

## What it takes to prepare and maintain a REACH registration dossier

### What are REACH dossiers?

- ✓ Every chemical substance manufactured, imported or used in the EU in quantities of 1 metric tonne or more per year must have its own registration dossier submitted to the European Chemicals Agency (ECHA)
- ✓ Core REACH principle of “no data, no market” - if no registration dossier has been submitted for a given substance, the substance may not be manufactured or imported in the EU and placed on the EU market
- ✓ Every dossier contains:
  - information about intrinsic properties of a substance
  - information about the way it is manufactured and used
  - how people and environment can be exposed to this substance
  - recommended operational conditions and risk management measures for a safe use
  - information about the substance’s hazard classification and labelling

### What it takes to register a substance (on average):

#### Time and resources:

- filling more than 2,000 data fields in IUCLID (ECHA software to record REACH registration data)
- up to 70 physicochemical, toxicological and ecotoxicological studies
- some of these studies take up to 3-4 years to complete
- testing of one substance manufactured in big volumes (> 100 metric tonnes) requires 1,500-5,000 lab animals
- 100-150 hours of work on average to fill in the information in the IUCLID IT system (once study results have been analysed and all information gathered). This can exceed 400 hours for substances whose manufacturing volume is more than 1,000 metric tons
- additional time to gather and assess uses and exposure & risk
- negotiating with consortia (if submitting a dossier with other companies)
- additional time to maintain and update dossiers

#### Costs:

€50,000-2,000,000 on average, including:

- ECHA fee for registration or update
- costs of toxicological & environmental studies
- cost to run consortia and employ contractors
- human resources involved in preparing a registration dossier.

#### Expertise required to fill in a REACH registration dossier:

- Regulatory expert
- Toxicologist
- Environmental fate and ecotoxicology scientist
- Industrial hygiene
- Exposure assessors
- Legal
- Safety Data Sheet authors
- Classification & Labelling experts
- Research & Development
- Business and marketing
- Manufacturing