Transparency Regulation Implementation
The new renewal procedure for PPP Active Substances

Sustainable Solutions to Protect Crops, 2021

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Outline

- Implementation of the Transparency Regulation in the renewal procedures for active substance in the PPP area related to:
  - Quality & reliability of studies
  - Transparency of EU risk assessment
- Update on other implementation activities

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The “Transparency Regulation” - Regulation (EU) 2019/1381 – amends the GFL and some sectorial legislation including 1107/2009

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Implementing Regulation (EU) 2020/1740 repealing Commission Implementing Regulation (EU) No 844/2012

- New renewal rules are required to implement the provisions in the Transparency Regulation
- Implementing Regulation (EU) 2020/1740 was adopted on 20 November 2020 and applies from 27 March 2021
- Key Changes:
  - ✓ Pre-submission phase – including notification of studies
  - ✓ Single step – submission of a renewal application 3 years before expiry
  - ✓ Contents of the renewal dossier more comprehensive
  - ✓ Full dossier published
  - ✓ Public consultation on the dossier
  - ✓ Dossier submission via IUCLID
  - ✓ New window for submission of information at the end of the peer review

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Planning phase before submission

Only in case of "renewals" (GM food and feed, Feed additives, pesticides), an additional procedure applies.

A pre-notification by a potential applicant of planned studies to EFSA is foreseen.

efsa

EFSA will then systematically launch a consultation on the planned studies and issue advice on the content of dossier.

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Pre-submission phase

- ✓ Article 3 - Notification of intended studies and advice on intended studies (only for renewals)
- ✓ Article 4 General pre-submission advice - any time before the submission of the application for renewal. EFSA shall inform the rapporteur Member State of the request and together they shall decide if the co-rapporteur Member State is required to participate in providing the general pre-submission advice.

Content of the renewal application

- ✓ Article 6 of Regulation (EU) 2020/1740
- ✓ Expanded scope to ensure renewal includes all data, old and new
- ✓ Submission via IUCLID

Peer-review – key changes

- Article 10 - Public consultation (60 days) on the renewal application
  - Comments to be taken into account by the RMS in its assessment

(Article 12 – public consultation on the RAR – remains as previous)

- Article 13(4) – new window for applicant's to submit comments and information
  - Applicants can submit comments to EFSA on the draft Conclusion (2 weeks)
  - Critical issues leading to no safe use which the applicant could not foresee or had no opportunity to address during the stop the clock:
    - Applicant can submit data or information (2 weeks)
    - RMS, co-RMS and EFSA evaluate = 75 days

When and to which substances will the new Regulation apply?

- See Articles 2 and 17 of Regulation (EU) 2020/1740
- This new Regulation shall apply to the renewal of the approval of active substances **whose approval period ends on or after 27 March 2024**.
- It shall **not apply** to the renewal of the approval of the active substances for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

Impact on the Renewal Programmes

- Some substances in AIR4 and the majority in AIR5 fall under the new rules whereas all substances in AIR3 remain under Regulation 844/2012

- Consideration of the impact on substances that fall under the new rules was undertaken with a view to avoiding significant changes to submission dates in 2021

- Implementing Regulation (EU) 2020/2007 was adopted on 8 December 2020 – extends the approval periods of 54 substances

- The work programmes on the **public webpages have been updated** and clearly indicate which rules apply and the dates for submission.

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What else?

- Adoption of the standard data format (IUCLID) for new AS applications
- Guidance for Basic Substances
- Administrative Guidance EFSA - including MRLs
- EFSA's Practical Arrangements
- Europa webpages

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