

# Simplifying REACH for industry and authorities

## How REACH administrative burdens can be effectively reduced, particularly for SMEs, without harming protection levels

Reducing administrative burdens under the REACH framework—particularly for SMEs—can be achieved without compromising the high level of protection for human health and the environment. Streamlining processes, applying new methods and approaches, and improving data management can help maintain strong regulatory standards while alleviating the burden on both authorities and industry. The following measures outline actionable steps that can reduce administrative complexity across various REACH processes, while promoting innovation, enhancing predictability, and safeguarding public health and the environment.

#### Hazard and Risk Assessment

- Grouping chemicals with similar properties enables authorities to fulfil their mandate of ensuring a high
  level of protection more effectively and with less administrative burden, compared to a piecemeal
  substance-by-substance approach. This approach helps avoid regrettable substitution, enhances clarity
  and predictability for industry, and helps companies avoid unnecessary investments in harmful or
  unsustainable alternatives.
- Applying a Mixture Assessment Factor (MAF) offers a practical and efficient way to assess risks from
  combined exposures. By increasing the risk characterisation ratio in chemical safety assessments, it helps
  identify potential risks that might otherwise be overlooked, thus simplifying the risk evaluation process.
- Apply 21st century science! Regulatory authorities should integrate new assessment methods, new approach methods (NAMs), including non-animal methods that are considered acceptable by regulatory authorities should also be used for identifying and regulating hazardous chemicals, gradually reducing animal testing and reducing the burden on both authorities and companies.
- The precautionary approach is the most cost-efficient way to enhance protection of health and the
  environment while reducing the burden on authorities and companies. Ensuring better use of existing
  data for hazard identification and taking precautionary action to phase-out the most harmful chemicals,
  will decrease the burden of evidence for authorities, while effectively minimising the need for animal
  testing.

#### Restriction

• Extending the generic risk approach (GRA) to cover all the most harmful chemicals in mixtures and articles intended for the general public and professional users, allows authorities to ensure a high level of protection more efficiently. The standard restriction procedure involves separate, lengthy, and burdensome specific risk assessments. GRA streamlines the process, reduces administrative burdens, and accelerates decision-making, making it less resource-intensive for all parties involved. Extending GRA to professional uses that are similar to consumer uses (e.g., paints or cleaning products) simplifies regulation by addressing multiple use scenarios together, reducing complexity and avoiding duplicated efforts. GRA also enhances clarity and predictability for industry, as it establishes clear criteria for action, thereby preventing companies from investments in unsustainable and short-sighted alternatives. Extending the right to initiate actions under Article 68(2) to Member States would distribute the workload with the Commission, speeding up regulatory action and increasing effectiveness.

- **Including by default** groups of chemicals in the scope of restrictions reduces the high burdens of the lengthy substance-by-substance approach and avoids regrettable substitution.
- Ensuring early information on uses of chemicals and available alternatives will reduce the burden on authorities when preparing restriction dossiers or making decisions about the availability of alternatives. It reduces the need for add-on calls for evidence, saving time and resources for all stakeholders. Improved data and a more specific reporting on chemical uses would enable supply chain actors to better identify and manage risks, leading to more targeted and efficient risk mitigation for companies.
- Applying the Essential Use Concept would ease the burden for authorities preparing and deciding on restriction dossiers and would increase stakeholders' predictability. Non-essential uses should be banned. Time-limited derogations should only be granted to uses deemed essential, this is, those uses that are critical for society and for which it is demonstrated that no alternatives are available.

#### **Authorisation**

- Limiting the possibility to obtain authorisation to essential uses would significantly reduce the number of applications for authorisation that authorities need to assess and decide upon. Companies would have more predictability as they would have clear criteria for which uses applications are allowed and for which are not. The burden on applicants would also be reduced, as they would only need to demonstrate the criticality of the use and the lack of alternatives, avoiding the need for burdensome socio-economic assessments.
- Worshipping the legal text, as well as <u>Court mandates</u> and <u>Ombudsman recommendations</u>, when implementing authorisations will reduce the burden on companies applying for authorisations and authorities assessing and deciding on these applications. This can be achieved by rejecting all applications that are not in conformity and ensuring that the burden of proof lies with the applicants and encouraging joint applications for similar uses with similar exposure scenarios.

### Information along the supply chain

- Developing a digital and centralised database of Safety Data Sheets (SDS) would reduce the burden
  on SMEs both in preparing SDS and assessing the risks of the products they use. A digital system, linked
  to ECHA's chemical database would facilitate accurate information on hazards and labelling, reducing the
  resources needed by SMEs. A centralised database of SDS would also make it easier for SMEs and
  workers to access accurate information.
- 'Report only Once': the horizontal reporting provision under REACH (Art 33) should be reinforced and complemented (outside REACH) enabling companies to submit chemical content information only once, rather than repeatedly across various regulatory frameworks, saving time and resources, while also ensuring regulatory compliance in a more efficient manner.

