House of Commons

European Scrutiny Committee

Twenty-second Report of Session 2022–23

Documents considered by the Committee on 6 September 2023

Report, together with formal minutes

Ordered by the House of Commons
to be printed 6 September 2023

HC 119-xx
Published on 12 September 2023
by authority of the House of Commons

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/

Staff

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

Contacts

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

Contents

1 Windsor Framework: EU protected geographical indications for craft and industrial products[1]

This EU document is legally and politically important because:

- It will establish a new EU-wide system restricting the use of specific 'Geographical Indications' (GIs) for the marketing of traditional craft and industrial products only to those made in relevant area. The EU has suggested it may want to apply the same scheme to goods sold in Northern Ireland under the Windsor Framework. It might also offer benefits for certain regionally-specific British exports to the EU, such as Harris Tweed or Savile Row apparel.

Action

- Write to the Minister.
- Draw to the attention of the Business and Trade Committee, the Culture, Media and Sport Committee, and the Northern Ireland Affairs Committee.

Overview

1.1 In May 2023, the EU announced that legislation had been agreed to establish a new scheme for the protection of 'Non-Agricultural Geographical Indications' for craft and industrial products ('the NAGI scheme').[2] This is similar to existing statutory protections in the EU (and the UK) that mean only traditional food and drink products made in a particular region can be marketed with references to that area (such as 'Cornish pasty' or 'Parmigiano Reggiano'). Under the new scheme, similar intellectual property protection would be created for manufactured goods marketed with a reference to its geographic origin, where the "quality [or] reputation is essentially attributable" to where they were made, for example Donegal tweed, Italian Murano glass or Limoges porcelain[3] Makers of similar wares, but based outside the designated region, would be prohibited from using or 'evoking' the relevant geographical area when marketing their products anywhere within the EU.

1.2 Broadly speaking, obtaining protected GI status will be a commercial decision taken by private entities. Producers of a relevant product within the EU will typically need to get approval from both a national intellectual property authority *and* from the EU Intellectual Property Office (EUIPO) in Alicante, Spain.[4] They will need to demonstrate, in particular,

1 Proposal for a Regulation on geographical indication protection for craft and industrial products; COM number: COM(2022) 174; Department: Business and Trade; Devolved Administrations: Not consulted; ESC number: 42098.

2 The NAGI Regulation is currently awaiting formal adoption by the European Parliament and the Council of the EU.

3 Some EU countries already operate GI schemes at national level for craft and industrial products. See European Parliamentary Research Service, 'Geographical indications for non-agricultural products' (November 2019). The EU scheme will replace any existing national NAGI schemes in its Member States, but existing protections under domestic laws will remain in force during a transitional period.

4 Individual EU countries can apply to opt-out of assessing applications at the national level, if they do not operate a domestic scheme and considers the level of interest from producers within their territory will be low.

that their product has a "quality, reputation or other characteristics linked to [its] geographical origin". Manufacturers of products linked to a region outside the EU can also apply for NAGI protection within the bloc. This requires the product to enjoy some form of legal protection for its geographic origin in its home market. Notably, under the scheme the EU will automatically consider giving protection to 'third country' NAGIs notified by other countries that are party to the Geneva Act (a treaty on geographic indications administered by the World Intellectual Property Organization). The Regulation will also allow non-EU producers to apply for NAGI protection for a specific product within the Single Market directly via the EUIPO, if their country is not part of the Geneva system. Applications for NAGI status can be rejected, for example if they conflict with a pre-existing trade mark.

1.3 Although the UK of course left the EU in January 2020, the scheme could still have implications here. This is, first, because the EU has indicated it may want its NAGI scheme to extend to Northern Ireland under the Windsor Framework (previously known as the Northern Ireland Protocol). As the new geographic protections for industrial and craft goods are set out in an entirely new EU law, this means the UK would have to agree to a formal EU request to that effect under Article 13(4) of the Framework, which to our knowledge has not yet been made. In addition, the EU scheme could also have implications for UK-EU trade in traditional manufactured products more generally, for example by giving British producers of traditional goods like Harris Tweed the possibility of securing a protected Geographic Indication for their sales across the entire EU market.

1.4 Since we initially reported on the EU proposal in our Ninth Report of this Session,[5] the legislative negotiations in Brussels have concluded and the Windsor Framework agreement has confirmed under which conditions new EU laws are to apply in Northern Ireland. It is therefore timely to make an update to the House with an assessment of the potential implications of the proposal for the UK.

The Government's position

1.5 The Government appears to have taken considerable interest in the EU NAGI scheme. In 2021, well after the UK's withdrawal from the EU, it replied to a European Commission consultation to argue that it "support[ed] the need for effective protection mechanisms for NAGIs, but that the evidence provided was not sufficient to advocate the introduction of an EU-wide sui generis scheme".[6] This was the same position taken by the UK while it was an EU Member State. The then Minister for Science, Research and Innovation (George Freeman MP), with responsibility for intellectual property issues, submitted an Explanatory Memorandum on the proposed EU NAGI scheme in Northern Ireland in June 2022.[7] This confirmed that the EU had, by that point, "informed the UK of its view that […] the legislation could fall under Article 13(4) of the [Windsor Framework]". That indicated the EU was considering formally requesting the UK's consent for the NAGI scheme to be included in the Framework, and therefore made applicable in Northern Ireland if that consent was given.[8]

5 European Scrutiny Committee, Ninth Report (2022–23) HC 119–viii, chapter 1 (1 November 2022).
6 Explanatory Memorandum submitted by the Department for Business, Energy and Industrial Strategy (27 June 2022).
7 Department for Business, Energy and Industrial Strategy, 'Explanatory Memorandum on the proposed EU Regulation on NAGI for craft and industrial products' (27 June 2022), p. 2.
8 ibid.

1.6 As regards the potential benefits for UK manufacturers of industrial goods who may want to apply for a protected geographic indication within the EU market, the Government said these were likely to be "limited" to approximately five products. Between a 2019 European Parliament study[9] and a separate paper published by the European Commission in 2020,[10] there appear to be at least six traditional UK products whose exports to the EU might qualify under the scheme: Harris tweed; Savile Row apparel; Irish linen;[11] North Staffordshire pottery; Sheffield steel; and Nottingham lace.[12] By comparison, these studies identified 229 different products that might be eligible in Spain, 96 in France, and 15 in Ireland. The Minister's Memorandum did not refer to any UK-specific research into the possible breadth of traditional industrial products manufactured in Britain that are marketed using a geographic reference. It also noted there are no current plans by the Government to introduce a UK scheme of a similar nature, because there are "no widespread calls amongst stakeholders for change". Instead, NAGIs can be protected under British law by individual companies through the general trademark system, "a common way to provide protection with similar systems operating in the US, Australia, and Canada".[13]

Analysis

1.7 The EU's new scheme for the protection of geographic indications for craft and industrial goods is an extension of its existing approach to protecting traditional food and drink. While there is a precedent in British law for similar protection for a specific product in the form of the Harris Tweed Act 1993, which restricts the use of that term to cloth made in the Outer Hebrides, there is no overarching NAGI scheme in existence in the UK and no plans to introduce one. As far as we have been able to ascertain, there is therefore no specific protection related to geographic indications of industrial products in UK law—for the five other traditional UK-made products already identified as potential beneficiaries of GI protection under the EU scheme as third country goods (Nottingham lace, North Staffordshire pottery, Sheffield steel, Savile Row apparel and Irish linen). They may have some protection through trade-marks where these incorporate a relevant geographic reference.

1.8 If the EU were to formally request its new scheme be made applicable in Northern Ireland under the Windsor Framework and the UK agreed, this would be a significant legal change in that part of the UK. It would mean that NAGIs approved by the EU Intellectual Property Office would have legal protection in Northern Ireland under EU law applying via the Windsor Framework, and the Government would be under an obligation to ensure official market surveillance activity to ensure non-compliant products were removed from that market. Conversely, Northern Ireland producers of craft and industrial products linked to a specific region, for example those making Irish linen, would be able

9 EPRS, 'Geographical indications for non-agricultural products' (November 2019).

10 European Commission, 'National legal frameworks available for the protection of non-agricultural GI products' [accessed 18 July 2023].

11 The Irish Linen Guild has members from both Ireland and Northern Ireland.

12 The studies also refer to Shetland wool, but this product is already protected under existing UK and EU GI schemes as an 'agricultural product', and it therefore would presumably not benefit significantly from additional NAGI protection.

13 Explanatory Memorandum submitted by the Department for Business, Energy and Industrial Strategy (27 June 2022), p. 3.

to apply for GI status for their goods under the scheme as if they were based within the EU (meaning that, unlike for relevant products made in Great Britain, they would not have to demonstrate prior protection under UK domestic law).

1.9 Given it is not yet known if the EU scheme will be added to the Framework, it is unclear if its operation could create any legal uncertainties or complexities within the UK internal market (for example in case of conflicting protected geographic indications in force in Northern Ireland under EU law applying via the Framework and similar trademarks in Great Britain under UK law).[14] However, for a new piece of EU legislation like the NAGI Regulation to be added to the Windsor Framework under Article 13(4), the UK must agree to a formal Decision to that effect within the UK/EU Joint Committee. This effectively gives the Government a veto over whether the Regulation will apply in Northern Ireland in due course.[15] If it were to refuse the EU's request, the EU would have the right to take unspecified "remedial measures". This scenario has not arisen to date.

1.10 The EU scheme could also give producers in Great Britain the option of securing GI protection for their exports to the EU Single Market. Some makers of some traditional UK products previously identified benefits in having their brand protected across the European market in this way.[16] Given the UK's status as a third country outside the EU, producers in Great Britain would need to prove that their geographic branding is legally protected in some way under UK law.[17] The Geneva Act route to obtaining NAGI status in the EU is not open to them, because it ceased to apply to the UK at the end of the post-Brexit transition period (when the Government declined to join that agreement independently of EU membership). As such, Great British producers would have to demonstrate protection within the UK market by other means. It may be possible for a Great British collective or certification trademarks incorporating a geographic reference to suffice for that purpose. In the longer term, it is also possible that the EU may seek to include reciprocal and binding protections with the UK for geographic indications of manufactured products as part of any future agreements building on the 2020 UK/EU Trade and Cooperation Agreement.[18]

1.11 Where producers of a particular good obtain NAGI status within the EU, this would restrict manufacturers from outside the specified region—including, where relevant, those based in the UK—from selling those goods in the EU using the protected geographic reference in their branding and marketing. For example, UK-made fabric might no longer be legally marketed within the EU as 'Donegal tweed' if that product obtains NAGI protection in Ireland. However, in his correspondence with us, the Minister did not identify any specific examples of significant UK exports that might be affected in this way.

14 If the Regulation were to be made applicable in Northern Ireland under the Windsor Framework, the Government would also have to consider whether the UK would operate a "national phase" for Northern Irish applications for NAGI protection, or seek a different arrangement under Article 11(4) or Article 15 of the draft legislation given the expected small volume of potential beneficiaries in Northern Ireland.

15 Under the draft Windsor Framework (Democratic Scrutiny) Regulations 2023, which have been approved by the UK Parliament but are not yet in force, any addition of new EU legislation under Article 13(4) would normally require cross-community support in the Northern Ireland Assembly in the form of an "applicability motion".

16 For example, the Savile Row Bespoke Association had, prior to Brexit, argued in favour of EU-wide protection of its geographic indication.

17 The same would apply to producers in Northern Ireland if the new Regulation did not apply under the Windsor Framework.

18 In the new NAGI Regulation itself the EU says that it may, in the future, seek to negotiate agreements on mutual recognition of specific NAGIs on behalf of all its Member States with individual trading partners (like the UK) directly through new or updated trade agreements.

Conclusions

1.12 The EU's new scheme to protect geographical indications for the marketing of traditional craft and industrial products is a new area of EU law. While we take no view on the policy merits of the new legislation, the NAGI scheme could have implications in the UK, both for Northern Ireland under the Windsor Framework and for trade of craft and industrial goods between the UK and EU more generally. We have written to the Minister for AI and Intellectual Property, Viscount Camrose, to seek some further clarifications in that regard, and a copy of that letter is included below. We draw these developments to the attention of the Business and Trade Committee, the Culture, Media and Sport Committee, and the Northern Ireland Affairs Committee.

Letter to the Minister for AI and Intellectual Property (Viscount Camrose)

The Committee today considered the potential implications for the UK of the EU's new scheme for protected non-agricultural geographic indications for craft and industrial products (NAGI), similar to existing protections for food and drink products like Yorkshire Wensleydale and Parmesan cheese.

We understand that six UK-made traditional products—Harris tweed, Savile Row apparel, Nottingham lace, North Staffordshire pottery, Sheffield steel and Irish linen—had previously been identified as potential candidates for NAGI protection under the new scheme, if they meet the relevant conditions as 'third country' (non-EU) products.

Of course, whether to apply for NAGI status will be a commercial decision for the relevant businesses, not a matter of public policy. We would be grateful if you could tell us what consultations you have had with potential beneficiaries of the scheme in the UK with respect to their exports to the EU, and what their views are.

However, we also note the EU's wish to have the Regulation added to the Windsor Framework under its Article 13(4), which would make the EU NAGI scheme applicable in Northern Ireland (but not the rest of the UK) if the UK agreed. What is the Government's position on such an EU request? In particular, what assessment has been made of whether having to enforce protected geographic indications on industrial products in Northern Ireland by virtue of the Windsor Framework would create a new regulatory border between NI and Great Britain?

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

2 Windsor Framework: Breakfast Directives[19]

This EU document is politically important because:

- it introduces changes applicable to honey, fruit juices and jams placed on the EU and Northern Ireland markets;
- the Government is consulting stakeholders on whether it is in the best interest of the UK to consider similar changes, noting that those concerning the reduction of sugar in fruit juices and jams are broadly in line with UK health policy; but
- some changes, such as allowing the term 'marmalade' to apply to all jams, could be confusing to UK consumers.

Action

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

Overview

2.1 To protect the interests of consumers, provide a level playing field for trade and ensure authenticity, various EU Directives[20] exist concerning the marketing of honey, fruit juice, jams, and preserved milks. They are known colloquially as the 'Breakfast Directives'. As the Directives are over 20 years old, the Commission has proposed a series of amendments to update them.

2.2 The Directives and the amendments apply to Northern Ireland (NI) under the terms of the Windsor Framework. Following the agreement in March 2023 to amend how the Windsor Framework is applied, goods moved from Great Britain (GB) to be placed on the market in NI will not have to comply with the new rules. Similar products produced in NI and marketed in NI will, however, have to comply in order that they can also be placed on the EU market.

2.3 The Government has summarised the proposal in its Explanatory Memorandum (EM). Among the changes, the following are noteworthy:

19 Proposal for a Directive amending Council Directives 2001/110/EC relating to honey, 2001/112/EC relating to fruit juices and certain similar products intended for human consumption, 2001/113/EC relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption, and 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption, COM (2023) 201; Legal base: Article 43(2) TFEU, QMV, ordinary legislative procedure; Department: Environment, Food and Rural Affairs; Devolved Administrations: Consulted; ESC number: 42207.

20 Council Directives 2001/110/EC relating to honey, 2001/112/EC relating to fruit juices and certain similar products intended for human consumption, 2001/113/EC relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption, and 2001/114/EC relating to certain partly or wholly dehydrated preserved milk for human consumption.

- all of the individual countries from which a jar of honey originates will need to be listed;
- the introduction of a new 'reduced-sugar fruit juice' or 'reduced sugar fruit juice from concentrate' category (if it meets a minimum 30% sugar content reduction compared to the standard product) along with associated new definitions and new technological processes to be used to achieve the removal of sugar;
- minimum fruit content of jams and marmalades to be increased to 45% from the current 35%; and
- products currently marketed as 'Marmalade' will have to be known as 'Citrus Marmalade', while the term 'Marmalade' can be used for all jams. This reflects national practice across the EU, where '*mermelada*' is commonly used to describe all jams. The change will help to distinguish the two product categories in line with international standards.

UK Government position

2.4 In his EM, the Minister for Food, Farming and Fisheries (Rt Hon. Mark Spencer MP) says that the Government has not yet fully assessed these proposals. They contain several technical changes to EU rules which the Government needs to investigate further and discuss with stakeholders, particularly those businesses that will be affected. This will include consideration of whether it is in the best interest of the UK to consider similar changes.

2.5 He considers the most significant change to be the introduction of a new category of reduced sugar fruit juice. This, says the Minister, offers potential advantages on the grounds of health and improved consumer choice. Encouraging the production of jams with higher fruit content is broadly in line with previous UK proposed measures to reduce the sugar content of jam in line with reducing sugar intake.

2.6 The Minister notes that the changes to use of the term 'marmalade' could be confusing for UK consumers as the terms marmalade and jam are not interchangeable in the UK and have differing requirements.

2.7 The Minister confirms that the proposal could lead to some regulatory divergence between affected products placed on the GB market and those placed on the EU and NI markets. The Minister notes, though, that the revised standards will not apply to goods moved from GB to NI via the new agri-food green lane.

2.8 The Department for Environment, Food and Rural Affairs, says the Minister, will discuss the proposal with the Devolved Administrations under the Provisional Food Compositional Standards and Labelling Common Framework to further assess and understand the implications of these proposed changes to the UK.

Analysis

2.9 While not applicable in GB or to products moved from GB to be placed on the NI market, these changes will apply to products produced in NI and to products produced anywhere in the UK and then placed on the EU market. This may well prompt change in any case as well as demand from stakeholders for the UK to consider similar changes.

2.10 We note that the changes proposed by the Commission are driven in part by a desire to reduce sugar consumption as part of health policy, a broad approach which aligns with UK Government policy.

2.11 We will respond to the Minister signalling our interest in the Government's full assessment of these proposals, including the Government's conclusions as to whether it considers that the best interest of the UK would be served by making similar changes.

Action

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

Letter from the Chair

We considered your Explanatory Memorandum on the above document at our meeting of 6 September 2023.

We note that the changes proposed by the Commission are driven in part by a desire to reduce sugar consumption as part of health policy, a broad approach which aligns with UK Government policy. On the other hand, we also note that some of the changes could be confusing to UK consumers, such as allowing the term 'marmalade' to apply to all jams.

We will be interested to review your full assessment of these proposals once completed, including your conclusion as to whether the best interest of the UK would be served by making similar changes.

We look forward to a response within four months, depending on when your full assessment is completed.

3 Windsor Framework: EU electricity market design[21]

These EU documents are politically important because:

- they will apply, for the most part, in Northern Ireland; and
- the Government acknowledges that they will need to be taken into account as the UK develops its own market design proposals due to the implications for the trade of electricity with both the EU and Northern Ireland.

Action

- Write to the Minister.
- Draw to the attention of the Energy Security and Net Zero Committee and the Northern Ireland Affairs Committee.

Overview

3.1 To protect consumers from price volatility in short-term electricity markets, promote a stable long-term price of energy and boost renewable energy investment, the European Commission has proposed revisions to the EU rules governing electricity markets.[22] Separately, the UK is developing its own proposals for electricity market reform, known as 'REMA' (Reform of Electricity Market Arrangements). The Government has acknowledged the need to take into account the EU's plans as the UK further develops its plans for REMA.[23]

3.2 A Single Electricity Market (SEM) operates on the island of Ireland and operates within the framework of EU rules. As a result, Article 9 of the Windsor Framework[24] applies certain EU energy rules (set out in Annex 4 of the Windsor Framework) to Northern Ireland (NI) insofar as the legislation is relevant to the generation, transmission, distribution, and supply of electricity, trading in wholesale electricity, or cross-border exchanges in electricity. The obligations apply to any of those rules as amended or replaced,

21 (a) Proposal for a Regulation (EU) amending Regulations (EU) 2019/943 and (EU) 2019/942 as well as Directives (EU) 2018/2001 and (EU) 2019/944 to improve the Union's electricity market design; COM (2023) 148: Legal base: Article 194(2) TFEU, QMV, ordinary legislative procedure; Department: Energy Security and Net Zero; Devolved Administrations: Northern Ireland consulted; ESC number: 42195; (b) Proposal for a Regulation (EU) amending Regulations (EU) No 1227/2011 and (EU) 2019/942 to improve the Union's protection against market manipulation in the wholesale energy market; COM (2023) 147; Legal base: Article 194(2) TFEU, QMV, ordinary legislative procedure; Department: Energy Security and Net Zero; Devolved Administrations: Northern Ireland consulted; ESC number: 42194.

22 European Commission, 'Commission proposes reform of the EU electricity market design to boost renewables, better protect consumers and enhance industrial competitiveness', 14 March 2023.

23 Explanatory Memorandum from the Minister of State for Energy Security and Net Zero, Rt Hon. Graham Stuart MP, 21 April 2023.

24 The European Union and the United Kingdom agreed on 24 March 2023 that the NI Protocol as amended by Joint Committee Decision No 1/2023 should be known as the 'Windsor Framework'. This was confirmed in the Joint Declaration No 1/2023 of the Union and the United Kingdom in the Joint Committee established by the Withdrawal Agreement.

which means that the proposed legislation is applicable to NI, except elements relating to retail markets and consumer protection and those that amend the Renewable Energy Directive.

3.3 We summarised the EU's plans in our Report[25] of 14 June 2023 and subsequently wrote[26] to the Minister of State for Energy Security and Net Zero (Rt Hon. Graham Stuart MP) seeking further information. He has responded as set out below.

UK Government position

3.4 In his reply of 10 July 2023, the Minister notes that the EU's Council of Ministers secured partial agreement on the proposals at its meeting of 19 June.[27] Agreement was reached on areas including consumer protection and energy market manipulation measures, but proposals relating to Contracts for Difference[28] and capacity mechanisms[29] were not signed off. The Government will assess the implications of the areas on which agreement has been reached while awaiting clarity on those that are still unclear and will provide a further update as the Regulations are finalised.

3.5 Concerning the implications of the proposals for NI, the Minister notes that it is necessary first to engage with the European Commission to understand what elements of the proposals will apply under the Windsor Framework. The Government will use the Windsor Framework's new structured expert group on the SEM to engage the EU to understand how the proposed Regulations would be applied and assess the regulatory and financial impact on NI before the EU's legislative process is completed. As energy policy is devolved in NI, the Government is also engaging closely with the NI Executive and the Utility Regulator to support the UK's engagement with the EU.

3.6 Finally, the Minister notes that the UK-EU energy relationship is subject to the arrangements and obligations set out within the UK-EU Withdrawal Agreement and Trade and Cooperation Agreement (TCA). Therefore, where relevant to the Withdrawal Agreement and TCA, the EU's proposed electricity market reforms are required to be consistent with these obligations.

Our assessment

3.7 It is disappointing that the Government has been unable to provide, even at a high level, how the EU's plans might affect both trade between NI and Great Britain and trade between Great Britain and the EU. Interestingly, however, the Minister recalls that the EU's proposed reforms are required to be consistent with the EU's obligations under the Withdrawal Agreement and the TCA. This suggests that the Government has indeed undertaken some analysis and that the analysis points to potential areas of inconsistency. We will clarify what specific obligations the Government has in mind and what elements, if any, the UK has identified as potentially inconsistent with those obligations.

25 European Scrutiny Committee, Nineteenth Report (2022–23) HC 119–xvii, chapter 6 (14 June 2023).
26 Letter from Sir William Cash CH MP to Rt Hon. Graham Stuart MP dated 14 June 2023.
27 Council of the European Union, 'Council reaches agreement on parts of electricity market reform', 19 June 2023.
28 Where renewable and nuclear energy producers are guaranteed a minimum price but must also pay back any revenues received above a ceiling price.
29 Used to procure electricity generation capacity to guarantee the availability of electricity at all times, including peak hours. The Commission has proposed that demand-side response also be included i.e., reducing electricity usage.

3.8 Since the Minister wrote, the European Parliament (EP) Energy Committee has adopted its position on the package,[30] with adoption by the EP Plenary expected shortly. We will ask the Minister to take that development into account when providing us with further analysis, which we will request be provided within three months.

Action

3.9 We have responded to the Minister as set out below.

3.10 We are drawing the correspondence and this chapter to the attention of the Energy Security and Net Zero Committee and the Northern Ireland Affairs Committee.

Letter from the Chair to the Minister for Energy Security and Net Zero (Rt Hon. Graham Stuart MP)

We considered your letter of 10 July 2023 on the above documents at our meeting of 6 September 2023.

While we accept that a definitive impact assessment of the Commission's proposals is not yet possible, we are disappointed that you were unable to provide even a high-level view on how the EU's plans might affect both trade between NI and Great Britain and trade between Great Britain and the EU.

You make the point that the draft EU plans must be consistent with the EU's obligations under the Withdrawal Agreement and the Trade Cooperation Agreement. Given that the EU—like the UK—must always act within the framework of its international obligations, we conclude that you have in fact undertaken some analysis and that the analysis has identified potential concerns. Both Parties to those Agreements are subject to a range of energy-related obligations. Can you please clarify what specific obligations you have in mind and what, if any, elements of the Commission's proposals the UK has identified as potentially inconsistent with those obligations?

We note that, since you wrote, the European Parliament Energy Committee has adopted its position on the package, with adoption by the Plenary expected shortly.

We ask that you respond to us with the further analysis that you have promised within three months. It would be helpful if the analysis would take into account latest developments in EU-level negotiations, including the EP's position and any further Council agreement.

30 European Parliament, 'MEPs back plans for a more affordable and consumer-friendly electricity market', 19 July 2023.

4 Windsor Framework: Revision of EU pharmaceutical rules[31]

This EU document is politically important because:

- it affects Northern Ireland directly, while the full implications are still being assessed, it may particularly affect the regulation of paediatric medicines; and
- it may affect the UK market more widely, both positively by facilitating the supply of a broader range of affordable medicines, but potentially negatively if the changes strengthen the EU security of supply at the expense of the UK's market.

Action

- Write to the Minister.
- Draw to the attention of the Health and Social Care Committee, Northern Ireland Affairs Committee, and the Science and Technology Committee.

Overview

4.1 EU pharmaceutical rules lay down requirements for authorisation, monitoring, labelling, placing on the market and other regulatory procedures for medicines authorised at EU and Member State level. The European Commission has proposed to reform the rules to make medicines more available, accessible and affordable. The Commission hopes that the revision will support innovation and boost the competitiveness and attractiveness of the EU pharmaceutical industry, while promoting higher environmental standards. It applies to medicinal products for human use and, for the first time, incorporates those for the treatment of rare diseases and for children. They currently have separate legal frameworks.

4.2 The revision is salient to the UK for two reasons. First, EU pharmaceutical rules continue to apply in Northern Ireland (NI), although the extent of that will soon be changing, as set out below. Second, the UK's pharmaceutical market is heavily supplied by EU-based suppliers. While a greater range of affordable products could benefit the UK, there may be risks if the changes strengthen EU security of supply at the expense of the UK's.

31 (a) Proposal for a Directive on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC; COM (2023) 192; Legal base: Articles 114 (1) and 168(4)(c) TFEU, QMV, ordinary legislative procedure; Department: Health and Social Care; Devolved Administrations: Northern Ireland consulted; ESC number: 42205. (b) Proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006; COM (2023) 193; Legal base Articles 114 (1) and 168(4)(c) TFEU, QMV, ordinary legislative procedure; Department: Health and Social Care; Devolved Administrations: Northern Ireland consulted; ESC number: 42206.

The Commission's proposals

4.3 This package consists of a draft Directive and a draft Regulation. It seeks to achieve its objectives by:

- introducing regulatory protection of up to a maximum of 12 years for innovative medicines, with the level of protection depending on factors such as whether the product is launched across all Member States at the same time and whether the product addresses unmet medical needs;
- facilitating the earlier availability of generic and biosimilar medicines and simplifying market authorisation procedures (i.e. European Medicines Agency authorisation procedures will take 180 days, helping reduce the current average of around 400 days, and using digitisation to reduce the regulatory burden of authorisation);
- addressing antimicrobial resistance (AMR) by offering transferable exclusivity vouchers to companies that invest in novel antimicrobials that can treat resistant pathogens (the voucher could be applied to one non-related medicine, extending its patent period up to one year, or it could be sold);
- making medicines more environmentally sustainable, by updating existing frameworks to adapt to scientific and technological changes; and
- enhancing security of supply through stronger obligations on marketing authorisation holders to notify potential or actual shortages and marketing withdrawals, cessations, and suspensions in advance of a foreseen interruption to the continued supply of a medicinal product to the EU market.

Application to Northern Ireland

4.4 The relevance of this proposed revision to NI is complex. As the Health Minister (Will Quince MP) notes in his Explanatory Memorandum (EM), it will require further analysis to understand fully. We have summarised below the key points as we currently understand them but will look forward to further analysis from the Minister.

The original Northern Ireland Protocol

4.5 Under the terms of the original NI Protocol (now known as the 'Windsor Framework'), EU rules concerning the placing of medicines on the market applied to NI. This meant, at least in theory, that the NI medicines market would be regulated by the European Medicines Agency, while the Great Britain (GB) market would be regulated by the UK's Medicines and Healthcare Regulatory Agency (MHRA). EU restrictions would apply to the import of medicines from GB, and NI medicines would need to be authorised and tested in the EU or NI rather than GB.

Negotiated easements

4.6 In practice, NI's historical dependence on supplies from—or via—GB meant that the new process would create serious logistical challenges and potentially reduce the volume of medicines on the NI market. It was therefore necessary to agree measures to

maintain the supply of medicines to the NI market. To do so, a grace period was applied before the adoption of a first set of permanent measures in April 2022[32] and a second set of measures[33] in June 2023 as part of the wider Windsor Framework agreement. The most recent easements will take effect on 1 January 2025 as long as the Government has provided the necessary written guarantees concerning public health protection.

4.7 The combined effect of the two sets of permanent measures is to include NI within the UK's medicines market as long as those medicines are labelled as such and are not at risk of entering the EU Single Market. This is only, however, an exemption from application of the rules under the Windsor Framework. The Commission maintains the right to withdraw the easements if the UK fails to comply with the strict conditions in place. The measures do not affect application of the EU rules to medicines produced in NI to be placed on the EU market.

The recent proposals

4.8 Formally, the whole of the new framework applies to NI, except where easements have been agreed. The easements adopted in 2022 are replicated in the new draft Directive, but the second set are not as they were adopted after the draft was published. As a formality, that second set of easements will need to be incorporated at some stage into the text in order to bring the new legislation into line with what was previously agreed.

4.9 The easements make targeted exemptions to the legislation, meaning that the new framework will still apply where no exemptions are in place. An example of where the new framework will apply to NI regardless of the easements is where medicines are produced in NI for the EU market.

4.10 In addition, the draft Regulation repeals and replaces EU legislation on medicines for rare diseases (the 'Orphan Regulation'—Regulation (EC) No 141/2000) and on medicines for children (the 'Paediatric Regulation'—Regulation (EC) No 1901/2006). That legislation is also applicable in NI. These medicines will now form part of a single regulatory framework covering all medicines. Some specific features are, however, retained and developed. More detail will be required in Paediatric Investigation Plans, for example and the default requirement will be for all medicines to be tested for use in children although waivers will be possible.

4.11 It is unclear whether the negotiated easements, once fully integrated into the texts of the legislation, will extend to features such as regulation of paediatric medicines. The adopted easements make no specific provision for such medicines.

UK Government position

Northern Ireland

4.12 In his EM, the Minister summarises the current legal situation concerning the regulation of medicines in NI. He notes that, even with the easements negotiated, all

32 Directive (EU) 2022/642 of 12 April 2022 amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta

33 Regulation (EU) 2023/1182 of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC

generic medicines[34] entering NI must be licensed in compliance with EU law. In substance, this means that the equivalence of a generic medicines with its reference product must be demonstrated so that the safety of the product is guaranteed.

4.13 The Minister observes that the medicines provisions outlined in the Windsor Framework are expected to come into effect on 1 January 2025. The implementation of the Windsor Framework will mean that the Commission's proposals relating to new and innovative medicines will not apply to NI.

4.14 The Minister explains that the Department for Health and Social Care and the MHRA are currently scoping potential interactions between the EU proposals and the Windsor Framework, but that further analysis will be required as details of the proposals emerge.

4.15 The Minister has identified at least two specific NI issues that are being considered:

- regulation of paediatric medicines; and
- independent batch testing performed by EU laboratories for vaccines and blood products for the EU market;

UK Supply Resilience

4.16 The Minister notes that the draft proposals include several measures aimed at ensuring the security of supply of medicinal products for the EU market. Given the UK market is heavily supplied by pharmaceutical manufacturers that are based in the EU, or have an EU touchpoint in their supply chain, changes that strengthen security of supply for EU Member States may, says the Minister, have indirect impacts on UK supply resilience. The measures aimed at strengthening security of supply, as currently drafted, will not impact GB to NI supply and are not expected to have differential impacts on NI.

4.17 These measures could, says the Minister, provide benefits to the UK by increasing the overall level of resilience held by medicinal product suppliers, encouraging them to improve their business continuity plans and capability to respond to disruption to supply. However, he adds, there may be negative impacts on UK supply resilience if these measures lead suppliers to prioritise the EU market over the UK.

4.18 As the EU proposals develop further and the detail of the implementation becomes clear, the Government will scrutinise the potential impacts on UK supply resilience.

Analysis

4.19 We note the wide-ranging nature of this package. It contains elements which may be controversial among Member States, notably the proposals for new incentives based around the idea that a product should be made available across the EU at the same time. We consider it possible that there will be significant changes to the legislative texts as they proceed through the European Parliament and the Council. It may not be possible for the EU to adopt this package of texts before the European Parliament elections next June, which could delay adoption for some time.

34 Non-branded versions of a particular medicine, which has already been authorised for placing on the market.

4.20 That said, we consider it noteworthy that the EU is seeking ways to reform the regulatory regime to promote innovation and make medicines more available, accessible and affordable. It is likely that the new framework, once in place, will have some implications for the availability of medicines in the UK and the timing of placing them on the market. Whether the package could encourage innovation in the UK or, alternatively, divert it to the EU remains to be seen. We consider it crucial that the Government monitor developments closely to assess whether the UK needs to respond in order to protect its interests.

4.21 Turning to the specific implications for NI, we note that the Government's analysis is ongoing. We look forward to receiving further analysis from the Government in due course about the potential interactions between the EU proposals and the Windsor Framework. It would be particularly helpful if the Minister could spell out the identified potential issues around batch testing and the regulation of paediatric medicines. We will also ask him to comment on issues arising for NI businesses placing medicinal products on the EU market.

Action

4.22 We have written to the Minister as set out below.

4.23 We are drawing this chapter and our letter to the attention of the Health and Social Care Committee, the Northern Ireland Affairs Committee and the Science and Technology Committee.

Letter from the Chair to the Minister for Health (Will Quince MP)

We considered your Explanatory Memorandum on the above proposals at our meeting of 6 September 2023.

This is clearly a significant package of draft EU legislation, which could have implications for both NI specifically but also the UK more widely. We are pleased to note the Government's intention to monitor the EU's negotiations as they progress and to scrutinise the specific UK implications.

On NI specifically, we look forward to receiving further analysis from you about the potential interactions between the EU proposals and the Windsor Framework. It would be particularly helpful if you could spell out the identified potential issues around batch testing and the regulation of paediatric medicines. We also ask that you comment on any issues arising for NI businesses placing medicinal products on the EU market.

Given the uncertainties over the EU's negotiations, we are content for you to respond within six months.

5 Windsor Framework: Classification, Labelling and Packaging of Chemicals[35]

These EU documents are politically important because:

- they apply in Northern Ireland (NI) and will create further divergence between Great Britain (GB) and NI, potentially affecting the supply of relevant goods to the NI market; and
- they may influence the direction of future policy in Great Britain.

Action

- Report to the House.
- Draw to the attention of the Northern Ireland Affairs Committee.

Overview

5.1 The UN Globally Harmonized System of classification and labelling of chemicals (UN GHS)[36] exists so that information can be provided consistently across languages, alphabets and different levels of literacy. While the UN GHS is a voluntary framework, it was made mandatory in the EU in 2008 through the Classification, Labelling and Packaging (CLP) Regulation.[37] The EU recently added six new hazard classes to the EU CLP Regulation.

5.2 Under the terms of the Windsor Framework (previously known as the NI Protocol),[38] NI must continue to apply various EU laws, including the EU CLP Regulation. This means that the changes will affect the placement of chemicals on the NI market, including by suppliers from GB.

5.3 We summarised the Commission's proposals in our Report of 12 July 2023,[39] following which we wrote to the responsible Minister (Mims Davies MP) seeking further information. The Minister responded on 1 August, as we have summarised below.

35 (a) Proposal for a Regulation amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures; 16258/22, COM(22)748; Legal base: Article 114(1) TFEU; Department: Health and Safety Executive (Department for Work and Pensions); Devolved Administrations: Consulted; ESC number: 42166; (b) Commission Delegated Regulation (EU) 2023/707 of 19.12.2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures; C(2022) 9383 + Annex; Legal base: Regulation (EC) No 1272/2008; Department: Health and Safety Executive; Devolved Administrations: Consulted; ESC Number: 42169.

36 United Nations Economic Commission for Europe, 'About the GHS' [Accessed 20 April 2023].

37 Regulation (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

38 The European Union and the United Kingdom agreed on 24 March 2023 that the Protocol on Ireland/Northern Ireland as amended by Joint Committee Decision No 1/2023 should be known as the 'Windsor Framework'. This was confirmed in Joint Declaration No 1/2023 of the Union and the United Kingdom in the Joint Committee established by the Agreement on the Withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community.

39 European Scrutiny Committee, Twenty-First Report (2022–23) HC 119–xix, chapter 9 (12 July 2023).

UK Government position

5.4 Concerning the extent to which the arrangements for enhanced EU-UK dialogue under the Windsor Framework have been useful for discussions on these texts, the Minister draws particular attention to the Joint Consultative Working Group (JCWG) structured sub-group on manufactured goods and the new Special Goods Body. She says that, through this new governance framework, there is the opportunity for early engagement on planned EU rules, with scope to agree appropriate solutions through the Withdrawal Agreement Joint Committee. This, she says, will be an important mechanism for considering future UK and EU rule changes to ensure that their interaction does not inadvertently lead to any new regulatory barriers. It will mean, she says, that the regulatory environment in N I can be better tailored to suit consumer and business needs.

5.5 As to whether any GB-based businesses are choosing to self-classify in accordance with the EU's new hazard classes, the Minister says that UK officials are not aware of any such instances. Moreover, says the Minister, industry stakeholder groups have not raised with officials any cases of GB duty holders (i.e. manufacturers, importers or downstream users) voluntarily applying the new EU hazard classes to substances or mixtures being placed on the GB market.

5.6 Finally, the Minister says that the UK will engage with the UN GHS consideration of the scientific evidence behind the new EU classifications. UK officials will also consider the wider policy context of any changes agreed at the UN GHS before adopting any changes in hazard classifications to the GB CLP. Officials will continue to actively contribute to the UN GHS informal working group on "potential hazard issues and their presentation in GHS". The Minister explains that this large group, of which the UK is a member, is comprised of delegates including the USA, Canada, EU Member States, China, Japan, international trade associations and Non-Governmental Organisations.

Our assessment

5.7 We raised three issues with the Minister, all of which have been addressed to a degree. The EU's new hazard classifications are already part of EU law, and it appears that further substantive policy developments will depend on international discussions.

5.8 We will continue to monitor to developments in this area—including the use of the new arrangements for enhanced UK-EU dialogue under the Windsor Framework—but we require no further information from the Government.

Action

5.9 We are reporting the Minister's reply to the House. We are drawing the Minister's reply and this chapter to the attention of the Northern Ireland Affairs Committee.

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

Department for Environment, Food and Rural Affairs

(42204) — COM(2023) 217	Detergents Regulation: Proposal for a Regulation of the European Parliament and of the Council on detergents and surfactants, amending Regulation (EU) 2019/1020 and repealing Regulation (EC) No 648/2004.
(42208) — C(2023) 2781	Commission Delegated Regulation (EU) …/... amending Regulation (EU) 2018/848 of the European Parliament and of the Council as regards detailed production rules for organic sea salt and other organic salts for food and feed.
(42217) — C(2023)2830	Commission Delegated Directive (EU) of 4 May 2023 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in melt pressure transducers for capillary rheometers under certain conditions.

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 and Trade Committee: Windsor Framework: EU protected geographical indications for craft and industrial products [Proposed Regulation]

Culture, Media and Sport Committee: Windsor Framework: EU protected geographical indications for craft and industrial products [Proposed Regulation]

Energy Security and Net Zero Committee: Windsor Framework: EU electricity market design [Proposed Regulations]

Health and Social Care Committee: Windsor Framework: Breakfast Directives [Proposed Directive]; Windsor Framework: Revision of EU pharmaceutical rules [Proposed Directives]

Northern Ireland Affairs Committee: Windsor Framework: Breakfast Directives [Proposed Directive]; Windsor Framework: Classification, Labelling and Packaging of Chemicals [(a) Proposed Regulation, (b) Commission Delegated Regulation]; Windsor Framework: EU electricity market design [Proposed Regulations]; Windsor Framework: EU protected geographical indications for craft and industrial products [Proposed Regulation]; Windsor Framework: Revision of EU pharmaceutical rules [Proposed Directives]

Science and Technology Committee: Windsor Framework: Revision of EU pharmaceutical rules [Proposed Directives]

Formal Minutes

Wednesday 6 September 2023

Members present:

Sir William Cash, in the Chair

Richard Drax

Mr Marcus Fysh

Mr David Jones

Craig Mackinlay

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 6 read and agreed to.

Annex agreed to.

Resolved, That the Report be the Twenty-second Report of the Committee to the House.

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

Adjournment

Adjourned till Wednesday 13 September 2023 at 1.45 pm

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.

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*)