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COMMISSION STAFF WORKING DOCUMENT
Accompanying the document

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE
Commission General Report on the operation of REACH and review of certain elements
Conclusions and Actions

Annex 1

{COM(2018) 116 final}

Annex 1: Procedural information

Lead DGs and internal references

The "REACH REFIT Evaluation (REACH Review 2017)" was co-led by DG Environment and DG Internal Market, Industry, Entrepreneurship and SMEs. It was included as item 2017/ENV/005 in the Agenda Planning (AP) and as Commission's REFIT Initiative item 1 in the Commission Work Programme of 2016[1].

This initiative is linked to other actions, REFIT action 52 of the Commission Work Programme of 2015 the " Fitness Check of the most relevant chemicals legislation not covered by REACH" to be delivered in 2018, the REFIT Ex-post evaluation of the EU occupational safety and health Directives (SWD (2017) 10 final) and the new initiative item 3 of the Commission Work Programme of 2016, the Circular Economy Package with the aim to address economic and environmental concerns by maximizing efficiency in the use of resources, covering the whole value chain (including sustainable consumption, production, waste management).

Organisation and timing

An Inter-service Group to steer and provide input for the REACH report 2017 was set up in September 2015 with representatives from the Directorate Generals for Environment; Internal Market, Industry, Entrepreneurship and SMEs; Budget; Competition; Employment, Social Affairs and Inclusion; Health and Food Safety; Joint Research Centre; Justice and Consumers; Research and Innovation; Taxation and Customs Union; Trade and the Secretariat General. In addition, representatives from the European Chemical Agency (ECHA) were invited to contribute to the meetings as external experts.

The group met seven times during the evaluation process (25 September 2015, 14 April and 8 September 2016, 22 February, 29 March, 20 April and 14 June 2017).

Table 1.1 ISG meeting dates and topics of discussion as well as other consultations

Date	**Topics of discussion**
25.09.2015	Context of the REACH report 2017;Presentation of the roadmap and planning of the work; Main elements of the roadmap; Ongoing and planned studies; the Consultation strategy
14.04.2016	Update on the roadmap; Ongoing studies with regards to the REACH report 2017; Presentation and discussion of the evaluation framework
08.09.2016	Update on the roadmap and consultation strategy; Update on work planning, Key milestones and timelines; Questionnaires for the public consultation and the SME panel
22.02.2017	Update on recent developments and work plan; Preliminary results of the online public consultation and SME consultation; Development of the evaluation report (SWD), Outline and general sections, Section 6: Implementation state of play, Section 7: Answer to evaluation questions

[1] Annex II of COM(2015) 610

29.03.2017	Update on recent developments ; Preliminary results of the online public consultation and SME consultation; Discussion on the draft evaluation report (SWD)
20.04.2017	Update and discussion on the draft evaluation report (SWD)
14.06.2017	Update and discussion on the draft evaluation report (SWD)
18.07.2017	Written consultation on the draft evaluation report (SWD) for submission to the RSB

External Expertise

The analysis underpinning this REFIT was undertaken via several thematic studies commissioned by DG Environment and DG Internal Market, Industry, Entrepreneurship and SMEs. In addition, the evaluation uses the regular reports from Member States Competent Authorities and ECHA submitted in accordance with Article 117 of the Regulation, which cover the implementation of all REACH processes and their enforcement. A description of those information sources can be found in Annex 3.

Relevant developments of the preparatory work for this REFIT evaluation were discussed at the Commission Expert Group CARACAL (Competent Authorities for REACH and CLP)[2].

In addition, a conference was held:

- Reporting on progress at Commission Conference "Towards phasing out animal testing" (follow-up to the European Citizen's Initiative).

Consultation of the Regulatory Scrutiny Board

The Regulatory Scrutiny Board (RSB) of the European Commission assessed a draft version of the present evaluation and issued its positive opinion on 29 September 2017. The Board made several recommendations to further improve the report. Those were addressed in the revised report as follows:

RSB recommendations	Modification of the report
(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 and suggests some improvements 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	This recommendation has been addressed by adding relevant data presented in the technical annexes as

[2] Link to CARACAL in the Register of Commission Expert Groups

processes affect effectiveness and competitiveness. A systematic international comparison would improve the evidence base in these respects.	well as providing a comparison of achievements of chemical legislation in other jurisdictions. See sections 6.1.1 and 6.1.2 of the SWD.
(2) The report does not identify the key findings calling for action.	The conclusions have been revised to identify issues requiring most urgent action. See section 7 of the SWD.
(3) The report does not sufficiently address enforcement issues and their consequences for the effectiveness of REACH for the single market objective.	Available evidence on enforcement issues has been added to the main body, specifically section 6.1.3 of the SWD.
(4) The report does not sufficiently explain the outcomes of measures already undertaken to address coherence of REACH with other legislations.	Concrete steps to address overlaps with other legislation, in particular with OSH legislation, have been added in section 6.3.2 of the SWD.
(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	The findings have been completed with relevant data collected through thematic studies and presented in the technical annexes. The comparison with regulatory approaches in third countries has been further elaborated. The contribution of several factors (e.g. shifting the burden of proof, comparison of the number of new restrictions, non-compliance of registration dossiers) to the overall effectiveness of the system has been further described, mainly in sections 6.1.1 and 6.1.2 of the SWD. The description of benefits and costs

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	has been further elaborated according to this recommendation. See section 6.2.1 of the SWD.
(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	This recommendation has been addressed by amending sections 4 and 7 of the SWD.

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.	This recommendation has been addressed by amending section 6.1.3 of the SWD.
(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.	This recommendation has been addressed by amending section 6.3.2 of the SWD.