

Data sharing and technical equivalence

Biocides Stakeholders' Day

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Suvi Takala
Scientific officer
European Chemicals Agency



Data sharing

Request for information

Dispute procedure



Request for information

- Obligatory for any person intending to perform tests or studies on vertebrates under the Biocidal Products Regulation (BPR)
- Voluntary for any person intending to perform tests or studies not involving vertebrates under BPR
- Data request to be submitted to ECHA via R4BP

Request for information

- ECHA provides name and contact details of the data submitter to the prospective applicant
- ECHA informs data submitter of the request
- Dossiers submitted and approved under Directive 98/8/EC and BPR are considered to contain all relevant data, ECHA will not provide information on individual tests or studies

Tips for data sharing

- Keep a record of any communication with the other party
- In case of an unsatisfactory reply, challenge the reply by addressing constructive, clear and precise questions or arguments to the sender
- Give reasonable time to the other party to provide appropriate answers
- Communication must be made directly between the parties involved (not via ECHA or including ECHA)

Data sharing disputes

- Can be launched by the prospective applicant under the following conditions:
 - a written request has been submitted to ECHA in accordance with Article 62(2)
 - ECHA has replied to the written request and at the earliest one month after receiving ECHA's reply
 - agreement not been reached during the negotiations despite making every effort to reach an agreement
- Last resort after all the possible arguments have been exhausted and the negotiations have eventually failed

Data sharing disputes

- Prospective applicant needs to provide ECHA documentary evidence regarding the negotiations
- Data owner is invited to provide their documentary evidence
- ECHA performs assessment of the evidence provided in order to issue a decision
 - Every effort has been made to reach an agreement
 - Costs shared in a fair, transparent and non-discriminatory way
- Positive decision pending until ECHA has received proof of payment

Technical equivalence

Technical equivalence (Article 54)
Chemical similarity check



Technical equivalence

- Active substances which have been included in the list of approved substance
- Required for:
 - product authorisation (Article 19)
 - permission to refer to data (Article 64) when the data protection period has expired
- Application to be submitted via R4BP as a IUCLID dossier

Chemical similarity check

- Proposal made by ECHA: discussion on-going
- Active substances which have not been included in the list of approved substance
- Voluntary
- Application to be submitted via R4BP as a IUCLID dossier (if implemented)

Thank you

suvmaria.takala@echa.europa.eu