

# Data sharing

## Biocides Stakeholders' Day

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Substance Identification and Data Sharing

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# Data sharing brings benefits



1. Minimises animal tests
2. Shares testing costs among all manufacturers
3. Levels the playing field for SMEs
4. It's fair...

...and it's a legal requirement

## **But there are concerns...**

“If I don’t get the data, I’ll be off the market”

“We invested in expensive tests, and now others will get our data for free within 60 days”

“My company is small, we have neither the time nor resources to negotiate”

## The good news is...

- Under REACH, data sharing works:
  - Close to 5 000 joint submissions so far, where data was successfully shared
  - 25 data sharing disputes lodged with ECHA
  - 9 decisions in favour of the applicant
  - 1 decision appealed

## When to share data on biocides

Data sharing is:

- Mandatory for tests on vertebrates
- Extended scope for Article 95  
Toxicological; ecotoxicological; environmental fate and behaviour
- Possible also for tests not involving vertebrates

You have to share data if:

- You intend to perform tests
- You are a data holder

## Data sharing - how to do it



# Effective data sharing



1. Make “every effort” to reach an agreement:
  - Proactive and constructive
  - Precise and in detail
  - Answer and explain
2. Act in time

## Effective data sharing



3. Every prospective applicant needs to submit an inquiry – final data sharing agreement is company-specific
4. Data holder might have legitimate interest in information about potential applicant



## Effective data sharing



5. “Technical equivalence” is no precondition
  - Data sharing is mandatory as soon as you want to perform a test
    - Technical equivalence (or chemical similarity check) is not a precondition for data sharing
  - There is no “substance sameness” under the BPR
  
6. Keep records of all your negotiations

## **You will struggle to demonstrate every effort if...**



- Meetings or negotiations are ongoing when you lodge a dispute
- You have not reacted to proposals from the other party
- You have not given the other party reasonable time to react
- You have not challenged slow progress
- You have not replied to messages
- You have not explained your needs



## If negotiations fail...

- File a data sharing dispute with ECHA showing the efforts you have made
- ECHA assesses overall context
- ECHA decision within 60 days
  - “permission to refer”, or
  - not granting “permission to refer”:  
negotiations need to continue – data sharing still mandatory
- File the dispute early
- Decisions published online

## Data holders

- Data sharing is mandatory
- Be transparent
- Be fair in determining cost
- Be a reliable and consistent partner in the negotiations
- Ensure negotiations are balanced



## Data sharing so far

Biocides inquiries

47

Disputes

5

Decisions issued

2

Cases under  
assessment

3



## More information available

### 1. Data sharing website

<http://echa.europa.eu/regulations/biocidal-products-regulation/data-sharing>

### 2. Data sharing dispute decisions (see also REACH)

<http://echa.europa.eu/regulations/biocidal-product-regulation/data-sharing/echa-decisions-on-data-sharing-disputes-under-bpr>

### 3. Practical Guide **NEW**

<http://echa.europa.eu/practical-guides>

### 4. Guidance

<http://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation>

## Remember



1. Data sharing on vertebrate tests is mandatory
2. Act in time
3. Make “every effort” – and record it
4. Continue negotiations when you submit a data sharing dispute

# Thank you

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