits introduced for application for changes
  - Interaction with Article 37 and 19(5) of the BPR: authorisations to which Art 37 derogations were applied or authorisations pursuant to Art 19(5) were granted are not eligible for grouped renewal
  - Period of grace: not applicable where no renewal application was submitted
  - Proposed start of application: 1 June 2026

Changes of biocidal products

- Amendment of Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products ('Changes Regulation') - CA-Sept24-Doc.4.4.-Changes Regulation
  - ✓ Classification of changes /Annex to Regulation
  - ✓ Grouping of changes: remove point (a) or (b) of Article 4(2)?
  - ✓ Content of applications
  - ✓ Notification of administrative changes
  - ✓ Request for additional data during the validation step for minor/major changes
  - ✓ Procedure for changes to simplified authorisations
  - ✓ Changes during ongoing renewal, mutual recognition or other ongoing applications for change

Union Authorisation – Similar Conditions of use across the Union

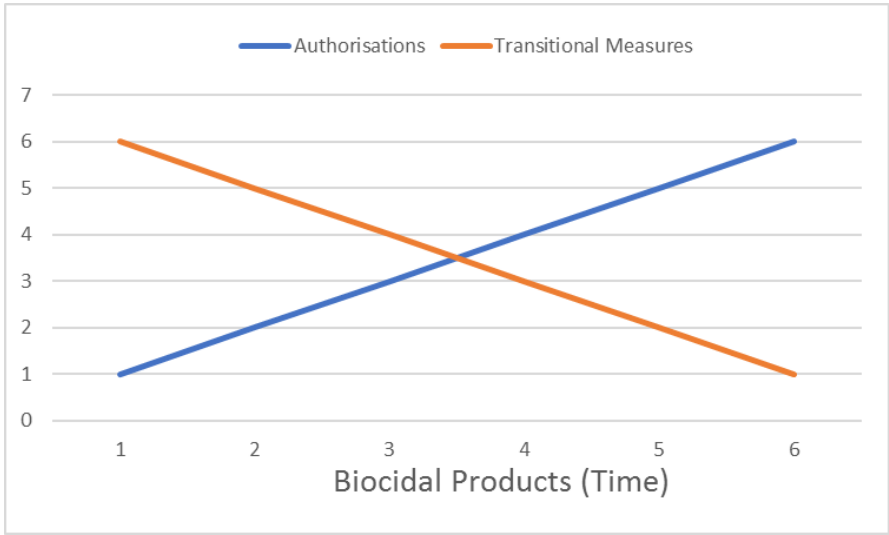
- Commission is preparing a formal guidance on similar condition of use in line with Article 42(2)
- Discussions on-going at CA level
  - *Conditions of use to be understood in the broad sense, referring to all aspects related to the use of the product*
  - *Burden of proof on applicants to check on conditions for use of the product in MS's*
  - *Harmonised Definitions for user types -'Professional' and 'Trained professional'*
  - *National/Local Rules for disposal*
  - *Commitment from all stakeholders is needed*

BPR REFIT

- The Commission intend to have a review of the BPR >> Conclude by end 2026
- The evaluation will assess how the BPR has performed regarding:
  - *Its stated objectives*
  - *Existing and emerging needs*
  - *Identify areas for improvement.*
- What will feed into it:
  - *Article 65(3) BPR Implementation Reports from MS's*
  - *Public Consultation 'Have your Say'(Q4 2025) Biocidal Products Regulation – evaluation*
- Implementation of the Review by 2030

Future

- Completion of the RP extended to 2030 >>Will this deadline be achieved?
- Knock on effect on product authorisations
- REFIT >> IMPLEMENTATION >> IMPACT??
- Efficiency >> One Substance One Assessment
- Less product availability >> Safe products
- 20XX End of Transitional Measures??



Further Information

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

PRCD: PRCD - Home (agriculture.gov.ie)

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

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

Thank you for your attention!

- **E-mail:** Mervyn.Parr@agriculture.gov.ie

Biocides (Helpdesk):
Biocides@agriculture.gov.ie

Biocide Notifications:
biocide-notifications@agriculture.gov.ie

Biocide Authorisations:
Biocide-authorisations@agriculture.gov.ie