

## Amendment 1 (NEW)

### Proposal for a regulation (AI Regulation)

#### Article 6 para 1

##### *Text proposed by the Commission*

Irrespective of whether an AI system is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system shall be considered high-risk where both of the following conditions are fulfilled:

(a) the AI system is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;

(b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.

##### *Amendment*

Irrespective of whether an AI system is placed on the market or put into service independently from the products referred to in points (a) and (b), that AI system shall be considered high-risk where both of the following conditions are fulfilled:

(a) the AI system is intended to be used as **a the only/main/basic** safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;

(b) the product whose **the only/main/basic** safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.

Or. en

##### *Justification*

*Only products which basic safety features are secured ONLY by the AI system should be considered high-risk. If basic safety functions required by e.g. LVD and RED are fully secured outside AI system and AI systems provides ONLY additional, non-essential safety function, then the product should not be considered high-risk.*

## Amendment 2 (NEW)

### Proposal for a regulation (AI Regulation)

#### Article 41 para 1

##### *Text proposed by the Commission*

Where harmonised standards referred to in Article 40 do not exist or where the Commission considers that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns, the Commission may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

##### *Amendment*

Where harmonised standards referred to in Article 40 do not exist **and none of the ESOs are willing to develop them or the Commission has justified THE reasons for not publishing in the Official Journal of the European Union harmonised standards, when developed by the Standardisation Organisations, vis-à-vis the Committee of Standards referred to in Article 22 of Regulation (EU) No 1025/2012 and that Committee has endorsed the justification applying Article 5 of Regulation (EU) No 182/2011** or where the Commission **presents objective evidence** ~~considers~~ that the relevant harmonised standards are insufficient or that there is a need to address specific safety or fundamental right concerns **and none of the ESOs are willing to take up the task**, the Commission may, by means of implementing acts, adopt common specifications in respect of the requirements set out in Chapter 2 of this Title. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 74(2).

Or. en

##### *Justification*

*All actors involved in the standardisation should have very clear overview in what situations the “implementing acts path” can be initiated. It cannot be arbitrary or left to subjective assessment of one party in the system.*