EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK-EU WITHDRAWAL AGREEMENT AND THE WINDSOR FRAMEWORK

Decision of the Joint Committee established by the Agreement on the Withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community to add the following EU legislation to the Windsor Framework.

Unnumbered EM

Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance)

Submitted by the Department for Business, Innovation, Science and Trade on 4 November 2026

SUMMARY

1. The following explanatory memorandum (EM) relates to the UK's intention at the UK-EU Withdrawal Agreement Joint Committee on 10 November 2026 to add a modified version of Regulation (EU) 2024/1689 ('the AI Act'), which lays down harmonised rules on artificial intelligence, to the Windsor Framework to the extent it extends to the placing on the market of physical products.

SUBJECT MATTER

Background

2. On 13 June 2024, the EU adopted a regulation to regulate artificial intelligence (full text here). Some aspects of the AI Act directly amended EU regulation falling under the Windsor Framework. These amendments were set out in the explanatory memorandum provided on 17 July 2024 and already apply in Northern Ireland under Article 13(3) of the Windsor Framework. As set out in the explanatory memorandum provided here, these amendments do not have substantive impact as they do not introduce new requirements – they set out that when further amendments are made to specified sectoral regulations already applicable under the Windsor Framework, the AI Act requirements shall be taken into account.

3. On 14 April 2025, the EU published its council position that it considered that other provisions of the AI Act should apply under Article 13(4) of the Windsor Framework, the process for adding new legislation that does not amend or replace existing regulation falling under the Framework. These provisions can only be added to the Windsor Framework subject to the agreement of the UK at the Withdrawal Agreement Joint Committee.

4. The AI Act introduces a horizontal regulatory framework for the development, placing on the market, putting into service and use of artificial intelligence systems. It is intended to promote the use of human centric and trustworthy AI while protecting against its harmful effects. Its scope reflects the wide-reaching uses of AI in sectors across the economy including medical devices, recruitment, surveillance and children's toys; and the varied functions of AI systems within those sectors including systems related to safety, user assistance, performance optimisation, service efficiency, automation, convenience, or quality control operations. Reflecting the differing levels of risk posed by different AI systems, the AI Act applies a risk-based hierarchy to in-scope products.

Limited application in Northern Ireland

5. In discussion at the Withdrawal Agreement Joint Committee on 29 April 2025, the UK requested an exchange of views with the European Commission to discuss the scope of the AI Act that should apply in Northern Ireland, with particular regard to understanding the interaction of the Act and the functioning of the Windsor Framework. Full application of the Act in Northern Ireland would have gone beyond the scope of the Windsor Framework and would not have been acceptable to the UK.

6. This exchange of views between the UK and the EU resulted in arrangements for a limited and specific application of the AI Act, recognising Northern Ireland's unique position. This is reflected in the detailed guidance that will be published by the Government.

7. As a result, the AI Act will apply only to the extent necessary to protect the EU's single market from the risk of non-compliant physical products entering the EU's market via the land border on the island of Ireland. The partial addition of the Regulation to the Windsor Framework means the AI Act will apply in Northern Ireland only insofar as it extends to provisions that contain technical specifications for the placing on the market of products or relate to the provision of services that may affect the free movement of products. The AI Act as applied in Northern Ireland would, therefore, be highly modified as follows.

8. **Standalone software (e.g. apps) and AI systems accessed online will be out of scope.** That means that where an AI system is not pre-installed onto a device or otherwise closely integrated with a product, meaning it is intentionally supplied, designed or supported for use with that product, the software and AI system would not be regulated under the AI Act in Northern Ireland. For example, where a phone is sold without an AI system pre-installed and a user accesses an online AI system with the phone, the AI system is not in scope of the Windsor Framework. Businesses and individuals can download or otherwise obtain online access to Large Language Models or specialist software (e.g. finance, credit scoring, HR) without any new restrictions, as the AI Act will not apply in Northern Ireland in these instances. The AI Act requirements, pursuant to the system's level of risk, would only apply if either the system is pre-installed or embedded in the product; or it is

downloaded separately but the physical product is specifically designed to be used by that AI system in order to fully function.

9. **Use or deployment of AI systems is almost entirely out of scope.** That means that users of AI systems in Northern Ireland are not subject to most provisions relating to the use of AI systems in the AIA. For instance, under the AI Act as applied in the EU, deployers of high-risk AI-systems would be required to take measures to ensure they are using the relevant systems in a manner compliant with its accompanying instructions and that there is sufficient human oversight and keep automatically generated logs of AI system use. Such provisions are out of scope in Northern Ireland. The only exception is deployment of in-scope high-risk AI systems; where the deployer has reason to believe a **risk** could occur and cause harm to health, safety or fundamental rights, they are obligated to report this.

10. In practice, these carve outs for Northern Ireland mean that, for example, where an individual or business accesses online or non-embedded standalone AI tools, they would not be subject to any new requirements, nor is the use of AI restricted. The application will be largely focused on safety of physical products, supplementing existing sectoral regulations that already apply under the Windsor Framework in areas such as toys, radio equipment and medical devices.

11. These two principles apply across the AI Act, which means that some provisions apply partially or in modified form. For example, the provisions regarding AI Act requirements apply but only in instances where the AI is closely integrated into the physical product.

12. Other provisions are **wholly** out of scope. This includes the following articles:
    a. 5(1)(h) and 5(2)-(7) - restrictions on the use of 'real-time' remote biometric identification systems in publicly accessible spaces for the purposes of law enforcement;
    b. 26 (except paragraph 5) - obligations on deployers of high-risk AI systems;
    c. 27 - the requirements for deployers of high-risk AI systems to complete a fundamental rights impact assessment;
    d. 50(3) - Obligations on deployers of emotion recognition systems or biometric categorisation systems;
    e. 50(4) - Obligations on deployers of AI systems that generate or manipulate image, audio or video content constituting a deep fake;
    f. 51-55 - Requirements relating to General Purpose AI models;
    g. 57-61 - The mandatory introduction of regulatory sandboxes;
    h. 76 - Obligation on surveillance authorities when supervising the testing of AI systems in real world conditions;
    i. 86 - Rights of those affected by an AI system to an explanation by the deployer of individual decision-making;
    j. 95 - Codes of conduct for the voluntary application of requirements;
    k. 102 and 108 - an amendment to the civil aviation security regulations (Regulation (EU) 300/2008, Regulation (EU) 2018/1139) to take

account of the requirements for high-risk systems in the AI Act, as these regulations do not apply under the Windsor Framework;

l. 110 - an amendment to the actions for the protection of the collective interests of consumers regulations (Directive (EU) 2020/1828) to add the AI Act to Annex I of the Regulation, as this Regulation does not apply under the Windsor Framework;
m. Annex 1 point 13 and 20 - as in point (k), the AI Act is not in scope of Regulation (EU) 300/2008 or Regulation (EU) 2018/1139; and
n. Annex 2 - A list of criminal offences referred to in Article 5(1)(h) which is out of scope;
o. Annex 9 - Information to be submitted upon the registration of high-risk AI systems listed in Annex III in relation to testing in real world conditions in accordance with Article 60 which is out of scope; and
p. Annex 10 - Union legislative acts on large-scale IT systems in the area of Freedom, Security and Justice.

13. Where AI systems are used for military, defence or national security, they are also exempt from the requirements of the AI Act, including where they are embedded in physical products.

14. We will be publishing guidance on GOV.UK, which we have developed with the Commission, explaining these carve-outs further.

15. The impact of the modified AI Act's application in Northern Ireland is expected to be limited given the reduced scope, the current relatively low prevalence of the most highly regulated products in Northern Ireland and the UK more widely, and the EU-facing nature of industry, with many businesses already preparing for compliance in order to sell into the EU market. Additionally, stakeholder engagement suggests that many of the requirements associated with even high-risk physical products comprise assurance activities that many businesses are likely to undertake in the course of normal responsible behaviour, such as ensuring appropriate data governance and risk management. More detail on the impacts in Northern Ireland is below at paragraphs 64-68.

16. The AI Act came into force on 1 August 2024 and has a phased implementation timeline. Some provisions have already been implemented in the EU (for example, in relation to prohibited systems and limited risk products) and will apply in Northern Ireland immediately from the decision at the Joint Committee. We have not found any evidence of prohibited risk products on the NI or wider UK market and limited-risk requirements are relatively light-touch. We therefore do not expect this to be problematic for businesses. Further guidance on GOV.UK.

17. The provisions in relation to high-risk products will apply from December 2027 or August 2028, depending on the type of product.

SCRUTINY HISTORY

18. The proposal for the AI Act was published in April 2021 and amended in June 2023, introducing new requirements for specific AI systems such as generative AI and high-risk AI systems as well as expanding the list of prohibited practices.

19. Following the final adoption of the AI Act (text here) on 12 July 2024, the then Department of Science, Innovation and Technology published an Explanatory Memorandum on Regulation (EU) 2024/1689.

20. The EU made amendments to the AI Act via a Digital Omnibus on Artificial Intelligence, which was adopted in July 2026. These amendments predominantly sought to reduce burdens on businesses and will also apply following our decision at the Joint Committee. The UK published an EM on the Omnibus proposal in January 2026 (text here), which was considered in the Northern Ireland Scrutiny Committee, with whom relevant ministers exchanged correspondence on the matter.

21. The UK also published an EM (text here) on the final Omnibus Regulation in August 2026 focused on the Regulation (EU) 2023/1230, the 'Machinery Regulation', which is included in Annex 2 of the Windsor Framework under Article 13(3). It was considered by the Democratic Scrutiny Committee.

MINISTERIAL RESPONSIBILITY

22. The Minister for Artificial Intelligence has responsibility for AI policy.

23. The Minister for Intergovernmental Relations and European Relations has responsibility for EU policy and relations, including the Windsor Framework.

24. The Secretary of State for Northern Ireland has responsibility for the constitutional and political relationship between Northern Ireland and the rest of the United Kingdom, including oversight of the Windsor Framework's operation.

25. The Secretary of State for Business, Innovation, Science and Trade has responsibility for product safety.

26. The Secretary of State for Health and Social Care has responsibility for medical device regulations across the UK.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

27. Subject to the UK's decision at the Withdrawal Agreement Joint Committee on 10 November, the notified provisions of the AI Act will apply in part in Northern Ireland.

28. AI policy engages both reserved and devolved competences. The regulation of AI systems as part of product safety is generally a reserved matter.

29. Engagement across Devolved Government and the UK Government will continue so that the benefits of AI can be realised across the UK, and the risks associated with AI and its adoption can be mitigated.

LEGAL AND PROCEDURAL ISSUES

30. i. EU Legal Basis

Article 114 of the Treaty on the Functioning of the European Union (TFEU), which provides for the adoption of measures to ensure the establishment and functioning of the internal market; and Article 16 of the TFEU for the specific rules on the protection of individuals with regard to the processing of personal data.

ii. Voting Procedure

Qualified Majority Voting.

iii. Timetable for adoption and implementation

The Regulation for the AI Act entered into force on 1 August 2024 and will be fully applicable in the EU from 2 August 2028.

31. As set out above, some provisions already apply in Northern Ireland under Article 13(3) of the Windsor Framework. Articles 103-107 and 109 of the AI Act amend existing sectoral regulations listed in Annex II of the Windsor Framework, requiring that the European Commission take into account the AI Act's requirements on high-risk systems, when the EU adopts certain delegated and/or implementing acts with respect to AI systems which are safety components. Sectors covered include:
    a. Agricultural and forestry vehicles;
    b. Two- or three-wheel vehicles and quadricycles;
    c. Marine equipment;
    d. Rail interoperability;
    e. Motor vehicles, trailers, and their components (including general safety and protection of vehicle occupants and vulnerable road users).

32. The provisions of the AI Act that have been notified under the scope of Article 13(4) of the Windsor Framework relate to conditions and technical specifications for the placing on the market of products or relate to the provision of services that may affect the free movement of products. As listed in paragraph 11, certain articles are out of scope. Application of the notified AI Act provisions in Northern Ireland is subject to the express agreement of the UK Government at the UK-EU Joint Committee on 10 November 2026.

POLICY AND LEGAL IMPLICATIONS

Scope

33. As noted above, requirements in Northern Ireland are limited to those provisions that contain technical specifications for the placing on the market of

physical products, or relate to the provision of services that may affect the free movement of physical products.

34. Compliance requirements fall primarily on manufacturers, with distributors and importers facing lighter-touch obligations.

35. In scope products are categorised into one of three risk categories, (i) prohibited; (ii) high-risk; and (iii) limited risk.

Prohibited systems

36. A limited and discrete list of AI systems are prohibited where they cut across fundamental rights and values and, specifically in Northern Ireland, where they are closely integrated in a physical product. AI systems in this category cannot be placed on the market, with some limited exceptions, for example where they are required for national security.

37. Where AI systems perform the following functions and are closely integrated with a physical product, the AI Act would prohibit their being placed on the market in Northern Ireland:
    a. Deploy subliminal techniques or manipulation with the objective or effect of distorting behaviour;
    b. Exploit vulnerabilities of a specific group or person arising from certain personal or socioeconomic characteristics with the objective/effect of distorting behaviour;
    c. Generate or manipulate realistic materials of an identifiable person's intimate parts or engagement in sexually explicit activities without that person's consent;
    d. Generate or manipulate materials or performances that constitute child abuse;
    e. Classify or evaluate natural persons based on social behaviour ('social scoring');
    f. Predict the risk of a person committing a criminal offence based on profiling;
    g. Create facial recognition databases based on untargeted scraping of images;
    h. Infer emotions in the areas of workplace or educational institutions;
    i. Categorise natural persons based on their biometric data to deduce race, political opinions, trade union membership, religious or philosophical beliefs, sex life, or sexual orientation.

38. Examples of how these provisions could be expressed in practice are as follows:
    a. In scope - An AI-powered toy designed to interact with children by encouraging them to complete risky challenges for rewards and pushing them towards dangerous behaviours such as climbing out of the window, exploiting children's natural curiosity. This would be in scope of the Windsor Framework as it is embedded in a product.
    b. Out of scope - An AI chatbot that impersonates a friend or person causing harm, such as pushing them to extremist views or to extract

financial information; software that categorises persons based on social media content. This would be out of scope of the Windsor Framework as it is not embedded in a product.

39. During stakeholder engagement, we could not find any examples of products that would be prohibited under the AI Act in Northern Ireland. This may be in part because there is some regulatory overlap between the instances in which AI systems would be prohibited under the AI Act and a range of existing UK laws which address similar aims to protect human dignity, freedom, equality, democracy and the rule of law and fundamental rights, for example the Crime and Policing Act (non-consensual nudification), Equality Act 2010 and consumer protection laws (e.g. manipulation, exploitation). **We therefore expect the impact of the provisions on prohibited AI systems to be largely theoretical**, although this could change in the future.

High-risk systems

40. AI systems are deemed high-risk and subject to the attendant requirements where they pose a high-risk of harm. The risk level accounts for the severity of the possible harm and its probability of occurrence.

41. High-risk products fall into two categories.

42. The first category of high-risk AI systems applies to products or safety components of products listed in Annex I of the AI Act. This includes those products listed below in section A of Annex I:
    a. Toys (Directive 2009/48/EC)
    b. Recreational craft and personal watercraft (Directive 2013/53/EU)
    c. Lifts and safety components for lifts (Directive 2014/33/EU)
    d. Equipment and protective systems intended for use in potentially explosive atmospheres (Directive 2014/34/EU)
    e. Radio equipment (Directive 2014/53/EU)
    f. Pressure equipment (Directive 2014/68/EU)
    g. Cableway installations (Regulation (EU) 2016/424)
    h. Personal protective equipment (Regulation (EU) 2016/425)
    i. Appliances burning gaseous fuels (Regulation (EU) 2016/426)
    j. Medical devices (Regulation (EU) 2017/745)
    k. In vitro diagnostic medical devices (Regulation (EU) 2017/746)

43. To fall into this category, an AI system would need to:
    a. be a component of a product, or be a product itself that is covered by a sectoral regulation listed in Annex I of the AI Act as in paragraph 41 and be within the scope of third-party conformity assessment under that sectoral regulation; and
    b. be intended for use as a safety component of that product where its intended purpose is to prevent or mitigate risks to health and safety of persons or property or **whose failure or malfunction would endanger health and safety**

    As this category of high-risk goods relates to regulations which are already in scope of the Windsor Framework and predominantly deal with physical

products, this category will fall almost entirely in scope of the AI Act. An example includes an AI system that regulates safety or gas appliances used in homes where failure to detect a significant combustion risk could lead to explosion or carbon monoxide leakage.

44. The second category of high-risk product applies to AI systems that are designed or intended to be used in ways that are considered to pose significant risks to health, safety or fundamental rights.

45. There are eight areas the Act considers could be particularly susceptible::
    a. Biometrics;
    b. Critical infrastructure (for example, digital infrastructure, road traffic, water, gas, heating, electricity);
    c. Education and vocational training;
    d. Employment and worker management;
    e. Access to essential private services and essential public services and benefits;
    f. Law enforcement;
    g. Migration, asylum and border control management; and
    h. Administration of justice and democratic processes.

46. Examples of in-scope high-risk AI systems in this second category (some of which are currently hypothetical as we have found no evidence these are currently available on the market) include body-worn cameras with AI-driven behavioural pattern recognition or pressure sensors utilising AI to adapt water pressure.

47. Many systems in this category are expected to be out of scope of the Windsor Framework. Examples of out of scope high-risk AI systems in this second category that we would typically expect to be provided as standalone software include:
    a. AI software used for the assessment of job applications or applications for higher education. In this instance, the AI system is not embedded in a physical product and so it is not in scope.
    b. AI system used in call centres to infer emotions of customers;
    c. AI system intended to be used to place targeted job advertisements to specific users on social media;
    d. AI systems intended to create a numerical representation of a person's creditworthiness based on their payment behaviour and income that will support decision-making on a credit or mortgage.

48. AI systems deemed high-risk must be embedded in a product to be in scope of the Windsor Framework in Northern Ireland. Many of the above systems will therefore be out of scope as they will largely be standalone software or relate to how AI is deployed and used, rather than be integrated into a physical product placed on the market for sale. We therefore expect the impact to be limited in the immediate term, although more AI systems could be developed in future that would fall into scope of the high-risk category and its requirements.

High-risk AI systems compliance standards

49. High-risk AI systems embedded into physical products would not be prohibited, but they would need to meet certain compliance standards. The compliance standards are the same for both categories of high-risk product and fall largely on manufacturers. Many of these are not novel requirements, for example many products will already require a conformity assessment or the CE mark to be placed on the NI market. Manufacturers of such AI systems must undertake relevant conformity processes (including affixation of CE marking where necessary) and meet the following requirements before placing the product on the market:

    a. Establish, implement, document, and maintain a continuous risk management system across the lifecycle;
    b. Use high-quality datasets and implement data governance practices (for example, relevance; representativeness; and bias mitigation);
    c. Draw up and maintain technical documentation demonstrating compliance;
    d. Design the AI system to automatically generate logs enabling traceability and monitoring;
    e. Ensure automatically generated logs are kept and can be made available when the AI system is placed on the market;
    f. Provide instructions for use, including intended purpose, accuracy, limitations, and oversight requirements;
    g. Design the AI system to enable effective human oversight, including intervention and override mechanisms;
    h. Ensure accuracy, robustness, and cybersecurity appropriate to its intended purpose.

50. In addition, they shall establish and maintain a Quality Management System covering design, testing, and compliance processes; apply internal control procedures to take corrective actions where necessary; and retain technical documentation for 10 years after the placement on the market, as well as retaining automatically generated logs. Providers of certain high-risk AI systems (listed in Annex III to the AI Act), are additionally required to register the high-risk system into the EU database.

51. Most in-scope high-risk products are expected to fall into the first high-risk category although stakeholder engagement suggests products currently on the market in Northern Ireland that meet this definition are likely to be rare. There are some exceptions, for example medical devices where this is more common and anticipated to become more prevalent in the future. Products in this category are already regulated under sectoral regulations applicable under the Windsor Framework (e.g. the Medical Device Regulations) and, across various sectors, we understand that industry supplying Northern Ireland, and often Great Britain, is often EU-facing. **The practical impact of these provisions applying in Northern Ireland is therefore expected to be generally minimal.**

52. To take medical devices as an example: there are 3.8 million devices registered in Great Britain. Of these, c. 130,000 or 3.4% are devices which require third-party conformity assessment under the EU Medical Device or In Vitro Diagnostic Regulations applicable under the Windsor Framework. The AI Act could therefore be applicable to a subset of these 130,000: these devices could be in scope of the AI Act high-risk requirements but *only* if they are AI enabled and AI fulfils a safety function. In any case, the market is EU-facing - over 95% of this set of 130,000 (c.123,000) are currently CE marked - and we expect industry to continue to supply NI in the majority of cases. Where the EU is not a primary or planned market for in-scope products, it is possible the proportion of CE marked devices in GB could decrease or lag in the future.

53. In addition, we would also be able to exceptionally authorise AI-enabled medical devices or other AI systems/products to be placed on the market for reasons such as the protection of life or health, public security, environmental protection and protection of key industrial and infrastructural assets, even if these have not undergone the conformity assessment procedures.

Limited risk systems

54. Where AI systems interact with people or generate synthetic content, they are considered to pose limited risk, whether or not they are also high-risk. Limited risk systems fall into two categories.

55. The first category of limited risk system applies where the AI system is intended to interact directly with the user. Requirements for these systems are limited to transparency, with providers needing to ensure users are aware they are interacting with an AI system unless this is obvious to a reasonably well-informed person. Where AI systems in this category are intended to be used by law enforcement to detect, prevent, investigate or prosecute criminal offences, and where appropriate safeguards for the rights and freedoms of third parties are in place, they are exempt from this requirement unless those systems are available for the public to report a criminal offence.

56. An example of an AI system <u>in-scope</u> of the first limited risk category includes an AI assistant that is embedded in a phone. Where it is not self-evident to a reasonably informed person that they are interacting with an AI system, the provider would be required to make this clear, for example by initiating interactions with a disclaimer that an AI assistant is in use.

57. An example of an AI system <u>out of scope</u> of the first limited risk category includes a customer service chatbot for a retailer. This is not closely integrated with a product and would therefore not be regulated under the Windsor Framework.

58. The second category of limited risk system applies where the AI system is intended to generate synthetic audio, image, video or text. In this instance, the outputs must be in a machine-readable format, clearly detectable as artificial intelligence and work as intended.

59. An example of an AI system in-scope of the second limited risk category includes a connected toy that uses a closely integrated AI system to generate synthetic speech in response to a child.

60. An example of an AI system out of scope of the second limited risk category includes online AI voice cloning software. This is not closely integrated with a product and would therefore not be regulated under the Windsor Framework.

General Purpose AI

61. The AI Act also contains requirements for General Purpose AI (GPAI) model providers. GPAI models are not in scope of the Windsor Framework as they are not physical products. However, if the model is a component of an AI system, which is in turn integrated in a physical product, the product manufacturer may need the GPAI model developer to provide information on the model to satisfy the risk related requirements.

Other

62. **Sandboxes:** Where the AI Act applies to relevant products in NI within scope of the Windsor Framework, the Government will look to engage industry to best understand how we can support businesses including through advisory sandboxing. In addition, where AI is not regulated by the AI Act in Northern Ireland, for example where it is not closely integrated in a product or where it relates to the use of AI, we would expect to be able to operate advisory and statutory sandboxes on a UK-wide basis. We will consider how to best support Northern Ireland industry on a case-by-case basis.

63. **AI literacy:** The AI Act as applied under the Windsor Framework requires providers of AI systems to support the AI literacy of their staff and others operating or using AI systems on their behalf. This is a very light-touch obligation: the AI Act is not prescriptive about the requirements and there is no specific level of AI literacy required. The EU will publish guidance to support providers to comply with this obligation.

64. While **use** is almost entirely out of scope of the Windsor Framework, there is a requirement for deployers of high-risk AI systems embedded in physical products. Deployers are those who use an AI system in a professional capacity. This excludes personal use. Deployers of high-risk AI systems that are closely integrated with a physical product are obligated to report to the provider or distributor and relevant market surveillance authority if they have reason to believe a risk could occur and cause harm to people's health, safety or fundamental rights when the system is used in line with the provider's instructions. They must also report if they are aware of a serious incident involving a high-risk AI system.

Summary of Impact of application of the Regulation in the United Kingdom (including Northern Ireland)

65. We consider the impact of the AI Act will likely be limited due to three core reasons.

66. **The scope of the AI Act has been significantly reduced.** As outlined above (paragraphs 5-12), standalone software, online AI tools and apps and almost all cases of use of AI systems are out of scope. Only the provisions that predominantly pertain to placing goods on the market will be applicable in Northern Ireland.

67. **Stakeholder engagement and desk research to date suggests that there is currently a low prevalence of AI systems subject to the most stringent requirements.** We note that this may change in future. However, to date we have been unable to find any examples of in-scope prohibited products currently for sale in Northern Ireland and high-risk products also appear to be rare, with the exception of medical devices.

68. **Many in-scope sectors are likely to be predominantly EU-facing.** Almost all products in-scope of the AI Act under the Windsor Framework are already subject to other EU regulations, such as toy safety or medical devices regulations in order to be placed on the EU market. Stakeholder engagement indicated that the vast majority of AI-enabled medical devices on the Great Britain market are compliant with the necessary EU regulations and can move from Great Britain to Northern Ireland. In order to maintain access to the EU market, these products will also need to comply with the AI Act and we expect businesses will choose to do so. The Windsor Framework is therefore unlikely to be placing new or additional burdens on this sector.

69. The UK Government is committed to supporting the AI sector in Northern Ireland and has for instance recently announced additional R&D investment for Queen's University Belfast Centre for Secure Information Technologies (CSIT) Cyber AI hub, to further grow Northern Ireland's cybersecurity and AI sector.

Approach to AI in Great Britain

70. To date, most AI in the UK is regulated on a sector-by-sector basis. While the UK does not have cross-cutting regulation targeting AI specifically, a number of UK laws address similar goals as the AI Act, aiming to protect human rights, equality, and fundamental rights including the right to non-discrimination, data protection and privacy and children's rights. This includes the Equality Act, Data (Use and Access) Act, consumer protection laws such as Digital Markets, Competition and Consumers Act 2024 and the Crime and Policing Act.

71. The UK Government remains committed to ensuring that the UK maintains its position as a world leader in AI and to supporting its safe and effective adoption. We also want to ensure that we can adequately address risks while remaining proportionate and supporting innovation. At a sectoral level, the Government is exploring how AI in devices should be regulated in Great Britain.

72. For example, we have set up an independent National Commission to advise on the regulation of AI in healthcare to ensure that any measures we take are proportionate and achieve the dual aim of supporting innovation and protecting patient safety. The Commission issued a report to the Government this summer, which identified many similar themes as the AI Act (e.g. around data governance, risk management and human oversight), and will help shape our future regulation of AI medical devices. Most recently, the Commission published 44 recommendations (10 September 2026) which included recommendations around proportionate lifecycle regulation focused on flexible mechanisms for safe device iterations and updating, staged routes to market, and greater use of regulatory sandboxes for medical devices. The UK Government accepted these recommendations in full, with an implementation plan currently in development.

73. On general product safety, we consulted on AI-embedded products earlier this year to help ensure the product safety legislative framework remains fit for purpose and we are currently considering the responses. When reviewing sectoral regulations and policies on AI in the context of product safety, we will take into account international frameworks, including the AI Act, to further support the internal market and UK exporters.

74. In line with the Government's commitment to ensuring Northern Ireland traders have unfettered access to the rest of the UK internal market, the partial application of the AI Act in no way impedes the movement of qualifying Northern Ireland goods from Northern Ireland to Great Britain. Such goods will continue to benefit from the market access principles set out in the United Kingdom Internal Market Act 2020. So long as those goods meet Northern Ireland standards, they can be sold anywhere in the UK internal market. In addition, to support businesses when placing their products on the market, the CE mark is still recognised in Great Britain in many sectors making it possible to place the same product on the UK-wide market.

75. In deciding to partially apply the AI Act to Northern Ireland as part of implementing the Windsor Framework, the Government has appropriately considered the Section 46 duty under the UK Internal Market Act to have special regard for Northern Ireland's place in the UK's internal market, and to facilitate the free flow of goods between Great Britain and Northern Ireland

Assessment under Schedule 6B to the Northern Ireland Act

76. The EU published its council position on 14 April 2025 that it considered the AI Act to be within scope of Article 13(4) of the Windsor Framework, with the exception of certain provisions. An exchange of views between the UK and EU has further clarified the application, as set out above. As the notified provisions did not amend or replace any of the Acts listed in the Annexes to the Windsor Framework, they could only be applied through explicit agreement of the UK at the UK-EU Joint Committee. Under Schedule 6B to the Northern Ireland Act 1998 a new EU act may be added to the Windsor Framework where a motion has not been passed by the NI Assembly if the

Minister considers that ‘the new EU act would not create a new regulatory border between Great Britain and Northern Ireland’.

77. Considering the significantly reduced scope of the AI Act, current limited prevalence of the highest risk products, and the EU-facing nature of many sectors that are impacted, it is the Government’s assessment that the decision to add the Regulation to the Windsor Framework would not create a new regulatory border between Great Britain and Northern Ireland.

78. As such, the Minister for EU Relations intends to agree to partially add the Regulation to the Windsor Framework at the UK-EU Withdrawal Agreement Joint Committee of 10 November and is satisfied that this will facilitate Northern Ireland’s unique access to the EU’s single market without affecting its place in the UK’s internal market.

CONSULTATION

79. On 3 June 2026, the EU closed their consultation seeking views on their draft guidelines on transparency obligations for AI systems.

80. On 23 July 2026, the EU closed their consultation seeking feedback on practical criteria and use-case examples for high-risk AI systems.

81. The UK Government has engaged with the European Commission on the Regulation and held informal discussions with key UK industry stakeholders to gather views on the potential impact of the partial application of Regulation (EU) 2024/1689 in Northern Ireland. This did not constitute a formal consultation. These discussions have informed the content of this EM.

FINANCIAL IMPLICATIONS

82. A previous EM on this subject is helpful for understanding the likely compliance costs for UK businesses (see paragraphs 33-34 here) although it should be noted that the costs referred to cover compliance with the EU AI Act in full, rather than the reduced scope applicable in Northern Ireland. Costs will therefore be lower for compliance with the EU AI Act as it applies in Northern Ireland.

83. Where the AI Act applies in Northern Ireland, the length of time between development and marketing as a result of compliance processes could increase costs and reduce innovation. However, many businesses that supply in-scope products to Northern Ireland are EU-facing and are likely to come into compliance and adapt their research and development programmes in order to continue supplying the EU irrespective of the partial application of the AI Act in Northern Ireland. Even where businesses are not EU facing, stakeholder engagement suggests that many will comply with the standards required under the AI Act as part of their normal voluntary assurance, in particular for high-risk AI systems. Noting also the limited number of products currently in scope (with the exception of medical devices), we expect the cost implications to be relatively limited.



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