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European Scrutiny Committee

First Report of Session 2021–22

Documents considered by the Committee on 12 May 2021

Report, together with formal minutes

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Notes

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. 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/.

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Contents

1 EU Research Programme: Horizon Europe[1]

This EU document is legally and politically important because:

- the UK and EU have agreed that the UK will associate to Horizon Europe for the period 2021–27, paying an estimated gross contribution over that period of approximately £12.7 billion, subject to adjustments and exchange rate variations.

Action

- Write to the Minister seeking clarity on the cost of Horizon Europe and how it is to be funded, as well as possible UK exclusions from the scope of the Programme, and how the UK intends to honour the reciprocal obligation to allow EU entities to participate in UK science programmes.
- Draw to the attention of the Business, Energy and Industrial Strategy Committee and the Science and Technology Committee.

Overview

1.1 Under the terms of the UK-EU Trade and Cooperation Agreement (TCA), the UK will associate to the EU's Framework Programme for Research—Horizon Europe—lasting from 2021 until 2027. This means that UK scientists and businesses will be eligible to access grant funding under the Programme and be able to continue to form and lead collaborative partnerships with EU and other international partners.

1.2 The UK's association requires a financial contribution, which is likely to be around £12.7 billion in gross terms over seven years (see below for further details), although this figure is necessarily speculative and could be adjusted both upwards and downwards based on actual spending as well as exchange rate variations. That figure is a gross contribution, so before funding flowing back to the UK is taken into account. Association will enter into force through the formal adoption of a Protocol to the TCA that is already agreed in principle, after the Horizon Europe Regulation has been adopted.

1.3 In her letter of 4 March 2021, the Minister for Science, Research and Innovation (Amanda Solloway MP) updated the Committee on the UK's association to Horizon Europe, considering that it would further "the UK's ambition to be a global science superpower".

1.4 The Minister explained that the overarching principles of the UK's association to the Programme are contained within Part Five of the UK-EU TCA. Specific terms of the UK association are contained in a draft Protocol, relevant to Part Five and published alongside

1 Proposal for a Regulation establishing Horizon Europe—the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination; EU reference numbers: 9865/18 + ADDs 1–6, COM(18) 435; Legal base: Article 173(3) TFEU, Article 182(1) TFEU, Article 183 TFEU, Article 188 TFEU (second paragraph), ordinary legislative procedure, QMV;. Department: Business, Energy and Industrial Strategy; Devolved Administrations: Consulted; ESC number: 39882.

the agreement together with a joint declaration with the EU. The agreed terms, she said, ensure that the UK's financial contribution is fair and appropriate and participation represents a real benefit to British people and industry.

1.5 The Minister explained that the UK will formally associate to Horizon Europe once the EU has adopted its legislation for the Programme, and the relevant Protocol published in draft alongside the UK-EU TCA is adopted by the joint UK-EU Specialised Committee on Participation in Union Programmes.

UK participation in Horizon Europe

1.6 Part Five of the TCA addresses UK participation in EU programmes. It is complemented by a financial annex specifying the implementation of the financial conditions and by a draft protocol, called Protocol I. This Protocol specifies the Programmes in which the UK will participate and the scope of its participation, as well as some rules specific to each programme, including Horizon Europe.

1.7 The Protocol will be finalised and adopted by the joint UK-EU Specialised Committee on Participation in Union Programmes once the Horizon Europe Regulation has been formally adopted by the Council and European Parliament and published in the Official Journal of the EU.[2]

1.8 In the meantime, several urgent Horizon Europe calls for proposals are already open[3] and UK entities are eligible to apply. The only restriction is that grant agreements can only be signed once the association has come into force.

1.9 In addition to financing, UK participation in Horizon Europe is based on other conditions as well as clear governance arrangements. As is the case for other third countries, the UK will have no decision-making powers in relation to how Horizon Europe is managed or run although it will be able to attend technical meetings as observers. The EU and UK must make "every effort" within their immigration systems to "facilitate the entry and residence of persons involved in the implementation" of Horizon Europe, "including students, researchers, trainees or volunteers". There is also a condition of reciprocity, meaning that EU entities "may participate in programmes of the United Kingdom equivalent to" the EU's research funds "in accordance with United Kingdom law and rules".

Financial contribution

1.10 The UK contribution to the Programme consists of two components:

- an operational contribution, calculated by applying the ratio of the UK's GDP compared to that of the EU (approximately 15.5%) to the EU's own budget for each of the programmes in which the UK participates; and
- a participation fee, calculated as a percentage of the operational contribution, rising from 0.5% in 2021 to 4% by 2026.

2 The Horizon Europe Regulation has been politically agreed, but still needs to be formally adopted and published in the Official Journal of the European Union.

3 The calls for proposals are available on the Commission's website, searching under Horizon Europe for the 2021–2027 programming period.

1.11 Any estimates of what the UK's contributions might be are necessarily speculative as they can be adjusted based on actual EU spending as well as the flow of funding into the UK, and a number of complex adjustment mechanisms to ensure that the UK's contribution and receipts do not diverge significantly. Based on the EU's overall ceiling for Horizon Europe over the period 2021–27, though, the UK could expect to make a gross contribution of €14.2 billion (£12.7 billion) as an operational contribution and around €294 million (£263 million) as a participation fee over those seven years.

Scope of Association

1.12 The UK is associating to the full Horizon Europe programme with the exception only of the European Innovation Council (EIC) Fund, as that is an EU financial instrument[4] and the UK decided not to participate in any such instruments. UK entities can still apply for direct grants under the "EIC Accelerator".

1.13 Exceptionally, Horizon Europe work programmes may restrict UK participation in elements of Horizon Europe for duly justified reasons relating to the EU's strategic assets, interests, autonomy or security. The UK may, however, unilaterally terminate its participation in Horizon Europe in the event that the UK is excluded from over 10% of Horizon Europe. In addition, the UK's contribution would be adjusted downwards to take into account exclusions. It was reported[5] that a recent European Commission draft of the Horizon Europe Work Programme for 2021–22 contained such exclusions, relating to the EU's strategic autonomy and specifically covering projects relating to space and quantum computing. The Work Programme is yet to be adopted by Member States, however, and some Member States are known to be concerned about the proposed exclusions, applying to the UK and other third countries.[6]

Financing of the UK's contribution

1.14 Concerns[7] have been expressed that research organisations are expected to make the contribution from existing UK research funding, thus reducing the overall funding for research as the costs of the EU Programme would previously have been covered by the UK's overall contributions to the EU budget.

1.15 In response,[8] the Government announced an additional £250 million of science funding for 2021–22, identified to pay for Horizon Europe participation, and noted that £400 million earmarked at Spending Review for 2021–22 to support Government priorities and drive the development of innovative ways to build new science capability would help to pay for association to Horizon Europe.

4 Financial instruments refers to EU funding arrangements that do not take the form of grants, but where the EU budget is used to provide loans or equity investment for a recipient, in pursuit of an EU public policy objective in areas like infrastructure, employment and climate change.
5 Daily Telegraph, "Brussels tries to freeze UK out of quantum and space projects" (30 March 2021)
6 Financial Times, "Germany resists EU move to limit UK role on R&D" (26 April 2021)
7 Letter from Universities UK, to the Prime Minister, 16 March 2021.
8 Department for Business, Energy and Industrial Strategy, "£250 million additional funding to boost collaboration and protect ongoing research" (1 April 2021)

Our assessment

1.16 The Government has not set out clearly its estimate of the cost of association to Horizon Europe. We will seek clarity on the Government's estimates, as well as information as to how association will be funded, noting the concerns expressed by researchers that the funding would mostly come from existing domestic research budgets.

1.17 Concerning scope, it is unclear whether UK entities are likely to be excluded from Horizon Europe space and quantum technologies projects, and so we will also seek further information on that matter.

1.18 Finally, the TCA includes reciprocity, meaning that EU entities "may participate in programmes of the United Kingdom equivalent to" the EU's research funds "in accordance with United Kingdom law and rules". We will ask the Government how it intends to facilitate such participation.

Action

1.19 We have written to the Minister raising the issues identified above. Our letter is set out below.

1.20 We are copying our letter to the Business, Energy and Industrial Strategy Committee and the Science and Technology Committee.

Letter to the Minister for Science, Research and Innovation (Amanda Solloway MP)

We considered your letter of 4 March 2021 on Horizon Europe at our meeting of 12 May 2021.

We were pleased to see that the UK and EU agreed that the UK should be able to associate to the EU's Horizon Europe research programme over the period 2021–27.

There are several outstanding questions about the UK's association concerning which we would welcome your comments.

First, we estimate the likely gross UK contribution over the seven year period to be in the region of £12.7 billion, although this is necessarily speculative given the potential for adjustments both upwards and downwards according to actual spending, UK receipts and the various safeguards built into the UK/EU Trade and Cooperation Agreement (TCA), and also given the potential for exchange rate variation. It would nevertheless be helpful if you could set out the Government's broad expectations as to the cost.

Second, there was some concern among the research community—expressed in a letter from Universities UK to the Prime Minister on 16 March 2021—that the UK's association to Horizon Europe would be funded from existing domestic research budgets. We note that, since then, some additional funding has been put in place, but the new funding does not appear to equate to the likely total cost of association. Could you tell us, please, how the UK's association to Horizon Europe will be funded?

Third, a draft of the Horizon Europe Work Programme 2021–22 suggested that UK entities might be excluded from some projects in the areas of space and quantum technologies. It would be helpful if you could clarify latest developments on the scope of UK participation in Horizon Europe.

Finally, the TCA included reciprocity, meaning that EU entities "may participate in programmes of the United Kingdom equivalent to" the EU's research funds "in accordance with United Kingdom law and rules". How does the Government intend to facilitate such participation?

We look forward to a response within ten working days.

2 Protection of critical infrastructure[9]

This proposed Directive is legally and politically important because:

- it seeks to ensure that the operators of critical national infrastructure in 10 sectors (energy, transport, banking, financial market infrastructure, health, drinking water, waste water, digital infrastructure, public administration, and space) have robust plans to address natural and man-made risks which might significantly disrupt the provision of essential services;
- it may affect the operation of the single wholesale electricity market in Ireland and Northern Ireland and the laws applicable in Northern Ireland under the Protocol on Ireland/Northern Ireland to the UK/EU Withdrawal Agreement;
- it may also affect UK national critical infrastructure or operators where there are strong links to the EU or other interdependencies, such as highly connected supply chains; and
- it raises broader questions about the Government's approach to regulatory alignment and divergence after Brexit.

Action

- Write to the Paymaster General (Rt Hon. Penny Mordaunt MP) requesting further information on the potential impact of the proposed Directive in Northern Ireland, its wider implications for UK national critical infrastructure or UK operators with links to the EU, and the Government's approach to regulatory alignment and divergence after Brexit.
- Draw to the attention of the Northern Ireland Affairs Committee and the Public Administration and Constitutional Affairs Committee.

Overview

2.1 The EU's Security Union Strategy for 2020–25[10] highlighted how much of the critical infrastructure we depend on in our daily lives such as transport, energy, health, and telecommunications is underpinned by interconnected networks which, if disrupted, may reduce or prevent access to essential services. An incident in one sector, such as a power outage, can cause significant disruption in other sectors which depend on a secure supply of electricity. It can also have significant cross-border effects if the operators responsible for the critical infrastructure provide services or rely on supply chains which cross national borders.

2.2 The European Commission considers that the EU's existing framework for protecting critical infrastructure does not adequately address this increased interconnectedness and interdependency. It says that a more comprehensive approach is needed to prepare and plan for adverse events, both digital and physical, which may disrupt access to essential

9 Proposal for a Directive on the resilience of critical entities; COM(2020) 829; Article 114 TFEU, ordinary legislative procedure, QMV; Cabinet Office; Devolved Administrations consulted; ESC number 41751.

10 See the European Commission's Communication, COM(20) 605 published on 24 July 2020.

services and to manage, mitigate and recover from the after-effects more quickly. As foreshadowed in its Security Union Strategy, the Commission has proposed two new EU laws ("Directives") which would replace and update the existing framework of EU rules governing the protection of critical services and infrastructures:

- a proposed Directive to ensure a high level of cybersecurity within the EU which we considered in our Fortieth Report of Session 2019–21;[11] and
- a proposed Directive on the resilience of critical entities which we consider in this chapter.

2.3 To ensure a coherent approach to cyber and non-cyber risks all "critical entities"—designated public or private bodies providing services which have a vital societal or economic function—which are identified under the second of the two proposals would also have to comply with the cybersecurity measures envisaged in the first proposal.[12] The European Commission envisages that this new framework covering both cyber and physical risks will need to be accompanied by further sector-specific initiatives in areas such as transport, space, energy, finance and health.[13]

The proposed Directive on the resilience of critical entities

2.4 Current EU rules on critical infrastructure date back to 2008 and only cover the energy and transport sectors.[14] They establish a procedure for identifying and designating European critical infrastructures ('ECIs')—those considered vital to the functioning of the economy or social well-being which, if disrupted or destroyed, would have a significant cross-border impact affecting at least two EU countries. According to the European Commission, 94 ECIs have been designated under this procedure, most in Central and Eastern Europe. ECIs must take steps to identify and mitigate major threats and put in place appropriate security measures.

2.5 The European Commission considers that the scope of the EU's existing rules is too narrow and that, as a result, EU countries are adopting their own (diverging) rules which are having a negative effect on the functioning of the EU internal market. Its proposed Directive would repeal the current EU rules and replace them with a more comprehensive framework covering critical entities operating in 10 sectors: energy, transport, banking, financial market infrastructure, health, drinking water, waste water, digital infrastructure, public administration, and space. Under the new proposal each EU country would have to adopt a national strategy to ensure the resilience of critical entities operating in these sectors, including measures to enable them to withstand a range of natural and man-made incidents or attacks. Critical entities providing essential services whose interruption would have a significant disruptive effect would also have to carry out their own risk assessments and develop and apply their own resilience plans. These should set out the steps they have taken to prevent or reduce their exposure to natural and man-made risks,

11 Fortieth Report HC 229–xxxv (2019–21), chapter 1 (17 March 2021). See also the Joint Communication published by the European Commission and the EU's High Representative for Foreign Affairs and Security Policy on 16 December 2020, EU Cybersecurity Strategy for the Digital Decade JOIN(2020) 18.

12 A critical entity is a public or private body providing one or more essential services in a designated sector (energy, transport, banking, financial markets, health, drinking water, waste water, digital infrastructure, public administration, and space) which, if interrupted, would have significant disruptive effects.

13 See p.7 of the Security Union Strategy for 2020–25.

14 Directive 2008/114/EC on the identification and designation of European critical infrastructures and the assessment of the need to improve their protection

ensure adequate physical protection, mitigate and recover from the consequences of any incident (such as business continuity measures and alternative supply chains), and maintain security amongst their staff. Specific provisions would apply to "critical entities of particular European significance"—those providing essential services to or in more than one third of EU Member States—to ensure that there is effective oversight of their risk assessments and resilience plans.

2.6 Given the possibility that incidents affecting a critical entity within the EU may not stop at the EU's external border, the proposed Directive would require EU Member States when carrying out their risk assessments to cooperate with countries outside the EU that may also be affected by a disruption in the provision of essential services. Similarly, where critical entities based in the EU are required to undertake their own risk assessments, these would also have to take into account the impact of any disruption on countries outside the EU.

The Government's position

2.7 In her Explanatory Memorandum of 11 March 2021, the Paymaster General (Rt Hon. Penny Mordaunt MP) notes that the UK is under no obligation to implement the proposed Directive on the resilience of critical entities as it is no longer an EU Member State. The proposal would repeal a 2008 Directive[15] on the identification and designation of European critical infrastructures which ceased to apply in the UK when the post-transition period expired on 31 December 2020. The Minister adds, however, that the 2008 Directive has continued domestic relevance as it "will remain on the UK statute book as retained law" (EU law which continues to have effect in the UK's domestic law under the European Union (Withdrawal) Act 2018). While the 2008 Directive only covers critical infrastructure in two sectors (energy and transport), the revised rules would cover a total of 10 sectors, signifying a significant expansion in scope.

2.8 The Minister indicates that the proposed Directive "may impact the Northern Ireland Protocol" because it includes a reference to an EU Regulation on risk preparedness in the electricity sector[16] which is applicable in Northern Ireland under the provisions of the Protocol on the single electricity market.[17] As policy on critical national infrastructure is "primarily devolved" she says that legal teams within the UK Department for Business, Energy and Industrial Strategy and the Northern Ireland Executive Department for the Economy are seeking to clarify the relationship between the proposed Directive and the Protocol as well as any financial implications. Scottish and Welsh Government officials do not expect the proposed Directive to have a direct impact in their areas of responsibility.

2.9 The Minister considers that the proposed Directive would have "minimal direct impact" (outside of Northern Ireland) on the energy and transport sectors which are already covered by the 2008 Directive, adding that "security and resilience policy regarding Critical National Infrastructure within these sectors is mature and much wider than the 2008 ECI directive so will continue to be driven by HMG and Devolved Administrations' priorities". She recognises, however, that the proposed Directive may indirectly affect critical national infrastructure in the UK "through potential impacts on

15 Directive 2008/114/EC on the identification and designation of European critical infrastructures and the assessment of the need to improve their protection.

16 Regulation (EU) 2019/941.

17 The Regulation is applicable by virtue of Article 9 and Annex 4 of the Protocol on Ireland/Northern Ireland.

EU supply chains". Divergent regulatory approaches to the protection of critical national infrastructure may also increase the burdens on operators in sectors (such as transport) with strong links to the EU. In both cases, the Government would seek to mitigate any negative impact "through sector-specific industry risk management procedures" and engagement in relevant international fora.

2.10 The Minister anticipates that there could be additional risks for UK suppliers operating in EU Member States if they are required to provide sensitive information to the critical entities they supply which may then be shared across EU Member States. She adds that it is difficult to see what mitigation measures could be taken to ensure the security of this information.

The Protocol on Ireland/Northern Ireland

2.11 Electricity is one of the sub-sectors covered by the arrangements set out in the proposed Directive on the resilience of critical entities. Since 2007, the electricity industry has operated a single "all-island" wholesale market—the Integrated Single Electricity Market—in the Republic of Ireland and Northern Ireland. To enable this arrangement to continue beyond 1 January 2021, the Protocol on Ireland/Northern Ireland requires Northern Ireland to apply a number of EU laws insofar as they concern "the generation, transmission, distribution, and supply of electricity, trading in wholesale electricity or cross-border exchanges in electricity".[18] These laws include a 2005 Directive which set out measures to safeguard security of electricity supply and infrastructure investment.[19] In 2019, the Directive was repealed and replaced by a Regulation on risk preparedness in the electricity sector. This Regulation (rather than the 2005 Directive it replaced) now applies in Northern Ireland under the terms of the Protocol.[20]

2.12 Article 4 of the proposed Directive stipulates that Member States should take into account sector-specific risk assessments already required by EU law when carrying out their general risk assessment of the critical entities covered by the proposal, including the risk-preparedness plans in the electricity sector which are required by the 2019 Regulation to ensure security of supply. The Minister indicates that the specific reference to the 2019 Regulation in Article 4 of the proposed Directive means that "there may be links to the Single Electricity Market through the [2019] Risk Preparedness Regulation".

Our assessment

2.13 The main issue of concern at this stage is to determine whether the proposed Directive (or certain provisions in it) may apply in Northern Ireland under the Protocol on Ireland/Northern Ireland ("the Protocol") or, if not directly applicable, have implications for critical entities operating in or providing services to Northern Ireland. The Minister also raises broader concerns about the impact that "increasingly divergent regulatory approaches" may have on UK national critical infrastructure or operators where, for example, there are strong links to the EU or other interdependencies, such as highly connected supply chains.

18 See Article 9 and Annex 4 of the Protocol.

19 Directive 2005/89/EC.

20 Under Article 13(3) of the Protocol on Ireland/Northern Ireland, the 2019 Regulation applies as it replaces an act made applicable in Northern Ireland by the Protocol.

2.14 Turning first to the implications for Northern Ireland, Annex 4 of the Protocol provides that a simple reference in the EU acts listed in that Annex to the provisions of other EU laws not included in the Annex does not make those provisions applicable in Northern Ireland unless the provisions govern wholesale electricity markets, apply in Ireland, and are necessary for the joint operation of the single wholesale electricity market in Ireland and Northern Ireland. Annex 4 does not explain whether and to what extent a reference in a proposed EU law (in this case the proposed Directive) to an EU act (the 2019 Regulation) which is listed in that Annex and is applicable in Northern Ireland may bring it (or some of the provisions contained in it) within the scope of the Protocol. Nor does the Protocol indicate whether a similar test, based on the relevance of the proposal to the operation of the single wholesale electricity market, would apply in these circumstances.

2.15 The official-level EU/UK Joint Consultative Working Group ("JCWG") is the forum in which initial discussions about the application of proposed EU laws in Northern Ireland should take place.[21] The EU must inform the UK of any planned EU acts that it considers would fall within the scope of the Protocol and should be added to it. The EU must also provide the UK with all the information it (the EU) considers relevant to allow the UK to comply fully with its obligations under the Protocol.[22] While the Protocol envisages that the JCWG should meet "at least once a month", so far as we are aware it has only met twice this year (in January to agree its Rules of Procedure and in April). The Government has made clear that the UK will in any event form its own assessment of proposals for new EU laws to determine if they are applicable under the Protocol.[23]

2.16 Beyond the work underway with the Northern Ireland Executive, the Minister says in her Explanatory Memorandum that the Government is not consulting external stakeholders or undertaking an impact assessment as "the UK is not required to transpose or otherwise implement the proposed Directive into domestic legislation". She also recognises, however, that there may well be direct and indirect impacts on critical national infrastructure in the UK or on UK operators supplying critical entities in the EU. It is unclear how the Government can quantify and seek to mitigate these impacts if it is not carrying out its own consultation of those most likely to be affected.

Action

2.17 We have written to the Minister asking her to provide further information on the potential impact of the proposed Directive in Northern Ireland, its wider implications for UK national critical infrastructure or UK operators with strong links to the EU or other interdependencies, such as highly connected supply chains, and the Government's approach to regulatory alignment and divergence after Brexit.

2.18 We have drawn this chapter to the attention of the Northern Ireland Affairs Committee and the Public Administration and Constitutional Affairs Committee.

21 The JCWG was established by Article 15 of the Protocol on Ireland/Northern Ireland.

22 Article 15 of the Protocol.

23 See the letter dated 13 April from the Minister of State at the Cabinet Office (Lord Frost) to the Chair of the Lords EU Committee.

Letter to the Paymaster General (Rt Hon. Penny Mordaunt MP), Cabinet Office

Thank you for your Explanatory Memorandum of 11 March 2021 on a proposed Directive on the resilience of critical entities which the European Scrutiny Committee considered at its meeting on 12 May.

We note that there is some uncertainty about the interaction between the proposed Directive and the Protocol on Ireland/Northern Ireland ("the Protocol"). This is because there is a single "all-island" wholesale market—the Integrated Single Electricity Market—in the Republic of Ireland and Northern Ireland and electricity is one of the sub-sectors covered by the proposed Directive. The Protocol requires Northern Ireland to apply a number of EU laws which are considered necessary for the joint operation of the single wholesale electricity market. One of these laws—a 2019 Regulation on risk-preparedness in the electricity sector—is referred to in the proposed Directive.

We would welcome further information on the outcome of your legal assessment of the relationship between the proposed Directive and EU law that is applicable in Northern Ireland under the Protocol, as well as your analysis of the broader policy implications of the proposal for the operation of the single electricity market (or other critical infrastructure) in Northern Ireland.

The Protocol itself envisages that discussions concerning the possible application of proposed EU laws in Northern Ireland should initially take place in the Joint Consultative Working Group ("JCWG"). We note that the JCWG met in January to agree its rules of procedure and again in April. Do you consider the JCWG a useful forum in which to discuss the relationship between the proposed Directive and the Protocol, not least to ensure that any UK concerns can be taken into account before discussions on the proposal in the Council and the European Parliament advance further? When do you next expect the JCWG to meet and do you anticipate that the Government will seek to include the proposed Directive as an item for discussion?

In your Explanatory Memorandum you also raise broader concerns about the impact that "increasingly divergent regulatory approaches" may have on UK national critical infrastructure or operators where, for example, there are strong links to the EU or other interdependencies, such as highly connected supply chains. You do not indicate how significant these interdependencies are or what effect a significant divergence in the rules applicable to EU and UK operators of critical national infrastructure would have. As the Government has no plans to consult external stakeholders on the proposed Directive, it is difficult to see how any negative impacts can be quantified and steps taken to mitigate them.

With this in mind, we would welcome further information on the Government's approach to weighing the costs and benefits of regulatory alignment and divergence after Brexit, taking into account the impact of divergence within the UK as well as between the EU and the UK. How does the Government intend to ensure that the interests and concerns of all relevant Government Departments, regulatory bodies, devolved administrations and external stakeholders are taken into account in reaching an informed decision on alignment or divergence?

We look forward to receiving your response within ten working days.

3 Privacy and Electronic Communications[24]

This EU document is legally and politically important because:

- the proposal (once operative) will apply to providers outside the EU if they offer electronic communications services to EU end-users, regardless of the end of the transition period (a similar extraterritorial effect to that of the EU's General Data Protection Regulation); and
- important provisions in the proposal relevant to national security and combatting child abuse online could have future implications for the UK in terms of maintaining UK data adequacy.

Action

- To wait until there is further progress in trilogue negotiations and confirmation that UK data adequacy decisions have been adopted, before seeking another update from the Minister.
- To draw this update to the attention of the Digital, Culture, Media and Sport Committee, the Science and Technology Committee, the Home Affairs Committee, the Justice Committee and the Joint Committee on Human Rights.

Overview

3.1 This proposed ePrivacy Regulation was published in January 2017 to replace the current 2002 Directive on the privacy and protection of personal data relating to electronic communications (e-comms). E-comms can concern highly sensitive information about an individual. For example, medical conditions, sexual preferences, religious and political views, or commercially sensitive information about a business. Disclosure could result in personal and social harm, even economic loss.

3.2 Once operative, the Regulation could have major implications for the way that sectors such as technology, digital advertising and publishing do business in the EU and for individual privacy. The current Directive[25] dates from 2002 and covers confidentiality of e-comms provided via traditional communications services (e.g. emails and SMS text messages). The proposal will update the rules in the Directive to apply to 'Over the Top' services, including internet-based messaging services such as WhatsApp and Voice over Internet Protocol services (e.g. Skype). It will also govern the use of cookies, other tracking technologies as well as email marketing.

24 Proposal for a Regulation of the European Parliament and the Council concerning the respect for private life and protection of personal data in electronic communications and repealing Directive 2002/58/EC; Council and COM number: 5358/17 + ADDs 1–6, COM(17) 10; Legal base: Articles 16 and 114 TFEU, ordinary legislative procedure, QMV; Department: Digital, Culture, Media and Sport; Devolved Administrations: informed; ESC number: 38455.

25 Directive 2002/58/EC (Regulation on Privacy and Electronic Communications).

3.3 An account of the scope and content of the proposed Regulation and the Government's view of it are set out in our predecessors' previous Reports.[26]

3.4 The current Directive was implemented by the UK by means of The Privacy and Electronic Communications (EC Directive) Regulations 2003[27] (PECR). From 1 January 2021, the PECR will continue to apply[28] in UK law as retained EU law.

3.5 The Commission had planned for the proposed Regulation to come into force at the same time as the General Data Protection Regulation (GDPR) on 25 May 2018. However, the proposal has proved very controversial, resulting in slow progress in negotiations in the Council.

3.6 Since the last time we considered the proposal—in our Thirty-third Report of Session 2019–21[29]—there has been a breakthrough. The Council has agreed a mandate for trilogue negotiations with the EP. This was only achieved after the end of the post-Brexit transition period on 10 February and so the proposal does not bind the UK as such. However, it still remains relevant because:

- The proposal as drafted has a similar extraterritorial effect to the GDPR:[30] the text as drafted and once operative would apply to providers outside the EU if they offer electronic communications services to EU end users.[31]

- The question of the equivalence of the UK's protection of personal data relating to electronic communications formed part of the Commission's adequacy assessment before publishing draft GDPR and Law Enforcement data adequacy decisions.[32] Even once a data adequacy decision is adopted, the Commission is under a duty to keep it under review and repeal, amend or suspend a decision if a third country is no longer providing adequate protection of EU citizens' data. Should the UK not update its current framework in the light of the ePrivacy proposal once adopted, then any divergence between that and the EU ePrivacy framework will fall to be considered by the Commission. As the UK's ePrivacy framework is currently aligned with the EU's, it has not yet been raised as an issue either by the Commission or by the European Data Protection Board in its recent opinions on the Commission draft adequacy decisions. For further detail on these draft decisions and the data adequacy process, please see our other chapter in this week's Report on "Data Adequacy" and our Fortieth Report of 18 March.[33]

26 Fifty-first Report HC 301-I (2017–19), chapter 3 (16 January 2019); Twenty-first Report HC 301–xx (2017–19), chapter 1 (21 March 2018); Thirty-first Report HC 71–xxix (2016–17), chapter 6 (8 February 2017); also see (38446), 5034/17: Sixteenth Report HC 301–xvi (2017–19), chapter 3 (28 February 2018).

27 Amended by the (as amended by the Privacy and Electronic Communications (EC Directive) (Amendment) Regulations 2011 (SI 2011/1208), the Privacy and Electronic Communications (EC Directive) (Amendment) Regulations 2015 (SI 2015/355), the Privacy and Electronic Communications (EC Directive) (Amendment) Regulations 2016 (SI 2016/524) and the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019/419) and the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019/419).

28 As amended by the EU Exit SI above.

29 Thirty-third Report HC 229–xxix (2019–21), chapter 2 (16 December 2020).

30 General Data Protection Regulation.

31 See Article 3 "Territorial scope" which extends the Regulation to providers established outside the EU.

32 See Article 45 of the GDPR for the wide range of factors that the Commission can take into account in its data adequacy assessment.

33 Fortieth Report HC 229–xxxv (2019–21), chapter 2 (17 March 2021).

3.7 For these reasons, the Committee has been closely monitoring developments in the negotiation of this proposal. The last time we wrote to the Government was on 16 December, when we also last reported to the House. In that letter we flagged our intention to pursue as part of any future scrutiny the potential for a Regulation to still have relevance to the UK even if adopted after transition. We also flagged the Government's omission to comment on the implications for the UK of last October's Court of Justice ruling in Privacy International case[34] which concerned whether processing for national security purposes fell within the scope of the current ePrivacy Directive.

Letter from the Minister for Media and Data (Rt Hon. John Whittingdale OBE MP)

3.8 In response to our letter of 16 December and a request for an update by Committee officials, the Minister for Media and Data (Rt Hon. John Whittingdale OBE MP) wrote to us on 16 April.

3.9 We highlight some points from the Minister's letter. On the legislative progress of the current proposal in the EU, he says:

- as the Council's compromise text reaffirms an extraterritorial element to the proposed ePrivacy regime, the UK has been closely monitoring its progress;
- trilogue negotiations are expected to begin soon but it is unknown when agreement on a text will be reached by Commission, Council and European Parliament; and
- the Government will be looking into the potential impact of the current draft text on the UK's electronic communications industry and other affected parties and on the UK's ability to protect national security and to prevent, detect, investigate and prosecute criminal activity.

3.10 On the related question of data adequacy, the Minister refers to the publication of the draft positive adequacy decisions for the UK earlier this year. He then says that they "will shortly be presented to Member States for formal approval in the Council".

3.11 We pause in our consideration of the Minister's letter here to clarify that this is not our understanding of the examination procedure[35] which is used for the adoption of adequacy decisions as Commission Implementing Acts. This process is specified in Article 93(2) of the GDPR and Article 58(2) of the Law Enforcement Directive. Implementing decisions are not adopted by the Member States in the Council and instead are presented for approval by qualified majority voting to national expert representatives of the Member States in a technical committee (formerly known as a comitology committee).

3.12 Continuing to address data adequacy, the Minister adds:

- The European Data Protection Board has now issued a non-binding opinion on the decisions, which the Government is now analysing.

34 C-623/17.

35 See Article 5 of Regulation (EU) No 182/2011 (the so-called Comitology Regulation).

- No other third country seeking adequacy from the EU has undergone an assessment from a position of such closely shared standards and such deep economic and law enforcement cooperation.
- The EU's adequacy test does not require other countries' rules to be exactly the same—they require the standard of data protection to be "essentially equivalent".
- EU Member States themselves can implement EU data legislation differently or apply derogations, and many do.
- The Commission did not voice any concern about the UK's Privacy and Electronic Communications Regulations when assessing the UK data protection framework to be "essentially equivalent".

3.13 The Minister ends with a pledge to continue to monitor relevant international legislation and consider any changes to our domestic laws that are needed to reflect developments.

Action

3.14 We will wait until trilogue negotiations have completed before seeking another update from the Minister. By that time, we hope that the EU will have adopted data adequacy decisions for the UK. We will then ask the Minister for a view on what provisions of the final text mean for ongoing equivalence between the EU and UK regimes on important matters such as national security and combatting child protection online.

3.15 We draw this update from the Minister to the attention of the Digital, Culture, Media and Sport Committee, the Science and Technology Committee, the Home Affairs Committee, the Justice Committee, and the Joint Committee on Human Rights.

4 Data adequacy[36]

These EU documents have not been deposited by the Government under the current interim scrutiny arrangements. These documents are, however, legally and politically important because:

- once adopted, they will provide the EU legal basis for the transfer of personal data from the EU to the UK which is vital for the conduct of trade and law enforcement cooperation under the UK/EU Trade and Cooperation Agreement (TCA);
- after adoption, they will expire after four years unless extended, be under constant review and monitoring by the EU Commission and be open to legal challenge; and
- effective Parliamentary scrutiny of the maintenance of adopted decisions and the corresponding UK data protection legal framework is a ground relied upon by the EU Commission and Government to support a positive adequacy assessment.

Action

- To update the House on the Minister's letter and the new European Data Protection Board opinions and draw this chapter to the attention of the Committees listed in paragraph 4.17.
- To defer writing to the Government again until there has been further progress in the process for adopting the decisions and Lord Frost has appeared before this Committee on 17 May.

Overview

4.1 A data adequacy decision that a third country provides "essentially equivalent" personal data protection to the EU comprises the most comprehensive and seamless basis for the transfer of data from the EU to that country. Whether for the purpose of trade or cooperation on law enforcement, data adequacy decisions enable data to flow lawfully to third countries from the EU without the need for further safeguards.

4.2 The flow of personal data from the EU[37] to the UK is vital for the EU-UK future relationship, particularly in terms of trade and law enforcement cooperation under the UK/

36 (a) Proposal for a Commission Implementing Decision;—; Article 45(3) of Regulation 2016/679 of the European Parliament and Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation); Department: Digital, Culture, Media and Sport;—; 41796; (b) Proposal for a Commission Implementing Decision;—; Article 36(3) of Directive 2016/680 of the European Parliament and Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties and on the free movement of such data and repealing Council Framework Decision 2008/977 JHA; Department: Home Office;—; 41797.

37 Strictly speaking, the data adequacy decisions cover personal data transferred from EEA countries, not just the EU.

EU Trade and Cooperation Agreement (TCA). Currently, this flow of data is continuing by virtue of the bridging provisions in the TCA,[38] but these are due to expire at the end of June at the very latest.

4.3 In order for data flows to continue in a similar manner after that date, data adequacy decisions need to be in place both in respect of trade and law enforcement cooperation. There is no set timetable for the internal EU process for adopting those decisions. It involves the EU Commission putting draft decisions to the European Data Protection Board (EDPB) for their opinion, then progressing the texts (amended in the light of any EDPB opinions) to national expert representatives for their approval in a technical committee. Our Fortieth Report of Session 2019–21 provides further background information on this process and the draft decisions.

4.4 So far:

- on 19 February the Commission published both a draft General Data Protection Regulation (GDPR)[39] decision and the Law Enforcement draft decision;
- on 22 March 2021, the committee of national experts met to discuss the draft decisions for the first time but without presenting any opinions or voting on the decisions; and
- on 14 April the EDPB adopted broadly positive non-binding opinions on the two decisions, but with work left for the Commission to do which may mean a further delay in the process and amendments to the drafts (for further information on the opinions, see paragraphs 4.8–4.11 and 4.14).

4.5 We are aware that the European Parliament (EP) is due to vote in plenary on 20 May on a Resolution in relation to the draft decisions and wait to see what the final Resolution says. Should the EP resolve that the Commission has exceeded its implementing powers under the GDPR and Law Enforcement Directive, the Commission will be under an obligation to (a)review the draft decisions, taking account of the EP's views and then (b) to inform the EP whether it will maintain, amend or withdraw the texts.[40]

4.6 After the publication of the draft decisions, we reported to the House on 17 March. We wrote to Ministers in both the Home Office and the Department for Digital, Culture, Media and Sport, asking for their view of the draft decisions and focussing on the questions which are set out at paragraphs 4.15–4.17 of this chapter.

4.7 We now report the Government's response to our letter and to update the House on newly adopted EDPB opinions.

Further information on the adopted EDPB opinions

4.8 On 14 April, the European Data Protection Board (EDPB) adopted a non-binding opinion on the GDPR draft adequacy decision and another on the draft Law Enforcement

38 Article.FINPROV.10A of the Trade and Cooperation Agreement.

39 General Data Protection Regulation.

40 See Article 11 of the "Comitology Regulation": Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

decision. While the opinions are broadly positive, the Commission may need to work further with the UK on particular aspects, perhaps amending the draft decisions to meet some specific concerns.

4.9 Their Press Release indicated that EPDB had concluded that there were key areas of strong alignment between the EU and the UK data protection frameworks on certain core provisions such as: grounds for lawful and fair processing for legitimate purposes; purpose limitation; data quality and proportionality; data retention, security and confidentiality; transparency; special categories of data; and on automated decision making and profiling. It therefore identified many "essentially equivalent" areas.

4.10 However, the Press Release sounded some notes of caution:

- as laws evolved, alignment "should be maintained" and so the EDPB welcomed the Commission's decision to limit the granted adequacy in time and the intention to closely monitor developments in the UK; and
- several items should be further assessed and/or closely monitored by the European Commission in its decision based on the GDPR, such as:
- the Immigration Exemption in the Data Protection Act 2018 and its consequences on restrictions on data subject rights; and
- the application of restrictions to onward transfers of EU personal data transferred to the UK, on the basis of, for instance, future adequacy decisions adopted by the UK, international agreements concluded between the UK and third countries, or derogations.

4.11 Regarding access by public authorities for national security purposes to personal data transferred to the UK, the EDPB welcomed the establishment of the Investigatory Powers Tribunal (IPT) to address the challenges of redress in the area of national security, and the introduction of Judicial Commissioners in the Investigatory Powers Act (IPA) 2016 to ensure better oversight in that same field. However, it identifies a number of points requiring further clarification and/or monitoring by the Commission:

- bulk interceptions of personal data by UK public authorities and intelligence services;
- independent assessment and oversight of the use of automated processing tools; and
- safeguards provided under UK law when it comes to overseas disclosure, in particular in light of the application of national security exemptions.

Government's letter of 19 April

4.12 On 19 April the Minister for Media and Data (Rt Hon. John Whittingdale OBE MP) responded to our letter of 17 March. The Home Office Minister for Future Borders and Immigration (Kevin Foster MP) was also a signatory to the letter. However, it is clear that DCMS is the lead department on this issue, so we assume for the purposes of summarising the letter that the Minister for Media and Data is the lead minister.

Progress and timeframe for the adoption process for the decisions

4.13 Recognising that adequacy decisions for the UK are of significant legal and political importance, the Minister first addresses the question of the timing of the adoption process. He says that:

- The Government is urging the EU to complete its technical approval process promptly, but ultimately that process is controlled by the EU.
- The EDPB's role in the approval process is to review the decisions and publish non-binding opinions, which they did on 16 April.
- The Government now expects the Commission to move on to the next stage of the process and sees no reason why the decisions should not be swiftly approved.
- The Council's Article 93 Committee of EU Member State representatives has already met to discuss the draft decisions and they will formally vote on them shortly.
- The Commission expects this process to be concluded by late May or early June 2021.
- Until the process is completed, the Minister notes that in the meantime, due to the time limited 'bridging mechanism' the UK agreed as part of the EU-UK Trade and Cooperation Agreement, personal data can continue to flow freely as it did previously, until the adequacy decisions are adopted (or 6 months from 1 January 2021, whichever is earlier).
- In terms of Parliamentary scrutiny, the Minister says that the Government will endeavour to keep the Committee informed about the progress of the process for adopting the draft decisions.

EDPB Opinions

4.14 On the question of the substance of the EDPB opinions, the Minister says:

> The EDPB noted the "strong alignment" between the UK and EU data protection systems, but also emphasised that the Commission should monitor future "relevant developments" in the UK. The UK Government is reviewing the EDPB opinions and the European Commission is also considering them.

Our specific questions

4.15 The Minister then addresses the specific questions that the Committee raised in its letter. For ease of reference we set out our questions and summarise the Minister's response below each one in the form of bullet points.

How will the Government assess and manage the risk to the maintenance of the adequacy decisions should it wish to diverge from EU data protection law in future?

Divergence seems likely to us, in the light of the article in the Financial Times (FT) written by the Secretary of State for Digital, Culture, Media and Sport (The Rt Hon. Oliver Dowden CBE MP) on 27 February, though the timing and extent is less clear.

- As the UK would like to be at the forefront of global, data-driven growth, it is inevitable that the UK and EU's data protection regimes will evolve independently over time.
- The UK is firmly committed to maintaining high data protection standards and protecting the privacy of individuals will continue to be a priority.
- As the EU Commission itself has made clear, a third country is not required to have identical rules to the EU in order to be considered adequate.
- The twelve EU countries with adequacy decisions, ranging from Israel to New Zealand, each have data protection laws that are different to the EU's.

Linked to this, how does the Government propose to approach the "invitation" in Recitals 275 of the GDPR decision and 165 of the LED decision which note the ongoing monitoring obligations of the Commission of UK adequacy and state: "To this end, the UK authorities are invited to inform the Commission of any material change to the UK legal order that has an impact on the legal framework that is the object of this Decision...". What would it consider to be a "material change" and how wide does it consider the relevant "legal framework" to be? Would that encompass any material future changes the Government may wish to make in due course to judicial review or the Human Rights Act? How will Parliamentary scrutiny be included in that process? Will Parliament be informed at the same time as the EU Commission?

- UK officials provided a significant amount of information on the UK's legal framework to the Commission as part of the adequacy assessment, and the Government also published detailed information on how the UK's framework meets the EU's adequacy test.
- The Government will keep Parliament informed regarding any major developments or milestones relating to EU adequacy or the UK's future data protection framework.
- It is for the EU to decide what constitutes a "material change" or the relevant "legal framework" with respect to its adequacy decisions, as this is a unilateral EU process.
- It is for the Commission to decide how to monitor adequacy decisions.
- The UK is firmly committed to maintaining high standards of data protection and the Government will continue to engage with the EU on these matters.
- What arrangements will there be in Government for monitoring EU developments that could cause divergence between the EU and UK legal frameworks in this area, both in terms of new data protection legislation and CJEU case law? How will dialogue take place between the EU and the UK about managing such divergence? How will Parliamentary scrutiny be included in that dialogue?

- The Government will monitor data protection developments across the world, including in the EU, and assess whether and how those developments can inform the UK's own laws and practices.
- The UK has legislated to treat all EU and EEA states as "adequate" under UK law.
- The Government will continue to monitor data protection standards in the EU and EEA states to ensure they provide an adequate level of protection for UK personal data.
- The UK's own legislation requires the Government to undertake a review of the relevant legislative provisions within four years of the end of the Transition Period in any event.
- Parliament will get the opportunity to scrutinise these "adequacy regulations" once the Secretary of State makes and lays them in Parliament.

How will the Government ensure that its own new adequacy assessments for non-EU countries do not cause "equivalence" difficulties in terms of onwards transfer from the UK to those countries of personal data originating from the EU? We note in this respect from the Secretary of State's FT article that the Government is keen to adopt significantly more adequacy assessments for non-EU countries than the EU currently has.

- The Government intends to expand the list of adequate destinations in line with UK national interests including a commitment to high standards of data protection.
- The EU is also working to expand its adequacy list, as shown by its recent announcement of a draft adequacy decision for the Republic of Korea.
- The Government will be publishing its priority countries for UK adequacy in due course.
- The Commission reviewed the UK's laws and independent approach to international data transfers as part of its comprehensive assessment of the UK.
- They found the UK to be 'adequate' for the purposes of EU law and outlined why in the draft adequacy decisions.
- They did not recommend in those decisions any restriction on the transfer of EU data from the UK to jurisdictions that the UK may in future find adequate.
- The UK will continue to ensure that individuals' data protection rights are protected and upheld when their personal data is transferred overseas from the UK.
- Any future UK adequacy decisions will only be granted to countries which are found to have high data protection standards.
- The test for adequacy provided for in the UK GDPR is that, when personal data is transferred to the third country, the level of protection under the UK GDPR is not undermined.

- To determine this, the Government will consider the overall effect of a country's data protection laws, implementation, enforcement, and supervision.
- Again parliamentary scrutiny will consist of looking at the "adequacy regulations" once they are laid.
- The Secretary of State will also consult the Information Commissioner's Office (ICO) on future adequacy assessments.
- More information on the roles and responsibilities between the ICO and DCMS on UK data adequacy assessments is set out in a Memorandum of Understanding.
- Once UK adequacy decisions are granted, the Government will review periodically and at least every four years.

How will the Government ensure that "equivalence difficulties" are not caused by data protection, data exchange and digital trade provisions in any international agreements between the UK and non-EU countries?

- The UK does not intend for free trade agreements (FTAs) to provide a legal basis for the cross-border transfer of personal data.
- Data adequacy is legally separate from provisions in FTAs.
- Nonetheless, adequacy decisions can help unlock the benefits of market liberalising provisions in FTAs, especially for services that depend on flows of personal data.
- The UK will not enter into international agreements that are incompatible with the UK's high data protection standards.
- The Government will continue to consider the implications—including for cross-border data transfers—of all international agreements and commitments the UK enters into.

What arrangements, if any, will there be for communication between the EU, UK Government and the Information Commissioner on matters potentially affecting the maintenance of the adequacy decisions?

- The Government is in regular contact with EU officials and representatives.
- The UK will engage in any future review processes, although these will be controlled by the Commission.
- The Government also in regular contact with the independent ICO on a wide range of data protection matters (see the MOU referred to above).
- When adopted, the UK's law enforcement adequacy decision will be the first of its kind and will help give confidence to law enforcement authorities based in the EU that when they share data with their UK counterparts that data will be protected to equivalent high standards.

- However, adequacy is just one way for which data can be shared internationally; both EU and UK data protection legislation provide alternative transfer mechanisms in the absence of adequacy.
- In the event that UK and EU legislation diverges in the future, the UK is committed to ensuring high data protection standards, as rightfully recognised by the Commission in their decision, and so the Government would expect to retain the adequacy decision.

How does the Government interpret the ART.LAW.OTHER 137 in terms of possible suspension of parts or the whole of Part 3 Law Enforcement Cooperation of the TCA? If one or either of the two adequacy decisions ceased to apply, would that be sufficient for one party to suspend obligations or it is beyond doubt that the "serious and systemic deficiencies" as regards the relevant party's data protection would also need to be established?

- Article.Law.Other 137 (2) is clear that the legal test for suspension is "serious and systemic deficiencies" in data protection—there is no direct link between cooperation under the Law Enforcement part of the TCA and adequacy although it is a factor either party could take into consideration.
- Furthermore, data protection concerns would not automatically lead to suspension—this would be a decision for the party in question.

How does the Government propose to keep Parliament and this Committee informed on these matters on a regular, timely, responsive and transparent basis, particularly in the lead-up to the four-year expiry/extension deadline?

- The Government endeavours to keep the Committee and Parliament informed and updated on important milestones in the EU adequacy process.
- When the EU formally adopts the UK's adequacy decisions, the Secretary of State will make a statement to the House of Commons.
- Again, Parliamentary scrutiny will also consist of looking at adequacy regulations when laid as a statutory instrument.
- The review and renewal of the UK's adequacy decisions is a unilateral EU matter.
- It is not for the UK to comment on any EU arrangements to facilitate this.
- The UK will engage in any future review processes and the Government will provide information and updates to Parliament at the appropriate time.

Action

4.16 We defer writing to the Government again on these documents until the process has progressed further and the Minister of State at the Cabinet Office (Rt Hon. Lord Frost CMG) has appeared before the Committee. We expect now that he will attend on 17 May, in light of his recent letter requesting to defer the date previously fixed for his appearance on 26 April.

4.17 The draft decisions are of cross-cutting relevance to the work of many Committees across the House. We are therefore also drawing this Report chapter and the Government's letter to the attention of the International Trade Committee; the Home Affairs Committee; Digital, Culture, Media and Sport Committee; the Business and Industrial Strategy Committee; the Science and Technology Committee; the Health and Social Care Committee; the Northern Ireland Affairs Committee and the Joint Committee on Human Rights.

5 European Maritime, Fisheries and Aquaculture Fund[41]

This EU document is politically important because:

- it concerns the sustainability of the seas and fish stocks shared by the UK and EU; and
- it relates to future UK domestic support for the fishing sector.

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

5.1 The EU's European Maritime, Fisheries and Aquaculture Fund (EMFAF) targets EU funding to support the implementation of the Common Fisheries Policy (CFP), the EU's maritime policy and the EU's international ocean governance commitments. The UK participated in its predecessor (the European Maritime and Fisheries Fund) until 31 December 2020 but will not participate in its successor Programme.

5.2 The nature of the EMFAF is relevant to the UK because any unsustainable subsidies could affect the sustainability of shared fish stocks, and consequently the fishing opportunities available to UK fishers. Separately, the Government is setting up a domestic replacement. Both the UK's scheme and the EMFAF operate against the backdrop of ongoing discussions at the World Trade Organization (WTO) on fishing subsidies.[42]

5.3 In her letter of 9 February 2021, the Minister for Farming, Fisheries and Food (Victoria Prentis MP) summarised the conclusion of the EU's negotiations on its future Fund.

5.4 The Minister explained that the Regulation establishing the EMFAF was provisionally agreed in December 2020, establishing the Fund for the period 2021–2027. The EMFAF would be worth €6.108 billion (£5.205bn), of which €5.3bn (£4.52bn) would be managed by Member States and the remainder retained under direct control of the European Commission. This compares to the €6.4bn (£5.45bn) European Maritime and Fisheries Fund (EMFF) over 2014–2020, of which the UK was allocated €243 million (£207m).

41 Proposal for a Regulation of the European Parliament and of the Council on the European Maritime and Fisheries Fund; Council and COM number: 9627/18 + ADDs 1–2, COM(18) 390; Legal base: Articles 42, 43(2), 91(1), 100(2), 173(3), 175, 188, 192(1), 194(2), 195(2) and 349 TFEU, ordinary legislative procedure, QMV; Department: Environment, Food and Rural Affairs; Devolved Administrations: Consulted; ESC number: 39938.

42 World Trade Organization, Factsheet: Negotiations on fisheries subsidies.

5.5 The new EU fund was expected to include measures that would support fishers to replace and modernise engines, assist in the purchase of new vessels, and provide aid for storage in the event of market disruption. The Minister's officials, she said, were monitoring developments and expected further details to emerge.

5.6 Turning to arrangements in the UK, the Minister says that the Government has gone beyond its manifesto commitment to maintain funding across the UK and support UK coastal communities. In addition to £32.7 million in repatriated EU funding to support fisheries across the UK, said the Minister, the Prime Minister had announced a further £100m of investment for the sector to modernise their fleets and the fish processing industry. The Prime Minister had also announced £23m of financial support for seafood exporting businesses which have suffered losses due to Covid-19 and to delays in shipments of live and fresh seafood produce to the EU.

Our assessment

5.7 Since the Minister wrote, the EU has published the text of the Regulation[43] on the EMFAF 2021–27, along with an accompanying note[44] explaining the outcome. As the Minister noted, support will be available to replace and modernise engines in vessels up to 24 metres in length, but under strictly controlled circumstances with a view to ensuring that there is no increase in capacity. For vessels between 12 and 24 metres, support will also be conditional on a minimum 20% reduction in greenhouse gas emissions.

5.8 Concerning aid for the purchase of vessels, this is limited to support for first acquisition of existing vessels under 24 metres, and specifically to those aged under 40 who have at least five years of fishing experience. They should own at least 33% of the shares in the vessel. It is only available in sustainable fisheries (where fishing capacity and fishing opportunities are balanced).

5.9 We note the outcome of discussions and observe that the EMFAF permits limited funding for the acquisition of new vessels as well as for the replacement and modernisation of engines. While the limits on this expenditure are welcome, we consider it important that the Government monitors the Commission's regular reports on this expenditure, as well as the work of the European Court of Auditors in that regard. Ultimately, any failure to apply the conditions around this spending could lead to an increase in capacity, which could have a detrimental impact on the sustainability of fish stocks shared between the UK and EU.

5.10 Concerning the UK's domestic expenditure on fisheries support, we note a number of commitments but also note that detail is outstanding, notably on the Prime Minister's announcement on 24 December 2020 of £100 million investment to rejuvenate the seafood industry and coastal communities across the UK.

43 6311/21 Proposal for a Regulation of the European Parliament and of the Council on the European Maritime and Fisheries Fund and repealing Regulation (EU) No 508/2014 of the European Parliament and of the Council (EMFF) –Political agreement.

44 6310/21. Proposal for a Regulation of the European Parliament and of the Council on the European Maritime and Fisheries Fund and repealing Regulation (EU) No 508/2014 of the European Parliament and of the Council (EMFF)—Political agreement.

Action

5.11 We require no further information from the Minister but we urge the Government to be vigilant in monitoring how the EMFAF is spent and we also look forward to clarity from the Government in due course on the various sources of financial support available to the industry across the United Kingdom.

5.12 We are drawing 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.

6 EU Pharmaceutical Strategy[45]

This EU document is politically important because:

- it suggests changes to EU pharmaceutical legislation with which Northern Ireland must remain aligned;
- this is an area of regulation where the EU and UK agreed to cooperate under the terms of the EU-UK Trade and Cooperation Agreement;
- any EU changes to incentives for the production of medicines could have implications for the competitiveness of the UK pharmaceutical industry if the UK did not adopt a similar approach;
- research is an important element of the Strategy and is an area where the UK has negotiated continuing participation in an EU programme; and
- it relates indirectly to discussions on a temporary intellectual property waiver to ensure widespread global access to medical products for the prevention, containment and treatment of Covid-19, including vaccines.

Action

- Report to the House.
- Draw to the attention of the Business, Energy and Industrial Strategy Committee, the Health and Social Care Committee, the International Trade Committee, the Northern Ireland Affairs Committee and the Science and Technology Committee.

Overview

6.1 The EU's Pharmaceutical Strategy is relevant to the UK for a number of reasons. Most directly, it signals an intention to propose, in late 2022, broad changes to the "pharmaceutical legislation"[46] and other pieces of legislation such as Regulations on paediatric[47] and orphan[48] medicines "pharmaceutical acquis", which would need to be applied in Northern Ireland and, if not mirrored in Great Britain, could create fundamental problems for medicine supply to Northern Ireland. The Minister of State for Health (Edward Argar MP) has written to us confirming the Government's commitment to ensuring that there is no impediment to securing access to vital medicines across the UK. How that commitment can be ensured without maintaining alignment between the EU and Great Britain, though, remains unclear.

45 Commission Communication—Pharmaceutical Strategy for Europe; COM number: COM(20) 761; Legal base:—; Department: Health and Social Care; Devolved Administrations: Consulted; ESC number: 41687.

46 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency.

47 Regulation (EC) No 1901/2006 on medicinal products for paediatric use.

48 Regulation (EC) No 141/2000 on orphan medicinal products.

6.2 The Strategy may also have wider UK relevance in terms of: competitiveness if the EU and UK pursue different approaches to incentives; research endeavours given that the UK has secured participation in the EU's research framework for 2021–27; and international collaboration, particularly as that type of regulatory cooperation on medicines is foreseen in the EU-UK Trade and Cooperation Agreement.

6.3 We set out further details of the Commission's Strategy in our Report of 24 March 2021, following which we wrote to the Minister requesting additional information.

Response from the Minister of State for Health

6.4 We have summarised below the Minister's response, under a series of headings.

Northern Ireland Protocol

6.5 The Minister confirms that, under the terms of the Northern Ireland Protocol annexed to the EU/UK Withdrawal Agreement, Northern Ireland (NI) will continue to follow EU law in relation to human medicines and medical devices. The Medicines and Healthcare Products Regulatory Agency (MHRA) will continue to be the regulator for the whole of the UK.

6.6 The Government is clear that the Protocol provides that, where a GB body or authority currently can approve goods for sale on the NI market, they will continue to be able to do so. Therefore, the UK regulator will be able to take sovereign regulatory decisions that will also apply directly in NI, as long as those decisions do not conflict with EU decisions whilst the Northern Ireland Protocol applies.

6.7 Going forward, the UK will ensure that changes to EU rules, including legislation on orphan and paediatric medicines, are implemented in NI in line with the Protocol in a way that helps ensure continued supply to NI, by issuing clear guidance and engaging with industry and patients.

6.8 The Government will ensure that any new rules applicable to the rest of the UK (i.e. Great Britain) are designed to ensure a coherent NI and GB approach. The Government remains committed to ensuring that there is no impediment to securing access to vital medicines across the UK, including NI, and the Government will continue to ensure an outcome that is equitable for patients in all parts of the UK.

6.9 The UK is enabling continuity with EU law by allowing, for a period of two years from 1 January 2021, the MHRA to rely on a decision taken by the European Commission on the approval of a new Marketing Authorisation (MA) in the Centralised Procedure.[49] Marketing authorisations approved by EU member states through the Decentralised and Mutual Recognition Procedures[50] will also be given regard by the MHRA with a view to granting the MA in the UK or GB. Regulatory divergence between the EU and the UK will risk delays in marketing applications for new products. The MHRA will work with industry to minimise risk, for example by consulting on changes and providing guidance ahead of changes taking effect.

49 A "centralised" decision taken by the Commission on behalf of the EU, and based on a recommendation by the European Medicines Agency.

50 Where decisions are taken by one Member State and recognised by the Commission and the other Member States.

Overall strategy

6.10 The Government, says the Minister, is committed to cementing the UK's position as a world leader in life sciences, ensuring that the UK remains an attractive place to do business and that patients benefit from access to cutting-edge treatments as soon as possible. Post-Brexit, he says, the UK has the flexibility to develop a dynamic regulatory system that allows it to be more innovative and to collaborate even more effectively globally.

6.11 The Medicines and Medical Devices Act 2021, explains the Minister, introduces powers to implement "new and innovative policy", including the ability to access novel medicines. The UK is already one of the world's leading centres for clinical trials, says the Minister, and the Act will enable the UK to make any future regulatory changes that are required to ensure it remains so. The Medicines and Healthcare Products Regulatory Agency (MHRA) is currently seeking to streamline the process and remain competitive in approval timelines. The UK will now build on the agility that has been central to the MHRA's response to Covid-19 and continue to make the UK system as efficient and sustainable as possible.

Innovating in areas of unmet clinical need

6.12 The Minister agrees that pharmaceutical innovation should meet the needs of patients and address areas of unmet need, although does not indicate that there is a need to review the incentives in place as suggested by the Commission in its Strategy. He highlights the following examples of UK action to promote innovation in areas of unmet clinical need:

- the Innovative Licensing and Access Pathway (ILAP), launched in January 2021, which provides a new pathway for accelerating the time to market for innovative medicines (focussing on medicines for rare diseases and those developed in line with public health priority and treatments for life-threatening or seriously debilitating conditions), and a similar pathway is in development for medical devices;
- the recent UK-wide vision for the future of clinical research delivery,[51] which is focussed on delivering a future environment which is patient-centred, pro-innovation and has the infrastructure in place to make use of the UK's unique data assets;
- the UK Rare Diseases Framework, which provides the high-level direction for rare diseases, outlining a coherent, national vision on how the UK will improve the lives of those living with rare diseases, including improving access to specialist care, treatments and drugs;
- establishment by NICE (National Institute for Clinical Excellence) of the "Highly Specialised Technologies" (HST) process, providing a higher cost Quality Adjusted Life Year (QALY) threshold for treatments targeting very rare diseases;

51 Saving and improving lives: the future of UK clinical research delivery. 23 March 2021, UK administrations.

- the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS), which improves patient outcomes through a series of pro-access and pro-innovation ambitions, while providing financial predictability by capping per annum growth in UK branded medicines spend at 2%; and
- the Early Access to Medicines Scheme (EAMS), which provides patients with life-threatening or seriously debilitating conditions from across the UK access to medicines that do not yet have a marketing authorisation when there is a clear unmet need.

6.13 The UK, adds the Minister, has developed new commercial processes to improve patient outcomes and value for the NHS whilst incentivising pharmaceutical companies to innovate and develop solutions to current and future healthcare challenges. For example:

- the launch of a new subscription payment model[52] to incentivise development of new antimicrobial drugs, with annual payments based on the health benefits to patients and the value to the NHS rather than payments being based on volume alone;
- the launch of the expanded Commercial Medicines Unit (CMU) in NHS England has been followed by the publication of a Commercial Framework which sets out the new commercial flexibilities available to the most clinically and cost-effective new treatments; and
- establishing a dedicated 'triage function' within NHS England's Commercial Medicines Directorate (CMD) to ensure that all companies with innovative treatments have a route to proactively engage and discuss potential commercial flexibilities and future deals.

Intellectual Property

6.14 The Minister explains that the UK's Intellectual Property (IP) regime aims to strike a careful balance to cater for the country's unique landscape: the country is home to major pharmaceutical innovators, and is also one of the largest users of generic versions of pharmaceuticals for which it pays among the lowest prices in the developed world.

6.15 A robust IP regime is an essential means of incentivising and rewarding innovation, says the Minister, and the UK's approach aims to encourage industry to undertake the lengthy and high-risk process of developing new products. Incentives to innovate newer, safer, more effective drugs are closely aligned with the interests of patients. IP rights remain a powerful incentive for innovative pharmaceutical companies to make investments in research and development for medicinal products that address patients' needs. This often underpins facets of the IP system, explains the Minister, such as orphan drug designation for medicinal products that target rare diseases, and paediatric extensions for Supplementary Protection Certificates[53] for medicinal products that can be used to treat children.

52 How the 'NHS model' to tackle antimicrobial resistance (AMR) can set a global standard, NHS England, 18 December 2020.

53 A form of IP that extends the protection of patented active ingredients present in pharmaceutical products in order to compensate for any delay in using the patent due to the regulatory approval process.

6.16 Internationally, the WTO's TRIPS (Trade-Related Aspects of IP Rights) Agreement sets out requirements for the global IP framework and it is positive to note that, while least developed countries are not required to adhere to all requirements, they are committed to working towards achieving those standards.

6.17 The Minister is equivocal on the question of whether there are benefits for the UK of third countries being encouraged to align with the UK's IP standards, noting that a number of factors need to be considered, such as the impact on the UK's life sciences industry, access to medicines, and the approach taken by other nations.

International regulatory cooperation

6.18 The Minister notes that medicines and devices regulation is increasingly globally harmonised. He considers that the MHRA is widely recognised as a regulatory leader and has played a fundamental role in shaping global standards in recent decades. As a sovereign regulator with its own seat on international regulatory forums, believes the Minister, the MHRA can build on this reputation and lead the development of world class, global approaches to innovative regulation.

6.19 On 1 January 2021, the UK joined Project Orbis (a programme coordinated by the US Food and Drug Administration to review and approve promising cancer treatments) and the Access Consortium (a programme involving Australia, Canada, Switzerland and Singapore to secure patient access to high-quality, safe and effective medicines). The UK is in the process of applying for full membership of the ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) and is a confirmed observer for the IMDRF (International Medical Device Regulators Forum) and MDSAP (Medical Device Single Audit Programme). For these bodies, like the ICH, a period of observing is required before full membership status can be granted.

EU cooperation

6.20 The Minister describes the UK-EU Trade and Cooperation Agreement (TCA) as good news for industry, citizens and the wider health and care system, and he notes that the Medicinal Products Annex to the TCA contains general text that promotes regulatory cooperation. This includes, for instance, encouraging the UK and EU to consult one another about changes to technical regulation or inspection practices.

6.21 The TCA also established a Working Group on Medicinal Products which is empowered to exchange regulatory information to facilitate discussion of issues arising from the provisions set out in the Annex. For medical devices, the agreement ensures ongoing co-operation between the EU and UK on market surveillance.

Research collaboration with the EU—Horizon Europe Programme

6.22 The Minister notes that research funding is a critical driver of innovation in healthcare. The UK's association to Horizon Europe as part of the UK-EU Trade and Cooperation Agreement will support continued partnerships between UK and European research and science experts, including cooperation in the development of pharmaceutical products. Beyond funding for UK research and innovation through this programme, the UK's participation will continue to give the UK access to cross-border networks, supply

chains for new products and access to global talent. In particular, the Innovative Health Initiative, to which the UK will have access, will foster collaborations between industry, including small and medium-sized enterprises (SMEs), and researchers, patients, healthcare professionals and regulators.

Our assessment

6.23 We welcome the comprehensive response by the Minister to our queries. Clearly, the UK now has a regulatory framework in place within which new and innovative approaches to pharmaceutical development can be pursued. Where the UK is constrained is in the context of the Northern Ireland Protocol. Realistically, the twin considerations of continued Northern Ireland alignment with EU pharmaceutical legislation, while remaining committed to "ensuring that there is no impediment to securing access to vital medicines across the UK, including NI" and to ensuring "an outcome that is equitable for patients in all parts of the UK" does mean that the EU and UK systems of medical regulation will remain closely intertwined. Consequently, the EU's regulatory intentions as set out in the Pharmaceutical Strategy are of direct relevance.

6.24 The role of IP in promoting pharmaceutical innovation as well as the availability of medicine has come under the spotlight in relation to Covid-19. A proposal from India and South Africa[54] to waive temporarily some elements of the TRIPS Agreement in order to provide timely and secure access to high-quality and affordable Covid-19 medical products (including vaccines) for all is under discussion at the WTO. While the Minister is clear as to the Government's view that IP rights remain a powerful incentive for innovative pharmaceutical companies to make investments in research and development for medicinal products that address patients' needs, we anticipate that the domestic and global approach to this matter is one which may come under further scrutiny in the medium to longer term as well as in the short term as a response to the challenges presented by Covid-19 specifically.

6.25 While we have no additional issues to raise with the Minister at this point, we expect the Government to be vigilant as the EU develops its policies in this area, engaging where necessary in advance of any draft legislative text. We anticipate returning to this matter in due course, and there may be interest among other Select Committees in pursuing the issues raised, including the future role of IP in promoting pharmaceutical innovation and availability.

Action

6.26 We require no further information on this Strategy. The policy implications may be of interest to other Select Committees and we therefore draw this chapter and the Minister's response to the attention of the Business, Energy and Industrial Strategy Committee, the Health and Social Care Committee, the International Trade Committee, the Northern Ireland Affairs Committee and the Science and Technology Committee.

54 WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19, COMMUNICATION FROM INDIA AND SOUTH AFRICA, World Trade Organisation, Council for Trade-Related Aspects of Intellectual Property Rights, IP/C/W/669, 2 October 2020.

7 Strengthening Europol's role in operational police cooperation[55]

This proposed Regulation is politically important because:

- Europol and its UK counterpart, the National Crime Agency, are strategic partners in tackling serious cross-border crime and terrorism; and
- proposals to strengthen Europol's role as a central hub for the processing and analysis of criminal intelligence in the EU may affect the scope and depth of Europol's cooperation with UK law enforcement under the EU/UK Trade and Cooperation Agreement and the collective ability of the EU and the UK post-EU exit to manage common security threats.

Action

- No further information is required at this stage. The Government is asked to provide details of the Working Arrangement between Europol and the National Crime Agency once negotiations have concluded and to provide a further update if negotiations on the proposed Regulation raise new concerns for the UK.
- Draw to the attention of the Home Affairs Committee, the Justice Committee and the Joint Committee on Human Rights.

Overview

7.1 Europol—the EU Agency for Law Enforcement Cooperation—plays an important role in preventing and combating serious cross-border crime within the EU, operating as a central hub for the processing and analysis of information which may assist Member States in their criminal investigations. When it was a member of the EU, the UK made a significant contribution to the information held in Europol's databases and the intelligence products it produced.[56] The UK no longer participates in Europol or has direct access to these databases following its exit from the EU, but the EU/UK Trade and Cooperation Agreement (TCA) includes provisions on cooperation with Europol.[57] The UK remains an important partner for the Europol, as is made clear in Europol's new External Strategy for 2021–23:

55 Proposal for a Regulation amending Regulation (EU) 2016/794 as regards Europol's cooperation with private parties, the processing of personal data by Europol in support of criminal investigations, and Europol's role on research and innovation; COM(20) 796; Legal base—Article 88 TFEU, ordinary legislative procedure, QMV; Home Office; Devolved Administrations consulted; ESC number 41725.

56 See the evidence given to the Home Affairs Committee by Europol's former Head, Sir Rob Wainwright, on 10 February 2021 (Q209).

57 See Part Three, Title V of the Trade and Cooperation Agreement. The TCA currently applies on a provisional basis (with effect from 1 January 2021) pending ratification by the EU.

> One of the main goals of Europol's external relations will be to establish an excellent operational partnership with the United Kingdom following its exit from the European Union. Cooperation with the United Kingdom is essential for all the crime areas falling under Europol's mandate.[58]

7.2 Europol's mandate determines what it can do. Changes to its mandate may therefore affect the scope and depth of the partnership it establishes with the UK as a third country outside the EU and the information and analysis it can share. Europol's current mandate and core tasks are set out in the Regulation establishing Europol which was last updated in 2016. In December 2020 the European Commission proposed a revision of the 2016 Europol Regulation to enable Europol to cooperate more effectively with private parties, such as transport, communication, or banking service providers who may hold data that are crucial in detecting, investigating and prosecuting serious cross-border crimes. The changes are also intended to clarify the rules which enable Europol to analyse large and complex datasets following criticism from the EU's data protection authority that personal data processed in this way might wrongfully link innocent individuals to criminal activity.[59] Our Thirty-ninth Report of Session 2019–21 provides a more detailed overview of the changes proposed.[60]

7.3 In our letter of 10 March 2021, we expressed concern that the Government's Explanatory Memorandum on the proposed Regulation failed to explain how changes to Europol's mandate might affect future cooperation between Europol and UK law enforcement authorities under the TCA. We raised a number of questions which are set out below with the response provided by the Minister for Future Borders and Immigration (Kevin Foster MP) in his letter of 15 April 2021.

Data protection

7.4 The proposed Regulation is intended to clarify the rules enabling Europol to process and analyse large datasets to support criminal investigations undertaken by individual Member States or by the new European Public Prosecutor's Office (EPPO) once it is fully operational. The datasets may include personal data held in specific criminal investigation files which UK law enforcement authorities decide to share with Europol. We asked the Minister:

- whether he considered that the proposal included sufficient safeguards to address the risk of false incrimination;
- whether he was satisfied that it would be appropriate for law enforcement authorities in the UK to share large datasets with Europol on a case-by-case basis; and
- as data processed in this way by Europol "shall be shared only within the Union"[61] and would not therefore be available to the UK, whether this limitation affected his assessment of the risks and benefits of sharing the details of an investigative case file with Europol.

58 See Europol's Programming Document 2021–23. The areas of crime which fall within Europol's mandate are listed in Annex Law-3 to the Trade and Cooperation Agreement.
59 See the EDPS Decision of 17 September 2020 on Europol's big data challenge.
60 Thirty-ninth Report HC 229–xxxiv (2019–21), chapter 5 (10 March 2021).
61 Article 18a(4) of the proposed Regulation.

7.5 The Minister notes that the UK's Data Protection Act 2018 requires UK law enforcement authorities to adhere to high standards when transferring data internationally. The proposed Regulation includes specific safeguards to protect personal data shared with Europol:

> For instance, the data must be kept separately from other Europol data and only accessed for the purposes of a specific investigation. It may only be stored to ensure the veracity, reliability and traceability of the criminal intelligence process, and only for as long as any judicial proceedings require this analysis. Moreover, the Europol Regulation includes further provisions, replicated in the UK-EU Trade and Cooperation Agreement (TCA), which require an assessment of accuracy.

7.6 He concludes that these safeguards collectively are sufficient to underpin UK cooperation with Europol. Moreover, limiting the sharing of data obtained from a UK criminal investigation file to EU Member States provides a further safeguard as they are all bound by the EU's high data protection standards. Given that the focus of Europol's activity is to support and strengthen action by EU Member States in combating serious crime, this limitation does not in the Minister's view significantly change the overall benefit assessment, nor does it preclude direct assistance between the UK and third countries.

SIS II alerts

7.7 The proposed Regulation would allow (but not require) Europol to create "alerts" in the Schengen Information System on third country (non-EU) criminal suspects based on information received from the UK (or other third countries) which would be immediately accessible to frontline law enforcement officers across the EU. We asked what assessment the Government had made of the operational implications of this new provision. While noting that it might increase the visibility in EU Member States of criminal suspects wanted in the UK (now that the UK no longer has direct access to SIS II and the ability to create its own alerts), it might also increase the risk that criminal suspects who are UK citizens would be apprehended and prosecuted abroad. We asked whether the Minister anticipated that alerts circulated in this way via SIS II (based on information provided by the UK) which led to an arrest would be followed by a request for extradition under Part Three, Title VII of the TCA on surrender so that the individuals concerned could be tried in UK courts.

7.8 The Minister notes that the proposed Regulation would not amend an existing provision in Article 19 of the 2016 Regulation establishing Europol which gives primacy to the body providing the information to determine how it may be processed and used by Europol. The UK would therefore continue to decide how data it provides to Europol is utilised and ensure that any onward transmission is in line with the UK's operational objectives. Subject to this safeguard, the Minister sees some merit in allowing Europol to create alerts in SIS II based on information received from the UK as "it would provide an additional mechanism by which UK data could reach EU frontline officers". He cautions that the operational benefits for the UK are likely to be limited:

> The proposal is limited to raising alerts on third-country (non-EU) nationals; it allows a broad degree of latitude to the receiving State on what action to take; and third countries would not necessarily be informed as to

what action had been taken. Further, the proposal is one-way only and third countries would not receive alerts from EU Member States in return. Our priority therefore remains to encourage the mutual sharing of information via Interpol alerts.

7.9 The capability to create these alerts "is just another way for data to be circulated (as it would be via Interpol channels) and does not affect our capabilities to extradite". The Minister says that the arrest or prosecution of an identified offender in an EU country as a result of a SIS II alert would be based on the relevant thresholds that apply in that country—"it is unlikely the Europol SIS II alert of itself would be sufficient for such action".

Data sharing with private parties

7.10 Where Europol has received and processed personal data provided by private parties based in the UK, the proposed Regulation would allow (but not require) Europol to share its analysis with the UK's national contact point (the National Crime Agency) if it is relevant to the UK. We asked whether detailed arrangements for sharing relevant personal data and the results of Europol's processing and analysis would be set out in the working and administrative arrangements to be agreed between the UK and Europol as envisaged in the TCA.[62] The Minister says only that the TCA governs personal data flows between the UK and Europol (and vice versa), that negotiations on a Working Arrangement are "ongoing", and that he "cannot comment on the detail of live discussions".

Europol support for EPPO investigations in the UK

7.11 The proposed Regulation would require Europol to "actively support" investigations and prosecutions carried out by the EPPO, allow the EPPO indirect access to its databases, and report to the EPPO any criminal conduct which falls within its areas of responsibility (currently, criminal offences affecting the EU's financial interests).[63] We asked the Minister to clarify the practical implications of this provision, given that the EPPO is an EU "competent authority" for the purpose of implementing the mutual legal assistance provisions of the TCA and may therefore play a role in investigating any financial irregularities or fraud involving the beneficiaries of EU funding in the UK.

7.12 The Minister says only that the UK would consider any request made by the EPPO under the mutual legal assistance provisions of the TCA "on a case-by-case basis".

Working and administrative arrangements

7.13 The TCA envisages that Europol and the UK will conclude working and administrative arrangements to "complement and implement" the provisions in Part Three, Title V (cooperation with Europol). We asked:

- whether the conclusion of such arrangements was an essential pre-requisite for cooperation with Europol to take place;

62 Part Three, Title V, Article LAW.EUROPOL.59.

63 Regulation (EU) 2017/1939 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO').

- what progress had been made in agreeing these arrangements and whether a final agreement would depend on the UK securing a law enforcement adequacy decision; and
- whether the Government intended to publish the details of the UK's working and administrative arrangements with Europol and inform Parliament of their content.

7.14 The Minister says that good progress is being made in negotiations on the Working Arrangement. While it is an important document covering the details of cooperation between Europol and the UK's National Crime Agency, "it is not a specific pre-requisite for UK-Europol cooperation, which has continued effectively under the TCA since the end of the Transition Period". He undertakes to update us on the Government's approach to the Working Arrangement "once negotiations are concluded".

Financial contributions to Europol

7.15 The proposed Regulation would allow Europol to receive financial contributions from third countries with which it (or the EU) has an agreement.[64] We asked what assessment the Government had made of this provision for future UK law enforcement access to Europol's data processing and analytical tools, as well as its products and whether, as a matter of principle, it would be reasonable for Europol to charge for any "added value" that its services provide to UK law enforcement.

7.16 The Minister says that "at this stage" he does not expect these provisions to affect the UK's relationship with Europol.

Stakeholder consultation

7.17 Finally, we sought an assurance that the Government had consulted external stakeholders—notably the National Crime Agency, the Information Commissioner and others with an interest in cross-border law enforcement—on the proposed changes to Europol's mandate and the implications for cooperation under the TCA and requested an overview of their responses.

7.18 The Minister indicates that officials "remain in regular close contact with UK operational partners on UK-Europol cooperation under the TCA, and as the EU's proposal progresses, we will consult as needed on implications for the UK".

Our assessment

7.19 Based on the additional information provided by the Minister, the proposed revision of the 2016 Europol Regulation is unlikely to have significant operational implications for law enforcement cooperation between the EU and the UK or expose individuals whose personal data are shared with Europol to unacceptable risks. The Minister is satisfied

64 Article 57(4) of the proposed Regulation and recital (41).

with the level of safeguards in place to underpin UK cooperation with Europol. The Government will nonetheless need to remain vigilant, given the possibility that poorly enforced safeguards may expose data subjects to wrongful incrimination or arrest.[65]

7.20 While recognising that there may be some merit in enabling Europol to create alerts in SIS II based on information provided by the UK, the Minister makes clear that the Government's priority is to encourage the use of Interpol alerts for sharing information amongst international law enforcement authorities. We note that in April the European Commission published a proposal seeking the Council's approval to negotiate a new cooperation agreement between the EU and Interpol.[66] One of its purposes would be to regulate cooperation between Europol and Interpol.[67]

7.21 While indicating that good progress is being made in agreeing a Working Arrangement, the Minister provides no information on its content, when it is likely to be concluded, whether it is linked to the wider law enforcement adequacy decision which has yet to be formally adopted by the European Commission, and whether (and where) it will be published. The Minister does not "at this stage" expect the UK to be asked to make a financial contribution to Europol but does not address the wider point of principle we raised about Europol charging for any "added value" that its services provide to UK law enforcement. We note his non-committal response concerning future cooperation with EPPO-led investigations and prosecutions involving beneficiaries of EU funding in the UK.

Action

7.22 No further information is required at this stage. We have written to ask the Minister to provide further details of the UK's Working Arrangement with Europol once negotiations have concluded.

7.23 We have drawn this chapter to the attention of the Home Affairs Committee, the Justice Committee and the Joint Committee on Human Rights.

Letter to the Minister for Future Borders and Immigration (Kevin Foster MP), Home Office

Thank you for your letter of 15 April 2021 responding to questions we raised about the impact that proposed changes to the 2016 Europol Regulation might have on future cooperation between Europol and UK law enforcement authorities under the EU/UK Trade and Cooperation Agreement.

It is clear from your response that you are satisfied with the level of safeguards in place to underpin UK cooperation with Europol and expect any operational impact from the proposed changes to be minimal. We urge the Government to remain vigilant, given the possibility that poorly enforced safeguards may expose individuals in the UK whose

65 See the findings of the EU's data protection authority: EDPS Decision of 17 September 2020 relating to EDPS own inquiry on Europol's big data challenge.

66 See COM(2021) 177, a Recommendation for a Council Decision authorising the opening of negotiations for a cooperation agreement between the EU and the International Criminal Police Organisation (Interpol)

67 The agreement envisaged would supplement or more likely replace a 2001 agreement between Interpol and Europol.

personal data are shared with Europol or entered as an alert in the Schengen Information System to wrongful incrimination or, possibly, arrest and prosecution in a foreign jurisdiction.

The proposal includes new provisions which would allow Europol to receive financial contributions from third countries with which it has an agreement. You indicate that "at this stage" you do not expect these provisions to affect the UK's relationship with Europol. We ask you to provide a further update if this position changes, or if wider developments in the negotiations on the proposed Regulation as they pass through the EU legislative process have consequences for the UK beyond those set out in your letter.

We are pleased to hear that good progress is being made in agreeing a Working Arrangement between the UK's National Crime Agency and Europol. We ask you to provide further details on its form and content once the negotiations have concluded.

8 Documents not considered to be legally and/or politically important

Department for Business, Energy and Industrial Strategy

(41810) 6871/21 + ADD 1 —	Commission Regulation (EU) …/… of XXX amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products.

Department for Digital, Culture, Media and Sport

(41089) 6266/20 COM(2020) 65	White Paper on Artificial Intelligence—A European approach to excellence and trust.

Department for Environment, Food and Rural Affairs

(41807) 6916/21 COM(21) 108	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2017/625 as regards official controls on animals and products of animal origin exported from third countries to the Union to ensure compliance with the prohibition of certain uses of antimicrobials.
(41815) — —	Commission Implementing Regulation (EU) 2021/419 of 9 March 2021 amending Implementing Regulation (EU) 2018/2019 as regards certain plants for planting of Jasminum polyanthum Franchet originating in Israel and adapting Combined Nomenclature codes for Ullucus tuberosus and amending Implementing Regulation (EU) 2020/1213 as regards the phytosanitary measures for the introduction of those plants for planting into the Union territory.
(41824) 7350/21 + ADD 1 C(21) 1784	Commission Delegated Regulation (EU) …/... of 23.3.2021 amending Delegated Regulation (EU) 2020/689 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases.

Department of Health and Social Care

(41783) 5371/21 C(21) 251	Commission Delegated Regulation (EU) …/... of 13.1.2021 amending Delegated Regulation (EU) 2016/161 as regards a derogation from the obligation of wholesalers to decommission the unique identifier of products exported to the United Kingdom.

Food Standards Agency

(41811)	Commission Regulation (EU) 2021/382 of 3 March 2021 amending the Annexes to Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs as regards food allergen management, redistribution of food and food safety culture.
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Health and Safety Executive

(41816)	Commission Delegated Regulation (EU) …/... of 11.3.2021 amending, for the purposes of its adaptation to technical and scientific progress, Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.
7007/21	
+ ADD 1	
C(21) 1533	

Department for Work and Pensions

(41528)	Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.
—	
COM(2020) 571	

Annex

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: EU Research Programme: Horizon Europe [Proposed Regulation (SNC)]; Data adequacy [Proposed Commission Implementing Decisions (SNC)]; EU Pharmaceutical Strategy [Commission Communication (SC)]

Digital, Culture, Media and Sport Committee: Data adequacy [Proposed Commission Implementing Decisions (SNC)]; Privacy and Electronic Communications [Proposed Regulation (SNC)]

Environment, Food and Rural Affairs Committee: European Maritime, Fisheries and Aquaculture Fund [Proposed Regulation (SC)]

Health and Social Care Committee: Data adequacy [Proposed Commission Implementing Decisions (SNC)]; EU Pharmaceutical Strategy [Commission Communication (SC)]

Home Affairs Committee: Strengthening Europol's role in operational police cooperation [Proposed Regulation (SNC)]; Data adequacy [Proposed Commission Implementing Decisions (SNC)]; Privacy and Electronic Communications [Proposed Regulation (SNC)]

Joint Committee on Human Rights: Strengthening Europol's role in operational police cooperation [Proposed Regulation (SNC)]; Data adequacy [Proposed Commission Implementing Decisions (SNC)]; Privacy and Electronic Communications [Proposed Regulation (SNC)]

International Trade Committee: Data adequacy [Proposed Commission Implementing Decisions (SNC)]; EU Pharmaceutical Strategy [Commission Communication (SC)]

Justice Committee: Strengthening Europol's role in operational police cooperation [Proposed Regulation (SNC)]; Privacy and Electronic Communications [Proposed Regulation (SNC)]

Northern Ireland Affairs Committee: Protection of critical infrastructure [Proposed Directive (SNC)]; European Maritime, Fisheries and Aquaculture Fund [Proposed Regulation (SNC)]; Data adequacy [Proposed Commission Implementing Decisions (SNC)]; EU Pharmaceutical Strategy [Commission Communication (SC)]

Public Administration and Constitutional Affairs Committee: Protection of critical infrastructure [Proposed Directive (SNC)]; European Maritime, Fisheries and Aquaculture Fund [Proposed Regulation (SNC)]

Science and Technology Committee: EU Research Programme: Horizon Europe [Proposed Regulation (SNC)]; Data adequacy [Proposed Commission Implementing Decisions (SNC)]; Privacy and Electronic Communications [Proposed Regulation (SNC)]; EU Pharmaceutical Strategy [Commission Communication (SC)]

Scottish Affairs Committee: European Maritime, Fisheries and Aquaculture Fund [Proposed Regulation (SC)]

Welsh Affairs Committee: European Maritime, Fisheries and Aquaculture Fund [Proposed Regulation (SC)]

Formal Minutes

Wednesday 12 May 2021

Members present:

Sir William Cash, in the Chair

Jon Cruddas	Mr David Jones
Richard Drax	Craig Mackinlay
Margaret Ferrier	Anne Marie Morris
Mrs Andrea Jenkyns	Charlotte Nichols

Scrutiny Report

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 8 read and agreed to.

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

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

[Adjourned till Monday 17 May at 1.45 p.m.

Standing Order and membership

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.

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*)