EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
Ares(2018)

Opinion

Title: Fitness Check of the most relevant chemicals legislation (excluding REACH)

(version of 19 July 2018)*

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.

The full EU legislative framework for risk management of chemicals contains several legal acts that interact with each other. This report is a fitness check evaluation of this wider legislative framework. It complements a recent evaluation of the specific regulation (REACH)[1] that works to make industry responsible for assessing and managing risks posed by chemicals.

The current REFIT evaluation assesses how well the full framework is achieving its objectives. It also looks for potential to simplify and to reduce burdens. The evaluation draws on evidence from several studies. It also draws on consultations with stakeholders and targeted data collection.

(B) Main considerations

The Board finds the fitness check to be thorough, robust and well organised.

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

(1) The report does not sufficiently investigate stakeholder concerns.

(2) The report does not draw evidence-based conclusions on which issues to prioritise for follow-up.

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted.

1 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on Commission General Report on the operation of REACH and review of certain elements Conclusions and Actions; 5 March 2018; COM(2018) 116 final and SWD(2018) 58 final.

(3) The report does not sufficiently examine the potential for simplification and burden reduction.

(C) Further considerations and recommendations

The report should provide more granular and systematic reporting of the stakeholder consultations. It should dig more deeply into areas of stakeholder concern, try to corroborate with other evidence, and express a considered view on the magnitude of the problems. The synopsis report should provide a more detailed analysis of the consultations of all stakeholders, including points raised in position papers.

The report should more transparently explain how it has made use of the background studies, and built on their conclusions. It should also clarify the departures from the studies' conclusions and stakeholders' views.

There are some discrepancies between the final conclusions and those in the main body of the report. It is difficult to tell what is most important. In its conclusions, the report should more systematically identify and prioritise areas for policymaker attention based on relevance and magnitude of the issues at stake, the available evidence, and on responding to stakeholders.

The fitness check is a REFIT initiative, yet the report is largely silent on the scope for simplification and burden reduction. The report should elaborate on the potential to simplify or reduce burdens, for example on SMEs. It should consider whether current outcomes could be achieved at a lower cost, e.g. by streamlining reporting requirements.

The report should clarify what it uses as benchmarks or a baseline. The fitness check relies on different studies, each with their specific focus and timeline, and the report could better explain when comparisons draw on different sources. This would provide a more accurate picture on how the EU chemicals acquis has delivered on overarching objectives of high level of protection of human health and environment, while supporting the functioning of and competitiveness in the internal market.

The scope of the fitness check could be clearer. Given the interlinkage of chemicals legislation, the report should better clarify the rationale for excluding some legislation from its scope. On this basis, the report should avoid referring to legislation outside the scope when explaining the effectiveness and efficiency of the EU chemicals acquis.

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 duly taken into account in the report prior to launching the interservice consultation.

Full title	Fitness check on the most relevant chemical legislation (excluding REACH), as well as related aspects of legislation of downstream industries
Reference number	2015/GROW+/050
Date of RSB meeting	12/09/2018