Technical Equivalence and related needs

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Overview

- Definition
- Main case – Technical Equivalence for Authorisation
- Other needs
- Proposal
- Follow-up actions/questions

Technical Equivalence – Definition

- Biocide Products Regulation - Article 3.1(w)
- Similarity in chemical composition and hazard profile …
  - Chemical composition → 'Tier 1'
  - Hazard profile → 'Tier 2'
- …between two sources (alternative vs. reference) of the same active substance
- 90 days to issue an (appealable) ECHA decision
- Two (linked) questions:
  - For what purpose/processes is TE relevant?
  - What is the reference source?

Need for Technical Equivalence – What processes? What reference source?

- Main case where TE may be requested:

  - Application for the authorisation of a product containing active substance(s) from alternative source(s) (Article 19.1(c))

  → Reference source from which the approved active substance listed in Annex 1/Union list is derived

Other needs (outside BPR scope for TE)

- Case 1: Alternative supplier, before investing in buying a LoA to the dossier of a substance under the review program (Article 95)
- Case 2: In the context of data sharing negotiation/dispute (Articles 62 and 63)
- Case 3: Change of source of the active for a product under national authorisation
- Case 4: Prospective applicants seeking confirmation, before applying, that different sources of the same active could be assessed jointly

Proposal

Following discussion during the *ad hoc* MSCAs and ECHA MB meeting on 18 – 19 April, the following proposal emerged:

1) Technical equivalence: only for approved active substances

2) *Chemical similarity* service when approval process of the active substance is not finalised or has not been initiated

Rationale for *chemical similarity* service

- Address Industry needs which are outside of the BPR scope for TE
- Differentiate the assessment from TE which main aim is to be used for product authorisation (Article 19)
- Avoid the confusion linked to the need to perform again the TE once the AS is approved
- Limit the risk of conflicting reference sources used in different processes (ECHA assessment vs. MSCA AS approval)
- Assessment limited to Tier 1 (*chemical similarity*) because of the absence of a peer reviewed reference hazard profile

Discussion