Council of the European Union
General Secretariat

PUBLIC

Brussels, 23 April 2026

Interinstitutional files:
2025/0133 (COD)
2025/0134 (COD)

WK 5778/2026 INIT

LIMITE

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Antici Group (Simplification)
Subject:	Omnibus IV (Digitalisation and common specifications): Presidency compromise - AGS on 27 April 2026

Delegations will find enclosed a note by the Presidency presenting possible compromises with the European Parliament in light of the interinstitutional negotations held so far. The proposed compromises cover the issues of (i) common specifications - last resort clause, and (ii) digitalisation - request of instructions of use and safety information.

Delegations are invited to discuss these elements at the Antici Group (Simplifcation) meeting of 27 April, with a view to providing the necessary flexiblity to the Presidency in advancing interinstitutional negotations.

Delegations will find below Presidency compromise solutions on the issues of the last resort clause and the request of use and safety information.

- Regarding the last resort clause, the Presidency proposes to focus on the Council red lines to extend the transitional measures for the ESPR and to delete the Accreditation Regulation, while in turn taking into account the Parliament's red line of including a last resort clause, in a strictly circumscribed manner, ensuring limited and proportionate use subject to effective control by the Council.

- Regarding the request of use and safety information, the Presidency proposes to focus on the Council's stance of not distinguishing between professional users and consumers, while in turn taking into account the Parliament's demands for a 24-months delay, which aligns with a product guarantee period.

Delegations are invited to provide the Presidency with the necessary flexibility to advance interinstitutional negotiations, on the understanding that concessions will be necessary on both sides to achieve a swift political agreement with the European Parliament. Delegations are encouraged, beyond sectoral considerations, to consider the wider simplification endeavour supported as a matter of priority by EU Leaders, and to also examine these proposals from a horizontal perspective.

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PRESIDENCY COMPROMISE PROPOSAL FOR COMMON SPECIFICATION AS A LAST RESORT CLAUSE

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Last Resort Clause:
Proposed wording in paragraph 1a (new)

1a. In accordance with paragraph 1(a), where no harmonised standard exists enabling compliance with the essential requirements set out in Annex II, and where no reference to such a harmonised standard is expected to be published in the Official Journal of the European Union within a reasonable period, the Commission may, as a measure of last resort, adopt implementing acts establishing common specifications to address the exceptional situation in which the lack of cooperation with international standardisation organisations prevents European standardisation organisations from developing relevant harmonised standards, and where such situation cannot be adequately mitigated by alternative measures.

Where the Commission considers that the conditions referred to in the first subparagraph are fulfilled, it shall submit an assessment to the Council, qualifying the situation, evaluating its implications for the internal market, listing the alternative measures which were taken and did not adequately mitigate the situation, and justifying the need to adopt common specifications. Together with the assessment, the Commission shall also propose that the Council authorise the adoption of common specifications by means of a Council implementing act.

The Commission may only start the process of drafting the implementing act referred to in the first subparagraph following prior authorisation by the Council by means of the Council implementing act referred to in the second subparagraph.

The implementing acts referred to in the first subparagraph shall be adopted in accordance with the examination procedure referred to in Article XX. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and Article 5(4), third subparagraph, of Regulation (EU) No 182/2011 shall apply.

Implementing acts adopted under this paragraph shall be temporary and shall cease to apply [36 months] after the entry into force of the legislative act repealing or amending Regulation (EU) No 1025/2012.

3. Before preparing the draft of the implementing acts referred to in paragraph 1 and paragraph 1a of this Article, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in, respectively, paragraph 1 and paragraph 1a of this Article are fulfilled.

4. When preparing the draft of the implementing acts referred to in paragraph 1 and paragraph 1a, the Commission shall take into account the views of the assigned Expert Group as well as of any other relevant bodies, and shall duly consult all relevant stakeholders.

5. Where a harmonised standard is adopted by a European standardisation organisation and proposed to the Commission for the purpose of publishing its reference in the Official Journal of the European Union, the Commission shall assess that standard in accordance with Regulation (EU) No 1025/2012. When reference of a harmonised standard is published in the Official Journal of the European Union, the Commission shall repeal or amend the implementing acts referred to in paragraph 1 or paragraph 1a, or parts thereof which cover the same requirements as those covered by that harmonised standard.

Draft recital

In order to account for the exceptional nature of and potential far-reaching consequences for the functioning of the internal market of a situation in which the lack of cooperation with international standardisation organisations prevents European standardisation organisations from developing relevant harmonised standards, and where such situation cannot be adequately mitigated by alternative measures, implementing powers should exceptionally be conferred on the Council to authorise the Commission to adopt common specifications under such circumstances, pursuant to Article 291(2) of the Treaty on the Functioning of the European Union.[1]

[1] This draft recital is given as an example and its wording will be refined if appropriate.

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Summary table 1

Common Specifications (last resort clause) - Accreditation Regulation - ESPR			
EP	**Council**	**compromise solution**	
Common Specifications (addressing the last resort clause)		addressing the last resort clause with safeguards (please see the text proposed)	EP (with new Council's text)
	Extension of the Transitional measures on ESPR (2024/1781)	Extension of the transitional period	COUNCIL
	Deletion of the Accreditation Regulation	Deletion of the Accreditation Regulation	COUNCIL

Summary table 2

Request of instructions of use and safety information			
EP	**Council**	**compromise solution**	
distinction between professionals and consumers	NO distinction . Use the term "USER"	one uniform term: "USER" without the distinction consumers vs professionals	COUNCIL
when the end-user is a consumer (not a professional), the period for requesting instructions is extended by EP to 24 months	The time period for request will be one single time period to be used: "6 months	The time period for requesting information in paper : 24 months (for all users)	EP
The reply to the request : Send the information within 15 Working Days	The reply to the request : To provide the information within one month	The time period for the reply to the request : one month or 15 working days	EITHER

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