095311/EU XXVIII.GP
Eingelangt am 06/10/26

EUROPEAN COMMISSION

19.06.2026

SEC(2026) 780

REGULATORY SCRUTINY BOARD OPINION

Impact assessment / European Product Act – update on the rules on standardisation

{COM(2026) 780}

{SWD(2026) 785-786-787}

EUROPEAN COMMISSION
REGULATORY SCRUTINY BOARD

Brussels,
RSB

Opinion

Title: Impact assessment / European Product Act – update on the rules on standardisation

Overall opinion: POSITIVE

(A) Policy context

The standardisation regulation organises the functioning of the European Standardisation System (ESS), the partnership between the European Commission and the European and national standardisation organisations to develop standards to support Union legislation and policy. [This initiative aims to revise this regulation to address the shortcomings identified in the 2025 evaluation. Its objectives are: 1) to improve the responsiveness of the ESS by accelerating the delivery of harmonised standards; 2) to ensure the sustainability of the ESS by balancing the requirement for free access to harmonised standards with the financial viability of the standardisation organisations while fostering participation from all stakeholders; 3) to consolidate the EU's influence in international standardisation.

(B) Key issues

The Board notes the additional information provided by lead Service(s) and commitments to make changes to the report.

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

(1) The report does not sufficiently analyse how the participation of stakeholders in the standardisation process affects the quality of the EU harmonised standards and their timely delivery.

(2) The second specific objective is not defined sufficiently clearly to address the identified problems, including the issue of balanced stakeholder participation.

(3) The report does not describe in sufficient detail some of the policy measures making the assessment of their impacts uncertain. The analysis of efficiency is not sufficiently clear to inform the comparison of options.

This opinion concerns a draft impact assessment which may differ from the final version.

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(C) What to improve

(1) The report should draw on additional evidence to analyse the impact of stakeholder participation from both SMEs as well as from civil society organisations on the quality and timely delivery of standards.

(2) The report should better explain how the second specific objective relates to the identified problems. The objective should be redefined to better reflect that it aims to ensure a balanced stakeholder representation, inclusive access to harmonised standards and a legally and financially viable standardisation system providing EU harmonised standards.

(3) The report should provide, to the extent possible, more details on the policy measures to be implemented such as requirements for stakeholder participation or approach to deadlines and the possible costs for stakeholders. The report should be clearer and comprehensive about the costs for all concerned stakeholders, including the EU budget.

(4) Building on a more comprehensive assessment of the costs to all stakeholders, the efficiency analysis should follow the standard methodology, i.e. be based on societal benefit cost ratio. In case other approaches to efficiency assessment are used in addition to societal benefit cost ratio, the report should explain the methodology.

(5) The limitations and uncertainties related to the analysis of the problems and the impacts need to be further clarified as well as the extent to which they affect the comparison of options.

Some more technical comments have been sent directly to the author Service.

(D) Conclusion

The lead Service may proceed with the initiative. The lead Service should take these recommendations into account before launching the interservice consultation.

Full title	Revision of the Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation
Reference number	PLAN/2024/2488
Submitted to RSB on	20/05/2026
Date of RSB meeting	17/06/2026

Electronically signed on 19/06/2026 12:33 (UTC+02) in accordance with Article 11 of Commission Decision (EU) 2021/2121

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