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Notes

Numbering of documents

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

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

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

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

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

Abbreviations used in the headnotes and footnotes

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

Euros

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

Further information

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

*Explanatory Memoranda (EMs) can be downloaded from GOV.UK: https://www.gov.uk/government/collections/explanatory-memoranda-on-eu-documents. EMs can be searched by Council or Commission reference number. Letters from the Committee and those issued by Ministers can be found in the correspondence section of the Committee's website: https://committees.parliament.uk/committee/69/european-scrutiny-committee/publications/3/correspondence/.

Explanatory Memoranda and letters published before 31 March 2022 can be found on the National Archives website—https://webarchive.nationalarchives.gov.uk/search/—by restricting searches to https://europeanmemoranda.cabinetoffice.gov.uk/

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Contents

1 Northern Ireland Protocol: New EU scheme for the protection of geographical indications for craft and industrial products[1]

This EU document is legally important because:

- It would establish a new EU-wide system for legally restricting the use of specific "Geographical Indications" (GIs) for the marketing of traditional craft and industrial products made only in those areas, like Meissen porcelain or Donegal tweed. This new EU scheme may in due course also apply directly to goods sold in Northern Ireland under the terms of the Northern Ireland Protocol, although its precise effects there remain uncertain (in part because of the Government's proposed changes, as set out in the Northern Ireland Protocol Bill); and
- Producers in England, Scotland and Wales that make goods linked by name to a specific region, for example, Harris Tweed, may also be able to apply for GI status for their products in the EU market, but the Government has suggested the number of British products that could benefit is low.

Action

- The Committee will keep the draft EU legislation under review and engage further with the Department for Business, Energy and Industrial Strategy when there is more clarity about the EU legislative process, and the outcome of the Government's proposed changes to the Northern Ireland Protocol.
- We will draw our initial assessment of these matters to the attention of the Business, Energy and Industrial Strategy Committee and the Digital, Culture, Media and Sport Committee.

Overview

1.1 In April 2022, the European Commission presented draft legislation to establish a new EU scheme to protect 'Geographical Indications' (GI) for craft and industrial products. It will primarily aim to safeguard traditional products made in EU Member States, like Donegal tweed from Ireland or Limoges porcelain from France. Similar to existing EU and UK schemes for traditional food and drink products, where such GI status is granted, it would be prohibited for makers of similar industrial goods based outside the designated region to use or 'evoke' the protected geographical area when marketing their wares.

1 Proposal for a Regulation on geographical indication protection for craft and industrial products; COM(2022) 174; Legal base: Articles 118(1) and 207(2) TFEU; ordinary legislative procedure; QMV; Department: Business, Energy and Industrial Strategy; Devolved Administrations: Northern Ireland Executive consulted; ESC number: 42098.

1.2 Although the UK has now of course left the EU, the proposal could still have implications here. This is, first, because EU rules relating to goods continue to apply in Northern Ireland under the Northern Ireland Protocol. The European Commission has already notified the Government that it may seek to have the CIGI scheme added to the Protocol in due course, which could mean its envisaged legal protections for industrial goods with GI status would also apply in the Northern Irish market.[2] Of course, the long-term future of the Protocol itself is still subject to considerable uncertainty at present, given the Government's policy of seeking to change its terms either in agreement with the EU or unilaterally. In addition, the EU scheme could also have implications for UK-EU trade in traditional industrial and craft products more generally, for example, by giving British producers of traditional goods like Harris Tweed the option of securing GI protection for their exports to the Single Market. In due course, the EU may also seek to negotiate a new agreement with the Government on protection of its CIGIs in England, Scotland and Wales.

1.3 Given the potential implications of the new EU scheme under the Northern Ireland Protocol, and for trade of traditional craft and industrial products between the UK and EU more generally, we have considered it in more detail below.

Intellectual property protection of Geographical Indications

1.4 Many countries seek to protect certain traditional products—especially in the field of food and drink—that are linked, by name, to the specific regions where they are made. Often, this is done via restricted 'Geographical Indications' (GI), in essence an intellectual property (IP) right for the marketing of a product using a geographic reference by producers from the designated area only (such as 'Parmesan cheese' or 'Irish cream').[3] While GIs are similar to trademarks in conferring IP associated with the branding of a product, there are various important legal differences. In particular, GIs do not belong to a specific company or individual, but rather all relevant producers from the designated region and, unlike trademarks, they do not usually have to be renewed periodically nor do they lose their status.[4] For this reason, GI schemes are often described as a *sui generis* type of intellectual property.

1.5 The European Union (EU) is a leading proponent of the use of Geographical Indications for agricultural goods. It has established several GI programmes[5] as part of a broader set of schemes[6] that aim to demonstrate the quality of traditional European food and drink products by reference to their place of origin.[7] Under EU law, once GI status has been granted by the European Commission, other similar products made elsewhere

2 Department for Business, Energy and Industrial Strategy, 'Explanatory Memorandum on the proposed EU Regulation on CIGI for craft and industrial products' (27 June 2022), p. 2.

3 World Intellectual Property Organization, 'Geographical Indications' (accessed 26 August 2022).

4 European Parliamentary Research Service, 'Geographical indications for non-agricultural products' (November 2019), p. 4.

5 These are 'Protected designations of origin' (PDO); Protected geographical indications (PGI); Traditional speciality guaranteed (TSG) and geographical indications (PGI) for spirit drinks and aromatised wines. More information on the different EU GI schemes is available from the European Commission website.

6 For example, the EU also has agricultural quality schemes for products made in mountainous areas, products from the EU's Overseas Regions, and "Traditional Speciality Guaranteed" products that are not linked to a specific region.

7 Under Article 2(1) of Regulation 1151/2012, EU Geographical indications are also available for a number of non-food agricultural products, including hay, essential oils, cork, flowers, cotton, wool, wicker, flax, leather, fur and beeswax.

cannot be sold using, or even 'evoking', that geographical indication when sold anywhere within the EU's Single Market.[8] The EU also actively seeks to protect some of its registered GIs in overseas markets through trade agreements, typically granting legal protection to those countries' protected geographical indications within the EU Single Market in return.[9]

1.6 With respect to GIs for food and drink, the UK is in a somewhat unusual position: it participated in the EU's schemes as a Member State of the European Union prior to Brexit. Under the terms of the Withdrawal Agreement, the UK is legally required to continue giving Geographical Indications granted at EU-level before 1 January 2021[10] the same protection under domestic law that they enjoyed under EU law indefinitely. In return, the EU has also preserved its existing GI status for 84 British products that had already been granted before that date.[11] While there is no automatic mutual recognition of *new* GI protections granted by the EU or UK respectively from January 2021 onwards under the EU/UK Trade and Cooperation Agreement,[12] the EU's schemes do continue to apply *directly* in Northern Ireland as a matter of EU law, as we discuss further in paragraphs 0.14 to 0.19 of this Report.[13]

1.7 The EU's current schemes for the protection for geographical indications are notably limited only to agricultural products. Even so, some countries—including many European ones—also operate statutory GI schemes at national level for craft and industrial products (CIGI) with established links to specific regions.[14] In the UK, for example, a product can only be sold as Harris Tweed if it is from the Outer Hebrides, as set out in the Harris Tweed Act 1993. However, there is currently no legislation for protection at EU-level of geographical indications for non-agricultural goods.

1.8 To address this perceived 'regulatory gap', which has been under discussion in Brussels for many years,[15] in April 2022 the European Commission published a draft Regulation to

8 For example, EU law prohibits cheese that resembles feta—a protected Geographical indication—from being sold as "feta style".

9 In particular, in 2020, the EU reached agreement with Beijing on legal protection of dozens of EU GIs in the Chinese market and vice versa. By contrast, the United States is a notably opposed to GI schemes, because it "does not want further limits on the ability of trademark owners and others to use, in foreign markets, names linked to geographic regions that the US argues are generic". See, Department for Environment, Food and Rural Affairs, 'Explanatory Memorandum on COM(2018) 350' (21 August 2018), p. 4.

10 The UK continued applying EU law, including in relation to Geographical Indications, as if it were still a Member State from its date of formal withdrawal on 31 January 2020 until the end of a post-Brexit transition period on 31 December 2020.

11 See Article 54 of the Withdrawal Agreement. Before the UK left the EU, 84 British agri-food products were granted GI status under EU law, including Caerphilly cheese, Ayrshire new potatoes and Cornish pasties. The EU has granted GI status for one additional British product, Gower Salt Marsh Lamb, since Brexit (on 8 December 2021).

12 As part of the negotiations on the new EU/UK Trade and Cooperation Agreement (TCA), the Government said in March 2020 that it wanted to replace the GI provisions of the Withdrawal Agreement as described above with a different approach to GIs in the EU/UK trading relationship. However, the EU did not agree to this and the TCA as ratified with the EU in December 2020 only states, in Article 275, that "the Parties may jointly use reasonable endeavours to agree rules for the protection and effective domestic enforcement of their geographical indications".

13 This means that products with GI status granted by the EU must be protected on the Northern Irish market as if it was still in the EU. The new post-Brexit GI schemes created for Great Britain do not currently apply there.

14 According to a study prepared for the European Parliament, European countries which operate 'CIGI' schemes include France, Germany, Spain and Italy. See European Parliamentary Research Service, "Geographical indications for non-agricultural products" (November 2019).

15 The European Commission issued a Green Paper as far back as 2014 on a possible EU CIGI scheme. In its Intellectual Property Action Plan from November 2020, the European Commission announced that it "would consider the feasibility of a GI protection system for non-agricultural products at EU level".

create an EU-wide CIGI scheme. Modelled on the existing GI schemes for food and drink, the proposal would allow producers of traditional industrial goods—from both within or outside the EU—to apply for protected geographical indications for the entire EU market with a single application (rather than needing to rely on national schemes in individual Member States, where these exist). They would have to demonstrate, in particular, the link between a "given quality, the reputation or other characteristic of the product and [its] geographical origin".[16] Under the proposal, applications for GI status of industrial products would normally be assessed by the European Union Intellectual Property Office (EUIPO).[17] As potential beneficiaries, the Commission has given the examples of Murano glass, Donegal tweed and Limoges porcelain.[18]

1.9 Like the EU's GI schemes for agricultural products, the proposed EU CIGI scheme would also have an international dimension. Broadly speaking, there would be three avenues for craft and industrial products from non-EU countries to obtain GI protection within the EU:[19]

- Since 2019, the EU has been party to the Geneva Act of the Lisbon Agreement, a treaty on GIs administered by the World Intellectual Property Organization (WIPO). The Act notably created a revamped International Register for Geographical Indications among its contracting parties.[20] The proposed Regulation would require the EUIPO to automatically assess CIGIs entered into that Register by non-EU participants in the 'Geneva system', and grant them protection under the EU scheme if it meets the relevant criteria for protection

16 The proposed CIGI Regulation sets various conditions to be met before a GI can be granted. In particular, the draft legislation recognises the potential impact of the new CIGI scheme for existing products that use a geographical indication without being produced in that region, as well as existing trademarks that contain geographic references. Therefore, it foresees an option for interested parties to lodge an objection if the registration of the proposed geographical indication "would jeopardise the existence of, an entirely, or partly identical name or of a trade mark" or other products which have been "legally on the market for at least 5 years". An application for GI status would have to be refused "where, in the light of a trademark's reputation and renown, registration of the name proposed as a geographical indication could mislead the consumer as to the true identity of the product".

17 The European Commission could in exceptional cases take over decision-making from the EUIPO in cases that "may affect the Union's trade and external affairs policy, or the public interest".

18 In parallel to the proposal to establish an EU GI scheme for craft and industrial products, the EU is also considering administrative changes to its GI schemes for agricultural goods. More information is available on the website of the European Commission.

19 The EU CIGI scheme is likely to be extended to the three non-EU countries of the European Economic Area, Norway, Iceland and Liechtenstein, as if they were part of the EU under the terms of the EEA Agreement.

20 As of 26 August 2022, there are 14 Contracting Parties to the Geneva Act, including the European Union on behalf of its 27 Member States and three EU countries (France, Hungary and Czechia) individually. Italy, Portugal and Romania have signed but not yet ratified the treaty. In any event, the existence of schemes of GI protection for non-food products will be different depending on each country's domestic legal arrangements, and the Register seems to indicate there are not many CIGIs notified by participants in the Geneva Act.

under EU law.[21] The practical impact of this would appear to be limited, however, as very few countries have ratified the Geneva Act to date and even fewer appear to have registered GIs for craft and industrial products;[22]

- if the Regulation is approved, the EU could in the future also negotiate agreements on mutual recognition of specific CIGIs on behalf of all its Member States with individual trading partners directly, outside the structures of the Lisbon Agreement and Geneva Act.[23] GIs recognised pursuant to such treaties would be automatically entered into the EU's register for craft and industrial goods on the basis of those agreements, without further assessment by the EU.[24] This is similar to the way the EU legislates to protect non-EU GIs for agricultural products as required by its trade agreements;[25] and

- lastly, producers of particular craft and industrial goods from any non-EU country could apply directly for the protection of their GI under the scheme within the EU market, even if their home country did not have an agreement with the EU on protection of CIGIs. However, their application would *only* be considered by the EUIPO if they can provide "legal proof of protection of the geographical indication in its country of origin".[26] If this is not the case, it would not meet the conditions for GI status in the EU. It is unclear from the text of the Regulation if a domestic trade or certification mark containing a geographical reference would be sufficient to demonstrate such 'legal protection'.

1.10 The legislative proposal to establish the EU CIGI scheme must be approved by the European Parliament and the EU's Member States in the Council of Ministers before the new system can become operational. The UK Government has said that "early indications show that some aspects of the proposal may prove controversial with Member States, including the role of the European Intellectual Property Office (EUIPO) in GI administration".[27] As a consequence, the Executive Director of the EUIPO itself has publicly commented that a "best case scenario" would see the Regulation "agreed by 2024 at the earliest, with registration of GI rights following two to three years after the

21 As such, CIGIs entered into the International Register by non-EU participants in the Geneva Act would not automatically be given EU protection. See Article 60 of the proposed CIGI Regulation, in particular the proposed amendment to Articles 4 to 7 of Regulation 2019/1753 on the EU's participation in the Geneva Act. For example, producers in the EU can lodge a notice of opposition to a GI registered by another, non-EU participant in the Geneva System e.g. if it overlaps with an existing trade mark.

22 See WIPO, 'Lisbon Express Structured Search of Appellations of Origin and Geographical Indications [accessed 26 August 2022]. In the same vein, given that there is no EU CIGI scheme at present, most EU producers of craft and industrial products cannot currently claim GI under the Geneva Act in non-EU signatories because the precondition for domestic recognition is not met. It may be different for producers from the three EU Member States that are independently also party to the Geneva Act, depending on the scope of their domestic CIGI schemes (Czechia, France and Hungary).

23 Once adopted, the new Regulation may also provide the possibility for the EU to pursue recognition of its CIGI through its free trade agreements. This is because the EU will have exercised competence in this area and therefore acquire implied competence to make agreements internationally to protect its 'stock' of GIs for industrial products.

24 See recital 23 and Article 26(4) of the proposed EU CIGI Regulation.

25 See for example Article 12 of Regulation 2012/1151. The EU's "eAmbrosia" register for agricultural GIs contained 274 entries for non-EU products as of 26 August 2022, including 85 (31% of the total) from the UK.

26 See Article 17(3) of the proposed EU CIGI Regulation.

27 Department for Business, Energy and Industrial Strategy, 'Explanatory Memorandum on the proposed EU Regulation on CIGI for craft and industrial products' (27 June 2022), p. 4.

establishment of the scheme". It is not clear at this stage if a qualified majority of Member States is in favour of an EU-wide scheme, which is required for the proposal to become EU law.

Possible implications of the EU CIGI scheme for the UK

1.11 The UK of course left the European Union in January 2020, and new EU legislation as a rule does not apply here. Given that the EU (like the UK) does not currently have a dedicated CIGI scheme, the EU/UK Trade and Cooperation Agreement agreed in December 2020 also does not contain any provisions on mutual recognition of GI registered in each other's markets.[28] However, for two reasons the proposed new EU CIGI scheme is still relevant for the UK:

- first, EU rules relating to goods continue to apply in Northern Ireland under the Northern Ireland Protocol, and new EU legislation can be added to that Protocol to make it applicable there. The European Commission has formally notified the Government that it may seek to have the CIGI scheme added to the Protocol in due course;[29] and
- second, the EU scheme could also have implications for UK-EU trade in traditional industrial and craft products more generally, for example, by giving British producers the option of securing GI protection for their exports to the Single Market, or if the EU wanted to negotiate an agreement with the Government on protection of its CIGIs within the UK.

1.12 We have considered these potential implications for the UK in more detail below.

EU GI legislation under the Northern Ireland Protocol

1.13 The Protocol on Northern Ireland in the Withdrawal Agreement, ratified by the UK and EU in January 2020, aims to maintain the pre-Brexit absence of customs and regulatory controls on the land border with Ireland even after the UK's withdrawal. Broadly speaking, it does so by requiring Northern Ireland to continue applying EU rules on the production, trade and sale of goods, meaning products on the market in Northern Ireland also meet all the requirements to move freely into Ireland and the wider EU. As such, Northern Ireland *de facto* participates in the EU's Single Market for goods and Customs Union, while the rest of the UK no longer does so.[30] As we discuss further below, the Government has argued the Protocol "is not meeting its original objectives"[31] and has published proposals for fundamental changes to its nature and operation, as well as introducing a Bill to make such changes unilaterally in UK law if the EU does not agree to a treaty change.

28 As noted above, GIs for agricultural products granted by the EU before 1 January 2021 are protected indefinitely in the UK by virtue of Article 54 of the Withdrawal Agreement.

29 Department for Business, Energy and Industrial Strategy, 'Explanatory Memorandum on the proposed EU Regulation on CIGI for craft and industrial products' (27 June 2022), p. 2.

30 By extension of the application of EU laws on goods in Northern Ireland, customs and regulatory formalities apply to goods entering Northern Ireland from outside the EU—including from Great Britain—instead.

31 Foreign, Commonwealth and Development Office, 'Explanatory Notes accompanying the Northern Ireland Protocol Bill' (13 June 2022).

1.14 Under the Protocol as ratified in 2020, EU laws which still apply in Northern Ireland under the Protocol are listed in its Annexes, and any 'amendments or replacements' to those laws adopted by the EU automatically take effect in Northern Ireland too.[32] Article 13(4) of the Protocol also foresees the possibility of the EU asking for *new* EU legislation relevant to trade in goods, which does not 'amend or replace' existing EU rules already listed in the Protocol, to be added to its Annexes. The proposed EU CIGI scheme is an example of such new EU legislation.[33] The then-Minister for Science, Research and Innovation (George Freeman MP), with responsibility for intellectual property issues, submitted an Explanatory Memorandum on the potential application of the EU CIGI scheme in Northern Ireland on 27 June 2022. This confirmed that "the EU informed the UK of its view that, if adopted [by the EU], the legislation could fall under Article 13(4) of the Protocol as a new Act which would not amend or replace any of the Acts listed in the Annexes to the Protocol".

1.15 If the Regulation were added to the Protocol, this would mean that CIGIs registered in the EU would have to be given the same level of legal protection in Northern Ireland (even though the UK does not operate a similar scheme of geographical indications for craft and industrial products, as we discuss below). Crucially, however, for a new piece of EU legislation to be added to the Protocol in this way, the UK must agree to a formal Decision to that effect within the EU/UK Joint Committee. While this effectively gives the Government a veto over whether the Regulation will apply in Northern Ireland in due course, the EU would have the right to take unspecified "remedial measures" if the UK refuses.[34] There has not yet been a case where the EU has made a formal request for a new law to be added to the Protocol under Article 13(4), so the possibility of the UK refusing and the EU considering remedial measures in response has not yet arisen. Unfortunately, the Minister's Memorandum does not make clear the Government's views on this matter. Instead, the Minister said that "it is not yet clear whether and how this measure, if implemented, would apply to Northern Ireland and how it would interact with the Northern Ireland Protocol". In any event, as noted, the EU's legislative process in Brussels is likely to take months if not years, meaning any formal EU request under Article 13(4) is some way off.

1.16 Even so, the lack of a public Government position on the potential applicability of the CIGI Regulation in Northern Ireland is presumably also linked to its wider policy of changing the operation of the Protocol. Under the Government's aforementioned Northern Ireland Protocol Bill, certain elements of the Protocol would be dis-applied in domestic law automatically, while Ministers would have wide-ranging powers to make further unilateral changes to its operation. In particular, the Government has proposed a unique 'dual regulatory' approach for Northern Ireland, under which "goods can be

32 As per Article 13(3) of the Protocol.

33 Department for Business, Energy and Industrial Strategy, 'Explanatory Memorandum on the proposed EU Regulation on CIGI for craft and industrial products' (27 June 2022), p. 2. The Commission raised the matter via the EU/UK 'Joint Consultative Working Group' (JCWG) that examines changes to EU rules relevant to Northern Ireland under the Protocol. The JCWG reports to the Specialised Committee on the Northern Ireland Protocol, which is in turn accountable to the EU/UK Joint Committee which oversees the implementation of the entire Withdrawal Agreement.

34 If the Regulation were not added to the Protocol, the draft legislation also foresees the possibility of producers making an application for a CIGI under the EU scheme for a product from a region that concerns both an EU Member State and a 'third country', which may in certain instances be relevant for craft products from UK border regions and neighbouring countries, including Northern Ireland/Ireland.

placed on the market in NI if they meet either UK rules, EU rules, or both".[35] To date, Ministers have placed no detailed information in the public domain about the practical workings of such a legal regime.

1.17 In the case of the EU's CIGI scheme, it is unclear—*if* the Regulation should be added to the Protocol—what its practical effect would be in Northern Ireland under such an arrangement. For example, a particular product like Donegal tweed could secure formal GI status under EU law, but not enjoy any of the associated specific protections under British law. Similarly, we do not know how a conflict between an EU-registered GI and a UK-registered trademark would be resolved if both are equally valid in Northern Ireland under the dual regulatory regime. The Minister's Explanatory Memorandum is again silent on how the EU CIGI scheme would work in this scenario, noting only that "we will continue to monitor the situation in relation to this". From a legal certainty perspective, it would appear to make sense not to have the EU CIGI scheme apply in Northern Ireland under a dual regulatory approach. That would avoid conflicting legal requirements, albeit at the risk of the EU, in the future, taking remedial measures against the UK under Article 13(4) of the Protocol.[36]

1.18 These matters are, of course, highly hypothetical at present while the future of the Protocol as a whole is still being decided, but it provides an interesting example of specific areas of regulation where the Government will need to balance various different interests and where the precise implementation of the dual regulatory approach requires further elucidation. In particular, it is clear the Government will need to provide more detail around the practical effect of its proposals in this and many other areas if it is to be implemented successfully.

Potential GI protection for British craft and industrial products in the EU

1.19 Irrespective of whether the EU's CIGI scheme will apply directly in Northern Ireland under the Protocol or not, the initiative may also have broader ramifications for trade between the UK and the EU in traditional craft and industrial products. It could affect such trade in two directions: British exports to the EU, and EU exports to the UK.

1.20 As regards exports of traditional craft and industrial products from the EU to the UK, the new scheme—as and when it becomes EU law—could also be a precursor to the European Commission seeking to negotiate legal protection for EU CIGIs in overseas markets, as the EU has already done for agricultural GIs through existing agreements. The proposed Regulation explicitly refers to this, arguing that creating an EU-wide scheme would allow the EU to "close this gap" and give EU producers of industrial products "protection [through] EU trade agreements".[37] The EU/UK Trade and Cooperation is silent on this particular issue, given neither the UK nor the EU had a CIGI scheme when it was ratified in late 2020. However, it does foresee a "review in relation to geographical

35 Foreign, Commonwealth and Development Office, 'Policy paper: Northern Ireland Protocol: the UK's solution' (13 June 2022), p. 2.

36 In addition, the option of not adding a particular area of EU law to the Protocol is not available for the many regulatory sectors already listed in the Protocol where dual regulation may present foreseen and unforeseen legal issues.

37 This is because the new Regulation would mean the EU had exercised competence in this area, and therefore acquire implicit competence to make agreements internationally to protect its 'stock' of GIs for industrial products in non-EU countries. European Commission, Explanatory Memorandum accompanying the proposal for a Regulation on geographical indication protection for craft and industrial product (COM(2022) 174) (13 April 2022), p. 1.

indications".[38] The EU could in due course propose amendments to the TCA to protect GIs for its industrial goods within the UK market, as and when its new scheme is operational, perhaps as part of the broader review of the TCA foreseen for 2025.[39] The UK may, of course, also have requests of its own for changes or additions to the trade deal at that point.

1.21 Any agreement with the EU obliging the UK to give protection to EU CIGIs, if the Government of the day were to enter into negotiations to that effect, would require a significant policy shift. While the Government has, as noted, retained the EU's approach to domestic GI schemes for food and drink in Great Britain, there is no specific scheme under UK law for GIs for non-agricultural products. Indeed, there are no current plans by the Government to introduce one, because, the Minister said in his Explanatory Memorandum, there are "no widespread calls amongst stakeholders for change". Instead, CIGIs can be protected in the UK by individual companies through the general trademark system, "a common way to provide protection with similar systems operating in the US, Australia, and Canada".[40] Reflecting this, the Department for Business, Energy and Industrial Strategy submitted a response to a public consultation on the EU proposals in July 2021, which "supported the need for effective protection mechanisms for CIGIs, but that the evidence provided was not sufficient to advocate the introduction of an EU-wide *sui generis* scheme".

1.22 It is also noteworthy in this respect that the Government let the UK's participation in the Geneva Act on Geographical Indications (which was held through its EU membership prior to Brexit) lapse at the end of 2020, rather than remain a signatory independently. The precise reasons for this are unclear, but they may be linked to the fact that the UK is seeking a trade agreement with the US, which is notably opposed to GI schemes that operate separately from trademarks.[41] Any future negotiations on incorporation of CIGIs into the EU/UK trade agreement could therefore present trade-offs elsewhere that will need to be carefully balanced.

1.23 The EU CIGI scheme may nevertheless also present certain opportunities for some British exporters. As proposed by the European Commission, it would be open to Geographical Indications for non-EU products from "third countries", including from the UK.[42] It is possible that makers of some traditional products like Harris Tweed or Sheffield steel cutlery may see benefits in having their 'brand' protected across the EU market under the new scheme in due course. To do so, they would need to prove that their Geographical Indication is legally protected in the UK as its home market. Given, however, that the UK has no plans to operate its own CIGI scheme, this would necessarily have to

38 Article 275 of the Trade and Cooperation Agreement.

39 Article 776 of the Trade and Cooperation Agreement states that the EU and UK "shall jointly review the implementation of this Agreement and supplementing agreements and any matters related thereto five years after the entry into force of this Agreement", namely by 1 January 2026.

40 Explanatory Memorandum submitted by the Department for Business, Energy and Industrial Strategy (date), p. 3.

41 In his Explanatory Memorandum of 21 August 2018 on the EU's accession to the Geneva Act on Geographical Indications, the then-Minister for Agriculture, George Eustice MP, noted that "the US [is] a strong proponent of trade mark protection for GIs" and "does not want further limits on the ability of trade mark owners and others to use, in foreign markets, names linked to geographic regions that the US argues are generic". In UK/US working groups on a bilateral trade agreement that had taken place by that stage, "GIs is a known area of tension". See Department for Environment, Food and Rural Affairs, "Explanatory Memorandum on COM(2018) 350" (21 August 2018), p. 4.

42 If the CIGI Regulation were to be added to the Northern Ireland Protocol, Northern Ireland would participate in the scheme as if it were in the EU and not as a 'third country'.

be through other means. While Harris Tweed is protected by a 1993 Act of Parliament, other products would presumably have to rely on other intellectual property rights. It is unclear if protection through a UK trademark would be sufficient to allow for protection in the EU under a CIGI.

1.24 In any event, the Government believes the potential benefits of the EU scheme for UK manufacturers are "limited", referring to a 2019 European Parliament study which found that "only five British products […] could potentially benefit from CIGI protection".[43] The precise products involved are not identified in the study itself, but from the international "OriGIn" database[44] it appears to include Harris Tweed from the Outer Hebrides[45] and "Savile Row Bespoke" apparel from the street in Mayfair. It also lists Shetland wool, but this is already protected under both the UK and EU GI schemes as an 'agricultural product',[46] and it therefore would presumably not benefit significantly from additional CIGI protection. However, the precise sources for "potential GIs" in the European Parliament study are unclear, and the Minister's Memorandum does not refer to any UK-specific research into the possible breadth of British CIGIs (for example those that have a trademark with a geographic reference).

Conclusions and action

1.25 The EU's proposed scheme to protect geographical indications for the marketing of traditional craft and industrial products is a new area of EU law, with negotiations in Brussels on its final legal form likely to take some time. Without commenting on the policy merits of the proposals, we are of the view, in light of the assessment above, that the CIGI scheme could have implications for the UK, both under the Northern Ireland Protocol and for trade of craft and industrial goods between the UK and EU more generally.

1.26 With respect to the former, the EU has already communicated the possibility that it may ask for the CIGI Regulation to be applied in Northern Ireland in due course. As in other areas, the potential impact of extending the EU scheme to Northern Ireland cannot be analysed with any degree of certainty at present, given the Government's intention to change the Protocol's operation (unilaterally if necessary, via the Northern Ireland Protocol Bill). In any event, the EU legislation itself is still subject to change, and the Government will need to wait for the final text of the legislation before it could reach an informed view of whether to approve the Regulation's addition to the Protocol. While Article 13(4) of the Protocol gives the Government the right to refuse to have the EU CIGI scheme made applicable in Northern Ireland, the EU would have the option for retaliatory measures if it did. At this stage, it is too early to speculate on the practicalities of this scenario (not least because the future of the Protocol itself remains uncertain).

43 See European Parliamentary Research Service, 'Geographical indications for non-agricultural products' (November 2019). The study indicates that the five possible UK products that might qualify for CIGI protection fall into the following categories: one each for wool, special woven fabrics and ceramics; and two for "articles of apparel".

44 The OriGIn database is run by the "Global Alliance of Geographical Indications" (GAGI).

45 See the Harris Tweed Act 1993.

46 Regulation (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs, including the version retained in UK domestic law for Great Britain post-Brexit, permits the protection of Geographical Indications to certain non-food agricultural products, including hay, essential oils, cork, cochineal, flowers and ornamental plants, wool, wicker, and scutched flax.

1.27 As regards the potential implications of the EU proposals for UK/EU trade more broadly, we have taken note of the fact that the Government is not currently considering establishing a similar UK CIGI scheme, nor seeking UK accession to the Geneva Act on Geographical Indications. As such, without prejudice to the potential application of the EU CIGI scheme in Northern Ireland, the UK will be under no obligation to protect EU-registered GIs for craft and industrial products within its domestic market. The EU may, of course, in the future seek to negotiate an agreement on recognition of specific CIGIs with the UK. Similarly, protection of any British geographical indications for traditional craft or industrial products within the EU Single Market would depend on relevant producers applying for such status with the EU directly.[47] Ultimately, of course, it will be for individual sectors and producers to determine whether applying for GI protection in the EU is a viable aspect of their export strategies. Of particular interest will be if a UK trademark with some kind of geographic reference would be sufficient 'legal protection' for a British product in its domestic market to qualify for CIGI in the EU.

In light of the above, there are therefore clearly a number of potential issues for the UK that result from the European Commission proposals for this new CIGI scheme. Given the early stage of the legislative process in Brussels and the broader questions around the future of the Northern Ireland Protocol, we will continue to monitor for relevant developments and correspond with the Minister on the EU proposals in the future were the need to arise. In the interim, we draw our initial assessment of these matters to the attention of the Business, Energy and Industrial Strategy Committee and the Digital, Culture, Media and Sport Committee.

47 This is of course without prejudice to the potential application of the EU scheme in Northern Ireland, which would give producers there direct access to the scheme without needing to prove protection for their GI under UK law first.

2 Northern Ireland Protocol: Substances of Human Origin[48]

This EU document is politically important because:

- It applies to Northern Ireland (NI) under the terms of the Northern Ireland Protocol and has implications for Great Britain (GB);
- The Minister acknowledges that divergence between GB and NI as well as the EU could have implications for patients in NI reliant on GB, and patients in GB reliant on the EU in some circumstances; and
- The Government is considering whether to introduce similar changes, subject to ongoing analysis and discussion with the UK's devolved governments.

Action

- Write to the Minister seeking further information.
- Draw to the attention of the Health and Social Care Committee and the Northern Ireland Affairs Committee.

Overview

2.1 In the wake of contaminated blood scandals[49] in the 1980s and 1990s—which saw thousands of patients in the EU, then including the UK, infected with HIV and hepatitis by blood and plasma-derived medicinal products—the EU adopted legislation[50] setting minimum safety requirements for blood, tissues and cells (the 'BTC Directives'). The BTC Directives are, however, twenty years old and so the Commission is proposing to update them through a replacement Regulation which will apply to Northern Ireland (NI) under the terms of the NI Protocol. It will have implications for NI directly but also for the rest of GB as NI is heavily reliant on GB for the supply of these products and some are sourced from the EU to treat GB patients.

2.2 Based on an evaluation[51] in 2019 of the BTC Directives, the Commission has proposed broadening the coverage to include all Substances of Human Origin (SoHO),[52] therefore including previously-excluded types (such as human breast milk and intestinal microbiota). The proposal provides measures to ensure safety and quality for patients treated with SoHO therapies and fully protect them from avoidable risks. The proposal also aims to facilitate the development of safe and effective, innovative SoHO therapies.

48 Proposal for a Regulation on Standards of Quality and Safety for Substances of Human Origin Intended for Human Application and Repealing Directives 2002/98/EC AND 2004/23/EC; COM (2022) 338; Legal base: ; Department: Health and Social Care; Devolved Administrations: Consulted; ESC number: 42110.

49 Factor 8, 'What is the contaminated blood scandal?' [Accessed 30 September 2022].

50 Directive 2002/98/EC ('Blood Directive') and Directive 2004/23/EC ('Tissues and Cells Directive')

51 European Commission, 'Executive Summary of the Evaluation of the Union legislation on blood, tissues and cells', SWD (2019) 376, 10 October 2019.

52 Any substance collected from the human body in whatever manner, excluding organs.

Recognising that the existing legislation has failed to respond to technical and scientific developments, the draft Regulation provides mechanisms to easily, but safely, update safety and quality standards.

2.3 In his Explanatory Memorandum, (EM) the then Minister of State (Rt Hon. Robert Jenrick MP) confirmed applicability of the legislation (once adopted) to NI. He observed that it is likely to be beneficial for NI as it aims to boost the safety and quality of SoHO. Noting that NI 'has a reliance' on the import of SoHO from GB, the Minister said that significant divergence between GB and NI may cause disruption to supply and limit NI's ability to import much needed SoHO from GB. The Government, said the Minister, is currently reviewing the Commission's proposal, and a decision will be taken in due course as to whether to introduce similar changes in GB. The Minister noted in his EM that elements of the policy are reserved to the UK Parliament and elements are devolved. The Government will therefore work with the UK's other devolved governments through the relevant Common Frameworks to maintain compatible minimum standards across the UK.

2.4 We have identified a number of issues on which we would welcome further information, as set out in the letter at the end of this chapter.

Commission proposal

2.5 An evaluation[53] in 2019 of the BTC Directives found that they have brought very good levels of overall safety and quality in these sectors but that:

- patients are not fully protected from avoidable risks due to out-of-date technical rules;
- blood, tissues and cells (BTC) donors and children born from donated eggs, sperm or embryos (offspring) are exposed to avoidable risks;
- Member States have divergent approaches to oversight that hampers cross-border exchanges of BTC;
- full potential of BTC processed or used in new ways is not reached for patients; and
- patients are vulnerable to interruptions in EU supply of BTC.

2.6 To improve harmonisation, ensure a uniform level of protection across the EU and simplify cross-border exchange and access of SoHO therapies, the Commission proposes to repeal the Directives and replace them with a single Regulation that will be equally applicable in all Member States. Member States may still add more stringent requirements, in particular to ensure alignment to the set-up of national healthcare systems.

2.7 Broadly, the draft Regulation promotes innovation and provides better protection for patients, donors and offspring.[54]

53 European Commission, 'Executive Summary of the Evaluation of the Union legislation on blood, tissues and cells', SWD (2019) 376, 10 October 2019.

54 European Commission, 'European Health Union: Stronger rules for greater safety and quality of blood, tissues, and cells', 14 July 2022.

2.8 To provide better protection, the draft Regulation covers all substances of human origin, except solid organs, and it extends rigorous safety and quality standards to SoHO donors and to children born from donated eggs, sperm or embryos. This reflects, for example, the evolution of human fertilisation technology since the Tissues and Cells Directive was adopted.

2.9 The Commission may adopt implementing acts to support implementation of the high-level standards set out in the text. Where there are no such implementing acts, professionals should, to meet these standards, apply safety and quality guidelines developed by the European Centre for Disease Prevention and Control (ECDC)[55] and the European Directorate for the Quality of Medicines & HealthCare (EDQM).[56] There is some flexibility for professionals to apply other, equivalent, guidelines accepted by national authorities and demonstrated as achieving equivalent standards of safety and quality. In the absence of a technical guideline from expert bodies, establishments can set their own technical method taking into account internationally recognised standards, scientific evidence and a documented risk assessment. The Commission says that this flexible approach will facilitate "an efficient and responsive implementation of safety and quality standards whenever risks and technologies change" and will limit the need for further EU legislation. Among measures to strengthen national oversight, the draft Regulation includes provision for joint inspections of SoHO establishments undertaken by inspectors from several Member States.

2.10 To promote innovation, the draft Regulation introduces: a common procedure to assess and authorise SoHO preparations, proportionate to the risks these bring; registration of all entities carrying out activities affecting safety and quality of SoHO; and the establishment of a SoHO Coordination Board (SCB) to support a common implementation of the new Regulation.

2.11 The draft Regulation proposes measures to improve the resilience of the sector, mitigating risk of shortage. This includes the requirement for SoHO entities to report their annual activity data and the establishment of an EU SoHO Platform to facilitate effective and efficient exchange of information, such as serious adverse occurrences related to SoHO and insufficiencies of supply.

UK Government position

2.12 The Minister confirmed that, once adopted, the Regulation will apply in NI as it replaces legislation already listed in the Northern Ireland Protocol. He added that the NI Executive has a particular interest in the proposal. The Minister judged that the new Regulation is likely to "have an overall positive impact on the SoHO sector in NI" given the proposal's objective to increase safety, quality, innovation and supply of SoHO.

2.13 The Minister warned that the inclusion of updates to minimum safety and quality standards under the Commission's proposals may introduce divergence between GB and

55 The ECDC is an EU agency of which the UK is no longer a part, although the ECDC works closely with third countries. It develops and updates guidelines on safety and quality of SoHO from a communicable disease threat perspective.

56 The EDQM is a Council of Europe body, of which the UK remains a part. It develops and updates guidelines on safety and quality of blood, tissues and cells.

NI; and between GB and EU Member States. This divergence, he said, would only occur once the proposals are in force in NI and the EU, and if the UK, Scottish and Welsh Governments elected not to voluntarily align with these changes.

2.14 Northern Ireland, said the Minister, has a reliance on import of SoHO from GB, such as blood imports from England for use in patient transfusions. If there is significant divergence between GB and NI, the Minister considered, this may cause disruption to supply and limit NI's ability to import much needed SoHO from GB. Movement from NI to GB is protected by the principle of unfettered access in the Internal Market Act.

2.15 There are also movements between GB and the EU, with some GB establishments continuing to have a strategic supply dependency on some EU Member States for SoHO. The Minister explained that patients often require a match to be able to proceed with their treatment and that, where a match cannot be found in the UK, registers in the EU are also searched. He concluded that it will be important to maintain minimum standards with the EU to allow the movement of NI and EU SoHO which is used in life-saving and life-changing treatments for patients across the UK.

2.16 The Minister explained that the Government is currently reviewing the Commission's proposal, and a decision will be taken in due course as to whether to introduce similar changes in GB. This decision will consider several factors that may be affected by the proposals including: patient safety; intra-UK and UK-EU supply of SoHO; innovation within the sector; and health inequalities.

2.17 Concerning possible voluntary alignment by GB, the Minister noted that UK regulators made recommendations to the EU as part of the consultation on, and evaluation of, the BTC Directives. Given that these recommendations fed into the development of the SoHO Regulation, the Minister considered it likely that, for GB, external stakeholders will support voluntary alignment with the minimum safety and quality standards included in the Commission's proposal. Certain elements of the proposal, such as encouraging Member State collaboration, would be unsuitable for GB to implement since the UK is no longer an EU Member State, and they are unlikely to affect the maintenance of equivalent safety and quality standards with the EU and between GB and NI.

2.18 Competence to regulate in this area across the UK is split between the UK Parliament and the devolved legislatures. The Minister explained that policy on reproductive tissues and cells policy is reserved, and that blood and non-reproductive tissues and cells policy is devolved. Across the UK administrations, said the Minister, policy in this area is covered by the Blood Safety and Quality Provisional Common Framework and the Organs, Tissues and Cells Provisional Common Framework. They support the continuity of good working relations, open communication and the maintenance of a compatible minimum set of high standards of safety and quality for blood and non-reproductive tissues and cells. Following the processes set out in both Frameworks, said the Minister, policy decisions may be made in GB to reflect some of the changes proposed by the Commission.

2.19 The Minister observed that the draft Regulation is of a framework nature, delegating certain standards and technical guidance to the EDQM and ECDC, as well as establishing further detail through EU Implementing Acts. The UK Government and devolved

governments will need to undertake further scoping before deciding whether to voluntarily align with new EDQM and ECDS guidelines and will assess the Implementing Acts once there is further information.

2.20 Concerning the increased scope of the legislation to capture all forms of SoHO (beyond just blood, tissues and cells), the Minister considered it unclear what the effect of such change could be in the UK. While the expansion of the scope will automatically apply in NI, this expansion has not been considered by the UK Government and devolved governments previously. Further time and work will be required, said the Minister, to assess whether there is any benefit to voluntarily implementing such a change at a UK-wide level.

2.21 The Minister drew attention to the Northern Ireland Protocol Bill, designed to protect the integrity of the UK, avoid a hard border and safeguard the EU Single Market. He said that the Government had been engaged in consultation over the summer with stakeholders on how the Bill will work in practice, including in the SoHO sector.

Our assessment

2.22 The Commission has proposed this legislation in the light of weaknesses identified in the implementation of the BTC Directives. We note that, when it was an EU Member State, the UK responded to the Commission's consultation on reviewing the legislation and we note the Minister's confidence that the outcome reflects, at least to a degree, the UK's input.

2.23 The BTC Directives were implemented in UK law[57] and the domestic implementing legislation forms part of retained EU law by virtue of the EU (Withdrawal) Act 2018. The Retained EU Law (Revocation and Reform) Bill contains a range of powers to amend, revoke, restate, replace or update retained EU law. Some of the powers cannot, however, be exercised in relation to "Northern Ireland legislation". Given the weaknesses identified by the Commission in its evaluation, and the UK's input, it seems to us likely that the domestic legislation which implemented the BTC Directives would be identified as the type of retained EU law that should be amended or replaced when the Government undertakes its review of that law. Furthermore, the direction of travel proposed by the Commission, at least for blood, tissues and cells may well be broadly in line with changes that the UK may like to see. That being the case and given the importance of ensuring that lifesaving SoHO from EU Member States remains available to UK patients, we agree that there are compelling arguments in favour of adopting an approach broadly in line with that proposed by the Commission.

2.24 The Retained EU Law (Revocation and Reform) Bill must be factored into the Government's work in this policy area. As a default, the sunset mechanism in the Bill

57 Blood Safety and Quality Regulations 2005 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007. Note these Regulations were amended by EU Exit Statutory Instruments under the EU (Withdrawal) Act 2018 (EUWA): The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 and The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020.; The Human Tissue (Quality and Safety) for Human Application (Amendment) EU Exit Regulations 2019 and The Human Tissue (Quality and Safety) for Human Application) (Amendment) (EU Exit) Regulations 2020. Both sets of 2020 Exit SI Regulations use the section 8C powers under the EUWA to implement the Northern Ireland Protocol. This is to ensure that the EU law as set out in the text of the Directives continues to apply to Northern Ireland, not the retained EU law version (as amended) which applies to the rest of GB.

would operate to revoke the domestic law which implemented the BTC Directives[58] with effect from 31 December 2023. We note that the sunset mechanism does not apply to "Northern Ireland legislation" but that the domestic legislation implementing the BTC Directives which applies in NI does not come within that definition. The effect of that, absent any other regulatory change, would be to leave a regulatory vacuum in this area of public health, which would clearly be undesirable. Moreover, it would also create immediate divergence with NI. To reiterate, as the Minister explained in his EM, this is because under the Northern Ireland Protocol, the Regulation (once adopted) will become directly applicable in NI.[59] The draft Regulation needs to proceed through the EU's decision-making process before it can enter into force and will only apply two years later. We will seek confirmation from the Minister that the Government will, at the very least, extend the sunset mechanism for this legislation as permitted under the Bill and pending finalisation of the EU's Regulation.

2.25 The Government identifies elements of the proposal which may not be relevant to the UK as a third country, such as provisions around cooperation among Member States. In that context, we will seek clarity on whether the Government envisages that the provisions on cooperation—including joint inspections, access to the SoHO Platform and membership of the SoHO Coordination Board—would be applicable to NI. We would be concerned if a delegation of inspectors from EU Member States would have the right to inspect Northern Irish SoHO establishments.

2.26 A further complexity relates to the scope of the measure, which is broader than the BTC Directives. We will seek clarity from the Government as to whether it believes that the entirety of the Regulation should apply automatically in NI. The broader scope inevitably creates potential difficulties for NI if GB does not adopt a similar approach. The Government says that it is assessing the broader scope. We will request a summary of the outcome of that assessment once complete.

2.27 The Government mentions that it is working with stakeholders on the implementation of the Northern Ireland Protocol Bill in this sector. We will monitor with interest the outcome of those discussions as well as the progress of negotiations between the UK and the EU on implementation of the Northern Ireland Protocol. We trust that, for movement of SoHO between GB and NI, patient safety will be the overriding objective.

2.28 Finally, the Government helpfully sets out how the Commission's proposal interacts with two of the common frameworks adopted to support policy-making across the UK following the UK's withdrawal from the European Union. We will seek information from the Government as to the stage at which intra-UK discussions have reached in response to the Commission's proposal. Noting that some of the policy is reserved and some is devolved, any changes to UK legislation replicating the EU rules, particularly under the Retained EU Law (Reform and Revocation) Bill (once enacted), would need to take that into account and require consultation between the different administrations.

58 See footnote 10.

59 He further notes that secondary legislation will need to be made under the EU (Withdrawal) Act 2018 (EUWA) to revoke the existing legislation implementing the BTC Directives and to deal with enforcement of the new directly applicable Regulation. We understand him to mean those Directives as they apply to Northern Ireland and to be referring to section 8C powers in EUWA to implement the Northern Ireland Protocol.

Action

2.29 We have written to the Minister of State as set out below.

2.30 We are reporting this document to the House as politically important and we draw it to the attention of the Health and Social Care Committee and the Northern Ireland Affairs Committee.

Letter from the Chair to the Minister of State for Health

We considered your Explanatory Memorandum (EM) on the above proposal at our meeting of 26 October 2022.

The domestic regulations implementing the Blood, Tissues and Cells (BTC) Directives form part of retained EU law, a body of law which the Government is reviewing. Depending on the outcome of the review, powers in the Retained EU Law (Revocation and Review) Bill may be used to make changes to the regulations. Given the weaknesses identified by the Commission in its evaluation, and the UK's input to that evaluation as an EU Member State, it seems to us likely that the domestic legislation implementing the BTC Directives ("the implementing regulations") would be identified as retained EU law that should be amended or replaced when the Government undertakes its review. Furthermore, the direction of travel proposed by the Commission—at least for blood, tissues and cells—may well be broadly in line with how the UK may have proposed amending the legislation. That being the case and given the importance of ensuring that life-saving SoHO from EU Member States remains available to UK patients, we agree that there are compelling arguments in favour of adopting an approach broadly in line with that proposed by the Commission.

The Retained EU Law (Revocation and Review) Bill includes a sunset mechanism under which retained EU law in this category would be automatically revoked on 31 December 2023. We note that the sunset mechanism does not apply to "Northern Ireland legislation" but that the domestic legislation implementing the BTC Directives which applies in NI does not come within that definition. Can you please set out your plans for retained EU law affecting SoHO? Also, to the extent that the implementing regulations are "relevant separation agreement law",[60] how will the Bill apply?

You identify elements of the proposal which may not be relevant to the UK as a third country, such as provisions around cooperation among Member States. In that context, can you confirm that the provisions on cooperation—including joint inspections, access to the SoHO Platform and membership of the SoHO Coordination Board—would be applicable to NI? How likely is it that delegations of inspectors from EU Member States would have the right to inspect Northern Irish SoHO establishments?

You also note in your EM that the scope of the proposed Regulation is broader than the BTC Directives. Are you satisfied that the entirety of the proposed Regulation should apply automatically in NI? We are concerned that the broader scope inevitably creates potential difficulties for NI if GB does not adopt a similar approach. We look forward to receiving a summary of the outcome of your assessment of the broader scope once complete.

60 Within the meaning of section 7(C)3 of the European Union (Withdrawal) Act 2018.

Finally, the Government helpfully sets out how the Commission's proposal interacts with two of the common frameworks adopted to support policymaking across the UK following the UK's withdrawal from the European Union. We would welcome information from you as to the stage at which intra-UK discussions have reached in responding to the policy implications of the draft Regulation.

We look forward to a response to our queries by 7 December 2022.

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

Department for Business, Energy and Industrial Strategy

(42111) — Commission Regulation (EU) 2022/1176 of 7.7.2022 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use of certain UV filters in cosmetic products

C(2022) 4647

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: Northern Ireland Protocol: New EU scheme for the protection of geographical indications for craft and industrial products [Proposed Regulation]

Digital, Culture, Media & Sport Committee: Northern Ireland Protocol: New EU scheme for the protection of geographical indications for craft and industrial products [Proposed Regulation]

Health and Social Care Committee: Northern Ireland Protocol: Substances of Human Origin [Proposed Regulation]

Northern Ireland Affairs Committee: Northern Ireland Protocol: Substances of Human Origin [Proposed Regulation]

Formal Minutes

Wednesday 26 October 2022

Members present:

Sir William Cash, in the Chair

John Baron

Jon Cruddas

Geraint Davies

Richard Drax

Margaret Ferrier

Gavin Robinson

Greg Smith

Document scrutiny

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

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

Paragraphs 1.1 to 3 agreed to.

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

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

Adjournment

Adjourned till Tuesday 1 November 2022 at 10.00 am

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*)

John Baron MP (*Conservative, Basildon and Billericay*)

Jon Cruddas MP (*Labour, Dagenham and Rainham*)

Geraint Davies MP (*Labour, Swansea West*)

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

Richard Drax MP (*Conservative, South Dorset*)

Margaret Ferrier MP (*Independent, Rutherglen and Hamilton West*)

Mr Marcus Fysh MP (*Conservative, Yeovil*)

Dame Margaret Hodge MP (*Labour, Barking*)

Adam Holloway MP (*Conservative, Gravesham*)

Mr David Jones MP (*Conservative, Clwyd West*)

Stephen Kinnock MP (*Labour, Aberavon*)

Craig Mackinlay MP (*Conservative, South Thanet*)

Gavin Robinson MP (*Democratic Unionist Party, Belfast East*)

Greg Smith MP (*Conservative, Buckingham*)