

Co-Rapporteurs Package proposal

1. Article 113 (3rd para)(d, e) (Entry into application of certain provisions):

(31) Article 113 is amended as follows:

(a) in the third paragraph, point (d) is added:

‘(d) Chapter III, Sections 1, 2, and 3, *with the exception of Article 6(5)*, shall apply *following the adoption of a decision of the Commission confirming that adequate measures in support of compliance with Chapter III are available, from the following dates:*

(i) 6 months after the adoption of that decision as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

(ii) 12 months after the adoption of the decision as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.

In the absence of the adoption of the decision within the meaning of subparagraph 1, or where the dates below are earlier than those that follow the adoption of that decision, Chapter III, Sections 1, 2, and 3, shall apply: (Rapp 24, RE 396, Left 397, RE 398, EPP 399, RE 400, Left 402, EPP 403, EPP 404, RE 406, EPP 407, RE 408, Greens 409, S&D 410, ECR 411, RE 412, EPP 413, EPP 417, RE 418, EPP 423, EPP 420, RE 427, RE 428, EPP 429, EPP 431)

(i) on 2 December 2027 as regards AI systems classified as high-risk pursuant to Article 6(2) and Annex III, and

(ii) on 2 August 2028 as regards AI systems classified as high-risk pursuant to Article 6(1) and Annex I.’;

(b) in the third paragraph, point (e) is added:

‘ 3. Articles 102 to 110 shall apply from [the date of entry into application of this Regulation].’;

2. Article 111 (2, 4) (AI systems already placed on the market and watermarking) (Keep grandfathering clause but shorten watermarking grace period - 3 months):

Article 111 is amended as follows:

(a) paragraph 2 is replaced by the following:

‘2. Without prejudice to the application of Article 5 as referred to in Article 113(3), third paragraph, point (a), this Regulation shall apply to operators of high-risk AI systems, other than the systems referred to in paragraph 1 of this Article, that have been placed on the market or put into service before the date of application of Chapter III and corresponding obligations referred to in Article 113, only if, as from that date, those systems are subject to significant changes in their designs. In any case, the providers and deployers of high-risk AI systems intended to be used by public authorities shall take the necessary steps to comply with the requirements and obligations laid down in this Regulation by 2 August 2030.’;

(b) the following paragraph 4 is added:

‘4. Providers of AI systems, including general-purpose AI systems, generating synthetic audio, image, video or text content, that have been placed on the market before 2 August 2026 shall take the necessary steps in order to comply with Article 50(2) by 2 ~~November~~ ~~February~~ 2027.’;

3. Article 4a (processing of personal data):

(5) the following Article 4a is inserted in Chapter I:

Article 4a

Processing of special categories of personal data for bias detection and mitigation

1. To the extent *strictly* necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur: **(AM 10)**

(a) the bias detection and correction cannot be effectively fulfilled by processing other data, including synthetic or anonymised data;

(b) the special categories of personal data are subject to technical limitations on the re-use of the personal data, and state-of-the-art security and privacy-preserving measures, including pseudonymisation;

(c) the special categories of personal data are subject to measures to ensure that the personal data processed are secured, protected, subject to suitable safeguards, including strict controls and documentation of the access, to avoid misuse and ensure that only authorised persons have access to those personal data with appropriate confidentiality obligations;

(d) the special categories of personal data are not transmitted, transferred or otherwise accessed by other parties;

(e) the special categories of personal data are deleted once the bias has been corrected or the personal data has reached the end of its retention period, whichever comes first;

(f) the records of processing activities pursuant to Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680 include the reasons why the processing of special categories of personal data was necessary to detect and correct biases, and why that objective could not be achieved by processing other data.

2. Paragraph 1 may apply *exceptionally* to providers and deployers of other AI systems and models and deployers of high-risk AI systems *to the extent the processing is ~~where~~ necessary* and proportionate *if the processing occurs* for the purposes set out therein and provided that *all* the conditions *and safeguards set out under the safeguards* set out in this paragraph *are met. This paragraph does not create any obligation to conduct such bias detection and correction with special categories of personal data (AM 11, 168, 169)*

4. Article 6 (safety component clarification + recital)

Article 6(1) is amended as follows:

1. Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be 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 *and whose functioning is necessary to ensure that the product or AI system complies with applicable Union safety requirements*, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I;

(b), the product whose safety component pursuant to point (a) 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 the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.

Recital XX: *“For the purposes of this Regulation, the fact that an AI system is integrated into, or operates within, a product subject to Union harmonisation legislation on product safety should not, in itself, imply that the AI system performs a safety function. An AI system should*

be regarded as performing a safety function only where its functioning is necessary to ensure that the product or the AI system complies with applicable Union safety requirements. By contrast, functionalities intended solely for user assistance, performance optimisation, service efficiency, automation, convenience, or quality control of non-safety-related aspects should not be regarded as safety functions under this Regulation, where their failure would not directly create risks to health or safety.”

Table Briefings

5. SMCs – Commission text for all inclusions of SMCs, except Article 99 references would be amended as follows:

6. In the case of SMEs, including start-ups, each fine referred to in this Article shall be up to the percentages or amount referred to in paragraphs 3, 4 and 5, whichever thereof is lower.

6a. In the case of SMCs, each fine referred to in this Article shall be up to the percentages or amount referred to in paragraphs 4 and 5, whichever thereof is lower.

6. Nudifiers (Article 5)

(5a) in Article 5, paragraph 1, subparagraph 1 the following point is added:

(ha) the placing on the market, the putting into service or the use of an AI system that alters, manipulates or artificially generates realistic images or videos so as to depict sexually explicit activities or the intimate parts of an identifiable natural person, without that person's consent.

This prohibition does not apply to providers or deployers of AI systems who have put effective safety measures to prevent the generation of such depictions and to avoid misuse continuously, after the system has been placed, on the market or put into service despite the intention of the provider or deployer

This prohibition shall not prevent AI providers from developing any capabilities referred to in the first subparagraph.

7. Section A/Section B in Annex I

(31a) In Annex I, Section A is deleted.

In Section B, the following points are added:

1. *Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);*

2. *Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);*

3. ***Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);***
4. ***Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);***
5. ***Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);***
6. ***Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);***
7. ***Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);***
8. ***Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);***
9. ***Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);***
10. ***Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);***
11. ***Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);***
12. ***Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).***
13. ***Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council Directive 73/361/EEC***

Draft Recital:

The parallel application of sectoral Union harmonisation legislation listed in Section A of Annex I to Regulation (EU) 2024/1689 of the European Parliament and of the Council and the requirements laid down in that Regulation for high-risk artificial intelligence systems may lead to overlaps of requirements and unnecessary administrative burden for economic operators. Such overlaps could create legal uncertainty, increase compliance costs and potentially lead to competitive disadvantages, without providing additional benefits for the protection of health, safety or fundamental rights. In order to ensure a more coherent and proportionate regulatory framework and to simplify the application of requirements for artificial intelligence systems embedded in products regulated under Union harmonisation legislation, the references to the Union harmonisation legislation currently listed in Section A of Annex I to Regulation (EU) 2024/1689 should therefore be moved to Section B of that Annex. This approach clarifies that artificial intelligence systems integrated into products covered by those sectoral acts are subject to the requirements of this Regulation where relevant, while allowing the conformity assessment procedures and product safety requirements under the respective sectoral legislation to remain the primary framework. Any remaining gaps relating to artificial intelligence systems integrated into such products should be addressed within the relevant sectoral legislation.

8. Article 2 (research, intra-group, business-to-business)

Article 2 of the AI Act remains unchanged

9. FRIA / DPIA - (Articles 27 and 96)

(9c) in Article 27, paragraph 4 is replaced by the following:

4. If any of the obligations laid down in this Article is already met through the data protection impact assessment conducted pursuant to Article 35 of Regulation (EU) 2016/679 or Article 27 of Directive (EU) 2016/680, **the deployer shall, when conducting** the fundamental rights impact assessment referred to in paragraph 1 of this Article **include cross references to the relevant sections of** ~~shall complement~~ that data protection impact assessment **or include relevant parts of that data protection impact assessment into the fundamental rights impact assessment.**

28b) in Article 96, paragraph 1, subparagraph 1, the following point is inserted:

(g) the application of the requirements and obligations referred to in Article 27, including the possibility to reference or include relevant sections or parts of the data protection impact assessment into the fundamental rights impact assessment pursuant to Article 27(4) of this Regulation, using, where relevant, standardised templates

10. Profiling Art 6(3)

Article 6(3) of the AI Act remains unchanged

11. Registration Art 6(4) (Council wording)

~~(6) in Article 6(4), paragraph 4 is replaced by the following:~~

~~‘4. A provider who considers that an AI system referred to in Annex III is not high risk shall document its assessment before that system is placed on the market or put into service. Upon request of national competent authorities, the provider shall provide the documentation of the assessment.’;~~

~~(14) in Article 49, paragraph 2 is deleted;~~

~~(32) in Annex VIII, section B, points 7 and 9 are deleted;~~

Recital 9:

~~(9) To streamline compliance and reduce the associated costs, providers of AI systems should not be required to register the registration of AI systems referred to in Article 6(3) of Regulation (EU) 2024/1689 in the EU database pursuant to Article 49(2) of that Regulation. Given that **should be simplified by streamlining the required content in Section B of Annex VIII to that Regulation. While it remains crucial for effective market surveillance and public accountability that such AI systems are registered in the EU database, the registration requirements should be simplified and made more proportionate. This simplification will strike a better balance without undermining the protection laid down by Regulation 2024/1689.** Such systems are not considered high-risk under certain conditions where they do not pose significant risk of harm to the health, safety or fundamental rights of persons, imposing registration requirements would constitute a disproportionate compliance burden. Nevertheless **Furthermore,** a provider who considers that an AI system falls under **applying** Article 6(3) remains obligated to document its assessment before that system is placed on the market or put into service. This assessment may be requested by national competent authorities.~~