

## The Commission's Summary Report on the Implementation of the REACH Regulation and the Review of Specific Elements – Conclusions and Measures

### Statement of the Zentralverband Oberflächentechnik e.V. (Central Association for Surface Technology) (ZVO)

The Commission's report on the implementation of the REACH regulation is prepared and published every five years. The first large-scale review of the REACH regulation took place in 2013<sup>1</sup>. On 5 March 2018 the second evaluation was published by the commission. The latest report<sup>2</sup> as well as the background documents<sup>3</sup> containing further details were published as part of the Regulatory Fitness and Performance Programme (REFIT).

The aim of the REFIT programme is to produce better results with regard to the achievement of the social, ecological and economic objectives which have been set by bringing legislation up to date and to limit the administrative burden for companies and citizens as much as possible. Against this backdrop, the ZVO has reviewed the REACH report and background documents using the five REFIT evaluation criteria and has been able to draw the following conclusions:

#### Summary Evaluation of the ZVO

1. The report shows numerous shortcomings within the context of REACH. The conclusion that REACH is already working is therefore misleading. Consequently, it is important to take a critical view of the fact that the Commission currently wishes to continue using or only minimally optimise processes that are recognised as being deficient, without inducing fundamental changes.
2. No information is given regarding the extent to which the aims set out in the REACH regulation have been achieved. The appropriate methods and criteria required in order to produce quantitative results do not currently exist and need to be determined by the authorities.
3. The plan according to Measure 11, to examine substances requiring authorisation for potential restriction prior to the expiry date,<sup>4</sup> will further exacerbate the lack of predictability and market uncertainty.
4. The Commission does not give any indication of the resources needed to ensure the standardised, verifiable implementation of REACH across the EU.
5. It was noted that it is absolutely essential to ease the burden on SMEs. However, the Commission fails to make any suggestions with regard to how this may be achieved, but rather shifts responsibility on to the ECHA, the member states and industry (Measure 14).
6. The attempt to identify relevant cases of risk minimisation in order to achieve greater efficiency is welcomed.
7. A positive outcome is that the Commission have called on the ECHA to improve scientific and technical expertise in the field of chemical safety and the resulting methods for chemical assessment by 2019 (Measure 15).

<sup>1</sup> Commission's Summary Report on REACH, 05/02/2013.

<http://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52013DC0049&from=EN>

<sup>2</sup> Commission's Summary Report on the Implementation of the REACH Regulation and the Review of Specific Elements, COM(2018) 116, 05/03/2018.

<http://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52018DC0116&from=EN>

<sup>3</sup> Commission Staff Working Document accompanying the COM(2018) 116, 05/03/2018. <https://ec.europa.eu/docsroom/documents/28202>

<sup>4</sup> The date from which it is forbidden use a substance or place it on the market if approval has not been issued.

## Evaluation of the ZVO According to the Five REFIT Categories

The existing evaluation is based on the five categories established by the Commission as part of its REFIT programme and applied in its evaluation of REACH (see appendix on page 4).

### 1. Effectiveness

- According to the report or background documents, the aims of REACH have not yet been achieved. This is expected to happen at some point during the next ten years.
- The report barely addresses the regulation's possible consequences for end consumers; focusing on the supply chain and occupational safety and health (OSH) instead.

### 2. Efficiency

- The Commission's accompanying documents to the report contained no cost-benefit information within the context of an efficiency review. Only different costs and cost factors for authorities, registrants and those who have submitted an application for approval, in addition to their apparent development, have been described.
- Transferring the burden of proof on to industry has significantly reduced efficiency. By way of comparison: the regulation costs per substance are ten times higher in Europe than in the USA. The burden of proof should be amended to be in line with that of other developed countries.
- The Commission's Measure 12, which relates to regulation of the interface between the REACH regulation and occupational safety law, is welcomed. However, the methods use to determine safe levels of exposure for chemical substances in the workplace do not only need to be adjusted, but also scientifically backed. Currently, the elaborations display scientific shortcomings (e.g. in the current drafts for guidelines on extended skin contact with nickel<sup>5</sup>), which must first be remedied.
- The Commission recognises that SMEs are particularly affected by the stringent requirements (obligations to provide information, authorisations with their requirements, etc.) and associated costs – especially with respect to the 2018 registration deadline (Measure 14). Consequently, one is left with the impression that a significant part of the burden will be shifted away from the SMEs following 2018, which is not the case!

### 3. Coherence

- According to Measure 12 of the report, there is a need for improvement with respect to coordination of the national authorities responsible for the implementation of the REACH regulation and the authorities responsible for the implementation of occupational safety law. To this end, clear, transparent criteria and boundaries (e.g. workplace vs. consumer; substances in products vs. process chemicals; etc.) need to be established. If this is not done, it becomes impossible to coordinate activities due to a lack of assessment criteria.

---

<sup>5</sup> ECHA, Draft guideline on articles intended to come into direct and prolonged contact with the skin in relation to restriction entry 27 of Annex XVII to REACH on: Nickel and nickel compounds, 15-16 November 2017

- The interrelation between authorisation and restriction is rooted in the REACH regulation, whereby in the case of substances that are subject to authorisation and for which the risk is insufficiently controlled, a restriction process is initiated. According to Measure 11, the ECHA is to systematically review the necessity of preparing a restriction dossier prior to the expiry date of each substance that is subject to authorisation and present in products. This approach will further exacerbate the lack of predictability and market uncertainty; the measures thus run counter to at least two REACH objectives: Free movement of substances and increased competitiveness.
- The Commission's report states that REACH has a strong influence on other countries and serves as an example for their own regulations - however, potential sensible adjustments are not discussed.

#### 4. Relevance

- The report or background documents focus almost exclusively on the concerns of the chemical industry. The chemical industry has lost some of its global market share - however, no assessments have been made with respect to downstream industries.
- Scientific studies seek to take into account the relevance of REACH with regard to health, consumer and environmental concerns as well as social and economic consequences. However, the scientific data and, to some extent, the results of the studies, must be transparent and verifiable – especially for the scientific community. Standards such as these are currently lacking.

#### 5. EU Added Value

- Implementation of REACH standards varies greatly between the individual member states. Without uniform, consistent and synchronous implementation, European legislation becomes obsolete. It is for this reason that Measure 13 relating to improvement of implementation (e.g. through recommendations, guidelines, training measures and pilot projects) should be implemented as quickly as possible.
- The establishment of the ECHA and the shift of many bodies from a national to a European level has transferred some of the chemical expertise to Europe. As such, responsibility for the implementation of REACH and the achievement of its objectives also lies with the EU.

## APPENDIX

The Commission's REFIT evaluation of REACH is based around the following questions<sup>6</sup>:

---

<sup>6</sup> Extract of page table of contents on PDF pages 2-3 of Part 1/7 of the Commission staff working document accompanying the Commission report on the operation of REACH and review of certain elements [SWD(2018) 58 final]. Link: [http://eur-lex.europa.eu/resource.html?uri=cellar:2834985c-2083-11e8-ac73-01aa75ed71a1.0001.02/DOC\\_1&format=PDF](http://eur-lex.europa.eu/resource.html?uri=cellar:2834985c-2083-11e8-ac73-01aa75ed71a1.0001.02/DOC_1&format=PDF)