Endocrine disruptors: work in progress in the area of biocides and pesticides

Maristella Rubbiani

DG SANTE

Unit E4 Pesticides and biocides

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Overview

- ED criteria and their implementation
- Review of tests methods for data requirement
- Procedures foreseen for on-going evaluations
- First experiences so far

The Commission adopted criteria for the identification of substances with endocrine disrupting properties in:

- **Biocides**: *Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017, applicable since 7 June 2018*
- **Plant Protection Products**: *Commission Regulation (EU) 2018/605 of 19 April 2018, applicable since 10 November 2018*

The criteria are **harmonised** for biocidal (**BP**) and plant protection products (**PPP**)

Implementation of the ED-criteria

Further to the decision making on ED-criteria:

- A **joint EFSA/ECHA GD** to implement the criteria was published in June 2018
- Review of **data requirements** / test methods for PPP and BP to align them with the new GD
- Amendment of Regulations and Procedural Guidance for PPP and BP to specifically foresee implementation of the criteria for **on-going evaluations** of applications

Assessment of ongoing evaluations

PPP: As ED criteria applicable to ongoing and future evaluations, "**stop the clock**" at EFSA or COM level foreseen to obtain and assess additional data to conclude on ED criteria

- ✓ Amendment of Reg. 844/2012 (November 2018) setting procedures for PPP active substances renewals adopted on 24 October 2018

https://op.europa.eu/en/publication-detail/-/publication/5ead42b2-e328-11e8-b690-01aa75ed71a1/language-en/format-PDF/source-179445128

BP: ED criteria also applicable to on-going and future evaluations

- ✓ Procedural guidance documents for on-going and upcoming procedures for the approval of biocidal active substances and the authorisation of BP were adopted in 2018

CA-March18-Doc.7.3a-final- EDs- active substances under assessment.docx
CA-March18-Doc.7.3b-final- EDs- biocidal products.docx

PPP: Review of test methods for fulfilling data requirements

- The Communications listing the test methods for data requirements for PPP evaluations under Reg. (EC) No 1107/2009 is being reviewed in light of the ED EFSA/ECHA Guidance

PPP : EFSA and RMS evaluation

- EFSA evaluating substances considers ED criteria when dossiers are at their level
- for "pending dossiers" : several are currently under "stop the clock" for implementing the ED part
- RMS are applying new ED criteria for the dossiers which were at their level (since Nov 2018)
- all decisions taken @ PAFF since 10 Nov 2018 considered the new ED criteria

PPP: When the stop the clock takes place

the applicant can also within the same period of time:

- submit information to address the conditions of approval (negligible exposure)

and/or

- apply for a derogation under Article 4(7) of Reg. 1107/2009

BP: Update of data requirements

- for biocidal active substances (BPR Annex II)
- for biocidal products (BPR Annex III)

Commission Delegated Regulation amending the Annexes of the BPR was adopted by the Commission last 19 October; currently under scrutiny of Parliament and Council (2 months), expected publication March 2021

https://webgate.ec.europa.eu/regdel/#/delegatedActs/790

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM%3AC%282020%296771

BP : experience so far

- Early review initiated for **3** biocidal active substances because of significant indications ED properties (iodine/PVP iodine, zineb)
- **3** biocidal active substances identified as ED (cholecalciferol, cyanamide, DBNPA)
- **16** biocidal active substances discussed in ED Expert Group at ECHA

BP: discussion ongoing on ED (1)

Non-active substances contained in biocidal products having indications for ED properties:

1. To clarify the interaction between Biocidal Products Regulation and REACH

2. To decide at which strength of indications to make public the name of those non-active substances

BP: discussion ongoing on ED (2)

- The status of an active substance containing an **impurity** identified as having ED properties

- Status of an active substance or biocidal product **generating disinfection by products** identified as having ED properties

PPP and BP : Training of risk assessors on endocrine disruptor criteria and guideline

Better Training for Safer Food (BTSF) events

- for PPP and BP risk assessors of MSs
- Trained by COM, EFSA and ECHA
- First edition: February 2019, second edition: November 2019, another session planned in 2021

Thank you for your attention!

maristella.rubbiani@ec.europa.eu

More information available at:

https://ec.europa.eu/health/endocrine_disruptors/overview_en