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# Revision of the Biocides Directive

## Data protection and data-sharing issues

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# Data protection in BPD

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- A Member State cannot use for the benefit of an applicant data submitted by a previous applicant without their written agreement
- For data submitted in support of a **new active substance**:
  - For 15 years starting from the inclusion of the substance in Annex I or IA
  - For 10 years starting from the authorisation of a biocidal product containing the new active



# Data Protection in BPD

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- for **all data** submitted for the purposes of the Directive:
- Until 14.5.2010, or
- For the period of data protection granted under national authorisation systems, in the territory of the Member States concerned, but not beyond 14.5.2010



# Data protection in BPD

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- **data submitted for the first time** in support of the first inclusion of an active substance:
- For 10 years after the entry in Annex I or IA
- **Further information submitted for the first time:**
- For 5 years from the date of the decision (active substances) or from the date of receipt (authorisation of biocidal products)



# Data-sharing

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- The Directive does not provide for mandatory data-sharing, however:
- Applicants for authorisations have to take “all reasonable steps” to reach a data-sharing agreement and avoid duplication of tests involving vertebrate animals (Article 13 BPD)
- Participants in the review programme for active substances have to make “all reasonable efforts” to submit a collective dossier (Article 8 of Regulation 1451/2007)



# Issues to tackle

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- Protection of new studies that have been used to renew national authorisations before their submission for the review programme
  - Mandatory data-sharing for vertebrate animal studies
  - Ensure a fast dispute resolution mechanism and a timely and equitable compensation
  - Provide for innovation incentives
  - If possible, simplify the system, but maintain the acquired legal rights
  - Import workable features of similar systems
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