



House of Commons  
European Scrutiny Committee

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**Fourth Report of  
Session 2021–22**

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Documents considered by the Committee on 23 June 2021

*Report, together with formal minutes*

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## Notes

### Numbering of documents

Three separate numbering systems are used in this Report for European Union documents:

Numbers in brackets are the Committee's own reference numbers.

Numbers in the form "5467/05" are Council of Ministers reference numbers. This system is also used by UK Government Departments, by the House of Commons Vote Office and for proceedings in the House.

Numbers preceded by the letters COM or SEC or JOIN are Commission reference numbers.

Where only a Committee number is given, this usually indicates that no official text is available and the Government has submitted an "unnumbered Explanatory Memorandum" discussing what is likely to be included in the document or covering an unofficial text.

### Abbreviations used in the headnotes and footnotes

AFSJ	Area of Freedom Security and Justice
CFSP	Common Foreign and Security Policy
CSDP	Common Security and Defence Policy
ECA	European Court of Auditors
ECB	European Central Bank
EEAS	European External Action Service
EM	Explanatory Memorandum (submitted by the Government to the Committee) *
EP	European Parliament
EU	European Union
JHA	Justice and Home Affairs
OJ	Official Journal of the European Communities
QMV	Qualified majority voting
SEM	Supplementary Explanatory Memorandum
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union

### Euros

Where figures in euros have been converted to pounds sterling, this is normally at the market rate for the last working day of the previous month.

### Further information

Documents recommended by the Committee for debate, together with the times of forthcoming debates (where known), are listed in the European Union Documents list, which is published in the House of Commons Vote Bundle each Monday, and is also available on the [parliamentary website](#). Documents awaiting consideration by the Committee are listed in "Remaining Business": [www.parliament.uk/escom](http://www.parliament.uk/escom). The website also contains the Committee's Reports.

\*Explanatory Memoranda (EMs) and letters issued by the Ministers can be downloaded from the Cabinet Office website: <http://europeanmemoranda.cabinetoffice.gov.uk/>.

## Staff

The staff of the Committee are Ravi Abhayaratne (Committee Operations Assistant), Joanne Dee (Deputy Counsel for European and International Law), Alistair Dillon and Leigh Gibson (Senior Committee Specialists), Nat Ireton and Apostolos Kostoulas (Committee Operations Officers), Daniel Moeller (Committee Operations Manager), Foeke Noppert (Senior Committee Specialist), Indira Rao MBE (Counsel for European and International Law), Paula Saunderson (Committee Operations Assistant), Emily Unwin (Deputy Counsel for European and International Law), Dr George Wilson (Clerk), Beatrice Woods (Committee Operations Officer).

## Contacts

All correspondence should be addressed to the Clerk of the European Scrutiny Committee, House of Commons, London SW1A 0AA. The telephone number for general enquiries is (020) 7219 3292/8185. The Committee's email address is [escom@parliament.uk](mailto:escom@parliament.uk).

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# 1 New EU health and safety requirements for machinery (EU Machinery Regulation)<sup>1</sup>

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**This EU document is legally and politically important because:**

- it could significantly alter the way the EU applies safety requirements to a range of machinery products, also affecting UK exports to the EU. In addition, the new safety standards could become law in Northern Ireland under the Brexit Protocol, and make machinery produced to EU standards legal for sale in Great Britain under the Internal Market Act (even if British safety standards diverge in the future).

## Action

- Write to the Minister for Small Business, Consumers and Labour Markets (Paul Scully MP) to seek further information on the Government's assessment of the implications of the EU proposal for UK machinery safety standards and the UK internal market.
- Draw the proposed EU Machinery Regulation to the attention of the Business, Energy and Industrial Strategy Committee, the International Trade Committee, the Northern Ireland Affairs Committee and the Work and Pensions Committee.

## Overview

1.1 The [EU Machinery Directive](#) (MD), agreed in 2006, sets essential health and safety requirements for a wide variety of machinery items that range from drones to lawnmowers to industrial robots.<sup>2</sup> In April 2021, the European Commission proposed to make significant changes to this legal framework by replacing the MD with a new Machinery Regulation. This would, among other things, introduce new safety requirements linked to technological developments such as Artificial Intelligence (AI) and set stricter market surveillance requirements to ensure unsafe machinery is removed from the EU market. The proposal is now being considered by the EU's Member States in the Council of Ministers and the European Parliament which must jointly agree on its substance before it can formally become EU law.

1.2 Although the UK left the EU in 2020, the proposed new Machinery Regulation is still of relevance to the British machinery manufacturing sector and, by extension, for users of their products. Under the Protocol on Ireland/Northern Ireland in the UK/EU Withdrawal Agreement, EU product safety standards remain binding on Northern Irish manufacturers and importers, and the new Machinery Regulation would automatically take effect there in due course. Moreover, under the Internal Market Act 2020, goods

1 [Proposal for a Regulation on machinery products](#); Council and COM number: 8095/21, COM(21) 202; Legal base: Article 114 TFEU; ordinary legislative procedure; QMV; Department: Business, Energy and Industrial Strategy; Devolved Administrations: Consulted; ESC number: 41827.

2 [Directive 2006/42/EC](#) as amended.

(like machinery) that are on the market in Northern Ireland — i.e. compliant with EU standards — are also automatically legal for sale in the rest of the UK under the principle of “mutual recognition”, even if British safety standards diverge from the EU’s in the future. In addition, those exporting machinery from Great Britain to the EU — which, according to the ONS, amount to billions of pounds every year — will need to comply with the new EU safety requirements in due course if they want to continue servicing the European market.

1.3 The Government has [acknowledged](#) the applicability of the proposed EU Machinery Regulation under the Northern Ireland Protocol, but not provided Parliament with an assessment of the implications for the UK market for machinery as a whole, or the merits of the new EU safety standards given that they may impact on the benefits of future UK divergence in this field. In light of this, we have considered the proposed EU Machinery Regulation, and its potential implications for the UK, in more detail in the remainder of this chapter. The proposal for a Regulation is also closely linked to the draft [EU Artificial Intelligence Act](#) (AIA), which aims to establish a number of horizontal regulatory requirements for “high risk” AI systems — including those used as safety components in machinery — and which we consider separately in more detail in chapter 2 of this Report.

## EU regulation of machinery products

1.4 The EU’s “Single Market” for goods is one of the most well-developed international free trade areas in the world: broadly speaking, a good that is legal for sale in one EU Member State can normally be sold freely in all others without further regulatory approvals or safety checks.<sup>3</sup>

1.5 This arrangement is underpinned not only by trust, but also by [binding EU legislation for many different types of goods](#) that aim to harmonise, to a large extent, the product standards that must be applied to “protect consumers, public health, and [the] environment”.<sup>4</sup> With respect to goods made by the mechanical engineering industry, which includes a wide range of products including lawn-mowers, industrial robots and 3D printers, the key piece of EU legislation in this respect is the Machinery Directive (MD), which was agreed in 2006 and has applied in EU Member States since 2009.<sup>5</sup>

1.6 The MD is part of what is termed the EU’s “new approach”<sup>6</sup> to the regulation of goods: this means it sets out — in the form of principles — the essential health and safety requirements (EHSR) that products must meet before they can be placed on the

3 In this chapter, references to the EU’s Single Market should be read as referring to the entire European Economic Area as the Machinery Directive has been [incorporated into the EEA Agreement](#) and therefore applies not only in the EU-27 and Northern Ireland, but also in Norway, Iceland and Liechtenstein.

4 For goods that are not, or are only partly subject to EU harmonisation legislation, market access between EU countries is underpinned by the principle of “mutual recognition” as set out in Articles 34–36 of the Treaty on the Functioning of the European Union and further defined in [Regulation \(EU\) 2019/515](#).

5 In some cases, particular types of machinery are not covered by the MD but instead by more product-specific EU legislation, such as the Low-Voltage Directive (LVD), the Pressure Equipment Directive (PED), the Lifts Directive (LD) or the Medical Devices Directive (MDD). Conversely, in some cases other EU rules may apply in parallel, such as the Outdoor Noise Directive (OND), the Radio Equipment Directive (RED), the Electromagnetic Compatibility Directive (EMCD). This means, for example, that “machines for use outdoors (such as in construction sites, road maintenance, gardening and forestry activities) may be subject to both the MD and the OND”.

6 Under what is termed the ‘old approach’, detailed technical specifications for particular products were embedded in the legal text of EU rules themselves.

EU market.<sup>7</sup> Manufacturers must make a risk assessment to determine what risks the machinery presents, and identify the safety requirements set out in the MD necessary to address them. Where the manufacturer legally accepts that its product meets those requirements, it draws up a “Declaration of Conformity”<sup>8</sup> and affixes the [“CE” marking](#) to its products, enabling the machinery to be sold and used throughout the EU.<sup>9</sup> For machinery manufactured outside the EU but intended for sale within it, the same safety requirements apply. To ensure the provisions of the Directive are complied with, exporters can appoint an “authorised representative”: a company established within the EU that “perform[s] on his behalf all or part of the obligations and formalities connected with” the Machinery Directive.

1.7 Usually, the checks needed to assess a piece of machinery’s conformity with the EU’s safety rules are carried out by the manufacturer internally. This is the case, for example, where the manufacturer relies on voluntary “harmonised standards” for different types of machinery as drawn up by standard-setting bodies such as [CEN](#) and [CENELEC](#) (provided that those standards have been [explicitly approved](#) for that purpose by the European Commission).<sup>10</sup> However, where a piece of machinery is classified as “high risk” under the Directive and it is *not* manufactured according to these harmonised standards, a conformity assessment must be carried out — for a fee — by an independent “[notified body](#)” to confirm the product meets the safety requirements.<sup>11</sup> Where CE marking is applied to a product that does not in fact meet the necessary health and safety requirements, it is for individual EU countries to take action against the company (or its representative) in line with their domestic legislation.

## Review of the Machinery Directive

1.8 The EU Machinery Directive has important industrial and economic implications, given the sector’s contribution to the EU’s manufacturing industry and the use of such products in other industrial processes.<sup>12</sup> In May 2016, the European Commission — which is the body responsible for proposing changes to EU legislation — [announced](#) that it would review the implementation of the Directive to determine its “effectiveness, efficiency, relevance, coherence and EU added value”.

1.9 The Commission [consulted stakeholders](#) to gather their views on the Directive in 2017. In the [resulting evaluation](#), published in spring 2018, the Commission made a number of

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7 The safety requirements are set out in Annex I of the MD. Some safety requirements are more general in nature, while others are specific to certain types of machinery.

8 A Declaration of Conformity also requires the compilation of a more detailed technical file, which must contain drawings, test reports, and risk assessments. This technical file can only be compiled by someone who is established within the EU.

9 Article 6 of the MD states that “Member States shall not prohibit, restrict or impede the placing on the market and/or putting into service in their territory of machinery which complies with this Directive”, supplemented by Article 7 which provides that “Member States shall regard machinery bearing the CE marking and accompanied by the EC declaration of conformity [...] as complying with the provisions of this Directive”. There is a safeguard clause, Article 11, which allows an EU country to prevent use of machinery where it “is liable to compromise the health and safety of persons” because it is not, in fact, compliant with the Directive.

10 The intention is for the rules to be “technology neutral” and supportive of innovation, because they do not prescribe “any specific technical solution for complying” with the health and safety requirements. Any harmonised standards used must be specified in the technical file that must be compiled for each machinery product.

11 A certificate of conformity issued by a notified body in one EU country is valid in all other Member States.

12 According to the European Commission, in 2017 the EU machinery sector — then still including the UK — recorded turnover of €663 billion, employing 2.8 million people across more than 80,000 businesses.

observations about potential shortcomings in the MD.<sup>13</sup> It concluded in particular that the legislation was not fully equipped to deal with the safety implications of “emerging digital innovations” such as industrial “[collaborative robots](#)” designed to work in close proximity to human employees,<sup>14</sup> connected machines that can be controlled remotely or operate autonomously,<sup>15</sup> and changes to machinery operations via software updates.<sup>16</sup> In addition, the Commission highlighted the potential risks related to the increasing use of Artificial Intelligence in industrial processes, which allows machinery to ‘learn’ and, consequently, adapt its operating behaviour on an on-going basis.<sup>17</sup>

1.10 Secondly, the Commission found that the current legislation does not adequately address issues related to “high risk machines”.<sup>18</sup> At present, the Declaration of Conformity for such products, asserting compliance with applicable safety requirements, must be issued by an independent “notified body” *only* if they are not manufactured fully in line with approved harmonised standards (see above). When consulting about possible changes to the MD, some stakeholders argued that, given the risks of unsafe machinery being put on the market because the manufacturers can ‘mark their own homework’, there should be a systematic requirement for such machinery to be subject to an independent conformity assessment even if harmonised standards are used.<sup>19</sup>

1.11 Finally, the Commission noted that the Machinery Directive had not yet been aligned to the EU’s “[New Legislative Framework](#)” (NLF), which is a standardised approach to the regulation of goods sold within the EU introduced in 2008 (two years after the MD was agreed). The NLF is already used for many other product-specific EU rules, including lifts, pressure equipment and toys. As a result, there are notable differences in the rules applicable to those goods and to items of machinery as regards the obligations of different businesses in the supply chain (namely manufacturers, distributors and importers).

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- 13 In addition, the evaluation also found that the Directive could be improved with respect to the legal clarity of the MD’s scope to avoid overlaps with or gaps between other EU rules, for example with respect to Wi-Fi-connected household appliances, certain means of transport, and “partly completed machinery”. The Commission also received evidence that there should be more detailed criteria to determine when a piece of machinery undergoes “substantial modification” after it is first placed on the market, in which case a new Declaration of Conformity must be issued to evidence compliance relevant safety requirements under the Directive.
- 14 For example, a number of EU countries raised concerns that the current safety requirements set out in the Machinery Directive related to keeping moving parts away from humans “may not be sufficient in cases of human-robot coexistence in a shared space, or in cases where humans and robots are simultaneously working on something, or in cases where humans and robots are alternating in their work on something”.
- 15 An [impact assessment prepared by the European Commission](#) on revising the Machinery Directive referred to a French study highlighting the “severity of safety issues due to incorrect control decisions taken based on erroneous sensorial data” in connected machinery. Machinery applications that are controlled remotely are also at risk of being manipulated or controlled by unauthorised third parties through cyber-attacks.
- 16 Some Member States called for the MD to be revised to ensure to “ensure that software updates not considered in the initial manufacturer’s risk assessment and that had an impact on safety should be considered as a substantial modification, thus requiring a new CE marking”.
- 17 The Commission is also seeking to address safety risks related to AI through a new EU “[Artificial Intelligence Act](#)”, which we discuss separately elsewhere in this Report. The evaluation also found potential shortcomings with respect to the substantive safety requirements for some types of ‘traditional’ machinery, which in some cases were considered insufficient or, conversely, overly prescriptive. This was the case in particular for low-speed lifts like stair lifts, seating on ‘ride-on’ mobile machinery such as excavators or agricultural sprayers, the risk associated with accidental contact with overhead power lines, release of hazardous substances generated by machinery, and harmful vibrations from handheld and hand-guided machinery.
- 18 In addition, the Commission noted that the list of high-risk machines under the MD is now 15 years old and may therefore benefit from being updated, for example to include machinery using AI as safety components.
- 19 Several ‘high-risk’ machinery products which were said to be made according to harmonised standards after the manufacturer’s internal checks have, in recent years, been found not to be compliant with those standards, including circular saws. Some of these products were manufactured outside the EU.

Moreover, under the NLF the rules on [market surveillance](#) — the monitoring of products on the market by public authorities to make sure unsafe goods are removed from the market — are also more stringent than they are under the Machinery Directive.<sup>20</sup>

1.12 In February 2019, the Commission [confirmed](#) that it had begun work on amendments to the MD to address these issues, and in April 2021 it formally tabled a [proposal for a new Machinery Regulation](#), which is now being considered by the EU Member States in the Council of Ministers and by the European Parliament. We consider the substance of that draft Regulation, its relationship to the separate proposal for an EU Artificial Intelligence Act and the implications for the UK in more detail below.

## The proposal for a new EU Machinery Regulation

1.13 The [proposal for a Machinery Regulation](#) would comprehensively replace the EU Machinery Directive. In terms of substance, the proposed legislation would maintain the general approach enshrined in the current Directive, where the company placing machinery on the market is responsible for meeting the relevant essential health and safety requirements for the product in question, as evidenced by a Declaration of Conformity and CE mark following a conformity assessment. Such conformity could still be demonstrated most easily by relying on harmonised standards approved by the EU for that purpose.

1.14 However, the proposal would also make significant changes to some of the legal requirements around the placing on the market of machinery within the EU compared to the MD, which can be summarised as follows:

- the scope of the legislation is defined more tightly, notably through a more general exclusion of transport vehicles and household appliances. A new definition of ‘substantial modification’ is also added, in a bid to ensure that a new Declaration of Conformity is drawn up where a piece of machinery is placed on the EU market after its previous design has been altered in a way by the manufacturer that requires a fresh assessment of its health and safety features.<sup>21</sup> There are also new requirements relating to the use of Artificial Intelligence (AI) in machinery, which we consider in more detail in paragraphs 16 to 18 below;
- under the MD, manufacturers can carry out their own conformity assessments even on [high-risk machinery](#) (like electric saws and cranes), provided they rely on approved harmonised standards. Amid concerns over that this might result in the sale of unsafe machinery,<sup>22</sup> the draft Regulation would remove this option. Instead, the conformity assessment for high-risk products would

20 [New EU rules](#) on market surveillance under the NLF are due to come into effect in July 2021. The European Commission is also planning an [evaluation of the NLF](#) in the near future.

21 The proposal defines “substantial modification” as a “modification of a machinery product, by physical or digital means after that machinery product has been placed on the market or put into service, which is not foreseen by the manufacturer and as a result of which the compliance of the machinery product with the relevant essential health and safety requirements may be affected”.

22 The European Commission impact assessment for the Machinery Regulation notes that notifications have been received of “some of the products [classified as high risk under the MD] were identified as not being compliant with the requirements of the MD and the relevant European standards”, including “circular saws and vehicle lifts”, and that “some of these products were manufactured outside the EU”. The market surveillance authorities of some EU countries also “challenged the effectiveness of dealing with high-risk machines using a procedure that does not systematically impose a third-party conformity assessment”, whereas manufacturers “prefer to have the choice of involving or not a third party whenever they follow the relevant harmonised standards” given the cost of an independent conformity assessment.

always need to be carried out by an independent “notified body” as a paid-for service.<sup>23</sup> In addition, the list of “high risk” machinery to which this more stringent conformity assessment process applies would be amended, to include “software ensuring safety functions” and any machinery that uses AI as a safety component;<sup>24</sup>

- in line with the EU’s “New Legislative Framework” (see above), the Regulation sets out explicitly that both those who manufacture machinery within the EU and importers who bring such products into the EU from non-EU countries are legally responsible for ensuring the goods meet the relevant health and safety requirements. In addition, where the safety requirements for a specific machinery are not (yet) covered by harmonised standards that manufacturers can rely on to demonstrate compliance with the Regulation,<sup>25</sup> the Commission would be able to establish “technical specifications” under EU law that fulfil the role of such standards as a “fall back solution”; and
- the Regulation would also amend some of the substantive health and safety requirements applicable to all or specific types of machinery, for example with respect to vibrations of hand-held tools, release of hazardous substances, and remotely controlled machinery.

1.15 It is also of note that the Commission proposal on machinery safety rules is in the form of a Regulation, rather than a Directive as is currently the case. This change of legal instrument has important ramifications: a Regulation, unlike a Directive, would be directly applicable in all EU Member States without the need for national legislation ‘transposing’ it into their domestic legal orders.<sup>26</sup> This, the Commission argues, is justified because the current Directive has given risen to differences in interpretation of the same concepts between different EU countries, and in some cases hinders the trade in machinery within the Single Market.<sup>27</sup> The proposed change to a Regulation also has significance in the context of the potential applicability of the Commission proposal in Northern Ireland as and when it becomes EU law, because it provides less room for the UK to apply the EU rules in Northern Ireland under the Brexit Protocol in a way that maximises compatibility with machinery regulations in effect in the rest of the UK (see paragraphs 23 to 31 below).

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23 While there is no specific derogation for small businesses from the need to pay for a conformity assessment for high-risk machinery, “notified bodies” would have to “reduce [their] fees proportionately” to the specific interests and needs of small businesses. For machinery not classified as “high risk”, manufacturers and importers would still be able to carry out internal conformity assessments.

24 The Commission has also proposed that the list of high-risk machinery could be amended in the future by means of a Delegated Act — a type of EU statutory instrument — in “view of technical progress and knowledge or new scientific evidence”.

25 For example, when the standardisation process in the relevant European or international standard-setting body is blocked due to a lack of consensus between stakeholders or there are “undue delays” in the establishment of a harmonised standard.

26 For example, the UK — while still an EU Member State — transposed the Machinery Directive into its domestic legal order by means of the [Supply of Machinery \(Safety\) Regulations 2008](#) under the European Communities Act 1972.

27 The Commission notes for example that Member States have used different definitions of “partly complete machinery” and “safety component”, and diverging approaches whether to consider software a safety component.

## **Use of Artificial Intelligence in machinery**

1.16 Of particular interest is that the draft Regulation also contains specific provisions on the use of Artificial Intelligence (AI) in machinery.

1.17 The Commission proposal would introduce new essential health and safety requirements where AI endows machines with an “evolving capacity”, notably by mandating a risk assessment to “identify the hazards that [...] may be generated during the lifecycle of the machinery product [...] as an intended evolution of its fully or partially evolving behaviour or logic”, in particular for robots in industrial use that operate in close proximity to people. There would also be AI-related safety requirements as regards physical interaction (both intentional and accidental) with people<sup>28</sup> and software-based control systems.<sup>29</sup> Manufacturers — or importers, as the case may be — could be liable for harm caused if items are placed on the EU market without these risks having been addressed in the design.<sup>30</sup>

1.18 There are, furthermore, close links between the proposal and the separate EU Artificial Intelligence Act (AIA) proposed by the European Commission in parallel to the new Machinery Regulation. The AIA would create additional regulatory requirements for “high risk” AI systems, which would include those “intended to be used as a safety component” in goods such as machinery.<sup>31</sup> These would come on top of the new, general health and safety requirements related to AI used in machinery referred to above.<sup>32</sup> The proposed new requirements relating to the use of AI in machinery under the draft Machinery Regulation and Artificial Intelligence Act taken in combination are shown in the table below:<sup>33</sup>

	<b>General AI safety requirements under the Machinery Regulation apply</b>	<b>Specific safety requirements for high-risk AI under the AIA apply</b>	<b>Conformity assessment by an independent “notified body” mandatory</b>
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- 28 For example, the draft Machinery Regulation states that products that use AI features must be able to “to communicate its planned actions (what it is going to do and why) to operators in a comprehensible manner”.
- 29 Annex III to the draft Machinery Regulation specifies that machinery with control systems that may adapt due to their AI “shall not cause the machinery product to perform actions beyond its defined task and movement space” and must be subject to human intervention “to correct the machinery product in order to maintain its inherent safety”.
- 30 Manufacturers must also provide market surveillance authorities, on request, with the “source code or programmed logic of the safety related software”. Annex IV of the draft Machinery Regulation sets out the contents of the “technical file” for machinery products.
- 31 In addition, the regulatory requirements for high risk AI under the Act would apply where the AI system in itself constitutes “machinery” for the purposes of the Machinery Regulation.
- 32 For those goods already subject to sectoral EU rules, like machinery, the AIA would insert the new requirements related to safety systems reliant on Artificial Intelligence into the existing conformity assessment process, but only where EU law requires those assessments to be carried out by an independent notified body. As noted above, under the proposed Machinery Regulation such a “third party” conformity assessment would become mandatory for all high-risk machines, which includes those that use AI as a safety component, and therefore the requirements of the AIA would apply to such machinery.
- 33 In summary, the use of any AI would need to be addressed by health and safety measures where necessary to meet requirements of the Machinery Regulation, before a Declaration of Conformity can be issued. For high risk machinery, which includes any kind that uses AI as a safety component, such a Declaration can only be issued after a conformity assessment carried out by a third party other than the manufacturer. In addition, AI systems which are in themselves “high risk” under the Artificial Intelligence Act such as a safety component in a good — and use of which also, by definition, renders a machine that uses them “high risk” — would need to comply with the new safety standards set out in the AIA.

<b>High risk AI (safety component in machinery)</b>	Yes	Yes	Yes
<b>Other AI systems used in machinery</b>	Yes	No	Only if the machine is classified as high risk for non-AI related reasons

### **Legislative deliberations on the proposal**

1.19 The Commission proposal for a Machinery Regulation is not set in stone: to become EU law, it must be approved jointly by a qualified majority of the EU’s Member States in the Council of Ministers, and by the European Parliament.

1.20 These two institutions are in the earliest stages of their respective legislative deliberations, and currently it is not clear to what extent they will amend the substance of the Commission proposal, or when the new rules may take effect.<sup>34</sup> The Parliament and Council may also change the legal form of the new legislation from a Regulation back to a Directive, if they feel this is more legally and politically appropriate (see paragraph 15 above).<sup>35</sup> It is likely that the legislative process will take well over a year.<sup>36</sup> Given that the Commission has proposed a two-year implementation period after the Regulation is formally approved, this means the new rules are not expected to take effect until 2024 at the earliest.

### **Implications of the draft EU Machinery Regulation for the UK**

1.21 The UK of course left the European Union on 31 January 2020 and EU law, including the Machinery Directive, ceased to apply generally speaking when the post-Brexit transition period ended on 31 December last year. However, for several reasons both the existing Directive and the proposed new Machinery Regulation remain directly relevant to the UK.

1.22 First, under the Protocol on Ireland/Northern Ireland in the Withdrawal Agreement, the Machinery Directive — “as amended or replaced” — remains in effect in Northern Ireland, despite Brexit. Secondly, the Directive — and, in the future, the new Regulation — affect the conditions for exports of machinery from the UK to the EU, which are economically significant. Thirdly, these two factors may in combination affect the benefits of divergence from the EU’s approach with respect to the regulation of safety standards for machinery put on the market in England, Wales and Scotland.

1.23 We have explored these three avenues by which the proposed new EU Machinery Regulation might impact on the UK in more detail below.

34 In the European Parliament, the proposal has been allocated to the Internal Market and Consumer Protection (IMCO) Committee for consideration. Within the Council of Ministers, the proposal is being discussed by officials representing the 27 Member States in the working party on technical harmonisation.

35 It is unclear at this stage what the views of the Member States and MEPs are on the suggestion to transition from a Directive to a Regulation. At one of the first exchanges on the proposal by the EU Member States in the Council [on 11 May 2021](#), the “choice of legal instrument” was on the agenda.

36 The current Machinery Directive was [first proposed by the Commission in 2001](#) but not adopted until 2006, with many amendments. The then-European Scrutiny Committee last considered the proposal that would lead to the 2006 Machinery Directive [in October 2001](#).

## ***EU regulation of machinery under the Northern Ireland Protocol***

1.24 The UK, Northern Ireland included, left the EU’s Customs Union and Single Market on 31 December 2020. In principle, that means that goods moved from the UK to the EU are now subject to controls at the border to verify compliance with, for example, the EU’s product safety standards and customs rules.<sup>37</sup> However, to avoid the need for any infrastructure on the land border on the island of Ireland, for example to allow customs officials to check the “CE” marking and documentation on imported machinery, the UK and EU agreed a special “[Protocol on Ireland/Northern Ireland](#)” in the Withdrawal Agreement (that set the terms of the UK’s exit from the European Union).

1.25 This Protocol, in particular, requires Northern Ireland to remain aligned to a long list of EU rules related to the production of industrial and agricultural goods until at least the end of 2026,<sup>38</sup> in return for which goods on the market in Northern Ireland can be moved into Ireland — and, hence, the entire EU Single Market — without physical controls at the land border.<sup>39</sup> The Machinery Directive is one of the pieces of EU legislation listed in the Protocol, and as such remains in effect in Northern Ireland even though it no longer applies as a matter of EU law in the rest of the UK.<sup>40</sup>

1.26 Moreover, the Protocol provides that references in it to EU rules “shall be read as referring to [them] as amended or replaced”. This means, in this particular case, that the new EU Machinery Regulation will automatically become applicable under the Protocol instead of the Machinery Directive if the alignment provisions are still in operation when the new EU rules take effect.<sup>41</sup> Any changes to the Machinery Directive that flow from the Commission proposal will therefore apply to businesses in Northern Ireland manufacturing machinery equipment, or importing it from somewhere outside the EU.<sup>42</sup> The Protocol also means that machinery brought into Northern Ireland from Great Britain, even if it is in line with the applicable safety standards under law in the rest of the UK, is only allowed onto the Northern Irish market if it also meets EU standards, as attested by the CE mark (and, where necessary, subject to an independent conformity assessment).

## ***Import of machinery with the EU’s CE mark into Great Britain***

1.27 While the Protocol means that EU safety standards must always be met for machinery items moved from Great Britain into Northern Ireland, the same is not necessarily true for trade in the other direction.

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37 The UK has [largely deferred](#) the imposition of controls on goods coming in from the EU until early 2022.

38 The provisions of the Protocol that require Northern Ireland to remain aligned with EU law on goods are subject to the periodic democratic consent of the members of the Northern Ireland Assembly under Article 18 of the Protocol. They are due to vote on whether to keep those provisions in effect for the first time no later than the end of 2024, and if they reject them that element of the Protocol will become inoperative after a two-year period, i.e. from the end of 2026.

39 Article 5(4) and Annex 2 of the Protocol.

40 The Machinery Directive was transposed into UK law by means of the [Supply of Machinery \(Safety\) Regulations 2008](#), which remain in effect in England, Scotland and Wales subject to certain EU exit related amendments.

41 Article 13(3) of the Protocol.

42 There is a reservation under Schedule 3 of the Northern Ireland Act 1998 that reserves the right to legislate with respect to all technical standards in products relating to EU obligations to Westminster. The Department for Business, Energy and Industrial Strategy has [noted](#) that the Government “may need to lay a statutory instrument to ensure that enforcement provisions are properly implemented” as and when the Machinery Regulation is approved at EU-level.

1.28 It is important to note in this context that EU safety standards no longer apply in England, Scotland and Wales, where they can now be changed in ways that divert from the EU’s approach. Moreover, while UK safety standards for machinery remain in substance identical to the EU’s for the time being,<sup>43</sup> the Government is also phasing out the use of the CE mark (as a sign of conformity with EU product safety standards) in Great Britain. The intention is for it to be replaced by the new “UKCA” mark from 1 January 2022,<sup>44</sup> including for items of machinery, to attest compliance with safety standards as they apply independently under UK domestic law.<sup>45</sup> However, the UKCA mark will not be used in Northern Ireland precisely because it remains bound by EU product safety rules under the Protocol and, consequently, will continue to use the EU’s CE mark where required.<sup>46</sup> Separately, the Government is also conducting a “product safety review” to ensure UK rules can “deal with new and novel products or business models”.

1.29 The possibility of divergence between UK and EU safety standards for products like machinery raises certain issues in the context of the Government’s commitment to providing Northern Ireland with “unfettered access” to the UK’s internal market (despite the trade barriers created by the Protocol). This means, in the Government’s words, that there “should be no additional process or paperwork and there will be no restrictions on Northern Ireland goods arriving in the rest of the UK”. More specifically, the United Kingdom Internal Market Act 2020 (UKIMA) provides for the principle of “mutual recognition” under which “a good that can be lawfully sold in the part of the UK in which it has been produced or imported into may be sold in any other part of the UK without needing to comply with any relevant requirements applying to the sale in that other part”.

1.30 However, special rules apply under the Act to goods from Northern Ireland, to reflect its current unique position straddling the UK and EU’s internal markets. This is because the “unfettered access” commitment means EU goods could enter the UK market via Northern Ireland without customs or regulatory controls (which they would face if they entered Great Britain directly from the EU). To avoid such circumvention of the UK’s customs perimeter, the mutual recognition principle under the UKIMA normally applies only to so-called “qualifying Northern Ireland goods”. However, the current legal definition<sup>47</sup> of such goods is extremely broad, described as products that “are in free

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43 The MD was transposed into UK law by the Supply of Machinery (Safety) Regulations 2008, which were amended — but retained — by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019.

44 While the UKCA mark has been in operation since 1 January 2021, the Government has advised that, to allow businesses time to adjust to the new requirements, the CE marking will currently remain valid in the UK as a sign of conformity for goods until at least 1 January 2022, provided the EU and UK technical standards have not diverged. In May 2021, it was reported that the CE mark might remain valid for longer.

45 The process for obtaining the Declaration of Conformity to which the UKCA attests is broadly speaking the same as it was pre-Brexit, including for items of machinery and the requirement for independent “third party” conformity assessments for high risk machinery.

46 Where an item that undergoes an independent conformity assessment carried out by a UK-based notified body, the CE mark must also be accompanied by the UK(NI) designation, which means it is not authorized to be placed on the market in the EU. Products that undergo a third party conformity assessment under EU law must have this carried out by an EU-based notified body, as the EU was keen to limit the extent to which the UK could act as a “certification hub” for the EU’s Single Market.

47 As set out in the Definition of Qualifying Northern Ireland Goods (EU Exit) Regulations 2020 made by the Government under Section 8C(6) of the European Union (Withdrawal) Act 2018.

circulation in Northern Ireland”.<sup>48</sup> As such, it appears that items of machinery (as well as other goods) that meet EU standards and have been placed on the market in Northern Ireland can, in principle, continue to be sold freely in Great Britain with the EU’s CE mark (but without the need for a UKCA mark or a conformity assessment for compliance with British standards).<sup>49</sup> This level of unfettered market access extends to goods manufactured outside Northern Ireland (provided they meet EU requirements), and even if the applicable safety standards in Great Britain diverge from the EU’s over time.<sup>50</sup>

1.31 For goods like machinery, while the CE mark on goods (and the safety standards to which it attests) remains valid to place a product on the market in the entire UK (until at least 1 January 2022),<sup>51</sup> this does not necessarily create any problems. However, from that date the interaction between the Protocol and the Internal Market Act would suggest that companies could legally circumvent the UK’s independent safety standards (and any applicable conformity assessment requirement) by bringing goods compliant only with EU rules into Great Britain via Northern Ireland.<sup>52</sup>

1.32 The Government is aware of such issues, and has [indicated](#) that it intends to change the definition of “qualifying goods” in this context in the second half of 2021, to “focus the benefits of unfettered access solely and exclusively on Northern Ireland businesses” and “ensure that goods moving from Ireland or the EU [via Northern Ireland] are subject to full third-country checks and controls” when they enter Great Britain.<sup>53</sup> Depending on the Government’s approach, that could mean only CE-marked goods with a genuine link to Northern Ireland would be valid for placing on the market in Great Britain, with the remainder required to meet British standards (for example by applying the UKCA mark, subject to the applicable conformity assessment procedure under UK law).

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48 In other words, goods in Northern Ireland that are not under a [customs procedure](#) or in an authorised temporary storage facility. In addition, [Section 11 of the UK Internal Market Act 2020](#) provides that goods which do are not “qualifying goods” but “are moved in a way that would, but for the fact that Northern Ireland is a part of the United Kingdom, amount for the purposes of the mutual recognition principle for goods to the importation of the goods into England, Scotland or Wales, the goods are to be regarded for the purposes of that principle as having been so imported” and therefore fall within the scope of the mutual recognition principle.

49 For example, the Health and Safety Executive has [confirmed](#) that businesses “will be able to place qualifying Northern Ireland goods on the market in Great Britain based on the conformity markings you use in Northern Ireland”, i.e. the CE mark.

50 Given that the Commission proposal for a Machinery Regulation would make a number of substantive changes to the essential health and safety requirements, the possibility of divergence between UK and EU standards in the coming years is not insubstantial.

51 It has recently been [reported](#) that the full implementation date of the new UKCA system may be delayed from its original date of 1 January 2022.

52 The Treasury has already created a general anti-avoidance rule allowing it to impose duty on goods brought into Great Britain via Northern Ireland from the EU where the purpose of moving those goods was to avoid any UK customs duty or customs obligation, although it is not clear to what extent this has made a difference in practice. This rule also appears limited to the issue of duty avoidance, not product safety standards.

53 For example, on 30 November 2020 the Government told the House of Lords that the current definition of “qualifying Northern Ireland goods” was “focused on avoiding disruption and maintaining continuity for the first half of [2021]”. However, imposing a more restrictive definition of “qualifying goods” raises the question of how the Government would differentiate between qualifying and non-qualifying goods, given its opposition to border controls on trade between Northern Ireland and the rest of the UK.

## UK exports of machinery to the EU

1.33 Setting aside the continued applicability of EU safety standards for machinery in Northern Ireland and the implications under the Internal Market Act, the new EU Machinery Regulation is also likely to have economic implications for businesses in Great Britain that sell machinery into the EU, and companies in their supply chains.

1.34 Before the UK left the Single Market at the end of 2020, the Machinery Directive was applicable to all relevant products manufactured in or imported into the UK, and as such they could be sold freely throughout the EU provided conformity assessments and related formalities were complied with. Following the end of the transition period, British exports of machinery to the EU still need to meet its existing health and safety requirements (and, in the future, those of the new Machinery Regulation). However, even while the safety standards in Great Britain remain *de facto* identical to the EU's, the legal reality is that the Government could pursue divergence at its own discretion at any point. As such, the formalities involved in such trade from Great Britain to the EU — and Northern Ireland — has changed substantially: like other goods, exported machinery must now undergo checks to verify their compliance with the MD when at the border (as well as any other relevant customs, VAT and regulatory controls).<sup>54</sup>

1.35 Any changes to EU machinery safety standards will therefore have a knock-on effect on businesses in the UK that export such goods to Europe, as well as companies in their supply chains. The precise economic ramifications cannot yet be quantified, not only because of the difficulty in establishing the flow of goods from the UK to the EU covered by the MD (given the complexity of the legal framework for machinery),<sup>55</sup> and the significant changes that recently occurred in the UK-EU trade relationship. However, it is clear UK machinery exports to the EU are significant: according to the Office for National Statistics, in 2020 the UK exported more than £9 billion in general and specialised industrial machinery to the EU.<sup>56</sup>

1.36 The combined impact of the application of the Machinery Regulation under the Northern Ireland Protocol, and the need for British businesses that export machinery to the EU to comply with any EU safety requirements, may also have an impact on the practical benefits of any UK divergence from EU standards in this area.<sup>57</sup>

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54 In addition, conformity assessments performed by UK bodies are no longer recognised in the EU. Instead, where necessary for placing a good on the EU market, these assessments need to be carried out within the EU. Despite the Government's negotiating objectives, the new UK/EU Trade and Cooperation Agreement (TCA) does not contain an agreement on mutual recognition of conformity assessments that would have allowed UK notified bodies to continue certifying that goods — like machinery — meet EU regulatory standards. Conformity assessments carried out by an independent "notified body" in Northern Ireland also do not entitle that product to be sold freely throughout the EU, but only Northern Ireland (and, as noted, the rest of the UK). Such products carry a "UK(NI)" mark in addition to the CE mark.

55 Not all items of machinery are subject to the Machinery Directive. See paragraph 4 of this chapter for more information.

56 Office for National Statistics, "[UK trade: March 2021](#)" (accessed 18 May 2021).

57 For example, divergent safety requirements may cause additional costs for GB-based manufacturers or exporters of machinery in terms of design changes and/or conformity assessments. In addition, manufacturers based outside the EU could potentially circumvent any GB-specific standards by bringing in CE marked goods via Northern Ireland.

## **The Government’s position**

1.37 Recognising the fact that the proposed Machinery Regulation would have direct legal implications for the UK under the Northern Ireland Protocol, the Minister for Small Business, Consumers and Labour Markets (Paul Scully MP) submitted an [Explanatory Memorandum](#) on the Commission proposal in May 2021, to facilitate parliamentary scrutiny of the potential implications of the draft legislation for the UK. The Memorandum confirms that the Regulation “will apply to machinery placed on the market in Northern Ireland” and that, as a consequence of the Internal Market Act 2020, “machinery that meets the qualifying goods criteria and that meets the technical requirements to be placed on the market in Northern Ireland will be able to be placed on the GB market”.

1.38 However, there is no assessment of the Government’s position on the merits of the proposal, despite the fact that the envisaged EU legislation might apply directly in part of the UK, and no information on its strategy — if any — for engagement with the EU institutions to influence the content of the new Regulation. Instead, the Minister notes only that “the UK will make its own decision for products placed on the GB market based on an assessment of the final Regulation and with due consideration of any impacts on the UK internal market, in due course”. As such, at this stage it is unclear if the Government intends to diverge substantially from the approach to product safety set out in the current Machinery Directive or the updated rules set out in the Commission proposal.

## **Conclusions**

1.39 It is clear that the proposal for a new EU Machinery Regulation has potentially significant implications for the UK, both under the Northern Ireland Protocol and for those businesses involved in the large volume of machinery exports from the UK to the EU.

1.40 In light of this, we have written to the Minister for Small Business, Consumers and Labour Markets (Paul Scully MP) to ascertain the Government’s views on the merits of the Commission proposal, in particular with respect to the substantive changes to the safety requirements applicable to certain items of machinery. We are also seeking clarifications on how the Government intends to safeguard the integrity of the UK’s domestic safety standards for machinery when CE marked machinery, produced only to EU specifications, can be sold freely within Great Britain provided it was placed on the market in Northern Ireland first. A copy of the letter is annexed to this chapter of our Report. As shown in chapter 2 of this Report, we have written separately to the Minister for Digital Infrastructure at the Department for Digital, Culture, Media and Sport (Matt Warman MP) in relation to the EU’s proposed Artificial Intelligence Act, which raises similar issues.

1.41 In the meantime, we draw the proposal for a new EU Machinery Regulation, and our assessment of its possible implications for the UK, to the attention of the Business, Energy and Industrial Strategy Committee, the International Trade Committee, the Northern Ireland Affairs Committee and — given the possible implications for machinery used in the workplace — the Work and Pensions Committee.

## ***Letter from the Chair to the Minister for Small Business, Consumers and Labour Markets (Paul Scully MP)***

### **The draft EU Machinery Regulation and implications for the UK**

Thank you for your Explanatory Memorandum of 11 May on the European Commission proposal for a new EU Machinery Regulation, which would revise the safety standards and procedures underpinning the use of the EU’s “CE” mark on machinery products.<sup>58</sup> We have taken note of the potential applicability of this EU legislation in Northern Ireland under the Withdrawal Agreement Protocol in due course, and your commitment that “the UK will make its own decision for [machinery] products placed on the GB market based on an assessment of the final Regulation and with due consideration of any impacts on the UK internal market, in due course”.

Our main concern in relation to this EU proposal is the interaction between the continued application of EU product safety rules in Northern Ireland, and the market access principles under the Internal Market Act 2020.

Given that “qualifying Northern Ireland goods” which are legally on the Northern Irish market can be sold in England, Wales and Scotland as well, there seems to be the potential for EU businesses to circumvent the new UK conformity assessment (UKCA) system (and with it the UK’s independent safety standards) for regulated goods like machinery, by lawfully bringing EU goods onto the market in Great Britain through Northern Ireland first.

This may not raise practical safety issues while EU and UK standards remain the same, and while the CE mark remains valid in the UK for a transitional period until the end of 2021. However, it does seem to have the potential to undermine the integrity of the new UKCA system if, in practice, the CE mark demonstrating compliance with EU requirements remains widely available in addition to the new UKCA mark. Moreover, the EU is now actively considering changes to its machinery safety standards. If the UK does not implement similar amendments to its own standards in due course, this will by definition result in divergent safety requirements between the EU (and Northern Ireland) and Great Britain, even though it seems that goods compliant only with EU standards could still be sold lawfully in Great Britain if they were brought in from Northern Ireland.

In light of this, it would be helpful if you could set out how the Government intends to ensure the integrity of the safety standards underpinning the new UKCA system from 1 January 2022 if CE marked goods on the market in Northern Ireland can still be sold freely in England, Scotland and Wales after that date, and more particularly how it will prevent EU businesses moving their CE marked goods into Great Britain through Northern Ireland for the purpose of avoiding the need to obtain a UKCA mark.

Naturally, any new safety standards and processes for machinery agreed by the EU will also impact on the substantial flows of relevant UK exports to the EU. The evaluation process for the Machinery Directive was initiated in 2018 (and the Government first accepted its

possible continued application in Northern Ireland post-Brexit that same year).<sup>59</sup> We note that the Government itself is also undertaking a review of UK product safety rules, the result of which is likely to be relevant in this context. We would therefore also be grateful if you could outline how the Government has engaged with the Commission and other EU institutions on the potential revision of the Directive to date, and what changes — if any — it would like to see made to the EU’s Regulation’s legal text in the context of the above.

We look forward to receiving your reply by the end of June.

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59 The Protocol requires Northern Irish alignment with the Machinery Directive pursuant to Article 5(4) in conjunction with section 14 of Annex 2. This requirement was present in the [first iteration of the Protocol](#) published in 2018 and remained, in substance, unchanged in the final version of the Protocol negotiated in autumn 2019 and ratified by the UK in January 2020.

## 2 The EU’s Artificial Intelligence Act: possible implications for the UK<sup>60</sup>

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This EU document is legally and politically important because:

- it would establish a new set of risk-based legal standards for certain Artificial Intelligence (AI) applications put on the market within the EU. The Government has said it is likely to have implications for the UK, not least because businesses exporting AI software to the EU will need to meet the new requirements and the EU is also seeking to mould international standards after its chosen regulatory approach; and
- in addition, it is possible that any new EU rules relating to the use of AI as safety components in physical devices could apply in Northern Ireland under the Protocol in the Withdrawal Agreement, with implications for the entire UK market for such goods because of the mutual recognition principle under the Internal Market Act 2020.

### Action

- Write to the Minister for Digital Infrastructure (Matt Warman MP) to seek further information on how the EU proposal might impact on the UK.
- Draw these developments to the attention of the Business, Energy and Industrial Strategy Committee, the Digital, Culture, Media and Sport Committee, the Foreign Affairs Committee, the Joint Committee on Human Rights, the Northern Ireland Affairs Committee and the Science and Technology Committee.

### Overview

2.1 The use of Artificial Intelligence (AI) systems in a range of public and private sector applications has become widespread and is growing. In April 2021, the European Commission published a proposal for a Regulation to establish an EU “[Artificial Intelligence Act](#)” (AIA). This would, for the first time, introduce general legal requirements for AI systems put on the market in the entire European Union. It would, notably, impose a range of new obligations for AI applications considered to be “high risk” (such as safety components in certain goods already subject to EU product standards, or where used for biometric identification of individuals). The Commission proposal can only become EU law after it is approved by the European Parliament and the EU’s Member States in the Council of Ministers. The Act’s substance is therefore still subject to change, and the new EU rules are not expected to take effect until 2024 at the earliest.

2.2 Although the UK of course left the EU in 2020, the EU’s regulatory approach to AI is of direct relevance, as set out in an [Explanatory Memorandum](#) submitted to Parliament by

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60 Proposal for a Regulation laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act); Council and COM number: 8115/21 + ADDs 1–5, COM(21) 206; Legal base: Articles 16 and 114 TFEU; ordinary legislative procedure; QMV; Departments: Digital, Culture, Media, and Sport and Business, Energy and Industrial Strategy; Devolved Administrations: Consulted; ESC number: 41828.

the Minister for Digital Infrastructure (Matt Warman MP) on 21 May 2021. In particular, any UK exports of high-risk AI software to the EU — a market segment the Government is keen to develop<sup>61</sup> — would have to meet requirements under the AIA. In addition, the EU is explicitly seeking to ensure that future international standards relating to AI are modelled on its own regulatory approach, directly cutting across the Government’s own objective — as articulated in the recent “[Integrated Review](#)“ — of taking a leading role in setting international standards for emerging technologies. There may also be implications for the free flow of personal data between the UK and the EU if the EU bans certain uses of such data by AI applications, for example in generalised facial recognition systems in public spaces, but the UK does not.<sup>62</sup> The risk of divergence is currently low, because the UK does not (yet) have a specific regulatory approach to Artificial Intelligence.

2.3 However, there is a further complication. It is possible that the elements of the AIA related to the use of AI safety components in certain industrial and consumer goods may in due course become directly applicable in Northern Ireland. This is because the [Protocol on Northern Ireland](#) in the UK’s Brexit Agreement, broadly speaking, requires Northern Irish rules to remain aligned with EU product standards for most goods. As we explore further in paragraphs 24 to 34, the legal complexity of the proposed AIA makes it difficult to ascertain precisely what the effect of the Act could be under the Protocol. This could also have wider ramifications for the integrity of any future UK regulatory requirements for AI: under the Internal Market Act 2020, goods legally for sale in Northern Ireland that meet EU standards are, with limited exceptions, also allowed to be marketed in England, Wales and Scotland (even if they do not meet any specific product standards applicable there). As Northern Ireland is not required to remain aligned with EU rules for services, the aspects of the AIA not related to physical goods — namely ‘intangible’ applications, such as the restrictions on facial identification technology in public spaces or the requirements relating to the use of AI in sectors like financial services, recruitment or education — would not be directly applicable under the Protocol.

2.4 Taking these factors in combination, it is likely that the EU’s Artificial Intelligence Act could have a significant impact on the future design specifications of AI systems in the UK, as well on the ambitions of the Government’s own [upcoming AI Strategy](#) (expected before the end of 2021)<sup>63</sup> and the future direction of any specific British regulatory approach to this technology. Given that the Government has recently [set itself the objective](#) of playing a “leading role in critical and emerging technologies”,<sup>64</sup> the extent to which the UK might find itself impacted or constrained by parallel EU initiatives in fields like AI could be an important factor for Ministers to consider in realising those ambitions.

2.5 In light of this, we have considered the Commission proposal in more detail below, followed by an assessment of its potential implications for the UK (in particular under the Northern Ireland Protocol).

61 In its [Integrated Review of UK foreign policy](#), published in April 2021, the Government stated it wants to ensure the UK remains a “global leader in developing AI technologies”.

62 As noted, the Government is due to publish an “AI Strategy” later in 2021.

63 The Scottish Government has published an [AI Strategy](#) that identifies “influencing national and international policy and regulation to enable AI technologies to thrive in Scotland” as a priority.

64 Cabinet Office, “[Policy paper: Global Britain in a Competitive Age: the Integrated Review of Security, Defence, Development and Foreign Policy](#)” (16 March 2021).

## Artificial Intelligence in goods and services

2.6 In recent years, the use of Artificial Intelligence (AI) to perform tasks previously undertaken by people has become increasingly widespread. Although there is no universally agreed definition of AI, the OECD [describes](#) it as a “machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments”.

2.7 AI can be used in a range of different contexts as variable as healthcare, transport and law enforcement, both as stand-alone systems or as software integrated into physical products like machinery or medical devices.<sup>65</sup> AI is already being deployed, for example, to use voice analysis to [assess the likelihood of certain medical conditions](#) of those calling an ambulance, to help ‘autonomous’ vehicles [monitor traffic conditions](#), and — in the UK — in trials to [identify individuals in public spaces](#) using facial recognition technology.<sup>66</sup>

2.8 However, the proliferation of AI technology — in both the private and public sectors — has also raised concerns about the new “risks or negative consequences for individuals or for society” that are specific to these systems.<sup>67</sup> Biased data can affect the output of AI systems for different segments of the population — especially, but not only, for ethnic minorities — in areas like healthcare, social security and employment.<sup>68</sup> The technology is also susceptible to false input — so-called “data poisoning” — to manipulate output for unforeseen, potentially illegal, purposes.<sup>69</sup> Similarly, there are human rights implications arising from the use of AI systems in law enforcement, notably through biometric identification of individuals, but also other uses such as “predictive policing” mechanisms.<sup>70</sup> Seeking redress in cases where the use of AI has led to potentially dangerous, unlawful or discriminatory outcomes for individuals or groups can be very difficult, given the typical opacity of the underlying systems and processes.<sup>71</sup>

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65 As defined by the OECD, AI systems in essence consist of three main elements, namely sensors, operational logic and actuators: “Sensors collect raw data from the environment, while actuators act to change the state of the environment. Sensors and actuators are either machines or humans. The key power of an AI system resides in its operational logic. For a given set of objectives and based on input data from sensors, the operational logic provides output for the actuators. These take the form of recommendations, predictions or decisions that can influence the state of the environment.”

66 Live facial recognition in public places been [tried](#) by UK two police forces (namely the Metropolitan Police and South Wales police) at a couple of big events. However, this has proved to be very controversial, and it does not appear to be used routinely at the moment. The Equality and Human Rights Commission has called for a suspension of the use of automated facial recognition and predictive policing tools until they have been independently scrutinised.

67 European Commission document [SWD\(21\) 84](#) (21 April 2021).

68 This might be the case, for example, where a medical device utilising AI technology to make a diagnosis is based primarily on data collected from white people and therefore does not function correctly for black people.

69 The European Commission cites the example of hackers ‘poisoning’ the data used to train a chatbot, such as those used to provide online customer service, to make it disclose sensitive information or adopt other inappropriate behaviour.

70 As [defined](#) by the EU’s European Crime Prevention Network, “predictive policing” systems use AI technology to “calculate the probability of where a crime is most likely going to happen in the future”.

71 See for more information the [note](#) by the Parliamentary Office of Science and Technology (POST) on interpretable machine learning. One potential route for redress is under data protection rules. It was [reported](#), for example, in May 2021 that facial recognition company Clearview AI has been referred to data protection authorities in various EU countries for alleged breaches of the EU’s General Data Protection Regulation.

## Regulation of Artificial Intelligence in the European Union

2.9 As a result of this unique combination of benefits and risks, the ethical implications of the use of AI systems in goods and services — and how these might be addressed through voluntary standards or binding regulation — have been on the national and international political agenda for some time.

2.10 For example, in the UK, the Government’s “[ten tech priorities](#)” include “leading the global conversation on tech” and using its “international voice [...] to champion our democratic values”. It has also produced [guidance](#) on AI ethics and safety and a [Data Ethics Framework](#). Internationally, the OECD issued [recommendations on Artificial Intelligence](#) in 2019 focussed on transparency, safety and accountability, which have formed the basis for “[AI Principles](#)” endorsed by the G20 group of countries that same year. Internationally, the Council of Europe is working on an [international convention](#) on the development, design and application of AI with respect to the protection of “human rights, democracy and rule of law”,<sup>72</sup> while UNESCO has also begun [developing AI ethics standards](#). The [World Trade Organisation](#)<sup>73</sup> and the [International Telecommunications Union](#) (ITU) are also undertaking relevant work. At national level, the UK Government is also preparing an “[AI Strategy](#)”, to which we return — in the context of the EU’s own regulatory efforts — in paragraphs 24 to 48.

2.11 In the EU, the European Commission kicked off the AI policy debate in earnest in 2018, when it published a “[European initiative on AI](#)”.<sup>74</sup> This emphasised the advantages of “AI uptake across the economy” combined with an “appropriate ethical and legal framework” to govern the use of such technology. The EU’s national governments [endorsed](#) this approach in 2019, and that same year the European “High-Level Expert Group on Artificial Intelligence” published [ethics guidelines](#), as well as certain [policy and investment recommendations](#).<sup>75</sup> This was followed in early 2020 by a more [detailed White Paper on Artificial Intelligence](#), in which the European Commission set out a “regulatory and investment oriented approach with the twin objective of promoting the uptake of AI and of addressing the risks associated with certain uses of this new technology”.<sup>76</sup>

2.12 This first objective, of encouraging and facilitating the use of AI in economically or socially beneficial ways, is done primarily by the EU’s individual Member States in line with their own national strategies. These are being linked-up to some extent under the EU’s “[Coordinated Plan on Artificial Intelligence](#)”, first published in 2018 and [updated in early 2021](#) (which has been drawn-up not only with the 27 EU Member States but

72 The Council of Europe has also recently issued [guidelines on the use of facial recognition technology](#).

73 In particular, the WTO is host to multilateral negotiations on a [new E-Commerce Agreement](#) which may impact, for example, on the possibility of signatories to force [external inspections or audits of software](#) (including those underpinning AI systems).

74 In 2015, the European Parliament [called it](#) “vitaly important” for policy-makers to consider the “legal and ethical implications and effects” of the “new industrial revolution” signified by the use of AI in robotics. In October 2017, the European Council — the meeting of EU Heads of State and Government, then still including the UK Prime Minister — [unanimously agreed](#) there was a “sense of urgency” to address emerging trends in Artificial Intelligence by ensuring “a high level of data protection, digital rights and ethical standards” while also boosting the EU’s industrial base and export opportunities for its businesses.

75 The European Commission endorsed the expert group’s ethics guidelines for AI in a 2019 policy paper entitled, “[Building Trust in Human-Centric Artificial Intelligence](#)”.

76 The European Commission terms these an “ecosystem of excellence”, namely measures which “support research, foster collaboration between Member States and increase investment into AI development and deployment” and an “ecosystem of trust” that imposes “robust [legal] requirements that would give citizens the confidence to embrace AI-based solutions, while encouraging businesses to develop them”.

also Norway and Switzerland, but not the UK). In addition, the EU itself is providing further support centrally, in particular by means of funding for research into Artificial Intelligence from its Horizon Europe and Digital Europe programmes,<sup>77</sup> investing in digital skills in the EU’s workforce, and regulating the use of data (an essential input for all AI systems).<sup>78</sup> The EU, UK and a number of other advanced economies also work together through the [Global Partnership on Artificial Intelligence](#) (GPAI) to “support cutting-edge research and applied activities on AI-related priorities”.

2.13 However, with respect to the regulatory element, there is currently no specific European legislation governing the use of Artificial Intelligence systems. Instead, within the EU, the deployment of such technology may be subject to existing European law relating to goods and services, especially product safety and liability rules. However, these do not yet fully take the specific characteristics — and risks — of Artificial Intelligence into account.<sup>79</sup> In addition, individual EU countries have also begun adopting national rules relating to AI.<sup>80</sup> However, as early as 2018, the Commission [noted](#) that the relevant EU rules “may need to be reviewed”, and in its 2020 White Paper it [said](#) that “new legislation specifically on AI may be needed in order to make the EU legal framework fit for the current and anticipated technological and commercial developments”, alongside certain changes to EU product safety and liability rules.

2.14 By July 2020, the Commission had [confirmed](#) it indeed intended to table draft EU legislation “laying down requirements for Artificial Intelligence”,<sup>81</sup> and in April 2021 it published a [formal proposal](#) for an EU Regulation to establish an EU Artificial Intelligence Act (AIA). In the [Impact Assessment](#) accompanying this proposal, the Commission describes two broad objectives for the Act:

- first, it would address the risks that certain uses of Artificial Intelligence pose to the “safety and security” and “fundamental rights” of the EU population, by requiring those that design and use AI systems take such risks into account throughout their lifecycle, and ensuring public authorities have the “powers, procedural frameworks and resources” to enforce those rules. That would also, it hopes, enhance public trust in AI technology;<sup>82</sup> and
- secondly, reflecting the push for increased use of AI, the Commission notes a new EU regulatory approach is necessary to overcome the current “legal uncertainty”

77 The use of AI in defence technology could receive financial support from the EU under the European Defence Fund. However, military applications are not considered further in this Report chapter because they are excluded from the scope of the proposed EU Artificial Intelligence Act.

78 Personal and non-personal data are subject to a range of EU regulatory initiatives, including the [General Data Protection Regulation](#), the [draft Data Governance Act](#) and the [Directive on Reuse of Public Sector Information](#).

79 For example, there is a General Product Safety Directive (GPSD) on consumer products and sector-specific safety legislation for machinery, medical devices and vehicles. Separately, the EU Product Liability Directive (PLD) on liability where defective goods cause physical or material damage to their users. The EU also has a comprehensive legal framework for different types of services that is applicable where AI software is used to provide such services, or integrated into them. However, these rules were not drawn up with AI in mind.

80 The European Commission has [noted](#) that various EU countries including Germany, Denmark, Malta, Spain and Finland have issued ‘soft law’ measures relating to AI, while Belgium, Sweden, Netherlands and Portugal “are considering the need for binding legislation on the legal and ethical aspects of AI”.

81 For example, the Commission received more than 1,250 responses to its 2020 White Paper on Artificial Intelligence, with a further 130 responses to an “Inception Impact Assessment” — an outline of the proposed Artificial Intelligence Act — in July that year.

82 The Commission cites the example of an authority having to examine whether a recruitment decision reached by an AI system was justified or involved discrimination, in the absence of “proper documentation and [...] traceability of these decision-making processes”.

on the division of responsibility and liability between manufacturers and users of AI technology that might deter their uptake in both the private and public sector.<sup>83</sup> In addition, a harmonised EU-wide legal framework would also avoid “diverging national approaches” in different Member States, and instead create a single regulatory space that makes it easier for companies that produce AI systems to scale up their operations across different countries within the EU Single Market.

2.15 Pursuing these objectives, the Commission argues, the Artificial Intelligence Act would boost the EU’s “global competitiveness” as well as its “digital sovereignty”. To achieve this, as we explore in more detail in paragraphs 17 to 20, the Act would establish a harmonised, EU-wide regulatory regime for “high-risk” AI systems, and override any national legislation within the EU Member States covering the same ground.<sup>84</sup> This proposal is now subject to detailed, and most likely lengthy, scrutiny by the 27 EU Member States in the Council of Ministers and by the European Parliament. These two institutions must [jointly agree on the legal text](#) of the Regulation, with amendments where necessary to the original Commission proposal, before it can take effect as EU law. More information on some of the likely flash points and issues of contention in those legislative negotiations is set out in paragraphs 21 to 23.

2.16 Moreover, the proposed Artificial Intelligence Act is only one element of the Commission’s overall strategy to put in place a wide-ranging regulatory framework governing the use of AI within the EU, especially where used in industrial and consumer goods. In parallel to the AIA proposal, it published a [draft EU Machinery Regulation](#) that would — among other things — create new safety requirements related specifically to the use of AI in products like industrial robots and drones. This proposal is the subject of a separate assessment of its implications for the UK in chapter 1 of this Report. By the end of 2021, the Commission is also expected to table AI-related amendments to the EU’s rules relating to [product liability](#) and [general product safety](#) for goods not covered by specific sectoral legislation.<sup>85</sup>

2.17 In the remainder of this chapter, we have assessed the Commission proposal to regulate the use of high-risk Artificial Intelligence systems in more detail, as well as its potential implications for the UK directly, under the Northern Ireland Protocol, and indirectly, because of its international economic and regulatory implications.

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83 The Commission notes, for example, that “providers of AI systems may have limited information with regard to the harm that AI can produce post deployment (especially if the application context has not been taken into account in the design of the system)”, while “users may be unable to exercise due care when operating the AI system if not properly informed about its nature and provided with guidance about the required oversight and ex post control”. In addition, there are no clear rules in the EU at present on how the “general principles or requirements on security, non-discrimination, transparency, accuracy, human oversight should be implemented specifically as regards AI systems in the design and development stage”.

84 The European Commission argues that EU-wide harmonised regulation is appropriate because AI systems “may be embedded in any product or service circulating freely within the internal market”. Moreover, it says, “an emerging patchwork of potentially divergent national rules will hamper the seamless circulation of products and services related to AI systems across the EU” and would be “ineffective in ensuring the safety and protection of fundamental rights [...] across the different Member States”, and “national approaches in addressing the problems will only create additional legal uncertainty and barriers, and will slow market uptake of AI”.

85 The European Commission has also [announced](#) that it intends to “map and analyse” how inventions created with the use of AI should be treated under EU intellectual property law, although no specific legislative initiative is foreseen in that regard at this stage. See for more information [chapter 2 \(EU Intellectual Property Action Plan\)](#) of our Thirty-eight Report of Session 2019–21.

## The proposed EU Artificial Intelligence Act

2.18 The [draft EU Artificial Intelligence Act](#) proposed by the Commission in April 2021 would establish risk-based, cross-sectoral European rules for AI technology for the first time.<sup>86</sup> A full, detailed analysis of all aspects of the proposed AIA is beyond the scope of this Report, and in any event the substance of the legislation is likely to change significantly as it is considered by the EU’s Member States and by the European Parliament. We therefore limit ourselves here to a brief description of the key elements of the proposal, followed by an assessment of some of the likely areas of contention in the legislative process in Brussels (paragraphs 21 to 23) and of the possible implications of the draft legislation for the UK (paragraphs 24 to 48).

2.19 In summary, the core elements of the Commission proposal are as below. The draft Regulation focuses mainly on addressing risks associated with the application of AI, with comparatively little provision on innovation and research:<sup>87</sup>

- first, the definition of what counts as “Artificial Intelligence”, as set out in the draft Act, is very broad and is meant to be “future proof” and technology-neutral. The UK’s Office for AI and Centre for Data Ethics and Innovation have [concluded](#) for example that it could cover certain databases and weather apps, in addition to more obvious systems such as facial recognition technology;<sup>88</sup>
- secondly, a number of uses of AI would be prohibited altogether throughout the EU because they “violat[e] fundamental rights”.<sup>89</sup> Blacklisted practices would include “subliminal techniques [...] to materially distort a person’s behaviour in a manner” considered harmful, as well as the use of ‘social scoring’ systems by public authorities to evaluate the “trustworthiness of natural persons” where this could affect, for example, their access to social security other public services. However, the Commission has not — as it had been encouraged by some — proposed an outright ban on the use of “remote biometric identification” (RBI), like facial recognition technology, in public spaces;<sup>90</sup>

86 As noted, it is flanked by a separate proposal to amend the EU Machinery Directive, with two further proposals under preparation relating to how AI affects product safety and liability requirements.

87 The draft Artificial Intelligence Act does contain a short section on “regulatory sandboxes”. Normally these are controlled environments where certain regulatory requirements are waived to “facilitate the development and testing of innovative AI systems under strict regulatory oversight”. However, under the Commission proposal, any AI systems being developed in such environments do not appear to benefit from any actual derogations from the usual safety requirements under the draft Regulation.

88 The definition of AI is set out in Article 3 and Annex I of the Regulation, and covers any software that “for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with”, where they rely on techniques including “machine learning approaches”, “logic and knowledge-based approaches” and “statistical approaches, Bayesian estimation, search and optimization methods”. The European Commission would be empowered to update the techniques that qualify as AI by means of a Delegated Act — a type of EU statutory instrument — taking into account “market and technological developments”.

89 Article 5 of the draft AIA.

90 The proposal in essence leaves the question of whether to permit use of RBI to each individual EU country. However, its use by law enforcement in public spaces to monitor people in ‘real time’ would be prohibited, unless certain safeguards are in place. Article 5(1)(d) of the draft AIA specifies that such use of real-time RBI would be permitted if it is for the “targeted search for specific potential victims of crime”, for the “prevention of a specific, substantial and imminent threat to the life or physical safety of natural persons or of a terrorist attack” or, broadly speaking, for the “detection, localisation, identification or prosecution of a perpetrator or suspect of a criminal offence” for which a [European Arrest Warrant](#) could be issued.

- thirdly, a number of applications of AI<sup>91</sup> are classified as “high risk” in the proposal, notably safety components in a range of industrial and consumer goods already subject to sector-specific rules under EU law,<sup>92</sup> but also certain “stand-alone” system (including biometric identification technology,<sup>93</sup> various AI applications in law enforcement,<sup>94</sup> and AI systems that determine access to public and private services such as social security,<sup>95</sup> education, financial services and recruitment). AI safety components in physical devices *not* already subject to product-specific rules under EU law would not be covered by the proposal;<sup>96</sup>
- artificial Intelligence systems considered “high risk”<sup>97</sup> would be subject to a range of new regulatory requirements that must be met before they can be placed on the market or put into service in the EU.<sup>98</sup> The draft Regulation would require, [among other things](#), that their designers ensure an “appropriate level of accuracy, robustness and cyber-security”, incorporate data governance safeguards (to ensure the quality of the data underlying the AI’s operations, and to counter “data poisoning”, for example), and include record-keeping capabilities to ensure that decisions made by their systems are traceable. Designers would be able to use international standards relevant for their product as a technical solution to meet these requirements, but only where those standards have been requested and approved for that purpose by the European Commission.<sup>99</sup> On request, designers would also have to give public authorities confidential access to the source code underpinning their AI software;
- conceptually, the proposed regulatory approach to high-risk AI reflects the EU’s existing legal framework for product safety. Like manufacturers of machinery or household appliances must do under the EU rules applicable to their sectors, providers of AI software would usually have to apply a “conformity assessment”

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91 The use of AI in systems used by the armed forces of the EU’s Member States are explicitly excluded from the scope of the Regulation.

92 Goods included in the scope of the Regulation are machinery, medical devices, toys, marine equipment and cars.

93 This would apply to use of AI for such purposes by both public and private entities, including in ‘real time’ and after the fact (for example matching a photo or video still to a data set of faces).

94 With respect to “high risk” AI systems in law enforcement, the proposal explicitly cites systems that assess the risk of someone “offending or reoffending” or becoming the victim of crime, or evaluate the reliability of evidence in criminal proceedings.

95 The draft AIA specifies that use of an AI system would be classified as “high risk” if it is used by (or on behalf of) public authorities in the course of their duties, including evaluating eligibility of natural persons for public services such as social security, determining the priority dispatch of emergency services, or the assessment of applications for visas, work permits or asylum.

96 However, the European Commission is separately preparing a revision of the EU’s General Product Safety Directive which will, among other things, address the use of AI in all goods placed on the EU market that are not covered by product-specific safety rules at EU-level.

97 The Commission would be empowered to add new types of AI uses to the list of systems defined as “high risk” in the future by means of Delegated Acts. These are a type of EU statutory instrument, which can be vetoed by either the EU Council of Ministers or by the European Parliament.

98 Under existing EU legislation like the Machinery Directive or the Toys Directive, the EU has set mandatory health and safety principles for these goods. Manufacturers must attest compliance of their individual products through a “Declaration of Conformity” as evidenced by the well-known “CE” mark. In some cases, conformity must be assessed by an independent “notified body”, while in others the provider can declare the product compliant after an internal assessment process.

99 The Government has [suggested](#) that “UK stakeholders, whilst not being party to defining the Commission request, can participate in the writing of harmonised standards”. The proposal would also give the European Commission the power to establish “technical specifications”, which would be EU-only standards to cover “areas where no harmonised standards exist or where they are insufficient”.

to ensure compliance with the new safety standards.<sup>100</sup> In many cases, this assessment could be carried out by the designer of the AI system ‘in-house’. However, in some cases it would be mandatory for the assessment to be made by an independent “notified body” (notably for high-risk AI used in certain biometric identification systems<sup>101</sup> and certain industrial goods). In many cases, the manufacturer would have to affix the well-known “CE mark” to their product to declare the product has been subject to a positive conformity assessment, allowing it to be sold freely throughout the entire EU without further national approvals; and

- fourthly, there would be a category of AI systems which pose a “limited risk” of manipulation of individuals like automated “chat-bots” or software to create so-called “deep fakes” (where AI is used to create convincing images or videos of events that have not actually taken place). These would be subject to a number of transparency obligations, for example to make sure that that users are aware the content they are viewing is not real, or that they are interacting with software rather than a person.<sup>102</sup>

2.20 The key features of the draft AIA are shown in the table below.

Type of AI system	Example	Regulatory approach	Conformity assessment
<b>Blacklisted</b>	Social scoring of individuals by public authorities	Prohibited	N/a
<b>High-risk</b>	Biometric recognition software, safety components in certain industrial and consumer goods	Expansive regulatory requirements related e.g. to data governance and record-keeping	Mandatory <sup>103</sup>
<b>Limited risk</b>	Automated chat-bots	Transparency obligations	N/a

100 The Regulation sets out two different approaches to the application of requirements for AI used as a safety component in goods, depending on the nature of the EU’s existing sectoral rules for each category of goods (the so-called “new approach” or “old approach”). The difference, broadly speaking, between the two is that under the “old approach” detailed technical specifications for a product are set out in EU law, for example for vehicles. Under the “new approach”, EU law sets high-level health and safety requirements that goods must comply with, but leaves it to the manufacturer to decide on the appropriate technical solutions to meet those requirements.

101 For biometric identification systems, developers would be permitted to rely on an internal assessment of compliance only if the software relies entirely on established technical standards (international harmonised standards or EU technical specifications) approved by the EU for that purpose. For the use of high-risk AI in other services, developers would be permitted to certify ‘in-house’ that the requirements of the Regulation are met. However, the Commission would be able to use Delegated Acts — a type of EU statutory instrument — to make high-risk stand-alone AI systems subject to independent conformity assessment procedures in the future. The proposal also foresees that the EU would establish a public database of high-risk stand-alone AI systems.

102 For AI systems which do not fall into any of the three categories above, the Regulation foresees the establishment of non-binding “codes of conduct” that would mirror the requirements of the AIA to be taken up by relevant AI providers on a voluntary basis.

103 Whether the conformity assessment must be carried out by an independent “notified body” or can be undertaken by the manufacturer itself will vary depending on the applicable sectoral rules and the provisions of the AIA.

Type of AI system	Example	Regulatory approach	Conformity assessment
Low risk	Spam filters	Voluntary Codes of Conduct	N/a

2.21 In principle, where AI software is imported into the EU from a non-EU country like the UK, the importer would be required to ensure that the product has been subject to the appropriate conformity assessment.<sup>104</sup> Enforcement of the AIA, namely through market surveillance activities *after* systems have been put on the EU market, would be primarily the responsibility of individual EU Member States.<sup>105</sup> Breaches of the Act could lead to significant financial penalties, capped at either €30 million (£26 million) or 6 per cent of total worldwide annual turnover, whichever is higher. However, despite [calls from some stakeholders](#), there are no specific provisions on redress for individuals who have been harmed by an AI application that contravened the new Regulation.<sup>106</sup>

### **Legislative deliberations on the draft Artificial Intelligence Act**

2.22 As noted, the Commission proposal for the Artificial Intelligence Act [must still be agreed](#) by the Member States in the EU’s Council of Ministers (by qualified majority) and by the European Parliament. These two institutions will in the first instance elaborate their own positions on the draft legislation, before eventually engaging in so-called “trilogue” negotiations — analogous to “ping pong” in the UK Parliament — to arrive at a jointly-agreed legal text. Realistically, given the novelty and technical complexity of the proposal, coupled with the breadth of sectors and systems on which the impact needs to be considered, this process is likely to take well over a year and possibly significantly longer.<sup>107</sup>

2.23 The proposed design of the AIA has not been without controversy, in particular the relatively short blacklist of forbidden practices.<sup>108</sup> The European Data Protection Supervisor [criticised](#) the Commission for not proposing a full ban on the use of remote biometric identification systems in public spaces, whereas — as civil rights organisation Statewatch has [reported](#) — the EU’s national Governments are ready to discuss *weakening* the proposed safeguards on use of AI for law enforcement and security purposes. Consumer rights umbrella body BEUC wants the AIA to incorporate [stricter consumer protection safeguards](#) for AI systems that may not be high risk in terms of possible “physical and

104 Article 26 of the draft AIA.

105 The EU Market Surveillance Regulation ([Regulation 2019/1020](#)) would apply to AI software. However, the European Commission would also have certain supervisory powers against “notified bodies” which may not be acting independently in assessing conformity of AI systems with the Act. See Article 37 of the draft AIA.

106 The draft Regulation foresees extensive transitional provisions to take into account the fact that a range of AI systems are already in use in the EU: the new rules will not apply to systems put on the market before date of application of the AIA, except if they are “are subject to significant changes in their design or intended purpose” afterwards.

107 The Slovenian Government, which holds the rotating Presidency of the Council of Ministers during the second half of 2021, is [hoping to secure a common negotiating position](#) among the 27 EU Member States — a so-called “general approach” — before the end of the year, which could enable talks with the European Parliament to begin in 2022. The Internal Market and Consumer Protection (IMCO) Committee of the European Parliament, which leads on the proposal on behalf of MEPs, has not published a timetable for its consideration of the draft Act.

108 The European Commission’s own Regulatory Scrutiny Board assessed a draft of the proposal in November 2020 and concluded that it did not adequately consider the different regulatory options open to the EU, or link them to the risks identified with respect to Artificial Intelligence, nor quantify the costs of the chosen legislative route.

psychological harm” (the threshold used by the Commission in its proposal), but could cause detriment through monetary loss or discrimination. Conversely, Digital Europe — a trade body representing companies including Amazon, Apple and Facebook — have [said](#) that the new requirements are not “simple and clear enough” and could, in particular, deter innovative start-ups using AI technology from establishing themselves within the EU. Indeed, it has been [argued](#) that the requirements of the AIA — when taken in combination with existing European rules for specific products like medical devices — could even stifle a ‘domestic’ AI industry within the EU.

2.24 In practice, most if not all of the components of the European Commission proposal will be up for debate in the legislative deliberations in Brussels, which will also complicate the timetable for the Regulation’s formal adoption and entry into force. As such, given that the Commission has suggested there should be a two-year implementation period after the legislation is agreed, the EU Artificial Intelligence Act is unlikely to apply until 2024 at the earliest.

### Implications of the EU Artificial Intelligence Act for the UK

2.25 The UK of course left the European Union on 31 January 2020, and EU law — generally speaking — no longer applies following the end of the post-Brexit transition period on 31 December 2020. As such, the EU Artificial Intelligence Act — as and when it is formally adopted and takes effect — will not apply directly in the UK’s legal order as it would have while it was a Member State of the EU.

2.26 However, this does not mean that the AIA has no implications for the UK. It may have direct legal effects because it is possible that these new EU rules, insofar as they relate to the safety of physical products that include AI software, could take effect in Northern Ireland under the UK/EU Withdrawal Agreement. Moreover, the EU’s regulatory approach may also eventually require UK exporters of AI software to modify their products, and influence any international standards in this field. The Minister for Digital Infrastructure (Matt Warman MP) submitted an [Explanatory Memorandum](#) with the Government’s position on the proposal on 21 May 2021, which also touches on these issues, and which we consider in more detail below.<sup>109</sup>

### *The potential application of the AIA under the Northern Ireland Protocol*

2.27 The UK, Northern Ireland included, formally left the EU’s Customs Union and Single Market on 31 December 2020. In principle, that means that goods moved from the UK to the EU are now subject to customs and regulatory controls at the border. However, to avoid the need for any infrastructure on the land border on the island of Ireland (which might otherwise be considered necessary for Irish authorities to verify compliance of goods entering Ireland from the UK with EU rules and vice versa), the UK and EU agreed a special “[Protocol on Ireland/Northern Ireland](#)“ in the Withdrawal Agreement that set the terms of the UK’s exit from the European Union.

2.28 This Protocol, among other things, requires Northern Ireland to remain aligned to a long list of EU rules related to the manufacture of industrial goods until at least the

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109 Following the end of the post-Brexit transition period, only EU proposals which may affect legislation in the UK under the Northern Ireland Protocol are ‘deposited’ for formal scrutiny by the Government and the subject of Explanatory Memoranda.

end of 2026.<sup>110</sup> In return, goods on the market in Northern Ireland can be moved across the border into Ireland — and, hence, the entire EU Single Market — without physical controls. These are, instead, carried out on trade between Great Britain and Northern Ireland.<sup>111</sup> Moreover, the alignment provisions of the Protocol are dynamic: its references to EU rules “shall be read as referring to [them] as amended or replaced” by the EU in the future.<sup>112</sup> However, for the inclusion of ‘new acts’ that the EU believes should apply under the Protocol but which do *not* amend or replace rules already listed, the Government must give its explicit consent before they would apply in and to Northern Ireland.<sup>113</sup> If the UK refused an EU request to that effect, the latter would be entitled to take (unspecified) “appropriate remedial measures”.<sup>114</sup>

2.29 The way the AIA would alter (or not) existing EU product safety rules already listed in the Protocol is therefore key to understanding whether its requirements related to AI in physical goods (but not stand-alone AI systems) might eventually apply directly in Northern Ireland.<sup>115</sup> As Northern Ireland is not required to remain aligned with EU rules relating to services, the aspects of the AIA not related to physical goods — namely ‘intangible’ applications, such as the restrictions on facial identification technology in public spaces, or the requirements relating to the use of AI in sectors like financial services, recruitment or education — would not be directly applicable under the Protocol. However, the European Commission proposal would also introduce new requirements for AI technology used as safety components in a range of regulated goods like machinery, medical devices and toys, supplementing existing EU rules applicable to those specific sectors. It is relevant in this respect that all but two of the 19 pieces of existing EU product safety legislation that would be supplemented by the AIA are listed in the Protocol, and thus remain in effect in Northern Ireland<sup>116</sup>

2.30 Nevertheless, even with respect to the safety standards for AI in physical goods, it is not necessarily straightforward to determine whether the AIA would automatically apply

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110 The provisions of the Protocol that require Northern Ireland to remain aligned with EU law on goods are subject to the periodic democratic consent of the members of the Northern Ireland Assembly under Article 18 of the Protocol. They are due to vote on whether to keep those provisions in effect for the first time no later than the end of 2024, and if they reject them that element of the Protocol will become inoperative after a two-year period, i.e. from the end of 2026.

111 Article 5(4) and Annex 2 of the Protocol.

112 We are of course aware that the operation of the Protocol is highly controversial because of the imposition of checks on trade between Northern Ireland and the rest of the UK, and talks are on-going between the Government and the EU about its implementation and potential flexibilities in that respect. In the absence of a clear decision on the future of the Protocol, we have assumed for the purposes of our assessment here that it will remain in effect until at least the end of 2026 as foreseen by the Withdrawal Agreement.

113 Article 13(4) of the Protocol. The inclusion of a new act in the Protocol would require a Decision of the UK/EU Joint Committee established by the Withdrawal Agreement.

114 Article 13(4) sets out the conditions for such measures “If the Joint Committee has not taken a decision referred to in the second subparagraph within a reasonable time, the Union shall be entitled, after giving notice to the United Kingdom, to take appropriate remedial measures. Such measures shall take effect at the earliest 6 months after the Union informed the United Kingdom in accordance with the first subparagraph, but in no event shall such measures take effect before the date on which the newly adopted act is implemented in the Union.”

115 As Northern Ireland is not required to remain aligned with EU rules relating to services, the aspects of the AIA not related to physical goods — such as the restrictions on facial identification technology in public spaces, or the requirements relating to the use of AI in sectors like financial services, recruitment or education — would not be directly applicable under the Protocol.

116 The two pieces of EU product safety legislation that would be supplemented by the draft AIA but are not listed in the Northern Ireland Protocol are Regulation (EC) No 300/2008 on common rules in the field of civil aviation security and Regulation (EU) 2018/1139 on common rules in the field of civil aviation (in so far as it concerns the design, production and placing on the market of unmanned aircraft).

under the Protocol. This is because the approach taken by the Commission in its proposal as to how the new rules would be integrated into the existing EU sectoral rules for specific types of goods is complex:

- For goods covered by the EU’s so-called “New Legislative Framework” (NLF), where EU law sets high-levels safety principles but leaves it to manufacturers to decide on the appropriate technical means to achieve them,<sup>117</sup> the AIA would create a stand-alone regulatory regime. This covers, for example, machinery, medical devices, toys and lifts. The Regulation as drafted would not make any *explicit* amendment to the EU’s existing rules for those products, and it cannot be said to “replace” them either. Rather, relevant businesses in the supply chain for such goods — notably manufacturers and importers — would be required to apply any new obligations under the AIA *in addition to* their existing obligations.
- For goods subject to the EU’s “old approach” — where EU law contains detailed technical specifications for particular products — the AIA would explicitly amend existing legislation to require the European Commission to incorporate the new requirements for AI safety components when updating those EU’s technical standards for those goods in the future. This notably covers vehicles (including autonomous ones) and marine equipment. This means the proposed legal requirements for AI would be indirectly integrated into the relevant legal frameworks in due course. Unlike for the goods covered by the “new approach”, the AIA itself would then not apply directly to those sectors.<sup>118</sup>

2.31 With respect to the implications under the Northern Ireland Protocol, it appears to us that the amendments the AIA would make to the EU rules for goods under the “old approach” would be applicable automatically under the Protocol. This means that the European Commission would be empowered to set legal requirements for AI safety components used in such goods derived from the provisions of the Artificial Intelligence Act, and these would also apply in and to Northern Ireland. However, for the goods covered by the “new approach”, where the AIA would create a stand-alone regulatory regime without explicitly amending the existing EU rules that are listed in the Protocol, it would seem that the EU would need the UK’s consent as described above before the new rules would apply to those manufacturing or importing relevant goods with an AI safety component into Northern Ireland.

2.32 As noted, AI safety components in physical devices *not* already subject to product-specific rules under EU law would not be covered by the new regulatory requirements. However, the European Commission is also [preparing a revision of the EU’s General Product Safety Directive](#) which will, among other things, address the use of AI in all goods placed on the EU market that are not covered by specific safety rules at EU-level. The implications of that draft EU legislation under the Protocol will need to be assessed separately in due course.

2.33 The UK Government’s position on the interaction between the Commission proposal and the Protocol is set out in the Minister’s Explanatory Memorandum. The Government’s view is that the Artificial Intelligence Act as a whole is “not already within scope of the

117 The EU’s NLF approach covers products including machinery, medical devices and toys.

118 Article 2(2) of the draft AIA provides that, with respect to goods covered by the “old approach”, “only Article 84 of this Regulation shall apply”. Article 84 relates to a future evaluation of the Artificial Intelligence Act.

Protocol”. This implication appears to be that, as far as the Government is concerned, the UK would have to give its consent before *any* of the goods-related provisions of the AIA would apply in Northern Ireland, including those that explicitly amend the<sup>119</sup> It is not clear whether the Government believes that this also applies to the explicit amendments the AIA would make to the “old approach” product safety rules to allow the Commission to set AI-related safety requirements for relevant goods, which *prima facie* would appear to be applicable automatically under the Protocol. Indeed, the Minister also adds that the Government “is currently considering how the proposals interact with the existing EU product safety legislation that is included in [...] the Northern Ireland Protocol”.

2.34 In any event, we consider it a strong possibility that the EU will, in due course, push for all aspects of the AIA that relate to physical goods to also apply in Northern Ireland under the Protocol. Otherwise, products manufactured in or brought into Northern Ireland which use AI as a safety component would not have to meet the EU’s new regulatory requirements, but could still be sold freely throughout the EU (because of Northern Ireland’s unique access to the Single Market for goods under the Protocol). Conversely, that could also mean that — in the future — products with an AI safety component that are legal for sale and use in Great Britain may not be permitted in Northern Ireland, if they do not meet the requirements under the AIA.

2.35 It is unclear if the Government and the EU have discussed the potential applicability of the AIA under the Protocol. The European Commission proposal and the accompanying Impact Assessment do not refer to Northern Ireland at all. The Minister’s Explanatory Memorandum does not indicate whether any bilateral discussions on this matter have taken place. Similarly, while the UK-EU Joint Consultative Working Group (JCWG), where the EU informs the Government of “planned [EU] acts within the scope of this Protocol” has met since the Commission published its proposal, there are no public statements or minutes to confirm whether the Artificial Intelligence Act was discussed.<sup>120</sup>

2.36 It therefore is not known at this stage whether the AIA will apply to some extent under the Northern Ireland Protocol. This will depend not only on the Government’s position, but also how the substance of the Regulation develops throughout the legislative process in Brussels. However, the question of whether the safety requirements for products set out in the AIA will apply under the Northern Ireland Protocol could also have implications for the market for such goods in the rest of the UK.

### ***Sale of goods with AI safety features that meet EU safety standards in Great Britain***

2.37 While the Protocol means that EU safety standards applicable under the Protocol — including, potentially, those relating to AI — must be met for goods moved from Great Britain into Northern Ireland, the same is not necessarily true for trade in the other direction.

2.38 In particular, the Government has a stated commitment to providing Northern Ireland with “unfettered access” to the UK’s internal market despite the trade barriers created by

119 As noted, if the UK rejected a request by the EU for a ‘new act’ to be included in the Protocol, it would subject to “appropriate remedial measures” by the EU.

120 For example, the JCWG is known to have met on 12 May 2021, a few weeks after the European Commission published its proposal.

the Protocol. This [means](#) that there “should be no additional process or paperwork and there will be no restrictions on Northern Ireland goods arriving in the rest of the UK”. More specifically, the [United Kingdom Internal Market Act 2020](#) (UKIMA) provides for the principle of “mutual recognition” under which “a good that can be lawfully sold in the part of the UK in which it has been produced or imported into may be sold in any other part of the UK without needing to comply with any relevant requirements applying to the sale in that other part”.

2.39 However, special rules apply under the Act to goods from Northern Ireland, to reflect its current unique position straddling the UK and EU’s internal markets. This is because the “unfettered access” commitment means EU goods could enter the UK market via Northern Ireland without customs or regulatory controls (which they would face if they entered Great Britain directly from the EU). To avoid such circumvention of the UK’s customs perimeter, the mutual recognition principle under the UKIMA normally applies only to so-called “qualifying Northern Ireland goods” (QNIG). However, the current [legal definition](#)<sup>121</sup> of such goods is extremely broad, described as products that “are in free circulation in Northern Ireland”.<sup>122</sup>

2.40 This might become problematic,<sup>123</sup> because it appears that any good that meets EU standards and has been placed on the market in Northern Ireland can, in principle, be sold freely in Great Britain without — where otherwise required — a conformity assessment to demonstrate compliance with British standards.<sup>124</sup> While UK standards remain de facto aligned with those it inherited from its membership of the EU, this does not necessarily create any problems. However, in the future, interaction between the Protocol and the Internal Market Act means EU companies could circumvent new independent UK standards (and any applicable conformity assessment requirement) by bringing EU-compliant goods into Great Britain via Northern Ireland.<sup>125</sup> If the elements of the EU Artificial Intelligence Act relating to physical goods do become applicable under the Protocol, that would include products with an AI safety component that meet EU

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121 As set out in the [Definition of Qualifying Northern Ireland Goods \(EU Exit\) Regulations 2020](#) made by the Government under Section 8C(6) of the European Union (Withdrawal) Act 2018.

122 In other words, goods in Northern Ireland that are not under a [customs procedure](#) or in an authorised temporary storage facility. In addition, [Section 11 of the UK Internal Market Act 2020](#) provides that goods which do are not “qualifying goods” but “are moved in a way that would, but for the fact that Northern Ireland is a part of the United Kingdom, amount for the purposes of the mutual recognition principle for goods to the importation of the goods into England, Scotland or Wales, the goods are to be regarded for the purposes of that principle as having been so imported” and therefore fall within the scope of the mutual recognition principle.

123 While UK safety standards for regulated goods remain in substance identical to the EU’s for the time being, the Government is — for example — phasing out the use of the CE mark (used as a sign of conformity with EU product safety standards for many goods) in Great Britain. It is being replaced with a new “[UKCA](#)” mark to attest compliance with safety standards as they apply independently under UK domestic law. However, the UKCA mark [will not be used](#) in Northern Ireland precisely because it remains bound by EU product safety rules under the Protocol and, consequently, will continue to use the EU’s CE mark where required. There have also been reports that full roll-out of the UKCA mark, originally planned for completion by 1 January 2022, [is being pushed back](#).

124 For example, the Health and Safety Executive has [confirmed](#) that businesses “will be able to place qualifying Northern Ireland goods on the market in Great Britain based on the conformity markings you use in Northern Ireland”, i.e. the CE mark.

125 The Treasury has already created a general anti-avoidance rule allowing it to impose duty on goods brought into Great Britain via Northern Ireland from the EU where the purpose of moving those goods was to avoid any UK customs duty or customs obligation, although it is not clear to what extent this has made a difference in practice. This rule also appears limited to the issue of duty avoidance, not product safety standards.

requirements, even if they do not meet — or not have been assessed for compliance with — any safety standards for such systems as may be set out in law in the rest of the UK in the future.

2.41 The Government is aware of the risk of circumvention of the UK’s regulatory regime where goods from the EU are imported into Great Britain through Northern Ireland, and has [indicated](#) that it intends to change the legal definition of “qualifying goods” for unfettered access in the second half of 2021. The aim will be to “focus the benefits of unfettered access solely and exclusively on Northern Ireland businesses” and “ensure that goods moving from Ireland or the EU [via Northern Ireland] are subject to full third-country checks and controls” when they enter Great Britain.<sup>126</sup> It is unclear at this stage how it intends to do so, and how relevant public authorities, like those engaged in market surveillance or customs, would differentiate in practice between qualifying and non-qualifying goods brought into the rest of the UK from Northern Ireland.

2.42 In any event, even if the Regulation did apply to some extent under the Protocol, there is no *immediate* risk that divergence in standards for AI safety components in goods between the EU (should they also apply in Northern Ireland under the Protocol) and Great Britain could lead to goods that do not meet UK requirements being circumvented through the “unfettered access” provisions, not least because the EU Artificial Intelligence Act is unlikely to take effect for several years.<sup>127</sup> In addition, there is no specific AI regulation under UK law at present, so by definition any EU product standards would seem to be compatible with British safety requirements (although this might change if the Government commits to new legislation under its [upcoming AI Strategy](#)).

2.43 Naturally, if the AIA does not apply in any way under the Protocol, the above considerations would not apply. However, the separate Commission proposal for a new EU Machinery Regulation, which we consider in chapter 1 of this Report, and its upcoming proposals updating EU rules on product safety and liability in light of emerging technologies like AI, could also amend or replace EU legal acts listed in the Protocol. The above considerations with respect to their future applicability within Northern Ireland — and with consequences under the Internal Market Act — also apply in those cases.

### ***Possible impact of the EU Artificial Intelligence Act on industry practices, UK regulation and international standards***

2.44 Aside from the potential direct legal ramifications of the AIA under the Northern Ireland Protocol, the Minister’s Explanatory Memorandum notes that EU’s approach to AI also raises broader policy issues for the UK.

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126 For example, on 30 November 2020 the Government told the House of Lords that the current definition of “qualifying Northern Ireland goods” was “focused on avoiding disruption and maintaining continuity for the first half of [2021]”. However, imposing a more restrictive definition of “qualifying goods” raises the question of how the Government would differentiate between qualifying and non-qualifying goods, given its opposition to border controls on trade between Northern Ireland and the rest of the UK.

127 There is a broader question of the extent to which the AIA, once in force, will overlap with the provisions of the Protocol that would require Northern Ireland to align with EU product safety rules. The Members of the Northern Ireland Assembly will vote on the continued operation of parts of the Protocol by the end of 2024, and it is possible the alignment requirements will cease to have effect (including, in this context, the application of the AIA) by December 2026. This is without prejudice to any new arrangements to replace the Protocol that the UK and EU might negotiate in such circumstances, which may still require some form of Northern Irish alignment with EU rules.

2.45 First, he notes that any exports of AI from the UK to the EU would need to meet the applicable EU safety requirements. This will require a conformity assessment to demonstrate compliance with the EU AIA, where necessary carried out (for a fee) by an EU-based “notified body”.<sup>128</sup> The Minister’s Explanatory Memorandum refers to this as the “extraterritorial” effects of the proposal, generating “financial and administrative burdens for such UK businesses developing or manufacturing “high-risk” AI systems”. Although the value of the EU as an export market for AI software from the UK is unclear, the Government has stated it wants to ensure the UK remains a “global leader in developing AI technologies” in its recent [Integrated Review](#), suggesting it is keen to develop exports further. The way the EU, as one of the UK’s largest trading partners, chooses to regulate this market will therefore also have an impact on the way British AI systems are designed.

2.46 In addition, the EU is also expected to push for international standards relating to AI to mirror its own regulatory approach.<sup>129</sup> The European Commission proposal refers to the “growing risk of divergence” between voluntary international standards for AI technology “adopted by different international organisations”. It added that the EU should “leverage its tools and regulatory powers to shape global rules and standards”, using its market size to utilise the “Brussels effect” and shape international standards after EU rules. The link between international standards and the AIA is also underlined by the fact that designers of AI software could benefit from a “presumption of conformity” with the requirements of the Act where they rely on such standards, provided they have been approved for that purpose by the EU.

2.47 The Minister’s Memorandum also states that “the EU’s chosen approach could also influence the direction of international AI governance”. Again, the Government in its [Integrated Review](#) identified “regulatory diplomacy” as a key UK priority, enabling it to “shape the standards and values that will underpin the global economy in the future” (including AI technology).

### ***Implications for exchange of personal data between the UK and EU***

2.48 The Artificial Intelligence Act as proposed would place restrictions on the use of AI applications by both public and private entities, in particular with respect to certain uses of biometric identification systems by law enforcement authorities that rely on personal data to identify individuals. In that sense, the Commission proposal complements existing EU data protection rules set out in the General Data Protection Regulation and the Law Enforcement Directive.

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128 Following the UK’s exit from the Single Market on 31 December 2020, “notified bodies” based in the UK — including those in Northern Ireland — can no longer carry out conformity assessments for goods intended for the EU market. The UK/EU Trade and Cooperation Agreement, despite the Government’s efforts, does not provide for mutual recognition of conformity assessments (which would allow UK bodies to certify conformity of a product with EU rules). As such, UK exporters of products requiring an independent “third party” conformity assessment now need to pay a “notified body” based in the EU instead. The UK is also phasing out acceptance of the “CE mark” as a valid sign of conformity with post-Brexit domestic safety standards for goods, replacing it with a “UKCA” mark instead. This is not immediately relevant in this context as there are no AI-specific standards in the UK and therefore no UKCA certification is currently required. However, this divergence does pose potential problems for other industrial goods, which we have explored in more detail elsewhere in this Report in relation to the proposed new EU Machinery Regulation.

129 The EU’s position in international fora is likely to be fluid for the time being, as deliberations in Brussels on the substance of the Artificial Intelligence Act continue.

2.49 These additional restrictions on how data could be used by AI systems within the EU may also, indirectly, have implications for the flow of personal data between the UK and the EU.<sup>130</sup> In June 2021, the EU is expected to formally put in place “[adequacy decisions](#)” that declare the UK’s statutory protections for personal data broadly equivalent to the EU’s laws, and allowing data relating to EU residents to continue to flow freely to the UK. These adequacy decisions have been [described](#) as “overwhelmingly in the interests of both sides, as well as the thousands of UK and EU individuals, businesses and civil society groups that exchange data every day” by industry body TechUK. The Government also considers it important enough that it [legally committed](#) under the UK/EU trade deal to remain aligned to EU data protection rules until the end of June 2021, to give the EU time to put ‘adequacy’ in place.<sup>131</sup>

2.50 However, if the UK were to permit the use of personal data in AI systems in ways not permitted in the EU under the Artificial Intelligence Act in due course, for example for biometric identification purposes by law enforcement or security agencies, that could potentially jeopardise the UK’s adequacy decisions (for example by making them more vulnerable to legal challenge before the EU Court of Justice).<sup>132</sup> The Minister’s Explanatory Memorandum does not explicitly address this risk, but it does note that there may be an “impact [...] for the UK’s own data protection framework”, which the Government “will monitor [...] closely as the proposals develop”.

## Conclusions

2.51 It is clear from the Minister’s Explanatory Memorandum that the proposed EU Artificial Intelligence Act is of direct interest and relevance to the UK. It is likely to impact on both UK industry and on the direction of international standards relevant to this technology, both key priorities for the Government as it seeks to position the UK as a leading producer of AI applications and a standard-setter when it comes to governance of such technology. Moreover, there is significant uncertainty about whether the provisions of the AIA related to safety components in goods could apply in Northern Ireland under the Protocol, with knock-on effects for the sale of goods that meet EU standards in Great Britain under the Internal Market Act, even if UK standards in the future are substantively different from the EU’s.

2.52 The impact of these various ways by which the EU’s Artificial Intelligence Act could impact on the UK will also necessarily be factored into the Government’s own AI Strategy. The decision of how to address any safety risks flowing from AI, and whether to do so in a way similar to or different from the EU’s, will need to take into account the implications of different possible options, in particular for the competitiveness of the UK industrial base but also, where relevant, the possibility of the AIA applying directly in Northern Ireland. It is also important for the Government to have a clear strategy on how to engage with the EU institutions on these matters. Given that the Government has recently [set itself the](#)

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130 As noted, the provisions of the AIA related to stand-alone AI software (and not incorporated into specific physical goods), for example facial recognition technology, would not be applicable under the Northern Ireland Protocol in any event.

131 Article 782 of the UK/EU Trade & Cooperation Agreement on “interim provision for transmission of personal data to the United Kingdom” from the EU.

132 Of possible relevance in this respect is also the [recent judgement](#) by the European Court of Human Rights that “some aspects” of the UK surveillance regime breached the European Convention on Human Rights (*Big Brother Watch and Others v. the United Kingdom*).

objective of playing a “leading role in critical and emerging technologies”,<sup>133</sup> the extent to which the UK might find itself impacted or constrained by parallel EU initiatives in fields like AI will be an important factor for Ministers to consider in realising those ambitions.

2.53 We therefore welcome the fact that the Minister, in his Explanatory Memorandum, confirms that the Government intends to “assess and consider the impact of the proposal on the UK AI ecosystem”, including any future UK regulatory approach, because the EU rulebook “could have implications for areas such as health, transport, finance, public sector uses of AI, security, product regulation [and] legal services”. We also welcome the Minister’s intention for the Government to “assess and consider the impact of the proposal on the UK AI ecosystem, and any impacts on a potential future UK regime”.

2.54 We appreciate that the final shape — and therefore impact — of the Artificial Intelligence Act and associated EU proposals<sup>134</sup> are unclear at this stage while discussions in Brussels continue. We intend to monitor developments in Brussels closely. At this stage, our main concern is around the lack of clarity as to whether the elements of the AIA related to physical goods might apply under the Northern Ireland Protocol. This is undesirable: not only could it have a significant impact on the UK’s own AI Strategy if one part of the Union is bound by EU rules in this regard, but it also raises fundamental questions about democratic legitimacy of laws being passed in Brussels that affect part of the UK.

2.55 We have therefore written to both the Department for Digital, Culture, Media and Sport to seek clarification as to the extent to which the EU Artificial Intelligence Act might be applicable under the Northern Ireland Protocol. A copy of the letter is shown in the Annex. In light of the response we receive, and any developments in the legislative process for adoption of the EU Artificial Intelligence Act in Brussels, we will consider the matter further in due course.

2.56 In the meantime, we draw the EU’s AI proposal and our assessment of its implications for the UK to the attention of the Digital, Culture, Media and Sport Committee, the Business, Energy and Industrial Strategy Committee, the Joint Committee on Human Rights, the Science and Technology Committee, the Northern Ireland Affairs Committee and the Foreign Affairs Committee.

### ***Letter from the Chair to the Minister for Digital Infrastructure (Matt Warman MP)***

Thank you for your helpful and detailed Explanatory Memorandum of 21 May on the recent European Commission proposal for an EU Artificial Intelligence Act (AIA).

The Committee has taken note of the various ways the proposal, once it becomes EU law in due course, could have implications for the UK. Your Memorandum cites in particular

133 Cabinet Office, “[Policy paper: Global Britain in a Competitive Age: the Integrated Review of Security, Defence, Development and Foreign Policy](#)” (16 March 2021).

134 In particular the new EU Machinery Regulation, which we discuss elsewhere in this Report, as well as the upcoming Commission proposals to update EU product safety and liability rules to take into account technological developments like AI.

the fact that UK businesses seeking to export AI applications to the EU market would have to comply with applicable product design requirements, as well as the EU's efforts to mould any international standards in this field after its own regulatory approach.

Given the complexity of the proposal and the likelihood that it will substantively change as the EU's Council of Ministers and European Parliament consider its provisions in detail, we appreciate that the Government's assessment of the potential ramifications for the UK are, necessarily, a work in progress.

However, we do wish to raise with you at this stage our concerns about whether the elements of the proposal related to the use of AI as safety components in goods could potentially engage the UK's obligations under the Northern Ireland Protocol in the Withdrawal Agreement. This is important not only for legal clarity and to frame engagement by both the Government and other interested parties in the legislative process in Brussels, but also because of the potential implications for the integrity of any future UK regulatory approach to AI systems (given that goods on the market in Northern Ireland that are compliant with EU standards, broadly speaking, "unfettered access" to the entire UK market under the Internal Market Act 2020, even if EU and UK standards diverge in the future).

In your Memorandum, you state that the AIA constitutes a 'new act' for the purposes of the Protocol and as such — "should the EU argue that this Regulation should apply in Northern Ireland under the Protocol" — the procedure foreseen in its Article 13(4) would apply. That means the Government would have to consent to the inclusion of a new EU legal act in the Protocol by means of a Decision of the Joint Committee. However, you also note your observation that the Government is still "considering how the proposals interact with the existing EU product safety legislation that is included in [the] Protocol".

We note however that the Commission proposal, in draft Articles 75 to 82, does in fact make certain explicit amendments to various pieces of EU product safety legislation included in the Protocol. These, broadly speaking, serve to empower the Commission to incorporate the safety standards for high-risk AI systems into future technical standards for the relevant types of goods, by means of Delegated and Implementing Acts under the applicable sectoral legislation. It seems to us that those amendments would apply automatically under the Protocol, and by extension any EU tertiary legislation — integrating the requirements for AI safety components for such goods as derived from the AIA — would also be applicable in Northern Ireland.

In light of this, we would welcome an update from you at the earliest opportunity on the Government's assessment of the potential implications of the proposal under the Protocol.

More generally, given that according to your Memorandum the EU proposal is likely to impact on UK industry and on international standards in this field, we would be grateful if you could revert to the Committee when there are significant developments in the legislative process in Brussels shaping the final content of the EU's Artificial Intelligence Act. We would be particularly interested to hear more about the Government's approach to pursuing its regulatory diplomacy with the EU to ensure that the AIA, to the extent possible, does not disadvantage UK exporters of AI technology and supports the UK's objectives for international standards relevant to this sector.

## 3 2021 Fishing Opportunities<sup>135</sup>

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**These EU documents are politically important because:**

- they relate to UK fishing opportunities during 2021 and beyond; and
- they signpost further discussions within, and decisions by, the Specialised Committee on Fisheries to be established under the UK-EU Trade and Cooperation Agreement.

### Action

- Report to the House.
- Draw to the attention of the Environment, Food and Rural Affairs Committee, the Northern Ireland Affairs Committee, the Scottish Affairs Committee and the Welsh Affairs Committee.

### Overview

3.1 After several months of negotiations, the UK and EU have reached agreement on fishing opportunities and associated conditions for 2021. Across the 70 fish stocks concerned, the outcome was a 19% increase in UK fishing opportunities, estimated to be worth about £27m in additional value compared to 2020. The EU, UK and Norway had already reached a trilateral agreement on six shared stocks. The UK did not reach a bilateral agreement with Norway or with the Faroe Islands.

3.2 This was the first such UK-EU annual negotiation following the UK's withdrawal from the European Union and the end to the post-Brexit Transition Period on 31 December 2020. The negotiation took place based on the parameters agreed in the UK-EU Trade and Cooperation Agreement (TCA). As such, outstanding issues will be pursued within the Specialised Committee on Fisheries (SCF) set up under the TCA.

### Correspondence from the Minister for Farming, Fisheries and Food

3.3 We last [wrote](#) to the Minister for Farming, Fisheries and Food (Victoria Prentis MP) about this matter on 21 April 2021, requesting an update on the EU negotiation as well as those with Norway and the Faroes and raising concerns about parliamentary scrutiny of the Government's approach. Following her initial [response](#) of 13 May, the Minister [wrote](#) again on 10 June confirming conclusion of the UK-EU negotiations.

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135 (a) Proposal for a Regulation fixing for 2021 the fishing opportunities for certain fish stocks and groups of fish stocks, applicable in Union waters and, for Union fishing vessels, in certain non-Union waters (b) Commission Communication — Towards more sustainable fishing in the EU: state of play and orientations for 2021; Council and COM number: (a) [12189/20](#) + ADDs 1–2, COM(20) 668 (b) [8871/20](#) + ADD 1, COM(20) 248; Legal base: (a) Article 43(3) TFEU, QMV (b) —; Department: Environment, Food and Rural Affairs; Devolved Administrations: Consulted; ESC numbers: (a) 41612 (b) 41347.

### ***Outcome of UK-EU consultations on fishing opportunities for 2021***

3.4 The Minister explains that agreement was reached on Total Allowable Catches (TACs) for 70 fish stocks and other fisheries management measures for 2021. It was, says the Minister, a challenging negotiation. Throughout, she says, the UK Government and Devolved Administrations worked closely together to secure a balanced and positive outcome for the whole of the UK.

3.5 The Minister adds that the agreement sets a good platform for the UK's future relationship with the EU on fisheries management. It includes, for example, commitments by the UK and EU to work together via the new Specialised Committee on Fisheries across a range of issues, including the challenges presented in the Celtic Sea mixed fishery and on combined TACs and deep sea species.

3.6 The Minister explains that the total value of fishing opportunities for the UK in 2021 across the 70 agreed EU-UK TACs is approximately 160,000 tonnes, worth approximately £333 million. For these stocks, the UK fleet will have available around 26,000 tonnes more quota than that which was allocated in 2020, estimated to be worth about £27m in additional value.

3.7 As in previous years, says the Minister, the UK negotiated this year's TACs and quotas taking full account of sustainability principles. Scientific advice on catch opportunities provided by the International Council for the Exploration of the Sea (ICES) relates to 66 of the 70 TACs negotiated. The UK's preliminary assessment shows that the UK expects 35% (23 out of the 66 TACs) to be in line with this advice.

3.8 In relation to maximum sustainable yield (MSY) advice, the UK's preliminary assessment of the negotiated outcome for 2021 shows that of the TACs which relate to MSY advice, 50% have been set consistent with MSY (16 out of 32 TACs). These figures are a preliminary assessment and subject to change once further analysis of catches by third countries has been completed.

3.9 As an independent coastal State, explains the Minister, the UK has undertaken an independent review of the method used to assess if TACs have been set consistent with MSY. As a result of this more rigorous assessment, this year's results are not comparable with previous years. A more detailed report will be published shortly outlining the revised assessment method and a comparison of this year's negotiated outcomes against previous years.

3.10 The Minister reports that exchanges of quota with the EU, as part of annual negotiations, was not possible this year. However, the EU and UK agreed to develop an interim arrangement for such exchanges ahead of a longer-term exchange system to be decided by the Specialised Committee on Fisheries. The UK expects that quota exchanges would be part of future annual negotiations, as provided for in the UK-EU Trade and Cooperation Agreement.

3.11 On non-quota species (such as scallops and crabs), the TCA requires that the EU and UK allow reciprocal access to fish such species "at a level that at least equates to the average tonnage fished by that Party in the waters of the other Party during the period 2012–16". The Minister explains that, due to the late conclusion of negotiations this year and the need to provide the respective industries with clarity, the UK and EU agreed

that, exceptionally, tonnage limits would not be applied in 2021. The UK and EU agreed to exchange data to monitor the uptake of non-quota stocks and agreed to work together through the Specialised Committee on Fisheries to develop multi-year strategies for non-quota stocks as a priority.

3.12 The EU and UK also agreed changes for 2021 on management measures for seabass to reduce wasteful discarding without increasing fishing mortality.

### ***No bilateral agreement with Norway***

3.13 In her letter of 13 May, the Minister confirmed that the UK and Norway had agreed not to conclude any bilateral access and quota exchange arrangements for 2021. The UK's approach to the negotiation looked to move UK-Norway arrangements beyond those that existed under the old EU-Norway agreement, which—said the Minister—saw Norwegian landings in UK waters worth eight times the value of UK landings in Norwegian waters. The UK therefore sought a more proportionate return for any access granted to Norwegian vessels in our waters, while Norway believed that the bilateral arrangements should be based on traditional levels of access dating from when the UK was an EU Member State.

3.14 The Minister added that, separate to discussions on the bilateral arrangements, the UK's distant water fleet already had access to fish in the waters around Svalbard through a distinct arrangement with the Norwegian authorities.

### ***No bilateral agreement with the Faroe Islands***

3.15 The Minister anticipated, in her letter of 13 May, the negative impact on the UK industry of a non-negotiated outcome with the Faroes to be low. Like EU-Norway, the old EU-Faroes arrangement resulted in an imbalance in value between the UK and the Faroes. While the UK sought a more balanced arrangement for 2021, the Faroes were unwilling to enter in an arrangement that compensated the UK for providing access. The absence of Faroese vessels in UK waters for 2021 would, said the Minister, reduce fishing pressure and improve prices of pelagic stocks.

### ***Trilateral agreement with Norway, the EU and the UK on shared stocks***

3.16 The Minister had explained in her earlier [letter](#) of 8 April that the UK had reached agreement with Norway and the EU on TACs for the six trilaterally-managed fish stocks in the North Sea for 2021. This agreement promotes the sustainable management and long-term viability of the relevant stocks, and the Parties established several working groups to this end. For example, a working group to review the management of North Sea herring.

## **Our assessment**

3.17 It is welcome that agreement has been reached between the UK and EU on fishing opportunities and associated measures. This sets an appropriate tone for future cooperation and demonstrates the mutual commitment to sustainability given that the gravest risk from non-agreement was to the sustainability of shared stocks.

3.18 We take note of the Minister’s summary of the outcome of the annual consultations with the UK, as well as the Written Record<sup>136</sup> of those consultations. There is some intriguing wording in the Written Record, reflecting some of the tensions within the negotiation. Concerning technical measures in the Celtic Sea, for example, “the Delegations identified differences in the Parties’ measures in place for 2021. The Delegations recognised that some technical measures may be more effective when brought into effect by both Parties.” This encapsulates the challenge of managing the shared resource post-Brexit: maintaining the regulatory autonomy of both Parties while also identifying where possible common solutions to shared challenges in order to protect the marine environment.

3.19 The Written Record highlights several areas for further work through the Specialised Committee on Fisheries, including:

- management of skates and rays;
- develop terms of reference for Celtic sea mixed fishery advice;
- develop proposals to improve the management of relevant fisheries to ensure the long-term conservation of deep-sea stocks;
- improve the availability of data for stocks with no scientific advice;
- monitoring the implementation of geographic flexibility (the possibility to take a proportion of a quota in other waters i.e. to take some North Sea quota in the West of Scotland area);
- review the agreed flexibilities, with consensual revision to avoid any risks to sustainability;
- discuss further the lists of species which both or either Parties prohibit from being fished;
- management of discards, including landing obligation exemptions and TAC deductions (noting that the EU and UK have divergent approaches to species that should be exempt from the landing obligation and to how TAC deductions should be calculated);
- technical measures, including the assessment and review of existing measures and consideration of additional measures (such as in the Celtic Sea);
- the development of multi-annual strategies for non-quota stocks and exchanges of data on those stocks; and
- seabass monitoring, management and assessment.

3.20 The Minister indicates that a revised method has been used to assess if TACs have been set consistent with MSY and, as a result, the outcome appears less sustainable than in previous years. The Minister helpfully promises a more detailed report shortly outlining the revised assessment method and a comparison of this year’s negotiated outcomes against previous years. We ask that this report be drawn to our attention.

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<sup>136</sup> [Written record of fisheries consultations between the United Kingdom and the European Union for 2021](#), Department for Environment, Food and Rural Affairs, 11 June 2021.

3.21 Concerning future arrangements for parliamentary scrutiny of these annual consultations between the UK and other coastal states, we accept that this has been an exceptional year. We look forward to early engagement between the Minister and Parliament in advance of the UK's international negotiations for fishing opportunities in 2022. We understand that the scientific advice to support those negotiations will be available imminently.

### **Action**

3.22 We consider that the matters raised are politically important because they relate to UK fishing opportunities during 2021 and beyond. We require no further information at this stage but expect to engage separately with the Minister in due course as the Specialised Committee on Fisheries begins its work.

3.23 We report the Minister's letters to the House and draw this chapter to the attention of the Environment, Food and Rural Affairs Committee, the Northern Ireland Affairs Committee, the Scottish Affairs Committee and the Welsh Affairs Committee.

## 4 Northern Ireland Protocol: Feeding animal protein to animals<sup>137</sup>

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### This EU document is politically important because:

- it concerns an EU proposal to revoke EU laws—introduced in the light of the BSE crisis—on the feeding of some animal proteins to non-ruminant animals, including pigs and chickens;
- the change would apply directly in Northern Ireland, but not in Great Britain, and so could affect trade in non-ruminant animals from Northern Ireland to Great Britain, subject to the decisions of each of the Devolved Administrations; and
- the UK, Scottish and Welsh Administrations have not yet decided whether England, Scotland and Wales respectively should align with the change.

### Action

- Write to the Minister.
- Draw to the attention of the Environment, Food and Rural Affairs Committee, the Northern Ireland Affairs Committee, the Scottish Affairs Committee and the Welsh Affairs Committee.

### Overview

4.1 In the light of the Bovine Spongiform Encephalopathy (BSE) outbreak in the 1980s and 1990s, notably in the UK, and the realisation that it could be spread from one species to the other through feed, the EU adopted a number of laws regulating the feeding of animal-derived protein to other animals. The laws were aimed not only at tackling BSE, but also targeted other such Transmissible Spongiform Encephalopathies (TSEs) affecting different species. Based on scientific evidence, the European Commission proposes to repeal some elements of those laws. The changes will apply automatically to Northern Ireland under the terms of the Northern Ireland Protocol to the UK/EU Withdrawal Agreement but will not apply by default to Great Britain. Unless the Government and other Devolved Administrations followed suit, Northern Ireland to Great Britain trade in non-ruminants (such as pigs and chickens)—and food produced from them—would likely be restricted.

4.2 The specific restrictions to be repealed are the bans on the feeding of:

- discarded ruminant-based collagen and gelatine (i.e. from cattle) to non-ruminants;

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<sup>137</sup> Commission Regulation (EU) .../... of XXX amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the prohibition to feed non-ruminant farmed animals, other than fur animals, with protein derived from animals; Council number: [8537/21](#) + ADD 1; Legal base: Regulation (EC) No 999/2001; Department: Environment, Food and Rural Affairs; Devolved Administrations: Consulted; ESC number: 41852.

- chicken-based processed animal protein (PAP) to pigs;
- pig-based PAP to chickens; and
- insect-based PAP to chickens and pigs.
- Strict requirements during the collection, transport and processing of those products should apply, and regular sampling and analysis be performed, in order to avoid any risk and contribute to the verification of the absence of cross-contamination with prohibited ruminant protein and intra-species recycling (i.e. not feeding protein from one species to the same species).

4.3 The Minister for Rural Affairs and Biosecurity (Lord Benyon) notes in his [Explanatory Memorandum](#) that the Commission’s draft Regulation is in line with the Commission’s Strategy on TSEs for 2010–2015 (“the TSE Road Map 2”),<sup>138</sup> which the UK supported as an EU Member State. He confirms that the changes will apply to Northern Ireland and says that the Government will review the evidence and develop policy advice on this matter, engaging closely with colleagues in the Devolved Administrations to consider the risks, impacts and opportunities of adjusting domestic legislation. He adds that, before making a decision about any changes to the feed bans in England, the Government needs to fully consider and assess the most up-to-date scientific evidence, consult stakeholders and develop options for the safe and practicable operationalisation of any substantive policy change.

## Our assessment

4.4 The Commission provides substantial justification for its approach, arguing that the risk to non-ruminants and to ruminants (through cross-contamination from non-ruminant feed) is negligible. On the other hand, notes the Commission, an estimated 100,000 tonnes of former foodstuffs containing ruminant collagen and/or gelatine go yearly for disposal in the EU, since they cannot be used in the feed of farmed animals under the current feed ban rules.

4.5 The Commission expresses confidence in the diagnostic methods able to detect ruminant material and to detect, for example, poultry protein within poultry feed, thus avoiding intra-species recycling.

4.6 Under the terms of the Internal Market Act 2020, market access for goods from Northern Ireland into other parts of the United Kingdom may be restricted on the grounds of unsafe food or feed. It would therefore be possible for England, Scotland and Wales to restrict the import of food or feed produced under the terms of the amended EU legislation or, alternatively, the Commission’s proposed changes could be adopted across Great Britain.

4.7 The Minister gives little information on the process underway to make this assessment, nor does he give any insight as to the potential impact in Northern Ireland of a) the changes to the Regulation or b) any restriction on access to the GB market. The Minister also says nothing about the potential impact in Great Britain if imports of food and feed from the EU are restricted as a result of this change.

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138 Commission Communication: The TSE Roadmap 2. A Strategy paper on Transmissible Spongiform Encephalopathies for 2010–2015. [COM\(2010\) 384](#), 16 July 2010.

## Action

4.8 We have written to the Minister as set out below raising the issues that we have highlighted in our Assessment above.

4.9 We are reporting this document to the House as politically important given its salience to the UK internal market and its relevance to matters of public and animal health. We are drawing it to the attention of the Environment, Food and Rural Affairs Committee, the Northern Ireland Affairs Committee, the Scottish Affairs Committee and the Welsh Affairs Committee.

### ***Letter from the Chair to the Minister for Rural Affairs and Biosecurity (Lord Benyon)***

We considered your Explanatory Memorandum on the above document at our meeting of 23 June 2021.

We note that, under the market access principles enshrined in the Internal Market Act 2020, any products from Northern Ireland produced under the terms of this amended legislation should in principle be accepted on the market across Great Britain. We recognise too, however, that Schedule 1 of that Act provides that threats to human and animal health are legitimate bases for exclusion from the market access principles. Our understanding is that England, Scotland and Wales could all prevent the placing on their markets of any food or feed from Northern Ireland containing ruminant collagen and gelatine or non-ruminant processed animal protein, and destined for feeding non-ruminants. Equally, though, England, Scotland and Wales could all mirror the changes to EU legislation.

Your Explanatory Memorandum lacked detail as to the process that is underway to make the requisite assessment across Great Britain. Could you please explain the process and consultation that you are pursuing for England and as part of a co-operative approach with Scotland and Wales? Do you have access to the same information as the European Commission had when making its decision? Please also give an indication of the potential impact in Northern Ireland of a) the changes to the Regulation and b) any restriction on access to the GB market. Finally, the change could also affect the import into Great Britain of feed from the EU. What impact might such a change have on Great Britain producers?

We look forward to a response by 7 July 2021.

## 5 Control of exports on ‘dual-use’ items<sup>139</sup>

### This EU document is politically important because:

- it raises questions regarding the Government’s plans for the operation of the UK’s ‘dual-use’ export regime from 1 January 2021; and
- the current iteration of the EU’s Dual-Use Regulation — Council Regulation (EC) No 428/2009 — is listed in Annex 2 of the Protocol on Ireland/Northern Ireland to the UK/EU Withdrawal Agreement and applies in respect of Northern Ireland. The proposal under scrutiny — a major update of this Regulation — will, post-adoption, replace Council Regulation (EC) No 428/2009 and apply in Northern Ireland.

### Action:

- Draw to the attention of the International Trade Committee, the Joint Committee on Human Rights, the Northern Ireland Affairs Committee, and the Committees on Arms Export Controls.

### Overview

5.1 The [proposal under scrutiny](#) was last considered by the Committee in its Twenty-seventh Report of Session 2019–21.<sup>140</sup>

5.2 The proposed (recast) Dual-Use Regulation will update the EU’s export control regime, specifically, that which pertains to ‘dual-use’ items.<sup>141</sup> Dual-use items are goods and technologies that can have legitimate civilian applications but can also be used for the development and deployment of weapons of mass destruction, the perpetration of terrorist acts and human rights violations. Special procedures — including authorisation requirements — apply to the export of dual-use items outside of the EU.

5.3 The updated Regulation would place greater emphasis on the protection of human rights and fundamental freedoms versus the current regime’s focus on military and state security-focussed concerns, and it seeks to update the EU’s rule book in light of previous high-profile controversies involving EU-based operators.<sup>142</sup>

5.4 On [4 November 2020](#), we wrote to the Minister previously responsible for the EU’s proposal, Rt Hon. Greg Hands MP, requesting further information on certain aspects of the draft Regulation and on the steps that the Government had taken/was going to take in light of the measures suggested by the Commission following the end of the post-Brexit transition period. Our letter principally focussed on the Government’s plans for the

139 Proposal for a Regulation of the European Parliament and of the Council setting up a Union regime for the control of exports, transfer, brokering, technical assistance and transit of dual-use items (recast); Council and COM number: 12785/16 + ADDs 1–3, and COM(16) 616; Legal base: Article 207(2) TFEU, ordinary legislative procedure, QMV; Department: International Trade; Devolved Administrations: Consulted; ESC number: 38114.

140 Twenty-seventh Report HC 229–xxiii (2019–21), [chapter 3](#) (4 November 2020).

141 [Council Regulation \(EC\) No 428/2009](#) of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items (Recast).

142 This includes the sale from the EU of surveillance equipment to Middle Eastern and North African governments during the ‘Arab Spring’ of 2010–12.

operation of the UK’s dual-use regime after the end of the transition period, and how it would manage divergence on dual-use rules between Northern Ireland and Great Britain when the proposal was adopted (consequent on dual-use rules being listed in Annex 2 of the Protocol on Ireland/Northern Ireland to the UK/EU Withdrawal Agreement).

5.5 Following our letter, the Council and European Parliament, on 9 November 2020, reached a provisional agreement on the Regulation and Ranil Jayawardena MP (Minister of State for International Trade) subsequently replied to us on 10 December 2020. His response is considered below.<sup>143</sup> Since the Minister’s latest correspondence, the updated Regulation was, on 10 May 2021, adopted by the Council and, pending final approval by the European Parliament, will enter into force 90 days thereafter.

### The Minister’s letter of 10 December 2020

5.6 In our letter of [4 November 2020](#), we noted that the political and legal context surrounding the proposed recast Dual-Use Regulation had changed a great deal since our predecessor Committee reported its assessment of the proposal — and the Government’s position on the dossier — to the House on 4 September 2019.<sup>144</sup>

5.7 While we welcomed the Government’s explanation of its stance on future alignment with EU dual-use rules, we sought further information on the Government’s longer-term plans for the UK’s dual-use regime and, more specifically, whether it would eventually seek to repeal and replace the Dual-Use Regulation — as saved by the European Union (Withdrawal) Act 2018 — or retain it on the statute book for the foreseeable future and amend it as and when deemed necessary. We also sought the Government’s view on whether priority should be given in any future UK regime to the mainstreaming of human rights concerns and improvements to the transparency of listing decisions and export authorisations.

5.8 In response, the Minister confirms that the Government will keep the Dual-Use Regulation as retained by the European Union (Withdrawal) Act 2018 for the foreseeable future and amend it, as and when deemed necessary, while lending consideration to longer-term plans for the UK’s own dual-use regime. The Minister also notes that there will be a need to make technical updates, periodically, to the list of controlled dual-use items which are set out in Annex I of the retained Regulation to implement changes to the international export regimes’ control list. This process of technical updates already occurs under current legislation and would, therefore, be a continuation of existing practice.

5.9 We also noted that the original Dual-Use Regulation — Council Regulation (EC) No 428/2009 — is listed in Annex 2 of the Protocol on Ireland/Northern Ireland to the UK/EU Withdrawal Agreement and highlighted that this listing means that the Dual-Use Regulation would continue to apply in Northern Ireland following the end of the transition period. Furthermore, as per Article 13(4) of the Protocol, the proposal under scrutiny would, once adopted, replace Council Regulation (EC) No 428/2009.

5.10 In light of this, the consequences of the Dual-Use Regulation being listed in Annex 2 are significant as it gives rise to the possibility of two separate regimes existing in the UK; one in Great Britain based on the original Council Regulation and another, in Northern

143 [Letter from Ranil Jayawardena MP to Sir William Cash MP](#), 10 December 2020.

144 [Seventy-third Report HC 301–lxxi \(2017–19\)](#), [chapter 4](#) (4 September 2019).

Ireland, based on the proposed recast. Depending on the final text of the recast, this could create major differences between the types of items and goods for export by operators based in Great Britain not subject to new EU licensing and authorisation requirements versus those in Northern Ireland which are. We, therefore, requested further information from the Government on how it plans to minimise future divergence between the different regimes applicable in Great Britain and Northern Ireland and, in particular, whether it will mirror the terms of the recast Regulation — following its adoption — on the British mainland.

5.11 In response, the Minister confirms that, following the end of the transition period, different rules will apply in Great Britain to those in Northern Ireland. Accordingly, EU Regulations and Directives relating to export control and listed in Annex 2 to the Protocol on Ireland/Northern Ireland will continue to operate in Northern Ireland.

5.12 The Minister helpfully outlines these as being:

- [Council Regulation \(EC\) No 428/2009](#) of 5th May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items;
- [Council Directive 91/477/EEC](#) of 18th June 1991 on control of the acquisition and possession of weapons;
- [Regulation \(EU\) No 258/2012](#) of the European Parliament and of the Council of 14th March 2012 implementing Article 10 of the United Nations' Protocol against the illicit manufacturing of and trafficking in firearms, their parts and components and ammunition supplementing the United Nations Convention against Transnational Organised Crime (UN Firearms Protocol), and establishing export authorisation, and import and transit measures for firearms, their parts and components and ammunition;
- [Directive 2009/43/EC](#) of the European Parliament and of the Council of 6th May 2009 simplifying terms and conditions of transfers of defence-related products within the Community; and
- [Regulation \(EU\) 2019/125](#) of the European Parliament and of the Council of 16th January 2019 concerning trade in certain goods which could be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment.

5.13 The Minister confirms that, when the EU's recast Regulation enters into force, the Government has no plans to mirror its terms in domestic UK legislation. The Minister notes that, while the Government will be able to review the text, it must be able to design bespoke rules for the UK, in the national interest, without the constraints of following EU Regulations.

5.14 Finally, we noted that the inclusion of the Dual-Use Regulation in Annex 2 of the Protocol means that dual-use shipments from Northern Ireland to Great Britain will be classed as exports for the purposes of the Regulation and will, therefore, require EU authorisation. Accordingly, we requested details from the Government on the number of

such shipments that have taken place in previous years and information on the steps being taken by the Government to assist and reduce future administrative burdens caused by this change.

5.15 In response, the Minister states that movements within the UK of items controlled by the Dual-Use Regulations have not traditionally been subject to export controls and, as such, the number of shipments of controlled dual-use items from Northern Ireland into Great Britain have not been recorded. That said, although the Northern Ireland Protocol will mean that dual-use goods will need an export licence from Northern Ireland to Great Britain, the Minister notes that the EU has proposed including the UK as a permitted destination on Union General Export Authorisation (GEA) No EU001. In effect, this would minimise the impact on Northern Irish exporters as they would only have to register to use this GEA to export the vast majority of controlled items in Annex I of the Dual-Use Regulation to the UK.

5.16 Until the Government has had an opportunity to study the recast Regulation, once it enters into force, the Minister is unable to estimate what further administrative burdens there may — or may not — be and what the Government might be able to do to minimise their impact on intra-UK business.

## Action

5.17 We draw this Report chapter to the attention of the International Trade Committee, the Joint Committee on Human Rights, the Northern Ireland Affairs Committee, and the Committees on Arms Export Controls.

## 6 Documents not considered to be legally and/or politically important

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### Department for Business, Energy and Industrial Strategy

(41837) Commission Delegated Regulation (EU) .../... of 10.5.2021 amending Delegated Regulation (EU) 2019/856 as regards the application and selection procedures under the Innovation Fund.

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C(21) 3188

### Department for Environment, Food and Rural Affairs

(41845) Commission Delegated Regulation (EU) .../... Of 12.5.2021 Supplementing Regulation (EU) 2019/787 of the European Parliament and of the Council with rules concerning applications for registration of geographical indications of spirit drinks, amendments to product specifications, cancellation of the registration and the register.  
8793/21  
C(21) 2837

(41846) Commission Delegated Regulation (EU) 2021/630 of 16 February 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of goods exempted from official controls at border control posts and amending Commission Decision 2007/275/EC.

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### Department of Health and Social Care

(41838) Commission Delegated Regulation (EU) .../... of 16.4.2021 amending Delegated Regulation (EU) No 2016/128 as regards the requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children.  
8060/21  
+ ADD 1

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(41839) Commission Delegated Regulation (EU) .../... of 16.4.2021 amending Delegated Regulation (EU) No 2016/127 as regards the requirements on pesticides in infant formula and follow-on formula.  
8061/21

+ ADD 1

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(41840) Commission Implementing Regulation (EU) 2021/686 of 23 April 2021 authorising a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health, and amending Regulation (EU) No 432/2012.

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## Department for Transport

(41834) Commission Delegated Regulation (EU) .../... of 19.4.2021 supplementing  
7997/21 Regulation (EU) 2019/2144 of the European Parliament and of the  
Council by laying down detailed rules concerning the alcohol interlock  
+ ADD 1 installation facilitation in motor vehicles and amending Annex II to that  
Regulation.

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(41835) Commission Delegated Regulation (EU) .../... of 23.4.2021 supplementing  
8164/21 Regulation (EU) 2019/2144 of the European Parliament and of the Council  
by laying down detailed rules concerning the specific test procedures  
+ ADD 1 and technical requirements for the type-approval of motor vehicles with  
regard to their driver drowsiness and attention warning systems and  
amending Annex II to that Regulation.

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(41836) Commission Implementing Regulation (EU) 2021/646 of 19 April 2021  
— laying down rules for the application of Regulation (EU) 2019/2144 of the  
European Parliament and of the Council as regards uniform procedures  
— and technical specifications for the type-approval of motor vehicles with  
regard to their emergency lane-keeping systems (ELKS).

## Food Standards Agency

(41847) Commission Delegated Regulation (EU) .../... of 26.4.2021 amending  
8329/21 Delegated Regulation (EU) 2019/624 as regards certification in case of  
slaughter at the holding of provenance.

C(21) 2703

## Annex

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### *Documents drawn to the attention of select committees:*

(‘SNC’ indicates that scrutiny (of the document) is not completed; ‘SC’ indicates that scrutiny of the document is completed)

**Business, Energy and Industrial Strategy Committee:** New EU health and safety requirements for machinery (EU Machinery Regulation) [Proposed Regulation (SNC)]; The EU’s Artificial Intelligence Act: possible implications for the UK [Proposed Regulation (SNC)]

**Defence Committee:** Control of exports on ‘dual-use’ items [Proposed Regulation (SC)]

**Digital, Culture, Media and Sport Committee:** The EU’s Artificial Intelligence Act: possible implications for the UK [Proposed Regulation (SNC)]

**Environment, Food and Rural Affairs Committee:** 2021 Fishing Opportunities [(a) Proposed Regulation. (b) Commission Communication (SC)]; Northern Ireland Protocol: Feeding animal protein to animals [Commission Regulation (SNC)]

**Foreign Affairs Committee:** The EU’s Artificial Intelligence Act: possible implications for the UK [Proposed Regulation (SNC)]; Control of exports on ‘dual-use’ items [Proposed Regulation (SC)]

**Joint Committee on Human Rights:** The EU’s Artificial Intelligence Act: possible implications for the UK [Proposed Regulation (SNC)]; Control of exports on ‘dual-use’ items [Proposed Regulation (SC)]

**International Development Committee:** Control of exports on ‘dual-use’ items [Proposed Regulation (SC)]

**International Trade Committee:** New EU health and safety requirements for machinery (EU Machinery Regulation) [Proposed Regulation (SNC)]; Control of exports on ‘dual-use’ items [Proposed Regulation (SC)]

**Northern Ireland Affairs Committee:** New EU health and safety requirements for machinery (EU Machinery Regulation) [Proposed Regulation (SNC)]; The EU’s Artificial Intelligence Act: possible implications for the UK [Proposed Regulation (SNC)]; 2021 Fishing Opportunities [(a) Proposed Regulation. (b) Commission Communication (SC)]; Control of exports on ‘dual-use’ items [Proposed Regulation (SC)]; Northern Ireland Protocol: Feeding animal protein to animals [Commission Regulation (SNC)]

**Science and Technology Committee:** The EU’s Artificial Intelligence Act: possible implications for the UK [Proposed Regulation (SNC)]

**Scottish Affairs Committee:** 2021 Fishing Opportunities [(a) Proposed Regulation. (b) Commission Communication (SC)]; Northern Ireland Protocol: Feeding animal protein to animals [Commission Regulation (SNC)]

**Welsh Affairs Committee:** 2021 Fishing Opportunities [(a) Proposed Regulation. (b) Commission Communication (SC)]; Northern Ireland Protocol: Feeding animal protein to animals [Commission Regulation (SNC)]

**Work and Pensions Committee:** New EU health and safety requirements for machinery (EU Machinery Regulation) [Proposed Regulation (SNC)]

# Formal Minutes

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## Wednesday 23 June 2020

Virtual meeting

Members present:

Sir William Cash, in the Chair

Jon Cruddas

Allan Dorans

Margaret Ferrier

Mrs Andrea Jenkyns

Mr David Jones

Marco Longhi

Craig Mackinlay

Anne Marie Morris

Charlotte Nichols

Greg Smith

## Document scrutiny

Draft Report, proposed by the Chair, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1.1 to 6 agreed to.

Resolved, That the Report be the Fourth Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

## Adjournment

Adjourned till Wednesday 30 June 2021 at 1.45 pm

## Standing Order and membership

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The European Scrutiny Committee is appointed under Standing Order No.143 to examine European Union documents and—

- a) to report its opinion on the legal and political importance of each such document and, where it considers appropriate, to report also on the reasons for its opinion and on any matters of principle, policy or law which may be affected;
- b) to make recommendations for the further consideration of any such document pursuant to Standing Order No. 119 (European Committees); and
- c) to consider any issue arising upon any such document or group of documents, or related matters.

The expression “European Union document” covers —

- i) any proposal under the Community Treaties for legislation by the Council or the Council acting jointly with the European Parliament;
- ii) any document which is published for submission to the European Council, the Council or the European Central Bank;
- iii) any proposal for a common strategy, a joint action or a common position under Title V of the Treaty on European Union which is prepared for submission to the Council or to the European Council;
- iv) any proposal for a common position, framework decision, decision or a convention under Title VI of the Treaty on European Union which is prepared for submission to the Council;
- v) any document (not falling within (ii), (iii) or (iv) above) which is published by one Union institution for or with a view to submission to another Union institution and which does not relate exclusively to consideration of any proposal for legislation;
- vi) any other document relating to European Union matters deposited in the House by a Minister of the Crown.

The Committee’s powers are set out in Standing Order No. 143.

The scrutiny reserve resolution, passed by the House, provides that Ministers should not give agreement to EU proposals which have not been cleared by the European Scrutiny Committee, or on which, when they have been recommended by the Committee for debate, the House has not yet agreed a resolution. The scrutiny reserve resolution is printed with the House’s Standing Orders, which are available at [www.parliament.uk](http://www.parliament.uk).

**Current membership**

[Sir William Cash MP](#) (*Conservative, Stone*) (Chair)

[Tahir Ali MP](#) (*Labour, Birmingham, Hall Green*)

[Jon Cruddas MP](#) (*Labour, Dagenham and Rainham*)

[Allan Dorans MP](#) (*Scottish National Party, Ayr Carrick and Cumnock*)

[Richard Drax MP](#) (*Conservative, South Dorset*)

[Margaret Ferrier MP](#) (*Scottish National Party, Rutherglen and Hamilton West*)

[Mr Marcus Fysh MP](#) (*Conservative, Yeovil*)

[Mrs Andrea Jenkyns MP](#) (*Conservative, Morley and Outwood*)

[Mr David Jones MP](#) (*Conservative, Clwyd West*)

[Stephen Kinnock MP](#) (*Labour, Aberavon*)

[Mr David Lammy MP](#) (*Labour, Tottenham*)

[Marco Longhi MP](#) (*Conservative, Dudley North*)

[Craig Mackinley MP](#) (*Conservative, South Thanet*)

[Ann Marie Morris MP](#) (*Conservative, Newton Abbot*)

[Charlotte Nichols MP](#) (*Labour, Warrington North*)

[Greg Smith MP](#) (*Conservative, Buckingham*)