





#### **Main focus**



Your obligations



What to pay attention to



ECHA support





# Your obligations (1)

- Keep dossier up to date as of registration date
  - Complete and compliant
  - Substance and uses fully identified
  - Need to propose further testing
- Update promptly if situations change
  - Generally within 3 months of change
  - Keep record for inspection authorities
- Even if you cease manufacture or import, some obligations remain





### Your obligations (2)

- Perform exposure and risk assessment if >10 tonnes per year and classified as CMR/PBT/vPvB
  - Report all hazards and outcomes in the chemical safety report and safety data sheet
  - Report all actual uses within the lifecycle
  - Identify how risks are controlled
- Keep classification and labelling up to date
  - Regardless of tonnage band
  - Using CLP criteria and most severe test results
  - Report all harmonised classifications





# Your obligations (3)

- React promptly to evaluation draft decisions and update by the deadline even if studies delayed
  - Get organised with co-registrants to give comments
  - Agree who will do requested tests on everyone's behalf inform ECHA within 90 days
  - Report studies in IUCLID format (robust study summaries)
  - Provide data adequate for classification and labelling for risk assessment



# What to pay attention to Tools (1)



- Use the public activities coordination tool (PACT)
  - Keep monitoring your substance's regulatory status
- Use REACH-IT regularly
  - Set up an email alert to receive notifications
  - Agree who monitors the inbox in your company
  - Use dossier evaluation status page to follow evaluation activities for your joint submission if you did not receive the decision
- Use IUCLID validation assistant
  - To enter required information in the correct sections







- Use the <u>EU Chemicals Legislation Finder (EUCLEF)</u>
- Use maps with brief descriptions of main uses by industry sector
- Follow status of dossier evaluations
- <u>Follow</u> substance evaluations





# What to pay attention to Information

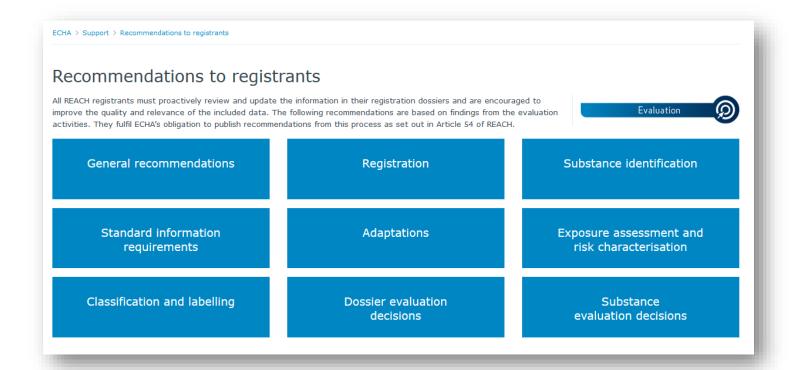
- Required information depends on substance property and tonnage
  - Deviations from standard information requirements must be thoroughly and appropriately justified
  - Testing on vertebrate animals only as last resort
- Results must be adequate for classification and labelling (CLP Regulation)
- Need to take further regulatory action and impact on other legislation
  - o if CMR, PBT, ED, ... properties





# Recommendations to registrants (2)

echa.europa.eu/recommendations-to-registrants







#### Take home



Your dossier is your business card

Your registration is as dynamic as your market volume and uses. Updates are always necessary over time



We screen all substances and dossiers, yours too



You have the means to check and follow activities around your substance and dossier – use them







#### Before registering

Strategy for gathering your data

<u>Preparing registrations for</u> nanomaterials

How to register

<u>Substance identification – get started</u>

Practical guide for SME managers and REACH coordinators - How to fulfil your information requirements at tonnages 1-10 and 10-100 tonnes/year

Sector use map formats

**C&L Inventory** 

#### Keep up to date

Questions and answers on information requirements, test methods and quality of data

European Commission
Implementing Regulation
2020/1435 on dossier updates

#### **Evaluation decisions**

**Evaluation process** 

<u>Practical guide: How to act in dossier evaluation</u>

<u>Practical guide: How to act in</u> substance evaluation



# Thank you!

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