

EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND NORTHERN IRELAND PROTOCOL

REGULATION (EU) 2026/1744 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2024/1689, (EU) 2018/1139 and (EU) 2023/1230 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI)

Submitted by the Department for Business, Innovation, Science and Trade on 3
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SUBJECT MATTER

1. The European Commission states that this Regulation (the digital omnibus on AI or Omnibus VII, henceforth referred to as 'the Omnibus') aims to streamline and simplify certain rules regarding artificial intelligence. It introduces amendments to three regulations: Regulations (EU) 2024/1690 ('the AI Act'), 2023/1230 (the 'Machinery Regulation'), and 2018/1139 on civil aviation.
2. The Machinery Regulation is included in Annex 2 of the Windsor Framework. Amendments to this Regulation therefore fall in scope of Article 13(3) of the Windsor Framework and apply in Northern Ireland. Amendments are also subject to the democratic scrutiny process set out in Article 13(3a). The other two Regulations are not included in Annex 2 and do not apply under the Windsor Framework. The EU has informed the UK of its view that the AI Act should apply in Northern Ireland, but the UK has not yet taken a decision. This Explanatory Memorandum is therefore only concerned with the amendments to (and related to) the Machinery Regulation.
3. For the machinery sector in Northern Ireland, the Omnibus principally seeks to improve the interaction between the AI Act and the Machinery Regulation. The changes are intended to reduce regulatory overlap, simplify compliance requirements and ensure that only genuinely safety-critical AI functions are subject to the AI Act's more stringent obligations. Existing conformity assessment routes will be preserved under the amendments, responding to feedback from industry, alongside the calls to clarify that household appliances and general automation or performance features are out of scope of the requirements.

SCRUTINY HISTORY

4. The Department for Science, Innovation and Technology published an Explanatory Memorandum on the draft proposal for the Digital Omnibus in January 2026. The proposal did not include amendments to the Machinery Regulation.

MINISTERIAL RESPONSIBILITY

5. The Secretary of State for the Department for Business and Trade has responsibility for *The Supply of Machinery (Safety) Regulations 2008* as they apply in Great Britain.
6. The Government recently laid *The Supply of Machinery (Safety) (Amendment etc.) and the EU Machinery Regulation (Enforcement etc. in Northern Ireland) Regulations 2026* which revoked *The Supply of Machinery (Safety) Regulations 2008* as they apply in NI and replaced them with an enforcement framework for the Machinery Regulation, which also applies in NI under the Windsor Framework.

INTEREST OF THE DEVOLVED GOVERNMENTS

7. Product safety is a reserved matter for Scotland and Wales and consumer safety in relation to goods is reserved in respect of NI. There is also a reservation under Schedule 3 of the Northern Ireland Act 1998 that reserves the subject matter of all technical standards and requirements in relation to manufactured products that had effect before EU Exit relating to EU obligations. The UK Government will continue to discuss these matters with the Devolved Governments regularly.
8. Under the UK Government's commitments to provide unfettered access to the rest of the UK market for qualifying Northern Ireland goods, machinery that meets the qualifying goods criteria and the current technical requirements to be placed on the market in Northern Ireland will also be able to be placed on the GB market. The Government recently laid *The Supply of Machinery (Safety) (Amendment etc.) and the EU Machinery Regulation (Enforcement etc. in Northern Ireland) Regulations 2026* which provides for the continued recognition of EU machinery safety requirements in Great Britain, including the CE marking. This means that the same product can be placed on the market across the UK.

LEGAL AND PROCEDURAL ISSUES

9. The Omnibus amendments to the Machinery Regulation apply under Article 13(3) of the Windsor Framework. This is the case regardless of whether the AI Act applies. The Omnibus amendments provide a power for the Commission to add essential health and safety requirements to the Machinery Regulation covering matters set out in the AI Act, which must be done by 2 August 2028.
10. There are no legal and procedural issues in Great Britain as the AI Omnibus does not apply to GB.

POLICY IMPLICATIONS

11. For machinery specifically, the AI Omnibus seeks to avoid overlaps between the Machinery Regulation and AI Act. It does this by moving to a sectoral approach for the regulation of AI in machinery, with the aim of simplifying the framework for AI-enabled machinery.
12. AI-related safety requirements from the AI Act (listed in paragraph 13 below) are now to be reflected in the Machinery Regulation. Previously, the Machinery Regulation was listed in Section A of Annex I of the AI Act, meaning that the AI Act would have directly applied high-risk requirements to AI-embedded machinery that would be considered high-risk under Article 6(1) of the AI Act. The AI Omnibus now moves the Machinery Regulation to Section B, meaning that the high-risk requirements will instead be reflected in the Machinery Regulation itself.
13. The AI Omnibus also directly amends the Machinery Regulation, including by adding a requirement for the EU Commission to adopt delegated acts. Changes will be enacted through the adoption of these delegated acts which will amend Annex III (essential health and safety requirements) of the Machinery Regulation in respect of machinery products that are classified as high-risk under Article 6(1) of the AIA. These amendments to Annex III will reflect the requirements in Chapter III, Section 2, and Articles 17, 19, 72 and 73 of the AI Act. These articles deal with the high-risk requirements, e.g. data governance, technical documentation, potential for human oversight, risk and quality management systems. The delegated acts made under the Machinery Regulation must apply from 2 August 2028 and will apply directly in Northern Ireland.
14. Only AI systems that perform safety-critical functions or could create safety risks if they fail would be treated as high-risk, rather than capturing all AI features within machinery. Specifically, Article 6(1) of the AI Act defines machinery as high-risk if two conditions are met:

- a. AI is intended to be used as a safety component, i.e. its purpose is to prevent or mitigate risks to health and safety of persons or property or the failure/malfunctioning of AI could endanger health and safety; and
 - b. The machinery product is already required to undergo a third-party conformity assessment under the Machinery Regulation, although this also includes cases where the manufacturer can opt out from this if it has followed the harmonised standards.
15. AI systems that are related solely to functions such as performance optimisation, service efficiency, automation, convenience or non-safety aspects for quality control are not safety functions and such products are therefore not high-risk.
16. The Omnibus sets out that the Commission must ensure that the relevant requirements of the AI Act are reflected in the Machinery Regulation. This may allow the Commission to consider the regulatory specificities of the machinery sector and existing governance, conformity and enforcement mechanisms. This would allow for further streamlining and sector-specific adaptation.
17. Existing conformity assessment routes under the Machinery Regulation would be preserved, meaning that the presence of AI should not automatically require third-party (notified body) involvement where it is not otherwise needed. In some instances, the Machinery Regulation allows manufacturers to opt out of third-party assessment provided they follow the harmonised standards. Only products contained within Annex I of the Regulation require third-party testing – Part A sets out the list of products where this is always mandatory, whereas products in Part B can be self-assessed where a relevant harmonised standard exists covering essential health and safety requirements and the machinery or related product has been designed and constructed in accordance with that harmonised standard. Until machinery-specific AI standards are developed, manufacturers can rely on AI Act harmonised standards to give rise to a presumption of conformity with the essential health and safety requirements regarding high-risk AI systems, avoiding delays or legal uncertainty during the transition period. For the avoidance of doubt, products which are not listed in Annex I of the Machinery Regulation are out of scope of the high-risk definition in Art 6(1) of the AI Act and are therefore not required to undergo third-party testing.
18. The UK Government has also announced an intention to update The Supply of Machinery (Safety) Regulations 2008 as they apply in GB, in line with the Machinery Regulation (Regulation (EU) 2023/1230 only) and therefore Northern Ireland, following overwhelming stakeholder support for this

approach. As part of this work, the Government will take the steps necessary to protect the UK Internal Market, including considering AI requirements to ensure any legislative updates are suitable for machinery being placed on the GB market, as well as compatible with requirements across the whole product safety framework.

CONSULTATION

19. Whilst the UK Government has not consulted industry on the AI Omnibus directly, it has consulted stakeholders on both machinery and AI policy. This included a Call for Evidence on the future of the UK's machinery legislation and roundtable events in 2025, across the UK and internationally. Two roundtable events were held in Belfast as part of this exercise, to seek views from NI based businesses on machinery regulation.
20. Conversations, through these roundtables, as well as targeted engagement with stakeholders interested in AI, included discussions regarding machinery and AI. Evidence from this engagement suggests that there is likely to be limited machinery that meets the required conditions as set out in paragraph 14.
21. Testing requirements set out in machinery and AI legislation are therefore seen as futureproofing for an evolving and developing market, with the aim of keeping pace with technological advancements, as and when they become more widely used on the market.
22. The UK Government also recently carried out a consultation on wider reform of the UK's product safety framework. This included a section seeking views and evidence on the impact of AI-enabled products on product safety, to help ensure our regulatory frameworks can remain fit for purpose. The consultation closed on 23 June and we are analysing responses.
23. Based on engagement with stakeholders, the Government's current view is that relatively few machinery products are currently likely to meet the high-risk threshold. Over time, AI-enabled machinery in scope of the high-risk definition will likely become more common, but, as the machinery sector is largely EU-facing, we expect most businesses to come into compliance with the EU requirements.

FINANCIAL IMPLICATIONS

24. Businesses that supply machinery in Northern Ireland, as with the rest of the UK, are predominantly EU-facing and will most likely come into compliance

with EU requirements on AI as part of their standard business practices, to alleviate any challenges with trade flow.

25. The changes introduced by the Omnibus are also designed to reduce overlap between regimes, so businesses can carry out one set of testing, documentation, and conformity assessment, rather than duplicating effort under both AI and machinery frameworks. Where the Machinery Regulation already addresses a risk (e.g. safety or control functions), relevant equivalent AI Act requirements may not be duplicated in Annex III, ensuring the same protections without regulatory, and therefore cost or admin, layering.

NAME AND SIGNATURE

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