Assessment of co-formulants in biocidal product authorisation

EFSA Technical workshop on assessment of plant protection products

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- → Authorisation of biocidal products
- → Outline of the risk assessment
- → Classification and labeling

Authorisation of biocidal products

→ Process of authorisation is rather similar to that of plant protection products

→ First step: active substance (AS) approval
- Risk assessment of representative product
- Establishing List of Endpoints (LoEP) listing the intrinsic properties of the AS

→ Second step: biocidal product (BP) authorisation
- Risk assessment based on composition of the BP combined with use pattern

The principle of the risk assessment

→ Use pattern is described in the Summary of Product Characteristics (SPC)

→ Composition of the BP is included in the Product Assessment Report (PAR) and IUCLID

→ Composition BP
- AS
- Co-formulants (each with a defined function)
  - Substance of Concern (SoC)
  - Other

Assessment of biocidal products (I)

- → Establish physical and chemical properties of the biocidal product and the identity of active substances and co-formulants (APCP)
- → Sufficiently effective (EFF)
- → No unacceptable effects for human health (HH) or the environment (ENV)

- → APCP and EFF are mainly established on the complete products
- → Risk for HH and ENV is mainly established on AS and SoC

Assessment of biocidal products (II)

- Active substance
  - Intrinsic properties are included in the List of EndPoints (LoEP) as established in the approval process
  - Exposure assessment models are included in guidance.

- SoC
  - Guidance available (for HH & ENV)
  - Depth of assessment based on the classification of the SoC

Assessment endocrine disruptors

→ AS:
- Endocrine disruptor (ED) status determined in frame of AS approval or renewal
- If status not determined yet: no assessment at BP level

→ Co-formulants:
- CA documents on
  - the use ED assessment/conclusion under REACH processes [a)]
  - the methodology to identify EDs [b)]
- Assessment at BP level
  - ED status of most co-formulants recorded in a list of products [c)]

a) see document CA-March23-Doc 4.13 – EDs-biocidal products
b) see document CA-March21-Doc.4.3_Final_Bridging Biocides with REACH
c) due to product compositional information this list can only be shared between biocides CAs

Classification and labelling

→ In addition to the risk assessment, classification and labelling is established

→ Based on entire composition

- In accordance with CLP Regulation
- Safety Data Sheets have to be provided for all AS and co-formulants
- Other data can be taken into consideration if available

Thank you

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