EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies

Periodic Review of REACH

Conclusions of the review in 2013

The Commission concluded that REACH functions well and delivers on all objectives that at present can be assessed. Some needs for adjustments have been identified, but balanced against the interest of ensuring legislative stability and predictability, the Commission will not propose any changes to the enacting terms of REACH.

Within the current framework, however, there is a need to reduce the impact of REACH on SMEs. The annex to the general report sets out measures that will contribute to this goal.

There are many other opportunities for further improvement of the functioning of REACH by optimising the implementation at all levels. Some key findings and recommendations are:

- The report makes recommendations to improve REACH implementation. These include improving the quality of registration dossiers, encouraging companies to enhance the use of safety data sheets as a central risk management tool, and addressing issues related to the transparency of cost sharing within the Substance Information Exchange Forums (SIEFs).

- The report recommends reducing the financial and administrative burden on SMEs in order to ensure the proportionality of legislation and to assist them to fulfil all their REACH obligations. The Commission will look into greater fee reductions to SMEs.

- There are no major overlaps with other EU legislation.

- Considerable efforts to develop alternative methods to animal testing have been made and will continue: since 2007, the Commission has made available € 330 million to fund research in this area.

- Enforcement could be improved. As this is the responsibility of the Member States, the report recommends to Member States to reinforce coordination among them.

- Although the report identifies a need for some adjustments to the legislation, the Commission wants to ensure legislative stability and predictability for European businesses. No changes to REACH's main terms are proposed at present.

The Report and the Commission Staff Working Document have been published on the EUR-Lex portal:

Report from the Commission {COM(2013)0049}

Staff Working Document {SWD(2013)0025}

A press release and a more detailed press memo with key messages and conclusions have been issued to mark this occasion. At the same time, the Commission has published the results of a recent Eurobarometer survey on the public perception of chemicals.

Technical workshop on the follow-up to the Review of REACH, 27 June 2013, Brussels

Follow-up

1. The Commission further reduced registration fees paid by SME to the European Chemicals Agency (ECHA).[1] For micro-enterprises the reduction amounts to 95% of the standard fee.

2. In cooperation with Member States and ECHA, the Commission developed a roadmap for assessing and identifying substances of very high concern (SVHC)[2] which sets out clear milestones, deliverables and the division of work between the Commission, Member States and ECHA to place all relevant known SVHC on the candidate list by 2020. The main objective of the Roadmap is to improve clarity and predictability of the processes, and thus allow for timely reaction from the relevant stakeholders.

3. ECHA prepared a Registration Roadmap 2018 which outlines activities to support industry towards the registration deadline, with a particular focus on SMEs.

4. As foreseen in Article 138 of the Regulation and taking into account the Commission's right of initiative, the Commission may, if appropriate, present a legislative proposal based on the review outcomes and after considering all the expected socio-economic effects through a proper impact assessment process, bearing also in mind, among others, potential impacts on the next registration deadlines (2013 and 2018). Two implementing acts are being prepared for adoption in the first half of 2016 - one to ensure fair, transparent and non-discriminatory practices in data sharing and another one aiming to simplify the authorisation process in specific cases.

5. With regard to nanomaterials, the Commission launched an impact assessment of relevant regulatory options, in particular possible amendments of REACH Annexes, to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers. If appropriate, the Commission will come forward with a draft implementing act by the end of 2015.

6. The Commission also follows up on evaluation of different approaches with regards to the registration requirements for substances in tonnages between 1 and 10 tonnes and for polymers.

New studies in preparation of the review in 2017

In continuation of the REACH Review of 2013 and as a part of the preparations for the next evaluation of REACH in 2017, DG Internal Market, Industry, Entrepreneurship and SMEs is monitoring a range of factors in order to identify the relevant policy responses.

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[1] Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013
[2] Commission document 5867/13 of 6 February 2013

1. **Study to monitor the impacts of the REACH Regulation on innovation, competitiveness and SMEs:**

REACH is considered one of the most burdensome EU regulations for SMEs, despite the fact that not all of its provisions are yet applicable to a large number of companies who did not yet have to register their substances. The next registration deadline in 2018 is expected to involve large number of SMEs that are new to REACH.

The monitoring objectives of this study include:

> o the impact of REACH on competitiveness and innovation;
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> o identification of business opportunities;
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> o the quality and availability of the support services provided by ECHA, Member States and industry associations;
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> o the situation of SMEs and their capacity to comply with the REACH Regulation;
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> o the costs of the 2018 registration deadline and the preparedness of the industry;
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> o the situation within downstream sectors, including the producers of articles.

The study was finalised in December 2015.

The consultant carried out an extensive primary data gathering among stakeholders through phone business survey and an on-line survey (in total, these two surveys received over 1600 replies). To refine the results, over 150 in-depth interviews were conducted with stakeholders and companies.

Based on this broad survey programme, an in-depth examination was done for twelve specific aspects of REACH operation which correspond with the aforementioned monitoring objectives (e.g. impacts on internal market and external competitiveness, costs of registration in 2013, impacts on innovation, transparency and fairness of cost sharing within SIEFs, business opportunities, authorisation and support instruments). In addition, the study contains updated estimates for the costs of the 2018 registration deadline if no changes are made to the implementation of REACH.

The report includes an overall assessment of REACH Regulation in terms of effectiveness, efficiency, coherence and sustainability; identifies strengths and weaknesses of implementation and provides policy recommendations.

2. **Upcoming studies:**

- The REACH Baseline Study – 5 years update (a follow-up of the baseline study of 2012)

- Study on the impacts of REACH and corresponding legislation governing the conditions for marketing and use of chemicals in different countries /regions on international competitiveness of the EU industry

Background and Scope of the Review in 2013

REACH has been in force for 5 years, and several important milestones in its implementation have already passed. The Commission launched a review which consisted of the legally required reviews and reports: (a) the review of ECHA (Article 75.2), (b) the review to assess whether or not to amend the scope of REACH in order to avoid overlaps with other EU legislation (Article 138.6), and (c) a general report from the experience acquired in the operation of the regulation (Article 117.4) including a review of the requirements relating to registration of low tonnage substances Article 138(3) and the information submitted by the Member States and ECHA in their respective reports on the operation of REACH (Art.117(1)(2)(3).

In addition, the review included a report on the first lessons learnt from the implementation of REACH with special attention to the costs and administrative burden on companies and impacts on innovation.

All of these reviews and reports are presented as a package, accompanied by a Chapeau Communication to give a complete overview.

Methodology

To inform the review process, the Commission launched several thematic studies. They addressed the following issues which provided input to the Commission services during the review:

- The (nominal) risk caused by chemicals in 2012 compared to the 2007 (a follow-up of the baseline study of REACH)

- Review of the European Chemicals Agency (ECHA) based on Article 75 of Regulation (EC) N° 1907/2006

- REACH contribution to the development of emerging technologies

- Implementation and enforcement of restrictions in Member States

- Impact of the REACH regulation on the innovativeness of EU chemical industry

- Inspections requirements for REACH and CLP

- Functioning of the European chemical market after the introduction of REACH regulation

- Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps

- Technical assistance to prepare the Commission report on operation of REACH

- Review of the registration requirements for 1 to 10 tonnes substances and polymers

- Assessment of health and environmental benefits of REACH

- Review of EU legislation (REACH) concerning nanotechnology

Contact

If you want to be kept informed about the launch of the registration for conferences or workshops, further consultation processes or surveys, or want to give feedback to the Report from the Commission or any of the above mentioned studies, please send an email to the following address, stating the study you are interested in: European Commission - DG GROWTH - REACH