Registration, evaluation, authorisation and restriction of chemicals (REACH); European Chemicals Agency

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In accordance with the requirements of Regulation (EC) No 1907/2006 (REACH), the Commission presents a report on the operation of the Regulation. The report also examines certains aspects of the operation of Regulation (EC) No 1272 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (CLP Regulation).

Human health and the environment: whilst it is still too early to quantify the benefits, the Commission states that overall, **progress towards meeting the human health and environment objective of REACH is materialising**, and will accelerate as the remaining key benefit drivers become fully operational. However, the Commission notes some key shortcomings which may hinder achievement of the benefits:

- many registration dossiers have been found to be **non-compliant**, including with regard to substance identity;
- **insufficient assessments** by registrants of persistent, bioaccumulative and toxic (PBT) and very persistent, and very bioaccumulative (vPvB) properties;
- problems with regard to the **content and format of the extended safety data sheet**.

The Commission discusses ways for industry, Member States and the ECHA to improve the situation, with particular reference to the quality of registration dossiers, and enhancing the use of safety data sheets as a central risk management tool.

Internal market and competitiveness: the report notes that industry acknowledges the **positive economic effects of REACH**. However, the Commission will (i) explore ways to **reduce the financial impact of the Regulation, in particular for SMEs**, and (ii) encourages ECHA and industry to address concerns about transparency, and cost sharing in the Substance Information Exchange Forum (SIEF).

Innovation: the report states that REACH has had a **positive impact on research into new substances**, due to generally equal treatment of new and phase-in substances. REACH fulfils its objective with regard to innovation even if, with regard to R&D, an innovation gap with regard to the US and Japan still exists and pressures from the emerging economies are increasing.

Alternative methods: considerable efforts to develop alternative methods to animal testing have been made and will continue: the Commission has made available EUR 330 million to fund research in this area in the period 2007-2011.

Enforcement: enforcement is the sole responsibility of the Member States and all of them have nominated enforcement authorities. The Commission wants Member States to maximise the effectiveness of available resources through better coordination and knowledge sharing. It will **develop enforcement indicators** and calls on Member States to monitor the effectiveness of enforcement.

Review of the requirements for registration of 1 to 10 tonnes substances and on the need to register certain types of polymers: at present, the Commission has insufficient information on the impact on innovation and competitiveness to propose changes to the information requirements for substances produced in low tonnages. Similarly, it is reviewing the need, if any, to register certain types of polymers.

Scope of REACH: overall, the Commission is of the view that the scope of REACH was set well and no major overlaps with other EU legislation have been identified. Nonetheless, it discusses the minor overlaps which were identified and adds that it has also identified certain areas where information generated under REACH processes could be used in the context of EU sector-specific legislation requirement.

Amendments: some needs for adjustments have been identified, but balanced against the interest of ensuring legislative stability and predictability, the Commission concludes that changes to the enacting terms of REACH will not be proposed.