EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
Ares(2017)

Opinion

Title: Evaluation / REACH

Overall opinion: POSITIVE

(A) Context

The European Union regulates chemicals for several reasons. The main goals of the regulation are to protect human health and the environment. Additional goals are to promote free circulation of substances in the internal market and to promote industrial competitiveness and innovation.

A vehicle to achieve these objectives is the REACH[1] regulation, in force since 2007. REACH works to identify the intrinsic properties of chemical substances better and earlier. It makes industry responsible for assessing and managing risks posed by chemicals. It also promotes alternatives to animal testing of substance hazards.

The current REFIT evaluation assesses how well REACH is achieving its objectives. The evaluation draws on evidence from several studies that followed a 2013 review of REACH. It also draws on consultations with stakeholders and contributions from Member States and the European Chemicals Agency.

The full EU legislative framework for risk management of chemicals contains several legal acts that interact with each other. The European Commission is undertaking a fitness check evaluation of this wider legislative framework. This fitness check should be complete in early 2018.

(B) Main considerations

The Board acknowledges significant efforts to collect evidence on how REACH is functioning and to report on implementation.

The Board gives a positive opinion, but considers that the report should be improved with respect to the following key aspects:

(1) The report does not make full use of the evidence to substantiate REACH benefits and effectiveness. It does not conclude either on how higher-than-expected costs and delays in REACH processes affect effectiveness and competitiveness. A

[1] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

systematic international comparison would improve the evidence base in these respects.

(2) The report does not identify the key findings calling for action.

(3) The report does not sufficiently address enforcement issues and their consequences for the effectiveness of REACH for the single market objective.

(4) The report does not sufficiently explain the outcomes of measures already undertaken to address coherence of REACH with other legislations.

(C) Further considerations and recommendations for improvement

(1) Effectiveness, benefits and costs

The report contains a wealth of information on the implementation of REACH and derives many of its findings on its functioning from stakeholders' views and opinions. These should be further corroborated and qualified with data extracted from the Annexes and supporting studies. The report should support the effectiveness assessment by comparing REACH to regulatory approaches in third countries.

When assessing effectiveness, the report explains why it is hard to evaluate the overall impacts of REACH on health and the environment (e.g. long latency period before benefits materialise). Nevertheless, the evaluation should elaborate further on whether shifting the burden of proof to businesses to demonstrate the safety of chemicals has been more effective and efficient than continuing with pre-REACH legislation. For instance, the report could address whether the number of actual restrictions put in place under REACH compared to the pre-REACH situation or to initial expectations is an indicator of the overall effectiveness of REACH. In this respect, the report should address aspects such as the value of the enhanced knowledge about chemicals or the deterrent effect of the authorisation process generated by REACH. The report should clarify the trade-offs between the incentives for firms to provide complete and accurate data vs regulators' ability to test and verify claims. It should present the current state of play.

In terms of costs, the report should address the reliability of cost estimates (e.g. not only based on business' views). It should further explain why costs were higher than expected. Some may be legitimate (e.g. forced data sharing was not considered in the original impact assessment) while others may require attention to avoid that the situation worsens (e.g. costs associated with delays generated by non-compliance, costs imposed on downstream businesses). The report should also better detail the issue of non-compliance of registration dossiers (e.g. by distinguishing between different types and seriousness of non-compliance). It should indicate the costs in terms of foregone benefits and address how these shortcomings are dealt with.

Finally, after weighing its pros and cons, the report should transparently discuss trade-offs of the REACH system. It could do so by comparing REACH more systematically with other approaches.

(2) Conclusions and priorities

The report should more clearly identify key findings for policymaking and clarify the urgency for action. It should explain the rationale and methodology used to prioritise. Priorities could be laid out with a view to evaluate progress in the future. This implies hypotheses that can be tested and indicators that can deliver useful benchmarks.

(3) Enforcement and market surveillance

Given the critical role of enforcement in the overall effectiveness of the system, the report should elaborate on the structures, resources and organisation in place at Member State and EU level to ensure compliance. It should further qualify the functioning of enforcement mechanisms. It should, where relevant, assess to what extent identified flaws and limitations are affecting the effectiveness of REACH in terms of ensuring the smooth functioning of the single market.

(4) Coherence

The report should better present the interplay of REACH with relevant EU priorities, strategies and legislation. It should further elaborate on the added value of different parallel initiatives to ensure coherence (e.g. roadmap, common understanding papers). Finally, it should explain the overarching approach undertaken to review and ensure the proper functioning of EU chemical legislation, in which the present evaluation takes place.

Some more technical comments have been transmitted directly to the author DG.

(D) RSB scrutiny process

The lead DG is advised to ensure that these recommendations are taken into account in the report prior to launching the interservice consultation.

Full title	REACH Evaluation
Reference number	2017/ENV/005
Date of RSB meeting	27 September 2017