

# Ensuring dossier quality

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**What does "quality" entail?**



## Good quality dossier

### ✓ **Demonstrates safe use of your substance**

- Clear scope: substance correctly identified
- Complete: increased ECHA check
- Compliance with information requirements
- Relevance: test material and information
- Transparency, consistency and conciseness
- Updated with new information and studies

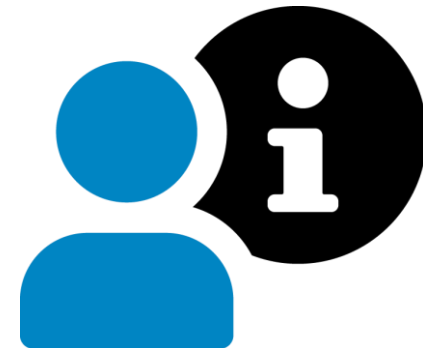
## Ensuring quality is a dynamic task

- Uses and volumes change
- Exposure and risk management measures evolve
- New information on hazards are generated
- New knowledge on hazards and risks emerges
- New EU and international assessments are published

✓ **Demonstrating safe use of your substance is as dynamic as your business**

**What can you expect from ECHA after successful REACH registration?**





## ECHA tasks

We will:

- publish key information from your dossier
  - Your "business card"
- screen your dossier
  - To select for compliance check or other measures
  - To (de-)prioritise substances for further regulatory action
- examine and conclude your testing proposals

# What you can expect from ECHA



We **may**:

- prioritise your substance if it raises concerns
- invite you to update your dossier
- give you prior warning (and a last chance to update) about a planned compliance check

# What you can expect from ECHA



We **may**:

- check your dossier for compliance
- request further information in a formal decision
- propose national enforcement action
- revoke a registration if your dossier is actually not complete, or it is not brought to compliance



# When you receive a compliance check decision....

## Receipt of draft decision

- You have 30 days to provide comments
- You can request to discuss with ECHA experts

## Review by EU member states

- You receive any proposals for amendments
- You have 30 days to provide comments

## Possible discussion in meeting

- Taking into account yours and the Members States' comments
- Final decision agreed

## Receipt of final decision

- Right to appeal
- Deadline by which you must submit the information

# What is your business model?

Happy to (just) get the registration number?

**OR**

Committed to demonstrating safe use?





# Being proactive pays off

## 1) Reputation

- ✓ Key information in your dossier is published - demonstrates that you are serious and committed to safe use
- Bad dossiers are visible
- ECHA compliance check decisions are published

## 2) Efficiency

- ✓ Getting it right from the start and keeping your dossier up-to-date means you are in control and can plan your work
- ECHA decision imposes deadlines on you

## 3) Business impact

- ✓ Authorities having confidence – no need for regulatory measures
- Risk of losing your business in case of non-compliance

## Take home messages

- Successful registration is not the goal but a milestone
- Demonstrating safe use is a dynamic task
- Your dossier is an investment and an asset – get it right from the start - and keep it right!
- It pays off to be proactive

✓ **Commitment to quality is an investment for a sustainable business model**

# Thank you!

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